MTAA SUBMISSION:
OPTIONS FOR REFORMS AND IMPROVEMENTS TO THE PROSTHESES LIST

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CONTENTS

EXECUTIVE SUMMARY

Key issues for reform

In response to the Department's *Consultation Paper: Options for Reforms and Improvements to the Prostheses List* MTAA strongly recommends maintaining the Prostheses List (PL) with improvements that are delivered in collaboration with industry via a new MTAA-Government Agreement. This option most closely aligns to **Option 2** in the Consultation Paper but with modifications that protect the value of the PL for consumers and support private health insurance sustainability.

Medical technology is an essential component of Australia's healthcare system. Through the investment companies make in research and product development, Australians continue to receive access to innovations that are close to, if not at, the frontier of medical science and engineering. Such technologies make a fundamental contribution to our enviable life expectancy, relatively high survival rates through life-threatening conditions and years of expected health. Alongside high functioning hospitals operating to leading quality standards, and the dedicated expert clinical and healthcare workforce, medical technology is one of three fundamental pillars of Australian health care.

The medical device sector was critical to shoring up capacity in the Australian health system from the beginning of the pandemic including ensuring Australia had the necessary equipment, expertise and support to diagnose, treat and prevent COVID-19 and ensure the private and public hospital sectors across Australia could continue to operate.

The medical device sector has repeatedly delivered savings to ensure the sustainability of our private healthcare system. The devices industry has been the sole financial contributor in keeping private health insurance premium increases to their lowest level in 20 years. MTAA's 2017 Agreement with the Government is on track to reach the $1.1 billion in savings that were forecast. Despite insurer claims, there is no existing emergency with the PL that warrants action that steps outside the current MTAA-Government Agreement on Prostheses Reform. As late as February 2020 the third major tranche of benefit reductions was implemented.

At the same time, health insurers have benefited from hundreds of millions of dollars in government reforms, including medical device price cuts across the board that have seen insurer costs for these items remain largely flat over the last three years while procedure numbers have grown.[1]

In addition, the Australian Competition and Consumer Commission's 2020 annual report into private health insurance noted that cumulative premium increases have been higher than inflation and wage growth in the past five years and that participation rates have continued to decline.[2]

To stem the flow of people dropping out of private health insurance, its imperative that consumers feel they are getting value from their policy – that means getting timely access to world-leading care and medical technology.

Despite this, private health insurers continue to malign medical devices as "overpriced"[3], "overused"[4] and of "little or no patient benefit"[5] thereby calling into question not only the integrity of medical practitioners but also the validity of their independent clinical judgements, and the value of the private care that insurance delivers. Insurers' relentless public political campaign against all components of their cost structure represents the most active impediment to stakeholder collaboration necessary to ensure the success of Australia's public-private health care model.

It is critically important for the medical technology sector, the hospital sector, clinicians and patients that the healthcare sector remains stable and able to continue delivering high quality care during these uncertain economic and social times. Stability and certainty for the medical technology sector are of the utmost importance as we face unprecedented

1. Australian Prudential Regulation Authority (APRA), *Quarterly Private Health Insurance Statistics* 17 November 2020
2. Australian Competition and Consumer Commission, *Health funds pay policyholders $500 million less due to COVID-19*, 8 December 2020
3. Private Healthcare Australia *Prostheses usage 2019-2020*, Draft 23 November 2020
4. 'Surgery items under review after insurer rort claims' *Sydney Morning Herald* 17 November 2019
5. Private Healthcare Australia 23 November 2020

economic challenges locally and globally. These impacts are felt through a sustained increase in freight costs and ongoing disruption to our global supply chain. A stable and predictable policy and business environment is critical for medical technology to continue playing its role of ensuring Australians have universal access to high quality care.

Throughout this period, the PL has continued to provide certainty for patients, their doctors and hospitals regarding which devices are reimbursable and the amount of reimbursement. The current legislative framework provided by the *Private Health Insurance Act 2007* and the Private Health Insurance (Prostheses) Rules guarantees that a private health insurer will pay a benefit for a product if the product is listed on the PL. Because of this, the PL largely ensures that patients do not face out-of-pockets costs for medical devices where they have the appropriate level of cover.

It also continues to provide clinicians and patients with guaranteed access to a much wider range of prostheses, including those that represent more complex technologies, than those offered in the public sector. This remains appropriate, because private health insurance is a voluntary act: Australians choose private insurance because they reasonably expect it to provide benefits not available through a reliance on the public system.

The Department's Option 1 would remove this protection and would shift the responsibility for securing technology choice away from private insurers and onto private hospitals, who would be required to manage costs around a broad-based average payment. This would impact private hospitals' ability to fund treatment of moderate-to-complex procedures and may encourage complex patient cases requiring more expensive devices to be pushed into the public system. It may also create the need for greater pre-operative financial consent from patients, hospitals and/or insurers for unforeseen implant and consumable use. Such a proposal introduces administrative rigidity into a clinical process that is likely to harm patient care and is burdensome for time-poor clinicians.

Any reforms to the sector must acknowledge that the healthcare sector faces the same, if not more, challenging commercial environments as other sectors of the economy and will do so for the foreseeable future. Any reforms proposed by the Australian Government must contribute to a high-functioning and sustainable private healthcare sector for all stakeholders.

We are keen to ensure that the Australian Government listens to the views of all relevant stakeholders in the private healthcare system – not just private health insurers. MTAA recommends the below key principles that must underpin any PL reform:

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

The PL is an effective means to ensure medical technology is accessible by patients and clinicians to improve health outcomes. While there are opportunities to improve its operation (with efficiency benefits for all parties), wholesale removal of this long-established method of pricing and delivering medical technologies at any time, let alone during a global pandemic, is an unnecessarily radical reform that would cause wholesale and widespread disruption to the Australian healthcare system.

Reasons for Reform

The Department consultation paper sets out a number of perceived issues with the PL which can be grouped under four broad headings:

- Scope of products on the PL
- Benefit levels relative to prices in other markets
- Utilisation rates
- Administrative complexity including listing processes

There are areas that MTAA believe need further reform that sit under the above headings. There is a need for clarity on the PL criteria and to reasonably expand the scope of the PL. It is also important that benefit levels on the PL are made more efficient and perceived as value for money. Utilisation of items on the PL should align with best practice and value for money. Administration of the PL, including listing processes, should be efficient and timely and the PL itself should be sufficiently transparent. The question is how best to improve these areas.

However, the claims of deficiency in the current PL are often exaggerated based on incorrect information or anecdotes that are used by the insurers to tar the PL in order to get rid of it. The unpublished report by IHPA cited in the consultation paper suggests a gap between public prices and PL benefit levels that are completely unaligned with comprehensive internal industry data. On two occasions in 2017 and 2019 MTAA collected data on public pricing from companies amounting to around 80% of the value of the PL. Comparison of this data to PL benefits shows a much smaller overall net gap of 12.3%. Many products on the PL have benefits lower than the public price. MTAA nonetheless agrees that the gap should be narrowed for products where benefits significantly exceed the public level.

The DRG model as a solution

The Department and insurers recommend a DRG payment model for prostheses as a solution to the above issues real and perceived. However, a DRG model brings with it more problems than it purports to solve. DRGs achieve the insurers' desired effect by financially forcing hospitals to limit choice. They are fundamentally at odds with the clinician-led model of private healthcare which, in most cases, allows the clinician to choose any item listed on the PL based on their patient's characteristics. They also place a considerable administrative burden on smaller and day hospitals to become coders and controllers of care when many of them do not play this role currently.

While DRGs are widely used in the public setting in Australia they are used as a tool to allocate total funding prospectively, not to calculate retrospective payment for a particular part of the procedure. Globally, DRGs are rarely used with such limited scope. Adopting this model increases the danger for error as the opportunity to smooth out irregularities in payments is decreased.

DRGs are well suited for the purpose of prospective funding using costs across the procedure, but lack the granularity needed to develop specific payments for devices that successfully avoid disconnections between average payments and actual costs. The transition requirements and administrative complexity of abolishing the PL and replacing it with a DRG model has been underestimated, particularly as a 'shadow PL' with a full device list will likely need to be retained and managed in any case.

Moving to DRGs is a risky option and is replacing a system with some correctable flaws with a fundamentally flawed system.

Retaining the PL

PL reform is needed and in this submission MTAA provides a series of proposals to retain its valuable core while addressing legitimate concerns. No reform should be seen in isolation as a solution to a single problem. For example, reviewing benefits to ensure they are appropriate can alleviate concern about whether some types of products should remain on the PL or whether a listing is value for money given its comparators. Improving transparency of the PL can at the same time encourage improved utilisation. MTAA is committed to working with other stakeholders and with the Government to reshape the PL so it delivers value for money for consumers.

Moreover, PL reform cannot be seen in isolation to other aspects of the Government's private health insurance reform package. The four additional reform proposals currently being examined would either directly expand the total addressable market for PHI or expand insurable risks to encompass treatments with lower cost of care than current hospital inpatient procedures. Each of these are likely to help address concerns about insurer sustainability, and reform of the PL will aid this objective as well. But the entire burden of righting any perceived imbalance in insurer balance sheets should not rest solely on the third largest source of insurer outlays.

Benefit Review Mechanism

MTAA proposes that PL benefits are benchmarked on a periodic basis against public prices with adjustments for market differences. The Australian public market is unquestionably competitive with tenders for devices run by the states and territories for major categories. It is also a domestic system with accessible data. By benchmarking to the public system, the disruption created by trying to leverage a private competitive market is avoided. It allows assessment and moderation for differences, as the Department notes in the consultation paper (but only for Option 1). Importantly, it allows the broad choice now on the PL to continue but with efficient pricing.

Public price benchmarking using billing code level data is easily achievable as MTAA has shown in the two sets of data it has collected in the last 4 years. If data is collected from sponsors retrospective audits can ensure data integrity or a third party can collect the data directly from state health systems.

In using this methodology, three factors need to be taken into account. Firstly, changes in product mix need to be reflected in the method for setting the public price. Secondly, an adjustment needs to be added to the public price to set a floor that accounts for volume guarantees in the public sector and higher cost to supply (such as service levels) in the private sector. Finally, the uniquely high post-implant services for pacemakers and defibrillators needs to be carved out from benefit reviews. Without these adjustments, the PL will just be replicating the public system and will significantly impact the incentive to bring new technology to Australia and the private sector in particular

To provide industry and sector certainty, MTAA proposes that the targeted reductions be phased over 4 years front loaded to ensure material savings to insurers in early years.

Based on MTAA's data from its members, using this methodology with a 20% increment over the public price and excluding $103 million per year for cardiac services (FY23), results in cumulative savings of $747 million to FY 2025-26 with $98 million in savings in FY 2022-23. Since some public prices have likely reduced since 2019 when MTAA collected the data this number is very conservative and savings are almost certainly greater. These savings do not account for any removals of items from the PL or moderation of utilisation through other initiatives.

Importantly, these are bankable savings that accrue from day one of implementation. MTAA's reforms also deliver on fairness, by reducing all benefits to a benchmark price that is based on the public price. This will eliminate outliers and inconsistencies among items.

PL criteria

MTAA does not believe in principle that there is a need to narrow the definition of the Prostheses List to exclude many General Miscellaneous items. While items that clearly don't meet current criteria need to be addressed, many products in General Miscellaneous proposed for removal add significant clinical value and provide important protections to clinician choice. Before any removals do occur, full clinical review to assess the impacts is needed and a funding pathway to incorporate costs into case payments must be laid out.

Other PL Reforms

MTAA proposes a range of reforms to improve the operation of the PL and strengthen it as a mechanism to protect consumers and their healthcare.

This includes improving simplicity and transparency and strengthening Department resourcing to improve the operation of the PL. MTAA proposes clinician-led reviews of utilisation to promote best practice and evidence based utilisation. Furthermore, improvements to listing process will be essential to ensure that the PL offers equal or better access to the latest innovation that benefits patients.

Conclusion

The PL is a critical part of the private health insurance value proposition. It provides access to a wide range of devices for clinicians to use in their insured patients without financial barriers or out-of-pocket costs. MTAA and a wide group of hospital, clinician and consumer groups believe it should be retained.

Reform of the PL is necessary to ensure its continued success and that it delivers value in the long term. Paying for prostheses through an average calculated based on a DRG will eliminate the PL and the choice of device it offers.

MTAA offers a range of reforms to improve the PL including bankable savings through periodic benefit reviews against public prices adjusted for private market characteristics. Proposed reforms will improve transparency, efficiency, utilisation and listing processes. Combined this will contribute to the value proposition of private health insurance by retaining its distinctive offering, including access to the best technology, and delivering savings into the future.

MTAA looks forward to working with the Government on reform. The Government must engage in face to face consultations with all stakeholders following the 15 February deadline for submissions. MTAA would welcome participation in a stakeholder roundtable on proposed reforms to inform the Government's decision.

SUMMARY OF RECOMMENDATIONS

Purpose of the PL

1. The purpose of the PL should remain broad and not be limited in scope: Provide consumer protection by ensuring access to devices necessary for hospital treatment covered by their private health insurance

Goals of Reform:

2. The Government adopts MTAA's proposed nine objectives for reform and issues are considered through the prism of these objectives to further improve PL arrangements.

Benefit Levels on the PL

3. MTAA's billing code dataset be used to assess true differences between public prices and private benefits

Problems with the DRG model Option 1

4. The Government does not adopt Option 1 in the Department's consultation paper of paying for prostheses using DRGs to avoid negative impacts and risks on the PHI value proposition, surgeon and patient choice of device, access to new technology and hospital viability
5. The Government considers MTAA's options for PL reform to achieve the objectives which a DRG model is considered to deliver

Benefit Review Mechanisms on the PL

6. A modified public-private referencing model proposed by MTAA be the preferred method to achieve efficient pricing on the PL without removing the unique characteristics of the private market
7. The public-private referencing model be modified to account for different volume mix, the absence of price/volume/choice trade-offs and higher service levels in the private sector
8. The public-private referencing model use an average net public price adjusted for private volumes
9. The public price has an added private adjustment of 20% across categories to adjust for price/volume/choice trade-offs in the public market and higher services in the private market
10. In addition to the above, cardiac implantable electronic devices (CIEDs) have their very high lifetime service requirements ($103m in FY23) recognised through a preserved component
11. The public-private price referencing methodology be run every 4 years with benefit reductions phased across that period
12. The process be conducted by the Department of Health either directly with sponsors or through an independent third party
13. Provide a 4-year moratorium on benefit review for new benefit groups created for new technology listed on the PL
14. The public-private price referencing data collection and calculation be run in the second half of 2021 for implementation of the first benefit reduction from 1 February 2022
15. The phasing in the first four years be frontloaded with 40% on 1 February 2022 to achieve at least $98 million in savings by FY23 and cumulative savings of at least $747m by FY26

Defining the Scope of the PL

16. Criteria for Part A of the PL is tightened but not narrowed significantly
17. In consultation with MTAA and other stakeholders identify and remove products clearly not meeting criteria from February 2022
18. Broad removals of product groups under General Miscellaneous do not occur unless there is clinical review of each sub-group and alternative funding arrangements are put in place
19. Single use technologies that are not implantable but meet other criteria should have a defined pathway to be included on Part C

Structure and Transparency

20. Consolidate benefit groups based on clinical interchangeability
21. Add clearer guidance on product descriptions on the PL
22. Create a lookup database with full product catalogue information preferably using the future TGA UDI database
23. Strengthen sponsor information disclosure responsibilities, including keeping the ARTG up to date, potentially through strengthening and broadening the application of the MTAA Code of Practice

Utilisation

24. Engage clinicians through colleges to conduct reviews of high utilisation groups on the PL to create recommendations for improved utilisation
25. Develop and share a comprehensive database on PL utilisation to enable action across stakeholders
26. Consider selective funding of additional registries to inform best practice utilisation
27. Further disseminate information on device approved intended purpose and consider use of MBS item codes and, in selected cases, restrictions to promote optimal utilisation
28. Strengthen sponsor promotion responsibilities, potentially through strengthening and broadening the application of the MTAA Code of Practice

Improving Listing Processes

29. Implement the Abbreviated Pathway listing process for all products that have an existing benefit group on the PL unless there is uncertainty or a specific issue of concern
30. Clinical Advisory Groups and the Panel of Clinical Experts should be used primarily to assess applications for new groups i.e. higher benefits
31. Sponsors of applications to form a new group should have the opportunity to use public benchmarking rather than an HTA process to set a price
32. MSAC reviews of PL applications should be limited to high clinical and financial risk applications
33. Focused HTA reviews should be continued with an emphasis on HTA reviews closely involving clinicians skilled in the use of relevant procedure

Department Resource and Cost Recovery

34. Staffing in the Department to manage the PL should include greater technical expertise in devices
35. The Department's IT system for managing the PL should be upgraded and the Health Products Portal should be assessed for this purpose
36. Cost recovery should be levied from both the device sponsors and from the private health insurers

THE NATURE AND STATUS OF PRIVATE HEALTH INSURANCE

Private health insurance (PHI) is a critical part of the Australian health care system. While there have been widespread reports about its decline, 43.8% of the population still take out private health insurance for hospital treatment.[6]

Australia's model of private healthcare arose from a context where private health insurance was largely the only form of healthcare insurance prior to the introduction of Medicare in 1984. Following the introduction of Medicare, it retained some of its past features, most notably community rating. This led to the debate set out in the report into private health insurance by the Industry Commission in 1997 on whether private health insurance in Australia replaces public funding or tops it up. The Industry Commission's conclusion was that it does both. It relieves the funding burden on the public system but also provides extra features in healthcare that policyholders value.[7]

MTAA submits that from the point of view of the consumer their only interest in taking out insurance aside from avoiding taxation penalties is to gain additional benefits on what a freely offered public system would otherwise provide. It is this that causes them to invest substantial sums of their income into insurance policies. Policymakers may recognise that by doing so a substantial burden on the public system is relieved and may choose to support the consumer's decision, but this doesn't thereby become the reason for the consumer's decision.

Therefore, if government support for private health insurance were to become a rationale to make the private system undifferentiated from the public system, then the consumer may as well take their money back. It is obviously important that these differentiators are not leading to public patients receiving worse patient outcomes. If this were the case, it would be an issue for the public system to address. Consistent investment by state and federal governments in public hospitals has meant that Australians achieve high quality care in both.

In light of this, the value proposition of hospital health insurance revolves around three key elements: taking the worry out of healthcare, choice of clinician and/or hospital and confidence in receiving the best possible care.[8]

Choice of clinician is an essential component. Privately insured patients expect their treatment to be led and determined by their clinician not by the government, insurers or hospital administrators. They also expect that their care will not simply involve the cheapest route to the basic outcome but provide an experience commensurate with the investment they have made in their care.[9] Otherwise the public system may do just as well.

Reforms to the Prostheses List (PL) need to take this into account.

6. APRA 17 November 2020
7. Industry Commission 1997 *Private Health Insurance Report* No.57
8. Galaxy research for Medtronic Australasia *Medical Devices Study* May 2015 Unpublished
9. ibid

VALUE AND PURPOSE OF THE PROSTHESES LIST

The PL is an essential part of the private health insurance proposition. Most consumers of private health insurance want their clinician and not insurers or hospitals administrators to decide which device is placed in their body to remedy a condition.

Furthermore, they want the device implanted that their clinician believes is specific to their individual needs, not a 'one-size-fits all' device at a lower cost.[10]

This is what the PL delivers and it does so with no out-of-pocket costs, which are a major source of consumer complaints about private health insurance. In fact, the lack of attention paid by clinicians and consumers to the operation of the Prostheses List is a sign of its success. With few exceptions, there has been guaranteed access to a wide range of devices to treat multiple conditions and therefore little reason to pay the PL any attention. There is a real threat that will now change.

The PL exists because it was championed by clinicians. In 1985 it was clear that insurers were not guaranteeing payments for required implants and this had to be rectified by establishing a regulated list. This was initially called Schedule 5 and became the Prostheses List in 2005.

Private health insurance can be a very important means for consumers to have peace of mind that their healthcare needs into the future will be met. However, it is impossible for consumers to foresee all the circumstances of their future treatment or to understand the myriad conditions imposed on any future payment by insurers. As a result of this knowledge gap, private insurers are in a position to deny claims for devices, even when their use is considered best practice, without immediately affecting the number of consumers taking out insurance. Only gradually does it become apparent that there is a disconnect between what consumers expected from their policy and what they have received or may receive when treatment is needed.

While some insurers are much better than others, in recent years various insurers have not paid for the following evidence-based technologies because they weren't on the PL, and therefore the insurers weren't legally required to pay:

- Cardiac ablation catheters for atrial fibrillation and other arrhythmias (now PL listed)
- Stent retrievers for mechanical thrombectomy (MT)
- Drug eluting balloons for revascularisation
- Ablation catheters for Barrett's oesophagus
- Cardiac remote monitors for patients with legacy defibrillators and pacemakers
- Pressure wires for fractional flow reserve (FFR)

Despite undertaking to make payments for remote monitors for legacy cardiac devices, some major insurers continue to deny requests. The Department has seen much of this evidence. These medical technologies are for serious and life-threatening conditions and in many cases can't be considered optional extras – interventions cannot work without them. Many of these come widely endorsed by both clinical guidelines as well as health technology assessments (HTA). Generally, they have not been listed on the PL because they don't meet one or more of the criteria. The biggest reason for this access gap is that advances in technology have made possible life saving interventions using high technology devices that are used once only, and not implanted in the body. Such devices were not envisaged when the PL was developed, but now exist, and expand the scope of possible treatments for serious conditions.

10. ibid

While some insurers have funded these willingly through *ex-gratia* or other forms of payment, this is at the discretion of the insurer and therefore inequitably applied. Arguments made by insurers that they do cover these either *ex-gratia* or in confidential contract payments ring hollow when a claim is not approved or a hospital has to absorb significant cost to use the device. This highlights why the PL is so important as a consumer protection.

Clinicians have also been responsible for the current diversity and arrangement of devices on the PL. The Clinical Advisory Groups (CAGs) and Panel of Clinical Experts (PoCE) now in existence, and their predecessor clinical advisors, have been formed from clinicians skilled in the specific procedures where the devices are used. Their assessment of devices based on both their practical knowledge and the evidence have created the extent and structure of the current list. The much-lamented and often-exaggerated elasticity in applying PL criteria when deciding what should be included on the list often reflects the clinicians' concern to ensure patients do have access to needed and valuable devices whose payment may go missing in case payment arrangements, rather than any alleged neglect or error.

The PL reflects the growing diversity of devices used by clinicians to achieve better outcomes for their patients. It is complex because devices are complex. However, through good reform the PL can continue to achieve the outcomes for which it is intended without excessive administrative burden.

The purpose of the PL should therefore be clear from the above:

To provide consumer protection by ensuring access to devices necessary for hospital treatment covered by their private health insurance.

This raises the question what 'ensuring access' means in the current context. MTAA believes the answer is that, since the use cost of capital equipment and certain types of consumables *are* covered by case payments, the PL should cover single use devices that are not liable to be covered by existing hospital-insurer arrangements. The problem with hospital contractual arrangements is that they are confidential between health funds and private hospitals, and are understood to vary from contract to contract.

This means that clinicians, consumers, the Department of Health and device manufacturers have **no way of identifying what products are already covered in a specific contract**. Indeed, it is sometimes unclear if hospitals and insurers themselves know.

Given patient access and certainty, rather than definitional perfection is paramount, the purpose and definition of the PL should not aim to exclude important technologies. The original Schedule 5 included stapling technology as well as orthopaedic joint replacements. There has never been, nor should there be, a pre-defined purpose of the PL that it is only for expensive permanent or long-term implants. This definition ignores both the need for consumer protection in the context of the private health insurance arrangements as well as the growing diversity of technology.

In this respect the definition of a 'prosthesis' is not relevant. It is already irrelevant due to the current criteria, which both exclude external prostheses and allow for implanted devices that play a role other than mechanically replacing a body part. A better name for the PL can be considered as part of reform. MTAA will continue to refer to the PL for simplicity in this submission.

Purpose of the PL Recommendation

- The purpose of the PL should remain broad and not be limited in scope: **Provide consumer protection by ensuring access to devices necessary for hospital treatment covered by their private health insurance**

MTAA-GOVERNMENT AGREEMENT

Savings achieved

While delivering substantial benefits, the PL only represents around 14% of total hospital benefits paid.[11] If insurer costs and margins, and patient out-of-pocket costs were to be added in, the proportion would be much lower again. Nonetheless, concern that benefit levels on the PL have been too high led to reductions to four major prostheses categories in February 2017. Savings from these reductions alone exceeds $380 million to date.

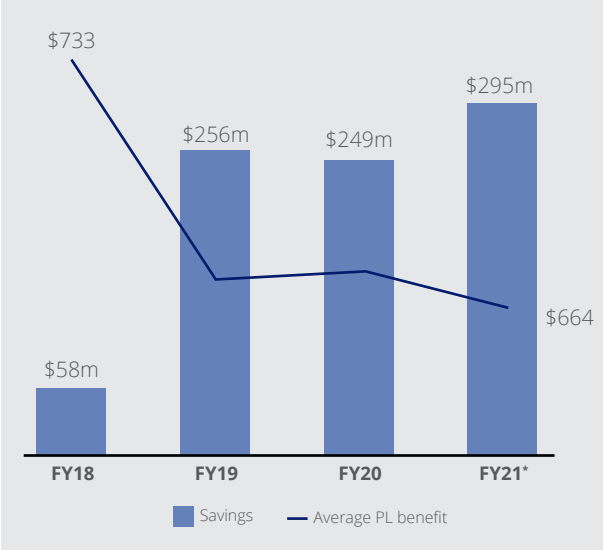
The agreement between the MTAA and the Government signed in October 2017 *Improving access to breakthrough medical technology and affordability of medical devices for privately insured Australians: Agreement between the Government and the Medical Technology Association of Australia (MTAA)* (the Agreement) has already been a policy success.

In response to concerns about the level of benefits on the Prostheses List, the Government negotiated with the MTAA to lower benefits on all PL categories ranging from 2.5% up to 26% for the largest category Cardiac. This was to deliver $1.1 billion in savings **compared to forecast expenditure growth** by the conclusion of the Agreement on 31 January 2022. There was no provision to limit volume growth which would have significantly restricted clinician and consumer choice.

There is no ambiguity about whether these savings have been achieved, contrary to what the Department's consultation paper suggests. The benefit reductions occurred as agreed. The average benefit paid on the Prostheses List in September 2020 is 10.8% lower than the average benefit in 2017 as a result of the reductions.

Using this method of calculation, savings under the Agreement to September 2020 have been $629 million with 16 months still to run. The benefit difference does not account for the addition and growth of valuable, life-saving technology, for example transcatheter aortic valve implantation (TAVI), or any changes to volume mix. Nonetheless savings are on track to reach the $1.1 billion forecast by the Department in 2017.

Figure 1: MTAA-Government Agreements Outcomes



*Projected based on FYTD result

Private health insurers have disingenuously claimed that they were promised absolute savings of $1.1 billion. With an industry full of actuaries, we respectfully suggest they know full well this was never the case. This would either require dramatically larger decreases in benefit levels or volume limits, neither of which were ever agreed. Instead policyholders are getting around 350,000 extra devices every year for roughly the same expenditure as in 2017. As a proportion of total hospital benefits paid, prostheses have fallen from 14.4% to 13.9% in the last 5 years. The Agreement is working well.

The further concern expressed by insurers and the Government relates to high volume growth rates, particularly in General Miscellaneous and Cardiac categories. This will be addressed further below. However, there is no existing emergency with the PL that warrants action that steps outside the Agreement. As late as February 2020 the third major tranche of benefit reductions was implemented. Due to a combination of these reductions and COVID-19, benefit payments declined by 1.1% and volume by 2% to September 2020. While volumes will recover, the benefit payment reductions will continue to impact overall annual expenditure.

11. APRA *Quarterly Private Health Insurance Statistics* September 2020

Reform process

The Agreement recognises that the reform process needed to continue in preparation for implementation at the end of the Agreement on 31 January 2022. MTAA engaged in the PL Reform Working Group process in good faith. Government imperatives and COVID-19 truncated the opportunity to achieve a clearer resolution. It is clear that clinician groups and societies have been missing from the reform process and have been engaged only relatively late ahead of the Government's planned announcements.

MTAA will work toward a February 2022 implementation of agreed reforms. However, it is important that the process is not rushed. The more significant the reform, the greater the potential for risk and the greater time is needed to plan key implementation steps.

While three papers have been released by the Department as part of this consultation, MTAA will respond to all of them collectively with a focus on the Department consultation paper.

ISSUES AND GOALS FOR FURTHER REFORM

Introduction

The Department's consultation paper raises a number of issues that the Department believes need to be addressed by PL reform. Without mirroring the Department paper exactly, MTAA identifies the following issues for discussion each reflecting a perceived problem:

- Definition of what is included on the PL
  - Is the definition too broad?
  - Should it be narrowed and to what?
- Benefit levels on the PL relative to other markets
  - Are they too high and by how much?
  - What does efficient pricing look like?
- Optimal utilisation of PL products
  - Are products overused on the PL?
  - How could utilisation be optimised?
- Efficient administration of the PL
  - Does the complexity of the PL make it unworkable?
  - What improvements could overcome this complexity?
- Listing new technologies onto the PL
  - How can new technologies be best assessed for inclusion on the PL?

Related to the above is the specific case of how to address products that the Department has labelled 'general use' which largely sit within the General Miscellaneous category. There are many other sub-issues, such as transparency, which go across several of the above headings and will be addressed within them.

It is important to examine these issues to understand the nature and the extent of the problem so that the solution is proportionate and does not undermine the benefits that the PL delivers.

The Department and insurers recommend DRGs as a payment mechanism for prostheses (Option 1) on the basis that this would address all of the above issues more effectively than a retained and reformed PL. MTAA disagrees with this and the goal of this paper is to demonstrate why, as well as how PL reform can effectively achieve the desired outcomes without losing the central value of the PL.

Goals of reform

The goals of reform combine both what the PL does well now, and should be retained, as well as the issues that need addressing and should be improved.

MTAA proposes the following objectives for PL reform:

- Achieve good outcomes for patients by protecting access to devices they need
- Maintain the unique components of the private system
- Maintain clinician choice of prostheses
- Narrow gaps between public prices and private benefits
- Maintain no out-of-pocket (OOP) costs for prostheses
- Promote improved utilisation of prostheses
- Improve management of the PL
- Maintain private healthcare sector viability
- Facilitate access to innovation

If achieved, these objectives would combine to help maintain and improve the value proposition of PHI and contribute to membership rates to the extent the PL can influence this. Each of these are discussed briefly below.

1 Achieve good outcomes for patients by protecting access to devices they need

As discussed already, the PL should provide for consumer protection to approved devices that can be used to address their condition. The devices listed should contribute to health outcomes and the level of evidence for this may vary depending on the device.

2 Maintain the unique components of the private system

Treatment of private patients is strongly clinician-led, with a focus on individual patient preferences, reflecting the investment the insured patient has made into their health. The principle centres around the patient's choice of their preferred clinician, making the clinician the key decision maker in consultation with the patient, and not the insurer.

3 Maintain clinician choice of prostheses

Following from 2 above, clinician choice of device is very important and should be maintained as a key feature of the existing system. This means institutional controls on clinician choice to achieve trade-offs on price and volume would undermine the value of PHI for consumers, exacerbating the current adverse membership trend.

4 Narrow gaps between public system prices and private system benefits

Notwithstanding the above, MTAA recognises that any gap that exists between public sector prices and private sector benefits should be defensible and not reflect inefficiencies on the private sector side.

5 Maintain no out-of-pocket (OOP) costs for prostheses

No OOP costs for patients for PL devices should continue as an important feature of the system. While everyone may be committed to this in principle, a poorly designed system can create the situation where they are unavoidable because the reimbursement does not cover the cost in the supply chain and delivery in every case.

6 Promote improved utilisation of prostheses

Utilisation of prostheses should be optimal from a value and health outcomes perspective within the context of private health insurance and the individual's and clinician's autonomy in directing the patient's healthcare. Best available evidence should be widely disseminated and anomalies around utilisation explored in consultation with the relevant clinical group or society.

7 Improve management of the Prostheses List

The PL should be in a form that it can be managed to achieve its goals with the minimum necessary administrative burden for all stakeholders.

8 Maintain private healthcare sector viability

Reform to the PL should ensure that all parts of the private healthcare sector: private clinical practice, hospitals, device industry and insurers remain viable and able to deliver the outcome for the patient into the future. This includes a device industry that can continue to bring the best technology and deliver health and economic benefits through research and manufacturing.

9 Facilitate access to innovation

The private sector should lead the way, not lag behind, in the adoption of new technology that benefits patients. If this isn't happening there is a problem that needs to be addressed.

Goals of Reform Recommendation

- The Government adopts these nine objectives for reform and issues are considered through the prism of these objectives to further improve PL arrangements.

Issues with the PL

PHI sustainability

The sustainability challenge for private health insurance provides the context for PL reform, so this will be briefly discussed here.

Health costs are growing at a significant rate for a range of reasons including population growth, demographic change, increased prevalence of chronic conditions, technology improvements and changing consumer expectations.

The Australian Government has recognised this by funding growth in public hospital expenditure up to 6.5% per annum[12]. This high level of commitment well above CPI is justifiably welcomed. However, there is an expectation that growth in private insurance premiums should not exceed CPI or wage growth. This suggests that there is something fundamentally wrong with the structure of PHI that has very little to do with demand on the PL or the services themselves. The willingness to invest in significant growth in the public sector through tax revenue is apparently at odds with the willingness of individuals to invest in PHI. It seems to be leading to a situation where less funding will go into the private system than the public system, which will further erase any incentive to take up private insurance.

Many of the reasons for this are well known. In particular, the structure of PHI must overcome the disincentive created by community rating in order to attract the young and healthy into an entirely voluntary system. MTAA is strongly supportive of proposals put out by the AMA in this regard.[13] MTAA's 2019 AlphaBeta report contains further recommendations.[14]

As noted earlier, expenditure growth on the PL has been very restrained in the last 4 years and has declined as a proportion of total hospital benefits paid down to 13.9% from 14.4% in 2016.

However, MTAA supports removing inefficiencies from the system so that consumers are not paying more than is required for the same service and outcome. While impacting 14% of total hospital benefit costs through the PL will not make a very significant difference to PHI overall, all sectors need to contribute to the sustainability of the system.

Benefit levels on the PL

A range of claims have been made in relation to benefit levels on the PL relative to the public or overseas markets. This includes the extraordinary claim in a confidential report by the Independent Hospital Pricing Authority (IHPA) (which MTAA has not seen) that benefits on the PL are 130 percent higher than public prices. The report relies on 2017-18 data so this would not account for much of the reduction delivered under the Agreement. Even allowing for this, it is extremely high and does not match MTAA member company records.

Costing of prostheses using DRG methodologies are not an accurate way of effectively measuring real prices differences between public and private. The problems of using DRGs to make this comparison include:

- Masking product, service and casemix differences between public and private
- Lacking sufficient granularity on the device for comparison
- Grouping procedures using different devices or no devices together
- Not accounting for additional treatment that would otherwise be classified under an additional DRG
- Unclear definitions of a 'prothesis' between systems and hospitals

In particular, these reported gaps do not take into account the very substantial differences in the public and private markets, particularly in services delivered by the industry for cardiac implantable electronic devices (CIEDs – defibrillators and pacemakers) as outlined in the Working Paper of the Cardiac Technical Support Services Industry Working Group[15]. The paper includes industry data on the services provided in the private sector to support these devices, which are the equivalent of hundreds of thousands of person-hours each year by highly qualified individuals. This service component for CIEDs needs to be independently recognised as discussed in more detail in a later section.

12. *Addendum to the National Health Reform Agreement* 2020-2025
13. AMA *The AMA Prescription for Private Health Insurance* 17 August 2020
14. AlphaBeta 2019 *Keeping Premiums Low: toward a sustainable private healthcare system*
15. Unpublished Working Paper

MTAA possesses the only dataset through which actual public vs private price comparisons can be meaningfully made accounting for all the relevant sector differences. In 2017 and again in 2019, MTAA collected from its members and some non-members data at a billing code level on: PL volumes, average public selling price and public volumes. This allows a direct comparison of prices to benefits at a billing code level which no other database can yield. This equated to 81% of the value of the PL.

Furthermore, this allowed MTAA to apply the only rational comparison method of public and private prices and benefits, namely public pricing calculated based on PL volumes (mix-adjusted). Only this approach accounts for the product mix differences that reflect differences in the public vs private sectors.

Based on the mix adjusted methodology, in the third quarter of 2019 there was a net 12.3% difference between public and private prices and benefits across the whole PL. This included many benefit levels that were well below the public prices. This was prior to scheduled price reductions to many major categories on the PL of between 3-10% under the Agreement in February 2020. Conversely the number would also be affected by any movement in public prices in the last 18 months.

Nonetheless this number is very significantly different from the non-specific claims made under the IHPA methodology and the rough calculations attempted by private health insurers using the same data sets as IHPA. The differences are explained by the inherent loss of specificity in DRGs described above for these comparisons.

The numbers in the Ernst and Young *Review of the General Miscellaneous Category of the Prostheses List* 31 July 2020 (EY Report) are not inconsistent with MTAA's dataset. While the Report headlines some more significant reductions in public in exchange for volume, in fact most of the lower public prices described in Appendix C were less than 20% below the PL price, while many other products were the same price as the PL benefit or more expensive. While these focused on a specific category of product, it comes nowhere near supporting a 130% difference across the whole PL and challenges the proposition made by private health insurers that 40-50% reductions are to be had across this category

In summary, while there is the opportunity for savings on the PL by setting benefits more efficiently, expectations around these savings should be far more modest than those being promoted, including by private health insurers. The relative impact on overall hospital cover cost would therefore be minor given the PL represents only 14% of the overall benefits paid under this type of policy. Pursuit of unrealistic savings will significantly impact the ability of the device industry to serve the Australian healthcare system, bring global innovation to market and invest in R&D and manufacturing. This impact will fall particularly hard on Australian SMEs.

Where benefit levels are significantly higher than in the public, the reason is clear. There isn't a mechanism for reviewing or adjusting benefits on the PL with or without reference to competition. Benefit reductions occur instead through ad-hoc reductions by the government such as those announced under the Agreement. Even in these cases, there is no clear information signal which would allow an efficient price to be set at a granular level to account for group differences.

Once a routine mechanism is in place that provides confidence in pricing efficiency, these concerns will be resolved. Many of the other claims about the PL being inflationary or creating false incentives fall away. Using competition is obviously the ideal way to do this, although the current private market does not lend itself to benefit setting based on competition. This forms the basis for MTAA's proposal to reference the public market with adjustments.

Benefit Levels on the PL Recommendation

- MTAA's billing code dataset be used to assess true differences between public prices and private benefits

Definition of what is included on the PL

It is important to be clear on the exact concern to be addressed in defining the PL more clearly. If there isn't confidence that benefits levels on the PL are efficient, that the system is transparent and that utilisation is rational, it is understandable that there would be significant concern that a wide group of products is listed on the PL, some of which may fall afoul of the criteria strictly applied or which don't seem to meet the archetype of a traditional prosthesis. As outlined in the Department's paper, and more extensively in the EY Report, these concerns do exist and therefore it is understandable that the conclusion drawn in these reports is that products should be taken off the PL on a wide scale.

Considering that widescale removals would have significant disruptive impacts, not least on private hospital viability, a reasonable alternative conclusion is that the PL can be reformed to address these issues if a suitable alternative funding mechanism cannot be developed. Introducing a rational benefit review mechanism as proposed by MTAA would very substantially address these concerns.

There is a need to more clearly define what should be on the PL. However, as noted in the section The Value and Purpose of the PL, the lack of clarity or the malleability of the criteria in the past is to some degree as consequence of the commensurate lack of clarity about what is truly funded under case payments or other arrangements between hospitals and insurers. As long as this is the case, there will be products which may be very important to a procedure but whose coverage is unclear. The PL is an important mechanism to set this straight. It does of course remove the product from the sphere which the insurer can negotiate, but this needs to happen to guarantee access.

As already noted, the first priority in establishing the PL criteria should be consumer protection. Clarity of scope is important for consistent decision making, but the desire to legislate the definition suggests that the Department is viewing the PL as primarily a public-funded list with universal scope. In fact, it is a decision on behalf of consumers as to what their policy payments should definitively cover. In this case, the inflexibility of legislation may be a hindrance rather than a good.

The value of the PL-listed products that are unambiguously outside the current criteria is relatively small even if some have been responsible for some recent growth. It is difficult to generalise exactly which product groups on the PL these are. MTAA will discuss this further with the Department as needed. Some products that potentially don't fit within the criteria have no alternative private funding source and the patient or public system impact of removal is potentially great. This would require resolution.

Utilisation of products on the PL

It is important to remember that in the private sector every decision to use a product on the PL reflects a decision by a clinician. When high rates of utilisation are treated as evidence of poor utilisation, it is the clinician's decision that is being called into question. It is therefore also clinicians who need to drive change. Every system change that is proposed to manage utilisation is designed to constrain the clinician's decision making.

It is impossible to point to any particular growth trend in utilisation of devices as inappropriate unless the reasons for its growth are known. More particularly, is the growth driven by a response to clinical need, or at the least, a more efficient way of achieving the same clinical outcome? Has new technology, new techniques or new quality targets led to the faster uptake, or some other factor? Given the experience-based nature of devices, only clinicians skilled in the relevant procedure can make this judgement.

As earlier noted, utilisation growth has been high in some sections of the PL, notably in the General Miscellaneous and Cardiac categories. Most other categories, such as hips, knees and ophthalmic, have been growing at around 4% or less. This likely reflects the underlying need in an ageing population combined with some incremental technology improvements.

The Cardiac category has seen the most significant additions of new innovations to the PL in recent years such as transcatheter aortic valve implantation (TAVI) and cardiac ablation catheters for atrial fibrillation. These are well-supported interventions recommended by HTA bodies for inclusion on the PL. Diffusion of this technology is largely responsible for the high growth in Cardiac.

Growth in the General Miscellaneous category has largely been driven by growth in wound closure and haemostatic devices. However, there may be important clinical factors behind this. For instance, use of haemostatic or wound closure devices may have increased as a direct result of the focus on reducing readmissions to hospital due to bleeding. Postoperative haemorrhage/haematoma and surgical wound dehiscence are specifically listed as avoidable readmissions by the Australian Health Ministers' Advisory Council from 2019 and have been built into many contracts as a cost private hospitals have to bear if readmission results, for example for an expensive blood transfusion. It is therefore unsurprising that haemostatic and wound closure devices are used more widely to manage this risk. Likewise, laparoscopic surgery has increased significantly in recent years and this requires greater use of specialised closure devices.

There are products in the General Miscellaneous and other categories that can be used more judiciously. If these remain on the PL due to a lack of alternative funding mechanisms, this should be the subject of education efforts owned by clinicians. There are also a few key products that have been listed on the PL in the General Miscellaneous category that do not meet the PL criteria, notwithstanding their clinical value. One of these has already been removed and removals of other products not meeting criteria would address other examples.

The PL is an open system that offers wide clinician choice with relatively few restrictions. This is appropriate to a private system in which treatment is clinician-led. What is missing is a shared ownership for best practice utilisation enabled by transparent reporting. Even the device industry is blinded to significant utilisation changes occurring across the PL unless it is their device specifically.

Administrative complexity of the PL

The Department has highlighted concerns with the complexity of the PL, pointing to the over 11,000 billing codes and ~1700 'price groups' (groups of products sharing the same categorisation and the same benefit on the PL. MTAA prefers the term 'benefit groups' to reflect that it is benefits and not price that is being discussed). Underlying this are perceived problems with:

- Potential for error in listing or grouping (benefit level)
- Monitoring and compliance
- Resourcing to address the above

Devices are complex and this has unavoidable implications for their management. Some institutional actor will need to manage the list of devices on the PL, it is a question of which one.

Errors of listing are relatively few considering the number of products on the PL and their overall impact on expenditure is not significant. Many of them pre-date the more recent and rigorous arrangements, including providing catalogue numbers to the Prostheses List Advisory Committee (PLAC) when decisions are taken. The impact of errors is compounded if benefit levels are not rational so that small differences in features can lead to big differences in benefit levels.

Errors are a function of two primary factors: resourcing and transparency. There has been a lack of adequate resource within the Department to properly manage the PL. This includes both the number of personnel, as well as the specific skillsets. High turnover of staff has not assisted the situation. There has typically been limited knowledge of devices among many staff in the

Prostheses Section. Furthermore, the IT system used to manage the PL, the PLMS, has its limitations. Data on PL billing codes has also gone missing when systems have been changed. Moreover, unless there is a relevant clinical expert within the committee itself, PLAC is often not qualified to review detailed product issues that arise from CAG/PoCE recommendations.

The PL has also not been optimally catalogued and described for clarity and transparency. While improvements have been made, grouping and product descriptions can still be opaque. These are readily resolvable with a proper restructuring and in some cases better disclosure by sponsors of the nature of their products. Relationships between components of a system are not described at all currently. The lack of transparency has led to much higher investment of time into many PL decisions than is necessary in an attempt to minimise possible mistakes.

In addition to the issue of errors, the Department has raised the challenge of monitoring compliance with the listing utilisation. Insurers are individually responsible for determining whether a claim for a PL item is required to be paid. Insurers also possess the data that allow them to raise issues of utilisation. Neither the Department nor other stakeholders have automatic access to data that would allow them to make assessments post-listing.

Listing processes

The Department's consultation paper recognises that listing processes can at times be slow and challenging for sponsors. Listing processes have become more rigorous due to recent incremental reforms that require higher evidence levels than in the past. Apparently simple amendments can lead to many issues being raised which leaves the current listing in limbo. A greater number of products have been referred to the Medical Services Advisory Committee (MSAC) for review and the alignment between MSAC decision making and PLAC decision making has sometimes been disjointed. The focused HTA pathway, which was intended to address lower risk applications for higher benefits, has resulted in very few positive outcomes for sponsors. There has continued to be a lack of clear feedback to sponsors on listing decisions, although this has seen some improvement recently. It should be recognised however that many other applications have been processed efficiently by an under-resourced Prostheses Section.

While the review by CAGs/PoCE and PLAC provides an additional layer of scrutiny beyond that provided by the Therapeutic Goods Administration (TGA), in many cases this could be considered duplicative or superfluous. The Abbreviated Pathway that was to address this was briefly piloted but hasn't been progressed since.

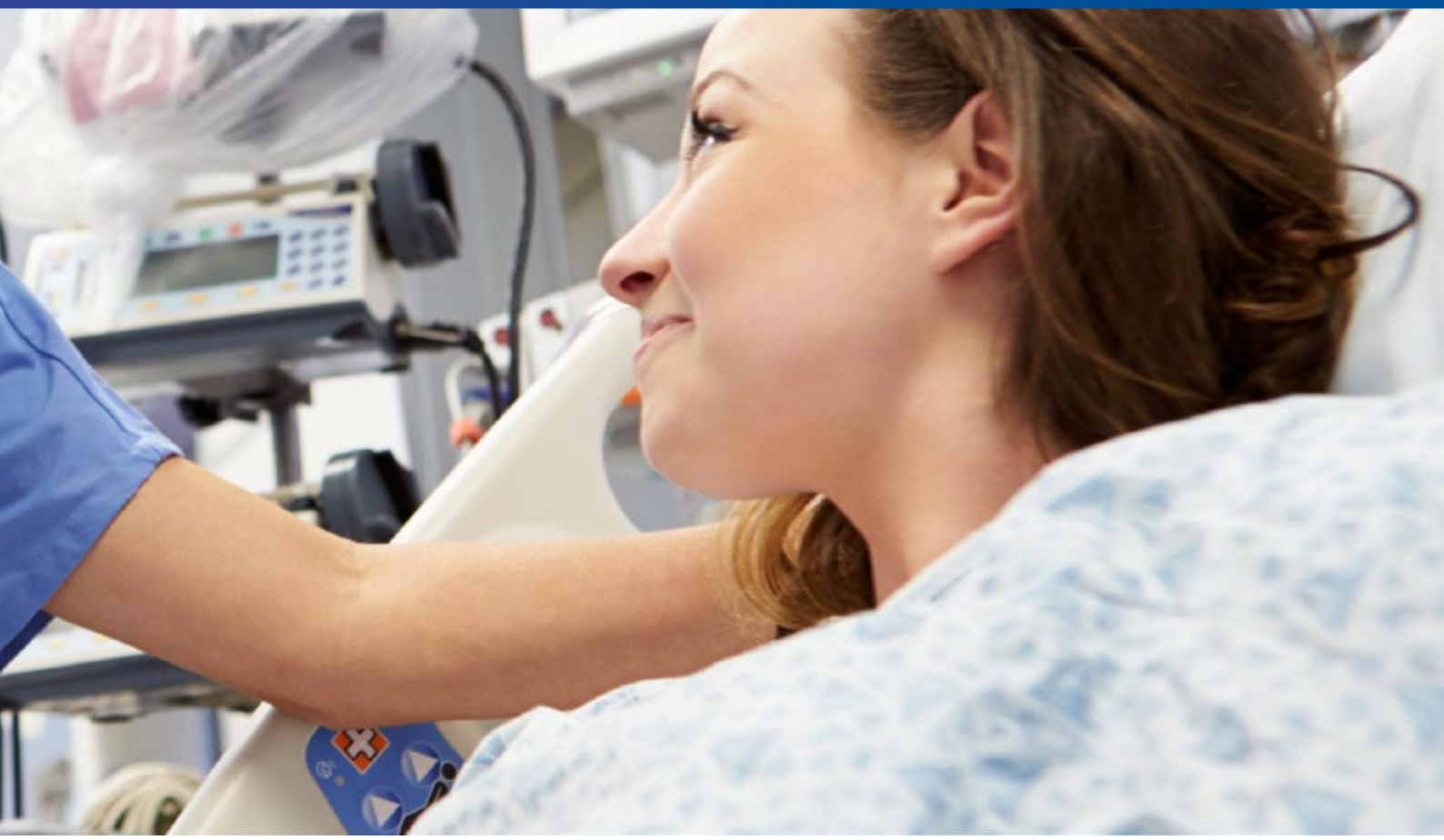
However, as discussed under the previous heading, there is a belief that these processes are not rigorous enough to avoid errors.

Listing processes do need to be recalibrated so that the depth of review is no more than necessary to achieve the objectives. It should be noted that under the DRG option there would be no centralised review for new technology except if a new DRG altogether is required. The Department's consultation paper suggests that the balance between adequate assessment to avoid errors and an efficient process that doesn't hold up market access is impossible to strike. MTAA does not agree this is the case.

Comments on the General Miscellaneous Category Review

Issues raised by the Ernst and Young *Review of the General Miscellaneous Category of the Prostheses List* 31 July 2020 (EY Report) have been addressed throughout this submission indirectly. MTAA considers the report to be flawed. MTAA notes the following concerns in particular:

- The report covertly seeks to blame suppliers and hospitals for inducing clinicians to overprescribe products on the PL, something that impugns the integrity of all stakeholders, without ever explaining what would motivate a clinician to use an unnecessary item
- The report ignores the clear capacity of private health insurers to negotiate with hospitals to account for trends in the PL
- Mistaking corrections in grouping as an application for higher benefits based on improved value, without recognising *downgrouping* also occurs on the same basis often at the sponsor's request
- Despite using an unnamed clinical panel of EY, there seems to be a lack of understanding of the clinical and technological changes that would lead to increased utilisation of wound closure and haemostatic devices, such as increased use of laparoscopic surgery, increased bowel resection due to higher bowel screening and an increased focus on preventable readmissions for bleeding



- Similarly, there seems to be a misunderstanding on differences in technology such as confusing bovine thrombin, which is associated with specific adverse events, with human thrombin
- There are errors in the report about the value of higher cost technology with suffixes and whether there is any evidence to justify this
- Many products the report claims were never intended to be included on the PL have been funded on the PL for many years and not been removed during past reviews e.g. infusion pumps have been on the PL at least since 2005
- A lack of understanding about key differences between product sub-groups on the PL
- Lack of understanding about the very specific procedures in which many wound closure and haemostatic devices are used and the lack of alternatives in these situations, e.g. advanced stapling products that are used in complex organ resection and recontouring
- Mistakenly suggesting other schemes such as workers compensation and the Department of Veterans Affairs include many PL items in theatre banding fees, when in fact they pay according to the PL in many or all circumstances[16]

There are issues in the management of items in the General Miscellaneous category that have been highlighted in the report. These warrant consideration in further reform. However, as noted in the EY Report, large scale removals of products shouldn't be implemented without alternative models of payment being established.

Goals and issues summary

As noted in the previous section, the PL is already a very effective instrument for preserving patient access to devices. In any system there is inevitably a focus on the issues particularly when these require time to resolve and there is a lack of confidence in the overall level of value.

The goals of reform should be to maintain what is working and address the issues that need correction. The PL is a system with correctable flaws but it is not a flawed system, which MTAA believes the DRG model to be.

The next section will examine the DRG mode (Option 1 in the Department's consultation paper) and explain why MTAA believes DRGs are fundamentally flawed as a means to addressing the goals and issues above. The following section will provide MTAA's solutions to reform the PL to address the outstanding issues.

16. For DVA in private hospitals: https://www.dva.gov.au/providers/health-programs-and-services-our-clients/hospitals-and-day-procedure-centres/delivering; and for workers compensation see e.g. NSW State Insurance Regulatory Authority *Private Hospital Maximum Rates Order 2020*

PROBLEMS WITH THE DIAGNOSIS RELATED GROUP (DRG) OPTION 1

Clarity on the option

Option 1 outlined in the Department's consultation paper has limited detail but it has a few essential elements:

- Abolition of the PL as a list of device-specific benefits paid
- Replacement with an average benefit for all 'prostheses' or a wider set of devices based on the DRG to which a procedure is allocated
- Calculation of the average DRG benefit for prostheses based on a public price referencing model
- Management of benefit calculations and utilisation issues by IHPA instead of the Department
- No further centralised review of efficacy, safety or cost-effectiveness of devices unless not able to be accommodated into existing DRGs – most devices can be sold immediately on TGA-approval
- Hospitals assume the responsibility for managing costs within the average DRG benefit including purchasing from suppliers

The DRG classification used would be the Australian-Refined Diagnosis Related Groups (AR-DRGs) managed by IHPA.

There are many questions about this proposed option that are yet to be answered which makes assessment challenging. However, the fundamental principle raises significant concerns in MTAA's view. By assigning an average benefit only, a DRG model intends to create a very different financial dynamic than what exists with the PL currently. While the Department's consultation paper suggests this will have upsides in addressing current concerns with the PL, there are downsides that also must be weighed up.

How this differs from other DRG funding systems

Providing a radical option with limited detail seems to be premised on the idea that DRGs are well known and understood, and with IHPA's expertise can be easily applied to medical devices in the private setting. MTAA doesn't share this optimism. The proposed use of DRGs in this way is very different to their application to the public system in Australia and overseas in a couple of key ways.

Firstly, in Australia DRGs are primarily a mechanism to assess funding to be prospectively allocated to public hospitals and providers, based on retrospective collection of data. For instance, the costing information used to determine the National Efficient Price (NEP) in 2020-21 has been drawn from the National Hospital Cost Data Collection Round 22 (2017–18), as provided by states and territories. This means that 3 year old data is used to project funding needs going forward.

While DRGs might be individually calculated and weighted, the states and territories and in turn their hospitals receive the funding as a total allocation. The states and territories often change the allocation to their hospitals from the way it is calculated at a national level, but the principle is the same. Hospitals are able to manage disparities between DRG payments and individual procedure costs because in effect they are still operating a global budget. Furthermore, public hospitals always have a safety net and problems balancing the funding never leads to closure. Public hospitals also receive multiple other sources of funding outside the DRG framework.

The concept under discussion here is a retrospective episode-based payment to private hospitals that uses an average. Any given episode may result in higher costs than the average prostheses benefit payable by insurers, and the private hospitals have no safety net or release valve available to them if costs and funding don't equalise

Secondly, the proposal is to apply it to a specific part of the episode only, namely the major medical device. Depending on the nature of the hospital's contracts with insurers it is likely that they have even less room to accommodate varying costs of the device. It makes it more important that the device cost is accurate and this requires specific knowledge of possible variations in the device.

There are no major healthcare systems that MTAA is aware of, and certainly none in Australia, that involve these two unique features. The approach therefore is not business as usual and carries risks particularly in the private system.

Risks of orphan patients and out-of-pocket costs

Two specific risks of this approach are orphan patients and out-of-pocket costs. Neither reflect bad intent but may be a consequence of financial pressures created by an average payment model. Since every patient potentially represents a possible loss for the hospital if the device cost is higher than the average payment, there will be patients requiring more expensive devices that will be financially unattractive. Hospitals operating on narrow margins may find ways to ensure they do not get these patients, pushing them onto the public system as 'orphan patients'. This has happened in the private sector in Germany where revision joint replacements that have higher costs occur largely in the public setting[17]. The public system is required to take all comers but the private system must manage its viability.

No stakeholder in private health insurance including MTAA wants to see patients pay out-of-pocket costs for devices. However, the risk of these are real when the cost to supply the device exceeds the payment provided. Where it is an average payment and the cost of the individual device is much higher than the average, a hospital whose viability is challenged may be forced to pass on costs.

Hospital control of clinician choice

The intention of introducing a DRG model to pay for prostheses is so that hospitals will exercise control over clinician choice for financial gain. The incentive in the system will be to deliver the device cost at less than the average DRG payment as often as possible. This will involve purchasing some devices at lower prices in exchange for volume that must be guaranteed. This will mean clinicians are directed to use some lower priced devices over others. It also means limiting the use of devices that might be considered optional but potentially beneficial to the procedure or the patient.

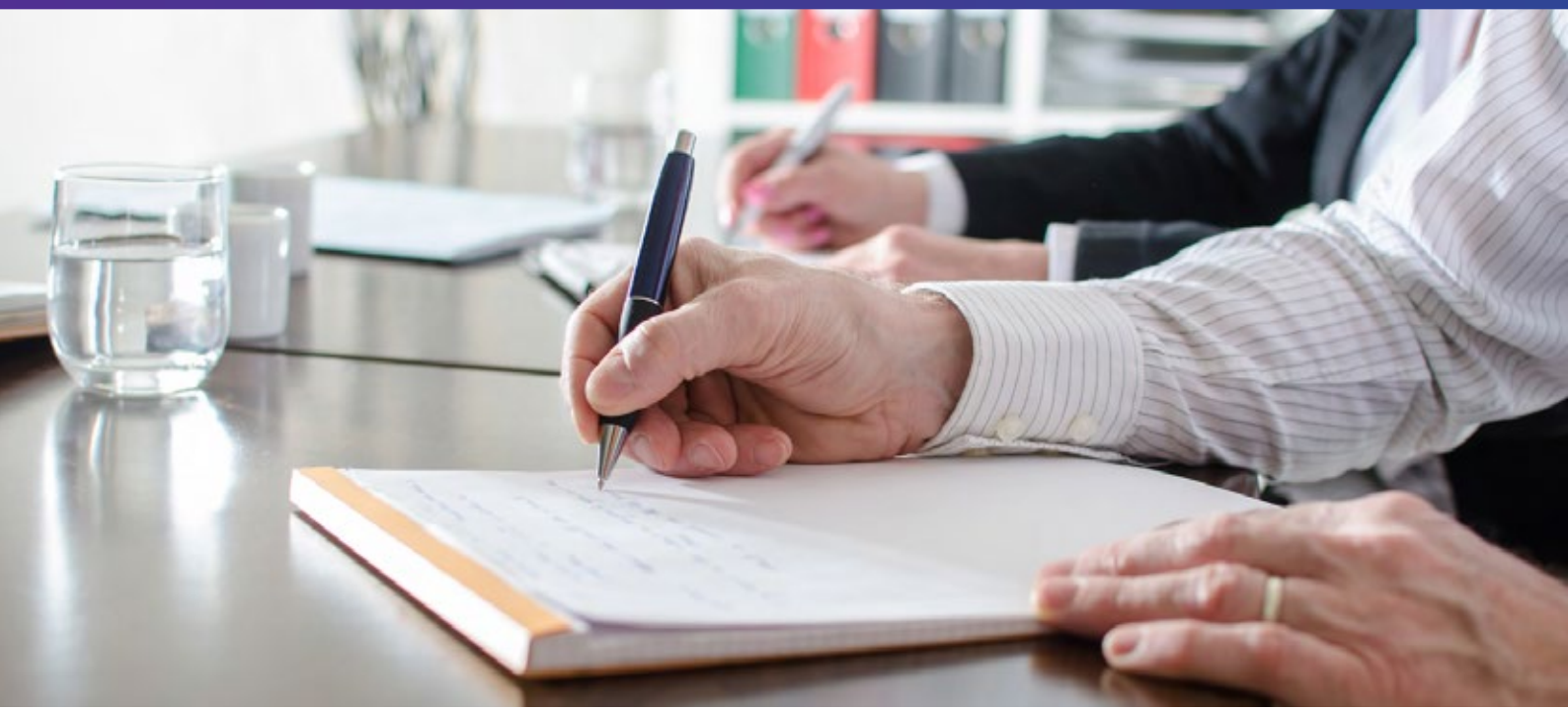
In other words, financial constraints begin to play a role in device selection in a way they did not previously. Arguing that that a DRG model still allows choice across a spectrum of procedures, for instance by allowing exceptions or by balancing costs across procedures, obscures the fact that under a DRG model device choice is no longer clinician-led and device access is no longer guaranteed irrespective of a policyholder's coverage level. Furthermore, in a private system of retrospective per-procedure payments, the drive to make every procedure profitable or financially neutral will be strong, particularly if the hospital is under financial stress.

The private hospital sector does not exercise control over clinician choice. Rather, hospitals offer infrastructure where private clinicians can undertake procedures as part of their private practice. Hospitals don't pay the clinicians, who draw their income from MBS and patient out-of-pocket payments. Clinicians are often mobile and can take their practices elsewhere. In many cases DRG-based payments for devices would require a new relationship between the hospital and clinician where hospital administrators begin to exercise control over operating room practice in order to maximise the economic value of each DRG payment.

In essence this replicates the public system. A DRG model is at odds with the consumer's desire that their clinician lead their care when privately treated.

The PHA proposal to provide the benefit directly to the clinician instead of the hospital does not mitigate this issue, but rather creates a financial incentive for the clinician to step outside his or her usual practice of care to earn more income by managing device procurement. It is likely this incentive would be very concerning to consumers.

17. MTAA member advice based on in-market experience



Furthermore, exception payments for high cost claims within a DRG model with retrospective audit create uncertainty about whether the payment will be made and a potential administrative burden including financial consent from patients, hospitals and/or insurers that may exceed the value of the claim itself. These would only apply to exceptional situations that are well beyond the average threshold in any case. Many other circumstances would arise where the right choice from the perspective of the clinician is significantly above the DRG-based benefit but not to the point of warranting an exception payment.

Impact on new technology

In a DRG model of retrospective case payments it is unlikely that the theoretical freedom to sell new technology into the hospital system upon ARTG registration would materialise to the extent suggested. For financial reasons, hospitals will be very wary of paying more than the average benefit for a new technology even if it may improve long term outcomes or if it saves costs to other parts of the system, as these are benefits they can't realise in their business model, however committed they are in principle to providing this care. This factor, combined with the (intended) downward trend in average device benefits brought on by using cheaper alternatives, would likely impede uptake of new technology that is more expensive but doesn't warrant the establishment of a new DRG. In recognition of this, the public system has a range of supplementary funding mechanisms for new technology outside DRGs. The Department's DRG model does not provide for such a situation.

This issue is combined with a long-standing criticism of DRGs across the board that they are slow to adjust to the entry of new technologies. The time from application to IHPA for inclusion of a new technology to the time that its costs are fully incorporated into national pricing for DRGs can be longer than 7 years including the application process.[18] For those technologies that are incremental improvements and add incremental costs, pricing already lags actual practice by 3 years, and the proposed move to 3 year cycles to update the AR-DRG classifications will see an even greater delay in adjusting DRG pricing. IHPA has proposals to speed up the incorporation of new technology but it is unclear how successful they will be and they won't apply to incremental improvements.

Specificity of DRGs

The Department's proposal is to combine the ~11,000 products and ~1700 benefit groups into the ~350 DRGs that now include prostheses costs out of a total of ~800 DRGs. These numbers illustrate how broad many DRGs are in the types of procedures and devices they cover. DRGs are constructed based on a primary diagnosis and/or intervention. Underneath the DRGs sit more than 6200 different procedure codes roughly corresponding to the number of MBS items, although they do not exactly match. Therefore, the diversity of procedures within each DRG is significant. Furthermore, there can be a very wide range of devices paid for within the DRG with significant cost variation. The modelling of the distribution of prostheses costs at DRG level can be problematic especially for DRGs where not all patients receive the devices, and it is

18. IHPA *Impact of New Health Technology Framework* Version 4.4 May 2020

further confounded when there is a large range in costs of devices used within the DRGs. International DRG classifications are frequently much more granular than those in Australia, with DRG groupings in England, Germany and France running into the thousands.

Examples of variation in devices across a single DRG within cardiac include:

- Transcatheter aortic valve implantation (TAVI) procedures group to the same adjacent DRGs (ADRGs) as surgical aortic valve procedures (ADRGs *F03 Cardiac Valve Interventions W CPB Pump W Invasive Cardiac Investigation* and *F04 Cardiac Valve Interventions W CPB Pump W/O Invasive Cardiac Investigation*) even though both types of devices have different price points, have different procedural costs and entail different post-procedure treatment and recovery. Not only do transcatheter and surgical aortic valve prostheses both group to ADRGs F03 and F04 but mitral, pulmonary and tricuspid mechanical valves also group to ADRGs F03 and F04
- Catheter ablation and coronary revascularisation procedures (for example stents) group to the same ADRGs *F10 Interventional Coronary Procedures, Admitted for AMI* and F24 *Interventional Coronary Procedures, Not admitted for AMI*, with vastly different prostheses costs
- Devices that have different features such as single chamber, dual chamber and CRT-enabled pacemakers with different clinical indications and costs group to the same ADRGs

Another example is that over 30 different ophthalmic lens interventions are all covered by the single DRG C16Z and may not include a prosthesis. These interventions may also group to other DRGs. The implications for benefit setting for the lenses would be very difficult to unravel.

DRGs may also significantly distort costs when an expensive technology is used only in some patients within the DRG or across multiple DRGs. For example, neuromodulation therapy is an evidence-based, effective treatment recommended for a number of indications including spasticity, Parkinson's disease, movement disorders, chronic pain and incontinence. Neuromodulation therapy is often not a first line treatment for these conditions and is predominantly offered as a treatment in the private and not the public sector.

Neuromodulation therapy mostly groups to low complexity and/or 'other' (catch-all) DRGs, with final DRG assignment being dependent on the patient indication such as Parkinson's disease or urinary incontinence. These 'other' DRGs include a broad range of procedures, including a number that tend not to require prostheses. For example neuromodulation for urinary incontinence groups to DRG *L09C Other Procedures for Kidney and Urinary Tract Disorders, Minor Complexity* and the low National Hospital Cost Data Collection (NHCDC) 2017-18 Prostheses cost bucket average of $363 suggests that this DRG includes a significant number of procedures that do not require prostheses and/or do not require prostheses of the degree of complexity required for neuromodulation. This would result in a very significant disincentive to provide this service in private hospitals.

A further challenge is that only one DRG can be assigned to an episode of care regardless of how complex the episode may be. Where different types of prostheses are used during one episode of care that would normally group to different ADRGs, only 1 DRG can be assigned based on a pre-determined hierarchy in the grouper logic that cannot be over-ridden. A DRG funding model, without significant adjustments, is not equipped to handle prostheses funding in these cases.

For example, a patient undergoing treatment for atrial fibrillation (heart rhythm disorder) may have a device inserted into their left atrial appendage for stroke prevention. If at the same time a clinician uses an ablation catheter to treat the underlying heart rhythm the DRG model will only accommodate payment for either the appendage closure device or ablation catheter, but not both.

Some prostheses do not drive DRG assignment and hence cannot be captured in a DRG model for benefit setting. Examples include:

- Advanced stapling products that are used in complex organ resection and recontouring are not coded (as per national coding standards); instead the procedures that they are used in are coded. This covers a broad range of procedures including bariatric, lung and liver surgeries
- Insertion of an implantable loop recorder drives DRG assignment to a medical DRG which would have a low average prostheses cost e.g. DRG F73B *Syncope and collapse, minor complexity* has an NHCDC 2017-18 average prostheses cost of $77.

Addressing these issues would not be an easy or quick exercise and would potentially lead to a splitting of DRGs well beyond what exists at present. Even then, many of the fundamental issues would remain.

Concerns about DRG data collection

Successful application of a DRG model depends upon high quality, accurate collection of data. At present, data to inform a DRG model is collected from only a portion of the overnight hospital sector and none of the day hospital sector. This would have to become a much higher percentage were a DRG model to successfully operate, which would involve ensuring the coding resource exists in each hospital. Where the data is collected, it remains very unclear how the prostheses bucket is counted, whether as an allocation of a proportion of the total cost or the actual prosthesis cost for the procedure.

These concerns also exist for current data collections in the public sector, but when all costs are wrapped up into the whole procedure and it is used as a formula for prospective total funding, the effects of inaccuracy are far less. Even allowing for this and any adjustments to casemix, it is wildly implausible that average prostheses costs in the NSW public system are 75% higher than in Queensland or that the ACT would see changes to prostheses costs of nearly 300% from year to year, as reported in the National Hospital Cost Data Collection Report, Public Sector, Round 22 (Financial year 2017-18).[19]

This suggests that inaccuracy is still inherent in the system and this risk would be compounded by a private sector where many hospitals are not set up to do this and the consequences of inaccurate numbers for device selection and hospital viability are higher.

It is at any rate impossible for MTAA to assess the suitability of the existing IHPA-managed AR-DRGs for prostheses payments without far more exposure to the data and the methodologies.

Administrative complexity and IHPA capability

MTAA has significant doubts that the intended administrative simplification from switching to benefit setting using DRGs managed by IHPA will materialise. The complexity for hospitals with this model has already been discussed. Furthermore, there would be significant work in assessing and testing whether DRGs are appropriate to technologies now on the PL and whether hospitals are being adequately remunerated.

However, aside from transitional issues, it is very likely that there will be no administrative simplicity gained at all. In addition to setting up a new DRG data and pricing process, almost certainly a PL-style list will need to be retained. This is especially true when there is a monitoring and compliance process in place which can't remain at the DRG level but must examine trends and behaviours by device. There will need to be a list of eligible products that can be included in the prostheses cost bucket by the hospital rather than under a case or per diem payment. Any new product would require certification that it is appropriate to include as suitable for separate payment. If insurers or IHPA want to track whether devices are being appropriately coded and utilisation more broadly, this will require specific lists of products. PHA advocates for the continued use of price disclosure as well, which would necessitate the list being retained. All this would result in a 'shadow PL' sitting behind the DRGs which would have to be managed.

Furthermore, IHPA is very skilled at managing classifications of procedures and diagnoses but have no knowledge of devices. They would face all the same challenges, if not more, as the Department in understanding the broad range of devices and their use.

19. https://www.ihpa.gov.au/publications/national-hospital-cost-data-collection-report-public-sector-round-22-financial-year

Hospital infrastructure

DRG-based benefit setting for devices would require the establishment of further hospital infrastructure and resourcing for much of the sector in three ways. Firstly, as noted above, there would need to be processes and resources in place to direct and oversee clinician selection of devices. Secondly, many hospitals would need to increase their procurement resourcing.

Finally, hospitals would need to invest significant resource in getting cost data collection up to speed. Day hospitals may not possess coding capability at all.

Transparency issues

The Department consultation paper states that the current PL lacks transparency. However, at a basic level, devices are listed in some detail and a benefit is clearly allocated to them that all stakeholders can see. In contrast, DRG processes undertaken by IHPA are extraordinarily complicated and impenetrable to anyone but the most knowledgeable observer. Furthermore, unless a 'shadow PL' is retained, the only benefit publicly available will be for a DRG that could encompass many different devices. Instead of clarity among clinicians and consumers as to what the policyholder's insurance entitles them to, this may be unclear until it is cleared by the hospital, or in some cases, even the insurer. Rather than greater transparency, the system may become more opaque.

Price mechanisms Option 1 vs Option 2

Theoretically methods for benefit setting are independent of whether the PL is retained or DRGs are used. It is unclear why the Department's consultation paper appears to suggest a public referencing methodology adjusted to private market conditions for the DRG model as an upfront reset with ongoing adjustments based on average DRGs but introduces mandatory price reductions and tendering in the case of retaining the PL. The approach for DRGs could equally apply to the PL if an adjusted public price reference mechanism is maintained.

Problems with the DRG model Option 1 Summary

Benefit setting prostheses using DRGs instead of the PL will constrain choice because this is how the system is designed to work to bring down costs. It introduces significant complexity for hospitals and changes the dynamic of the clinician relationship with the hospital in many cases. MTAA also has significant concerns with the process of allocating prostheses costs through DRGs and the significant administrative work to ensure that the model does not create distortions that harm patients and put private hospital viability under further pressure.

The purported upsides of DRGs, in particular lower benefits and utilisation, as well as administrative efficiency, come at the cost of the private system retaining its unique offering. MTAA argues that the PL can achieve these outcomes with appropriate reform and without sacrificing the clinician-led care that is at the heart of the private system.

Problems with the DRG model Option 1 Recommendations

- The Government does not adopt Option 1 in the Department's consultation paper of paying for prostheses using DRGs to avoid negative impacts and risks on the PHI value proposition, surgeon and patient choice of device, access to new technology and hospital viability
- The Government considers MTAA's options for PL reform to achieve the objectives which a DRG model is considered to deliver

INTRODUCTION TO THE MTAA PROPOSAL

Once it has been established that the Prostheses List needs to be retained, the focus is on necessary reform to the PL and how this can be implemented.

MTAA proposes a number of reforms that combine to address concerns with the PL and match any presumed benefits that a DRG model may deliver. Specifically, these reforms will ensure the PL is:

- Priced efficiently
- Administratively simpler
- More transparent and accountable
- Promoting optimal utilisation
- More conducive to listing new technology

The reforms MTAA proposes to achieve these outcomes, while retaining all the benefits the PL already provides, are as follows:

1. A benefit review mechanism for listed products
2. A clear definition of included products on the list
3. A simplified and more transparent list
4. Processes to review and promote evidence-based utilisation
5. Improved access pathways
6. Enhanced Department capabilities for list management

The Prostheses List can be made to function effectively while continuing to offer the clinician choice, consumer protection and coverage transparency that already exists. A key to this is better understanding by all stakeholders about the devices listed and how they can be appropriately managed to achieve the intended goals.

Understanding medical devices

There is a diverse array of medical devices on the PL. Existing devices may change incrementally over time as new additions or enhancements are made while maintaining the underlying core technology. More significant innovative advances can also result in new types of technology being added to the list. There is no sidestepping the management of this diversity and innovation. As already noted, the only question is who does this. By retaining a PL, MTAA is arguing this should continue to be a core role of the Department of Health, if this role is clearly described and understood. Applying a pharmaceutical industry approach will not work for medical devices and will lead to distortions, unnecessary costs and access restrictions.

All of the following reform proposals stem from a clear understanding of the nature of single use devices covered by the PL. This includes an understanding of their regulation as individual devices, systems, accessories and procedure packs at different risk classifications, the evidence required for each and how regulation relates to the catalogue numbers used on the PL.

Based on this understanding of devices, an effective PL will transparently catalogue the devices on offer but apply no more regulation to their assessment and management than is necessary to ensure integrity. The oft-cited errors of past PL listings, where these actually existed, are symptom both of lack of clarity about the technology, as well as the perceived inflexibility of the case payments system to incorporate technology innovation that sat outside the envelope of PL criteria.

While intuitively it may make sense to begin reform proposals with the *scope* of the PL and therefore criteria for inclusion, the biggest issue raised about the PL and one that has ramifications for all other reforms of the PL, is the process for reviewing benefits. Furthermore, this question arises whether or not the PL is retained, as the Department's proposal is also to apply these methodologies to DRGs, rather than simply using an average DRG method of pricing as exists in the public funding arrangements.

Therefore, this will be the initial focus of this paper. It will then return to the question of the PL criteria and other reforms.

Clarifying benefit vs price

While the terms benefit and price have at times been used interchangeably when discussing the PL, it is important to note that these are two different terms.

The PL sets a benefit level for the reimbursement of listed prostheses by private health insurers to hospitals when these devices are used for members with the appropriate level of hospital policy. The PL does not regulate the price that suppliers are able to provide their products in the market.

If the benefit level – the amount reimbursed – goes too low i.e. below the amount that suppliers charge in a competitive environment then there will be a gap between benefit and price that will need to be collected or passed on.

BENEFIT REVIEW MECHANISMS ON THE PL

MTAA recognises that benefit levels on the PL do not change once they are set, and this can create a cycle where inefficient prices may compound upon each other.

As a consequence, there are some groups of products on the PL that are priced higher than a genuinely competitive market would have, which otherwise has the same conditions. It is appropriate that this issue is addressed, and MTAA proposes doing this through a modified public price referencing mechanism. However, before discussing this there needs to be a better understanding of the factors relevant to setting this mechanism and the savings likely to be achieved.

Evaluating benefit review mechanisms

Since 2017 benefit reductions have been implemented in an ad-hoc manner by the Federal Government based on a range of factors but with no clear methodology. The program of reductions under the Agreement concluded with the February 2020 reductions, which are still washing through the annualised PL benefit statistics.

However, to create confidence that benefits are being set efficiently a new benefit review mechanism must have two components. Firstly, it must have regularity so that benefits are reset to reflect updated conditions of the market. Secondly, it must be a known and transparent mechanism that achieves the appropriate outcome over time.

The question of the appropriate cadence of benefit review will be addressed further below once the mechanism is outlined.

Determining what mechanism is appropriate for the PL should account for a number of success factors:

- Retaining clinician choice for private patients
- Reflecting a genuinely competitive environment
- Reflecting the particular conditions of the private sector in Australia
- Ensuring sector viability and avoiding market failure
- Avoiding the possibility of out-of-pocket costs

The options to review benefits routinely should be measured against these criteria. These options include:

- Public price referencing
- International price referencing
- Private price disclosure
- Tendering
- Statutory price adjustments

While the Department's consultation paper suggests that all these benefit review methods could be blended together or used at different times (at least in the case of a retained PL – this is less clear in the case of the DRG model), it is important to realise the different options have different impacts on the success factors above and can't just simply be combined or selected *ad hoc*.

The options are described further below and their strengths and weaknesses as a PL benefit review mechanism are outlined.

1. Public price referencing

This option would peg PL benefits to existing prices in the public sector (state and territory public hospitals). The public sector is unquestionably a competitive market. States and territories engage in aggressive tendering and purchasing arrangements, particularly for high expenditure items. It also reflects Australian conditions. However, a critical element of this approach is how the public price would be calculated and what adjustments are made for the private sector.

As described in an earlier section, the public sector operates very differently to the private sector. Firstly, the public sector takes consolidated taxation revenue from the Federal Government and states and territories to treat all patients who present, as per Medicare arrangements. Through a combination of triage and trade-offs the public sector aims to maximise population health and focus on ensuring the most serious conditions are treated promptly and effectively. Following from this, the public sector aims to purchase medical devices in a way that enables it to provide the essential treatment necessary, but not to cater to choices that otherwise might be important to clinicians or patients alike. As a consequence, the public sector will trade off choice by offering guaranteed greater volume to devices it believes meet the minimum requirements in exchange for lower prices on those items. It will then control or disallow use of other devices for the same condition.

As an immediate consequence of these two factors, there will be a patient and product mix difference between the public and private sectors. There will also be price differences in many cases that don't immediately mirror competition as it would exist in a private market where there is no guarantee of any volume.

A further relevant factor is that the public sector may have different purchasing and servicing arrangements to the private, which means the overall cost to supply is different. For example, the public sector will often have their own in-house technical support that the private sector does not have or assume more of the freight cost.

Consequently, the public price referencing approach has pros and cons as follows:

PROS	CONS
• Competitive market • Domestic market reflecting Australian conditions	• Different market dynamics to the private reflecting sector differences • Reflects an environment of constrained device choice • Potential loss of manufacturer services in private leading to switch to the public sector

2. International price referencing

International price referencing (IPR or IPC) adjusts prices in line with an average (or multiple of an average) basket of overseas prices. It is clearly critical which countries are chosen to be included in the basket.

International price referencing is an approach widely used by countries for pharmaceuticals although there is no formal mechanism for Australia's Pharmaceutical Benefits Scheme (PBS) to price medicines using overseas prices. It is not widely used in devices, Japan being a notable exception. It can be used to provide 'comfort' that prices are not higher domestically than they are worldwide.

The fact that the method is not widely used indicates both the challenge of using international referencing and the availability of other approaches. International price referencing is difficult because it is complicated and open to gaming by both payers/regulators and suppliers. This is even more the case for medical devices than pharmaceuticals because devices often have a plethora of minor variations across markets and because there are an enormous range of prices reflecting the large number of buyers (usually hospitals) in a given market. It is also distorted by currency fluctuations.

Furthermore, this approach runs against an issue of principle which is that overseas market conditions should not be used to set domestic prices that reflect their own local unique conditions. Market conditions can differ in a multitude of ways including:

- Scale of market
- Financing of health care systems
- Structure of the health care system
- Purchasing methods
- Reimbursement systems for hospitals, insurers and other payers of both medical devices and medical services
- Market segmentation
- Volumes being used/market size
- Price/benefit determination methods
- Currency exchange rate changes
- Differences in regulatory and product liability
- Different costs of sales, distribution and overhead
- Differences in product lines and product type by country
- Differences in taxes and other fees associated with selling and marketing products
- Differences in the level of technical manufacturer support required
- Geographical differences
- Economic differences

A local competitive market is the best guarantee against excessive pricing. In addition, most overseas markets outside the United States are also public markets and so international price referencing would need to be modified to reflect this.

PROS	CONS
• Provides comfort that domestic prices are not too high relative to overseas	• Does not reflect local conditions • Complicated and open to gaming due to variety of products, pricing and exchange rates • Reflects overseas public markets without adjustment • Resource intensive to administer

3. Private price disclosure

There have been repeated suggestions from insurers that rebates are being paid by manufacturers to hospitals on a wide scale and neither the insurer nor the policyholder benefit from these. This accusation has ebbed of late and insurers have focused more heavily on public and international price comparisons. Private price disclosure requires companies or hospitals to disclose the rebates they are giving/receiving on the 'list price' (benefit level for PL) to provide a net price. The benefit level is then adjusted downward to reflect the net price. Methodologies vary on what difference must exist (e.g. 10%) before a downward adjustment is made and what is included in calculating the net price.

The PBS currently uses price disclosure mainly for generic products where sponsors may provide rebates or other incentives to the pharmacy. A wide range of incentives are included well beyond rebates or discounts on the invoice. It has generally been successful in lowering PBS benefits for generic medicines. The Department advises it requires significant resource to administer.

This method utilises competition that exists in the market already. The positive for the PL is that it would reflect the dynamics of the private market not other markets. It would also avoid imposing further control on the market. However, questions have been raised about whether there is always a sufficiently competitive market for a broad spectrum of products such that rebates and incentives are widespread. Questions have also been raised about the possibility of identifying all relevant incentives and benefits without a disproportionate administrative burden.

PROS	CONS
• Reflects competition in the private market which retains choice • Doesn't impose a new market distortion	• Assumes a competitive market which may not always exist • Administrative complexity if all incentives are included

4. Tendering

Tendering is a complicated process practiced by state and territory public hospitals as described above under public price referencing. Generally, it involves establishing the product requirements of a payer then inviting suppliers to tender based on their available products and best prices. Where applicable, pricing can be submitted assuming pre-specified volume levels. The outcome is that a limited choice of products is available at lower prices, and clinicians or hospitals have to apply to use non-preferred items at higher prices. It assumes the principle that a certain group of products will be 'good enough' to achieve the main outcome and clinician or patient preferences play a diminished role.

A less restrictive tender process is an open tender where sponsors of all products have the opportunity to submit their best price and the tendering organisation takes the best price and offers the other sponsors the opportunity to supply at the same price. Savings rely on behaviour of individual players who hope to submit a price low enough that others will not be prepared to match it, giving them a greater market share. If the others do match it, the lowest price tender gains nothing but loses revenue. As a result, it tends to work only in limited circumstances. It follows that in most cases it will either limit choice or not produce a lower price.

Tenders are long processes to run. Best practice tenders begin 12 months or more before submission by sponsors and may take a number of months to finalise following these submissions. It involves a careful and detailed itemisation of each individual product involved in the tender.

As noted above, tenders rely exclusively on narrowing choice, or at least its prospect, to be successful. This is problematic in the private system where clinician and patient preference should be accorded a higher priority. They also risk established suppliers withdrawing support from the market which can be important in the private sector.

PROS	CONS
• Restrictive tenders will often lower price in exchange for volume • Open tenders may, in a few cases, result in the same choice at lower prices	• Clinician choice is generally restricted which is incommensurable with private care • Complicated process requiring significant infrastructure • Manufacturer support services will typically fluctuate or decline

5. Statutory price adjustments

Statutory price adjustments are pre-specified price changes (typically downward) based on some pre-defined factor, usually time in market. An Australian example are the anniversary price reductions applied to medicines on the PBS between the time of their listing, when an initial value is set, and the time they become widely substitutable, usually when they go off-patent. During this period when there is limited or no price competition possible on the PBS, the Federal Government mandates reductions at specific time points following market entry, as a surrogate for competitive forces that may operate in a genuine market.

If the prices don't go too low they will typically retain choice in the market. They are predictable and guarantee savings, but since they don't reflect actual competition they may either be greater or lower than prices in an efficient market. Consequently, they are a blunt tool. Furthermore, they offer no natural floor price and if applied *ad infinitum* could result in unsustainable prices and market failure. Therefore, they generally have to be modest changes at best.

PROS	CONS
• Retain choice • Predictable savings and impacts	• Don't reflect competition so may be too high or too low • No natural floor price possibly leading to market failure

MTAA PROPOSAL – MODIFIED PUBLIC-PRIVATE REFERENCING

The summary of the above non-DRG options shows that while some benefit review mechanisms have their advantages, none of them meets all the criteria described above without amendment.

The answer is not to combine them all to increase savings, as this compounds their collective negatives including significantly limiting clinician choice and creating an ever greater administrative burden.

A better solution is to take the competitive domestic public market as a reference point and modify it to reflect the objectives and features of the private sector. The application is relatively straightforward once the key principles are established.

Proposal fundamentals

Before discussing modifications, the basic method is outlined below:

i. Grouping (as currently or consolidated)

The PL is broken into groups that share the same benefit based on the lowest distinguishing feature e.g. suffix, sub-group or group. Therefore, billing codes that have the same Category - Sub-category – Group - Sub-group – Suffix would be a 'benefit group'. Other billing codes that have no suffix but share a sub-group would also be a unique benefit group etc. As will be discussed further below, there is opportunity to consolidate and more clearly describe groups based on whether they are clinically interchangeable, so that like-for-like products are being compared. Innovative technology that is sufficiently distinguished from existing groups would be placed into a new benefit group and kept separate for reference purposes.

ii. Collection of data

For each billing code, an independent third party collects data on volumes of sales on the PL and total volumes and average price across all state and territory systems (or states only). Data could be collected from sponsors or directly from state and territories.

iii. Calculate pricing

Based on the data collected the independent third party calculates the relativity of the average public price to the PL benefit and where necessary adjusts the benefit based on the agreed methodology (see below).

The above approach provides a straightforward mechanism that can be easily implemented. MTAA members and some non-members have collected this data on two occasions in 2017 and 2019 and an independent consultant has run the calculations within weeks.

Accounting for public-private differences

As outlined under 1. Public price referencing, there are important differences between the public and private health systems:

- Funding sources and objectives
- Product and patient mix
- Purchasing arrangements and price/volume/choice trade-offs
- Service costs

The question becomes how to adequately adjust for these without losing the price efficiencies achieved by benchmarking the competitive public system.

MTAA proposes three adjustment approaches:

1. The public average benchmark is calculated using private volumes (mix adjusted)
2. There is an adjustment added to the average public price to set the PL benefit floor
3. High discrete post-implant service requirements for CIEDs are calculated separately, but paid for through the device on the PL

1. Mix-adjustment for private volumes

The first question with a public-private reference model is how to set the public price benchmark. The main premise of the methodology should be that the public benchmark should most closely reflect the product mix in the private market. This will account for usage patterns in the private market, while still taking advantage of the competitive public market.

2. Public plus adjustment factor

While the mix-adjusted methodology accounts for different volume mix in the private sector, it does not account for other differences between the sectors already mentioned:

- The public system utilises a model where volume is treated differently to that in the private, both in volume terms and in level of certainty to purchase.
- Certainty of volume purchase generates operational efficiencies (include freight charges and planning, storage level, warehouse staffing and clinical & hospital support staff) which are passed through to the public hospitals generating lower prices.
- Trade-off between higher volume and lower price that occurs in the public (with the consequent loss of choice for clinicians)
- Higher service costs in the private sector

Contracts in the public sector typically involve lower prices for particular devices in exchange for certainty of higher volume delivered by categorising certain products as preferred, while non-preferred devices require an exception process to utilise.

An example tender document from HealthShare NSW is below in Table 1. It invites manufacturers to offer different reduced pricing bands based on increased market share utilisation. A successful supplier would therefore be assured that the accepted price is associated with a pre-agreed volume. This volume certainty is entirely absent on the PL where no sales are guaranteed. It is important to realise that the public hospitals ability to guarantee the market share required to achieve the reduced band price by concentrating volume, is often predicated upon the hospital restricting product choice and therefore limiting clinician choice to a narrower range of options, and in some cases single source or dual source only.

Table 1

Category	Award Level	Banded Price Stipulation by Market Share				
Tier 1	**NSW**	**0%**	**30%**	**50%**	**70%**	**90%**
	State-wide	Band 1	Band 1	Band 2	Band 3	Band 4
	LHD					
	LHD A	Band 1	Band 1	Band 2	Band 3	Band 4
	LHD B		Band 1		Band 2	Band 3
	Hospital					
	Hospital A Metro	Band 1	Band 1	Band 2	Band 2	Band 3
	Hospital B Regional		Band 1	Band 1	Band 1	Band 2

Furthermore, historically the PL benefits were negotiated based on the inclusion of all costs associated with a technology being included. This included implant tooling and consumables, delivery costs and any support or service to ensure its effective functioning. In the public sector some of these costs are broken out and removed. For example, some states use centralised distribution hubs rather than relying on supplier distribution. This further contributes to the price differences.

With the major exception of cardiac implantable electronic devices (CIEDs) dealt with under the next heading it is preferrable that these differences are addressed through a simple increment that is easily applied and does not significantly increase PL benefits over public prices. Except in the case of CIEDs, calculating individual volume impacts in the public and service costs in the private would be resource intensive relative to any gain in granularity.

MTAA therefore proposes the floor below which PL benefits don't fall is calculated as the public price (mix adjusted) plus a price adjustment calculation additional increment of 20% to account for differences in public guaranteed volumes, operational efficiencies and services provided. PL benefits that are already below this level would remain as they are or an adjustment for very low benefit items facing supply issues could be considered.

Through this private adjustment factor, the device industry can ensure that it continues to supply to the private sector regardless of actual volume and foregone efficiencies and it maintains the higher service levels that are typical in the private setting. This will correspond to a private sector that supports clinician choice whilst also ensuring that PL benefits are efficiently priced.

3. Separate calculation for CIED services

What are CIEDs and why a need for service?

Cardiac Implantable Electronic Devices (CIEDs)[20] have been listed on the PL since its formation in 2005, and previously on Schedule 5. These devices diagnose and treat cardiac rhythm disorders. CIEDs have become progressively more complex, sophisticated, smaller and longer lasting due to innovations in battery technology and programming algorithms.

Appropriate programming is important for optimising outcomes from device therapy as well as device longevity. The programming often needs individualisation to a patient's circumstance and needs adjustment over time as the patient's clinical condition changes. A modern appropriately programmed CIED can provide therapy to the patient for 10 to 15 years before the battery is depleted.

To obtain optimal device performance and longevity, CIEDs are checked on a periodic basis. The need for regular evaluation of device function and the adjustment of the programmed settings is relatively unique to CIEDs as compared to other products on the PL, such as joint replacements and ocular lenses. This regular evaluation is required for the life of the device or the life of the patient to ensure ongoing patient safety.

How are these services provided?

In the public sector, patients are required to attend dedicated outpatient 'pacemaker' clinics in which the cardiologist on roster supported by hospital technicians performs the CIED check. The costs are largely borne from within the hospital's funding envelope. Company support for the public sector is very minimal.

By contrast in the private sector, the patients are seen in the treating clinician's private rooms for their CIED checks post implantation and for the life of the device. Clinicians are supported by device company staff (industry-employed allied professionals, IEAPs) who are highly qualified to provide this technical support. IEAPs support services for private patients with CIEDs Australia wide and in diverse settings across the health care system, often one patient at a time (rather than in organised clinics as in the public sector).

There are between 1 and 4 scheduled follow-up checks that occur each year for each patient, based on guidelines by the Cardiac Society of Australian and New Zealand (CSANZ). This occurs every 3-6 months for both PPMs and ICDs, and 6-12 months for ILRs. In addition, there may be unscheduled follow-up checks if the patient develops new symptoms or an event was detected via remote monitoring (see below).

Remote Monitoring

CIED checks have historically been performed by the patient attending a dedicated clinic in the physician's room or hospital. Increasingly CIED interrogation and data retrieval is performed remotely utilising external

20. CIEDs include permanent pacemakers (PPMs), implantable defibrillators (ICDs), cardiac resynchronisation devices and implantable loop monitors (ILRs).

transmitter devices carried by the patient or installed in the patient's home. However, for safety reasons, **remote monitoring does not offer the ability to adjust device settings** remotely. However, it allows the clinic to detect anomalies earlier and to react accordingly, for instance by calling the patient into the clinic for an in-person check and re-programming. When employed prudently, remote monitoring can avoid unnecessary clinic visits (those carried out on a calendar basis in the absence of any information about the patient's device status and in hindsight turning out to be unnecessary) and allow focus on actionable events. The majority of remote follow-up for CIED patients has IEAP involvement.

Funding

Unlike in the public system, where cardiology outpatient clinics in hospitals are funded from within hospital budgets, there is no specific funding pathway to cover the services provided by IEAPs to private patients. Clinicians are reimbursed through Medicare for periodic in-office as well as remote examinations of CIED patients. However, technical services by industry professionals, usually delivered ancillary to other medical services, are not, despite the necessity of the services and the need for a highly trained technician to provide them. Instead, CIED manufacturers have been funding the services provided by IEAPs from the PL benefit for the CIEDs.

Outcome of the IWG on Cardiac Technical Services

Following reductions imposed in February 2017, the further cuts announced in the Agreement brought the total benefit reductions for CIEDs to 37.5%. In response, CIED manufacturers expressed concern that reduced reimbursement would limit industry's ability to sustain the existing technical services for CIED patients provided by IEAPs.

An Industry Working Group (IWG) on Cardiac Technical Support Services was formed consisting of clinicians, representatives of the private health funds, private hospitals, CIED manufacturers and the Department. The IWG was tasked with detailing the clinical need for, and extent of, technical support services for private CIEDs.

The IWG report (as yet unpublished) acknowledges the importance of the technical support services provided by the suppliers of cardiac devices and notes that the provision of these services has been, and will continue to be, an important part of ongoing patient care.

The IWG attempted to estimate the number of services provided by IEAPs. Medicare Benefits Schedule (MBS) statistics provided a reasonable estimate for the total number of scheduled in-office services provided. The IWG acknowledged that the majority of those have some industry involvement. The IWG recognised that the number of unscheduled CIED services was more difficult to establish. These unscheduled services do not attract a Medicare payment and the vast majority of these services are supplied by industry employees.

MTAA member companies supplying CIEDs thus were asked to provide details about the volume and nature of all peri-implant CIED services that they supported. Aggregated industry data (Table 2) collected over a six-week period in 2019 demonstrates the significant service burden for clinically necessary technical services provided by IEAPs:

Table 2: Count of services provided by IEAPs over a six week period

Type of Follow-Up Service Request	Total	Weekly Average
Day 1 Post-Implant Check	1,794	299
Doctor Room Clinic/Check	19,419	3,236
Hospital Device Follow-up Clinic	5,857	976
Ward Check	892	149
Emergency Department Check	426	71
MRI Check	365	61
Radiation Oncology Check	145	24
Pre Op/Theatre Check	169	28
ICU Reprogramming	43	8
EP Procedure Reprogramming	95	16
Nursing Home Check	28	5
Palliative Reprogramming	26	4
Morgue/Funeral Check	4	1
Remote Monitoring Transmission Review	19,579	3,263
Total	**48,842**	**8,140**

48,842 services over a representative six week period is approximately 423,000 technical services per year, none of which are specifically funded.

From the work of the IWG it became evident that there is a need for technical services in association with CIED therapy. The aggregate data provided by the MTAA had not been collected before and provides an important baseline from which any future change in service levels can be measured.

Independent Validation of Technical Service Costs

To estimate the cost of providing these services, and to have the costs validated by a third party, on behalf of companies that are members of MTAA's Cardiac Forum, MTAA contracted KPMG to determine the resource requirements of CIED services in private health in Australia using data supplied by cardiac companies and publicly available sources. KPMG's report is provided at Appendix 1.

KPMG modelled the cost of providing IEAP technical services in the private setting. Modelling considered each resource component required to provide CIED services in a private healthcare setting under current arrangements and service levels. The KPMG analysis is underpinned by several assumptions, so a Monte Carlo simulation was applied with 1,000 iterations to assess the impact of uncertainty in key assumptions, providing an upper and lower bound of cost, with the median reported. By KPMG's analysis, the total cost of services provided by IEAPs in FY20 is expected to fall in the range of $66 million to $96 million, with a median cost of $78.59 million. The total costs by FY23 are expected to fall in the range of $86 million and $125 million, with a median total cost of $102.98 million.

Table 3

	FY20	FY21	FY22	FY23
95th percentile	$95.79m	$104.81m	$114.39m	$125.00m
5th percentile	$65.63m	$71.83m	$78.44m	$85.88m
Median	$78.59m	$86.06m	$94.08m	$102.98m

Note: all values are reported in nominal terms

It is estimated that there are a limited number of CIED services in the public sector which is estimated based on company-supplied data to be only 2% of the total number of services provided across public and private systems. MTAA recognises that while the modelling is very detailed and rigorous there are limitations to the analysis undertaken by KPMG, including gaps in available data, as outlined in KPMG's report. However, this analysis provides the first detailed quantification of the cost of providing CIED services in the private system and MTAA welcomes further discussion about the data and assumptions (see Future Considerations below).

Considerations for PL reform and IEAP technical services

As noted by KPMG, the cost of providing these services contributes to the value of CIED therapy received by patients. However, there are other drivers of value that are not captured by measuring costs alone. Some examples include the responsiveness and universal accessibility of needed services, patient experience, clinical outcomes or clinical productivity.

While the IWG considered the current lack of a funding model for industry provision of technical services for CIEDs, it made no recommendations about how CIED support services should be funded into the future.[21]

Recommendation

MTAA's position is that the Cardiac Technical Services cost of $103 million in FY23 must be considered as a core cost component of implantable cardiac devices in any benefit review process. It needs to be included as a preserved component on top of any public/private pricing benchmarking mechanisms which may be adopted. This cost should be maintained as a component of the PL benefit due to its direct influence on the CIED device's longevity and functionality. Further including it in the PL benefit is administratively simple and protects patients from potential out-of-pocket costs.

Future Considerations

Industry welcomes further work to consider cardiac services for patients with private health insurance. This work would be best informed by the involvement of clinicians from a broad range of practice sizes and varied geographic locations in private and public settings, coupled with further detailed data collection. Importantly, it should be undertaken with the Department and aim at gathering data on the CIED service effectiveness. This could be achieved via the proposed extensive cardiac patient registry where the full patient journey can be captured and the value of the CIED service can be measured.

The MTAA proposal balances the need to protect equity of access to high quality patient care with ensuring PL benefits are commensurate with patient outcomes. Ultimately, any changes to funding or provision of CIED services need to consider the quality of care expected by a patient holding private health insurance and avoid increased patient costs to access this level of care.

Review frequency and phasing

While there are categories and groups of products that are relatively unaffected by benchmarking to the public price, the impact on other groups is significant. This will require changes to business and service models. For this reason, MTAA proposes that reviews occur every 4 years and reductions are phased across that period.

MTAA proposes a review of PL benefits based on the above methodology in the second half of 2021 for implementation from 1 February 2022 following the expiry of the Agreement. The target reductions from this calculation are then phased in over four years. To provide an early savings benefit to insurers, MTAA proposes an upfront loading to the phasing. MTAA proposes the following schedule for reductions:

Table 4

Date	Benefit reduction – Percent of target
1 February 2022	40%
1 February 2023	20%
1 February 2024	20%
1 February 2025	20%

The four year benchmarking intervals will be sufficient to capture the impact of public savings which occur as a result of tenders that typically hold for 3-5 years. The interval and phasing delivers certainty to the industry and the sector. This is especially important for smaller companies based in Australia.

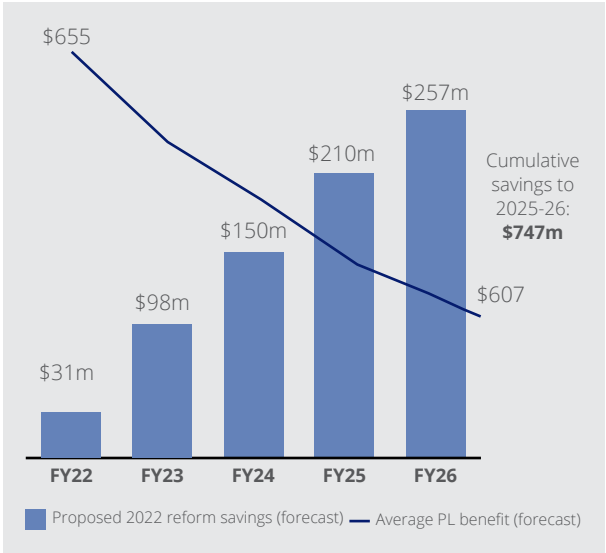
In order to support the entry of innovative products into the private sector, MTAA proposes a 4 year moratorium on benefit review for new benefit groups established on the PL. This will assist in making Australia and the private sector an attractive destination for cutting edge medical technology.

21. The Working Wroup's terms of reference state that "the role of the Cardiac IWG is to make recommendations and provide advice to the Prostheses Reform Governance Group on how technical support services for active implantable cardiac devices should be funded to ensure the Australian healthcare system and privately insured patients receive maximum benefit from this technology".

Savings calculations

Based on MTAA's database of public prices and benefit comparisons, the proposed benefit review mechanism delivers the following savings:

Figure 2: MTAA proposed reform savings and average benefit reductions



These savings represent a material benefit to insurers over the period and represent a significant impact to forecast device industry revenues from the PL. Importantly, these are bankable savings that accrue from day one of implementation. MTAA's reforms also deliver on fairness, by reducing all benefits to a benchmark price that is based on the public price. This will eliminate outliers and inconsistencies among items.

Benefit Review Mechanisms on the PL Recommendations

- A modified public-private referencing model proposed by MTAA be the preferred method to achieve efficient pricing on the PL without removing the unique characteristics of the private market
- The public-private referencing model be modified to account for different volume mix, the absence of price/volume/choice trade-offs and higher service levels in the private sector
- The public-private referencing model use an average net public price adjusted for private volumes
- The public price has an added private adjustment of 20% across categories to adjust for price/volume/choice trade-offs in the public market and higher services in the private market
- In addition to the above, cardiac implantable electronic devices (CIEDs) have their very high lifetime service requirements ($103m in FY23) recognised through a preserved component
- The public-private price referencing methodology be run every 4 years with benefit reductions phased across that period
- The process be conducted by the Department of Health either directly with sponsors or through an independent third party
- Provide a 4 year moratorium on benefit review for new benefit groups created for new technology listed on the PL
- The public-private price referencing data collection and calculation be run in the second half of 2021 for implementation of the first benefit reduction from 1 February 2022
- The phasing in the first four years be frontloaded with 40% on 1 February 2022 to achieve at least $98 million in savings by FY23 and cumulative savings of at least $747m by FY26

IMPLICATIONS FOR OTHER ASPECTS OF PL REFORM

Once an efficient pricing methodology is established for appropriate groups many of the other concerns with the operation of the PL are diminished. For instance:

- The number of benefit differences now on the PL between similar products will be reduced as some of these differences are not reflected in the public system
- Any perceived opportunities for gaming by misgrouping products are reduced because similar products are likely to be closer in price
- Similarly, the consequences for grouping errors are likely to be reduced
- There can be greater confidence in the pricing of comparators when listing new products

The impact of these changes should be kept in mind when considering other PL reforms discussed below, as they are based on the premise that efficient pricing has been achieved.

DEFINING THE SCOPE OF THE PL

The Department has indicated that the definition of what belongs on the Prostheses List lacks clarity resulting in products being listed on the PL that do not meet the current definition.

The Department further proposes that the definition of the PL no longer requires that a device be implantable. Instead, the PL only lists 'specific purpose medical devices where the intention of the accompanying medical procedure is to remedy disease or dysfunction through use of the specific medical device (e.g. hip replacement, stent, balloon angioplasty)'. This definition is intended to exclude items that are 'adjunct' to the procedure. Under this definition many wound closure and haemostatic devices are proposed to be removed.

Listing products not strictly meeting the definition

There are products currently on Part A of the Prostheses List that do not meet the criteria, particularly Criterion 4. Their value is not significant in the totality of the PL, probably less than 3%, so this should not be overstated as an issue. There are four possible reasons for this:

1. The eligibility criteria were unclear to the decision-makers
2. There was a misunderstanding about the nature of the product
3. The decision-makers believed a funding mechanism was needed and no other mechanism was available
4. The product was originally listed correctly but has since become ineligible because of changes in technology.

The last reason primarily applies to products that originally qualified under criterion 4b as specific and unique to implanting the main device but since then alternatives have emerged.

Reasons 1 and 2 really relate to perceived errors and there is likely an opportunity to both articulate the criteria for Part A more clearly, and to better describe products in applications, using transparency measures that have already been introduced to PL listing processes and can be further enhanced through transparency proposals later in this paper. Furthermore, improved technical expertise and enhanced processes and systems within the Department would also help to address these types of errors.

In fact, many of the items not strictly qualifying for Part A of the PL were probably listed due to reason 3. This speaks to the fact that clinicians assessing applications for new product groups frequently identified devices of value that weren't, or wouldn't be, funded properly through case payments, *ex gratia* payments or any other mechanism. For example, drug delivery devices were included as early as the 2005 PL. In the 2013 *Review of Funding Arrangements for Chemotherapy Services*, the report highlighted that there is no other means of funding drug delivery devices outside the PL. It also states that the funding of drug delivery devices would become an issue in the future.[22] This suggests that listing occurred to meet a clearly identified clinical need rather than to strictly conform to criteria. Surgical guides for craniomaxillofacial surgery where they are used for off-the-shelf products likely also fall into this category.

While prices may have declined over time so that this funding pressure no longer exists, removal of some of these products may also create the problem that put them on the PL in the first place: inadequate coverage. This would need to be considered and resolved on a case by case basis.

It should be clear from the above that products being added to the PL that do not strictly qualify does not reflect the fact that it is an irredeemable mechanism, but rather in some cases is a sign of the PL's value in providing a funding pathway where none exists. However, MTAA recognises that criteria need to be

22. https://www1.health.gov.au/internet/main/publishing.nsf/Content/chemotherapy-review/$File/review-of-chemotherapy-funding-arrangements.pdf

consistently applied and so these products should be removed from February 2022. MTAA is willing to engage in a discussion to identify these products for removal and consider other appropriate funding mechanisms where required to ensure coverage and patient access.

This is a much smaller sub-set of products than those proposed by the Department for removal. Nonetheless it would remove products that have caused confusion and inconsistency in decision-making and allow the definition of a prostheses to be reset and reinforced. This will be discussed further below.

The 'Intended Purpose' of the PL

The PL has not drifted from its original intended purpose. Only technologies and clinical practice have changed. The forerunner of the PL is Schedule 5, established as a result of an identified need to ensure clinicians could access the prostheses they needed to use for their private patients. The very first Schedule 5 already included stapling technology for wound closure. Wound closure products have remained on the PL since that time and the intensive reviews in both the 2000s and the early part of last decade that resulted in removals of non-qualifying products left wound closure products, for example, on the PL. This includes items that are temporarily implanted or absorbable. Therefore, the idea that the PL has dramatically departed from its 'original purpose' is false. This does not prevent a discussion about what role it should play into the future that may be different.

The primary purpose of the PL should be to give private patients access to single-use devices their clinician chooses to use to undertake the procedure to treat the condition. There is no reason in principle why this should preclude devices that are used to manage consequences of the operation such as bleeding or wound closure, even if there are some practical considerations with these products that require careful management. Patients also need access to these and the compound costs of their use can be significant. There is no question that they qualify under the TGA definition of a 'device' as listed in the Department's consultation paper. The concept of a 'consumable' sometimes used for these products is slippery and is of limited use as different stakeholders could define this in many different ways.

Furthermore, it should be noted that there are procedures where devices that may be considered 'adjunct to the procedure' (in the Department's terminology) are in fact central to achieving the clinical outcome. For example, a right hemicolectomy procedure (MBS 32000, 32003, 32005) to remove cancerous tumours in the right colon would not be performed without a surgical stapling device to reconnect the remaining colon. Nonetheless, stapling technology has been labelled 'general use' in the EY Report.

Therefore, products that are considered for removal require careful clinical evaluation beyond that in the EY Report before this type of change could be implemented. The potential for error that impacts clinical outcomes is high.

MTAA understands that PHA proposes to exclude devices from the PL that are temporary or absorbable. It is anachronistic to think of single use devices only in terms of a permanent or long term implant. If a new device becomes available that achieves the same outcome as a permanent implant but is absorbable, such a narrow definition would preclude its use and either the hospital or the patient would be forced to pay for it. For example, there is evidence that absorbable surgical sealants achieve clinically superior outcomes than permanent staples when fixating mesh for hernia repair.[23] The definition should not second guess the types of technologies that will be introduced into the future. This submission will return to the best definition further below.

Financial and access implications of removals from the PL

Apart from any considerations of principle or clarity, the Department's proposal to remove all general use products following the recommendations in the EY report would be a very significant change to the number and value of products on the PL. The PL value of the removals would be approximately $250 million in 2021 terms which is a very significant financial change for private hospitals. The (intended) consequence of removal is that they would be covered by case payments hospitals receive from insurers.

23. Fortelny et al 2012 *Use of fibrin sealant (Tisseel/Tissucol) in hernia repair: a systematic review* Surg Endosc 2012 Jul;26(7):1803-12.

Therefore, the very significant cost of all these products would need to be absorbed by private hospitals unless:

- there is some compensatory change to case payments; and/or
- they are able to reduce utilisation; and/or
- they are able to negotiate lower prices from suppliers

As noted earlier, the EY Report flags some significant discounts in the public sector compared to the PL in exchange for volume in the General Miscellaneous category. However, the large majority of reductions are less than 20% and in many cases there is no difference at all or public prices are higher than the PL. Furthermore, MTAA's dataset shows that the General Miscellaneous category is on average already approximately equally priced to the public ($-1.04m in 2019). In addition, many hospitals are not set up with a strong procurement capability that approximates the public sector. Therefore, it is unlikely that negotiated lower prices from manufacturers would make up the shortfall.

The assumption of private health insurers is that utilisation of these products would dramatically fall if they were removed because growth has been high and hospitals would have a lot of room to pressure clinicians to limit utilisation within clinically required levels. The assumption behind this is that the growth has no clinical justification, which at the very least is disputable. As noted earlier, the introduction of penalties for hospital acquired complications by some private health insurers from 2015 drove a stronger risk management approach.[24]

It also assumes that clinician judgement can easily be overridden by hospitals which is often not the case.

These constraints would require an equitable longer term adjustment to case payments to make removal of such a large group of products viable, something that insurers appear unwilling to do and for which no concrete proposal has been presented. A one-year stop gap solution is inadequate. Removals of so many products could compromise patient care in the private sector and force some hospitals on the margin of viability into non-viability. The EY Report also makes it clear that models for removals need to be developed, including through pilots, so that negative impacts are avoided.

Any removals of the large section of General Miscellaneous proposed by the EY Report and in the Department's consultation paper could only occur if there is a sufficient alternative funding mechanism created between insurers and hospitals.

Changes to Part A Criteria

It should be clear from the above that there is no in-principle need to significantly change the current criteria. Instead it would be helpful if the existing criteria were further explained to eliminate lingering confusion that hasn't already been resolved. For instance, sutures are named in the rationale for Criterion 4b) as not eligible for the PL. Given the variety and advances in suture technology, the definition of a suture could be more clearly defined. Other particular cases merit further clarification, such as whether products registered as pharmaceuticals or devices that are integrated with pharmaceuticals that are responsible for the mechanism of action, should be included. As outlined above consistent application, improved transparency and enhanced Department resources should eliminate the addition of products that are not properly eligible.

There is potentially an argument to be made that Criterion 4b) be removed and that all devices that are currently eligible by virtue of the fact that they specifically and uniquely implant the device qualifying under 4a) be bundled and share a benefit with the 4a) device. However, this should account for two factors: firstly, a device may be used to specifically and uniquely implant another device in some, but not all, instances, so this could result in overpaying. For example, laparoscopic versus open procedures require different accessories, or sometimes open procedures do not require accessories at all. Secondly, the price in the public market may separate the items into two for the same or other reasons. Therefore, bundling will not be appropriate in all cases and 4b) should be retained for some circumstances.

24. Majid, B et.al 2017 *Pricing for safety and quality in healthcare: A discussion paper* Infect Dis Health 23(1):49-53

Changes to Part C Criteria

Part C of the PL offers an important avenue for private health insurance funding for devices that don't otherwise qualify for Part A, usually because they don't meet Criterion 4. At the moment there is no mechanism for a sponsor to make a submission for a Part C product other than by invitation of the Minister for Health. However, the Department's consultation paper and the IWG report recognise that single use devices that are not implantable are currently excluded from coverage on the PL and this limits patient access to innovative technologies that help improve outcomes and reduce long term costs. Single-use non-implantable devices may play a critical role in patient treatment, avoid additional treatment costs and in some cases replace or reduce the need for an implant that is listed on the PL. Examples of single-use devices not covered by the PL or any other formal funding mechanism include:

- Stent retrievers for mechanical thrombectomy (MT)
- Drug eluting balloons for revascularisation
- Ablation catheters for Barrett's oesophagus
- Disposable instrument kits to perform non-invasive thalamotomy to treat essential tremor
- Pressure wires for fractional flow reserve (FFR)

As an example, stent retrievers for MT were recommended for reimbursement by MSAC in 2017 (Application 1428) and MSAC specifically noted its concern that patients would be affected because they are not covered under Part A of the PL. Since that time no action has been taken to list these devices. Drug eluting balloons for revascularisation are a substitute for drug eluting stents which are listed on Part A of the PL since they are implantable, while the balloons are not. The balloons may offer clinical value in some cases over the stents. Part C offers the opportunity to include these kinds of technology which are currently excluded from Part A because of the implantable limitation. However, the arbitrary barrier to listing – Ministerial activation – inhibits private patients' access to cost effective therapies.

Based on MTAA surveys of its members, the type, number, and costs of these kinds of technologies is limited and would not significantly impact expenditure on Part C. Criteria for inclusion could be narrower than Part A; for instance, general use items could be excluded. Importantly, a recognised pathway for application to be included on Part C should be created that doesn't rely on Ministerial direction, although the decision whether to list or not remains with the Minister's delegate as it does in the case of Parts A and B items.

While the general purpose of the PL is directed toward therapeutic products, there are also instances of single use diagnostics that should be included on the PL. Again, these instances are likely to be very limited if appropriate criteria are placed around them.

Pressure wires for fractional flow reserve (FFR) have been recommended by the Government-appointed Cardiac Services Clinical Committee as an objective criterion for percutaneous coronary intervention. However, they can't be listed on Part A of the PL because they are not implanted and have been rejected for listing on Part C because they have a diagnostic purpose. While private health insurers claim these are covered in procedure banding and contracts with hospitals, there is no guaranteed access to this critical technology at present and clinicians and hospitals advise that coverage is frequently not available. Appropriate use and further clarification of opportunities for listing on Part C can help address this.

Implied in the above is that the term 'prosthesis' may no longer be helpful in naming the PL and renaming to reflect its actual use should be considered. MTAA endorses the PL as a list of devices that are:

- ARTG listed
- Used within a hospital procedure or hospital-substitute treatment with an associated MBS code
- Single-use devices

Furthermore, for Part A, we support the continued application of the criteria of being:

- Implanted (broadly defined) or specifically aiding use of an implanted device; and
- For a therapeutic purpose

For Part C however, the definition should be more flexible to include products that are not general use but may be:

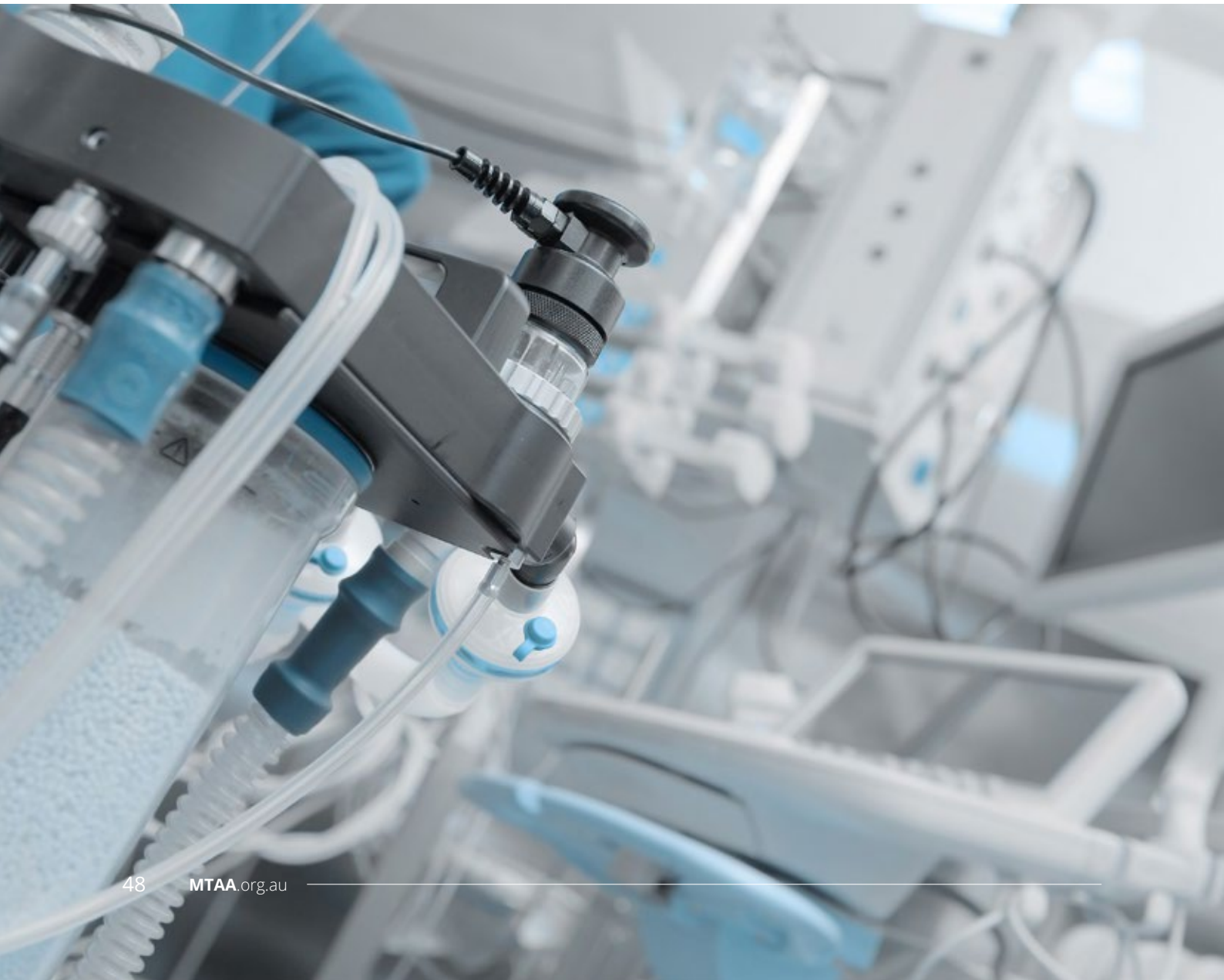
- Non-implanted but 'specific purpose medical devices where the intention of the accompanying medical procedure is to remedy disease or dysfunction through use of the specific medical device' (using the Department's terminology)
- Single-use intraoperative diagnostic technologies with an applicable MBS code

Scope of the PL summary

The current criteria for inclusion on Part A of the PL can be tightened and improved but should not be narrowed significantly unless there is careful clinical review of sub-groups of items and very significant alternative funding arrangements are put in place to account for the removals. To do so would have significant clinical and financial consequences. Retrospectively applying a presumed 'original purpose' shouldn't substitute for assessing the important role the PL currently plays in ensuring patient access to a diverse range of devices selected by their clinician. Issues that may arise as a result of general use products remaining on the PL could also be addressed through improved transparency and utilisation reviews, described in the next sections. Single use technologies currently excluded from Part A should have a defined pathway to be included on Part C if not general use.

Defining the Scope of the PL: Recommendations

- Criteria for Part A of the PL is tightened but not narrowed significantly
- In consultation with MTAA and other stakeholders identify and remove products clearly not meeting criteria from February 2022
- Broad removals of product groups under General Miscellaneous do not occur unless there is clinical review of each sub-group and alternative funding arrangements are put in place
- Single use technologies that are not implantable but meet other criteria should have a defined pathway to be included on Part C



IMPROVING THE STRUCTURE AND TRANSPARENCY OF THE PL

What is the exact issue?

It is important to be clear on exactly what is the problem with the operation of the PL leading to the drastic recommendation that it be scrapped, which would create a new set of problems. MTAA's belief is that sustained and rational attention to the actual issues can result in a set of reforms that address concerns and don't involve a significant administrative burden. This requires a clear understanding of devices and their regulation and use.

As outlined earlier devices are a complex set of technologies. There are many different types, they often work as part of systems and small adjustments are being continually made to improve them or offer more options. Furthermore, the public data available about them is often less than for pharmaceuticals for example, often due to their lower anticipated or realised revenues and due to regulators having less information in the public domain. Added to this, their use is not based on academic published information alone (or at all) but is closely interwoven with the clinician's technique and experience. The clinician has a first-hand knowledge not only of their results in practice but their mechanical operation and interrelationship with the patient's physiology, other devices and the clinician's skill, training and technique. The value of the device is bound up with value of the overall procedure with many literal 'moving parts'.

This complexity and deep knowledge of the clinician can create challenges in categorising products and making purchasing decisions. For instance, the variety and rapid change in products can lead to confusion about what exact product is being discussed. The perspectives of clinicians skilled in the relevant procedure will have a greater relative importance in assessing the value of a device. It will be harder for a clinician or academic not skilled in the procedure to make a correct judgement on this when it doesn't rely on published data only.

As discussed, in the case of a DRG model the burden of complexity is placed nearly entirely on private hospitals who are required to proactively manage the purchasing of each individual product, their assessment of value and utilisation by clinicians. The current PL sees the Department and its advisory groups assume responsibility for this management, with insurers responsible for determining if payment is within the rules. Outside of this, clinicians are given relatively open choice as to the devices they use.

The Department's consultation paper and PHI suggests that, in view of the complexity, the current PL is fatally flawed. This is not an assessment MTAA shares. Indeed, abolishing the PL simply transfers responsibility.

Having addressed the question of whether benefits are set at appropriate levels, this submission will go on to focus on other real or alleged issues with the PL. However, as noted, appropriate benefit levels mitigate the impact of other potential issues. Importantly, this means that, even if an error in PL listing were to occur, there is likely to be far less or even no net impact on overall expenditure on the PL.

Nonetheless, it is important that there is confidence that products only get on the list if they genuinely qualify and that the PL list is accurately organised so overpayments are not made due to misgrouping. The criticism is that this does not always occur and can never be fully prevented. A further criticism is that it consumes significant resources – for which the device industry will be charged – to avoid these errors.

It is also important that utilisation is optimised in the context of clinician choice; this will be discussed in a later section. Applications for listing and assessment of value will also be discussed in a later section.

The focus in this section is on structuring the PL and making it more transparent which enables a range of issues to be addressed and the appropriate level of resources to be applied.

Improving grouping

The Department's consultation paper notes that there are around 1700 different 'device groupings' or 'price 'groupings (MTAA suggested terminology: 'benefit groups').

It is important that grouping of products on the PL is as accurate and clear as possible. Fewer benefit groups, particularly those with fine distinctions, would also help administrative complexity in some cases. As a result, MTAA proposes to clarify groups descriptions and to consolidate groups in some cases.

1. Clarifying group descriptions

It is important that it is relatively easy to identify what products belong in a group. This would assist with decision-making, transparency and accountability. At present, groups have been created over time and are given brief names for categorisation purposes. More recently the definitions of suffixes have become readily available but for many years these were not. This meant that past decisions particularly by CAGs may be difficult to understand and imitate or change. A simple written description of a benefit group that augments the headings that now exist would assist the understanding of those who do not routinely perform the procedures but nonetheless need to make decisions, such as sponsors, the Department, advisory committees and insurers.

2. Consolidation of groups

Of the ~1700 benefit groups, MTAA has identified some opportunity for consolidation of groups. The use of public pricing as a reference will eliminate some current benefit distinctions and render some benefit group distinctions non-material. A review by MTAA members of orthopaedic benefit groups suggested that the number of groups could be reduced by 25% without any loss of relevant clinical distinctions.

MTAA proposes a methodology broadly based on a concept of clinical interchangeability. Where products are interchangeable they should be grouped together and share a benefit. MTAA is willing to provide recommendations on consolidation of groups that could be reviewed by CAGs for final approval. MTAA welcomes the opportunity to work with the Government on this consolidation process.

While due to the diversity of devices, the number of benefit groups will still necessarily be higher than the Department would prefer, MTAA believes that there could be a material reduction in the overall number, which combined with further clarity on the group description would render accurate decisions on grouping significantly easier to make.

The products in these new benefit groups would then be compared to one another in the benefit review process MTAA is recommending.

Transparency improvements

One of the greatest criticisms that has been made of the PL, and the assumed source of many issues raised by the Department and insurers, is that the PL is not sufficiently transparent. As a publicly available system of over 11,000 billing codes with descriptors, it is in fact much more transparent that any other device list in Australia. However, the more substantial criticism is that it is not always clear exactly what product and product range is being sold under a given billing code and how this relates to what is being sold and paid for in practice. The issues here are exaggerated and many have been already fixed by providing product codes to PLAC when decisions on listing are being made. However, MTAA agrees that there is a need to increase transparency and is willing to contribute to this process.

There are several initiatives that MTAA believes can assist with transparency:

Improved product descriptions

While most product descriptions are sufficiently clear to enable easy identification there are some listings where this isn't the case. Furthermore, there is a lot of variation in what is included in product descriptions. Guidance on how sponsors should write product descriptions, including a minimum amount of information needed, would improve immediate transparency of the list.

Improving descriptions should also include better articulation of other devices on the PL that the device listed under the billing code is typically used with. As defined by the TGA, a device may be part of a 'system' or included in a 'procedure pack', or be an 'accessory' to another device. Where this is the case, the PL should include this or it can be included in a look up database (see below). This allows much easier navigation of relationships between billing codes on the PL, even if products are not used together in all cases.

Maintaining up to date ARTGs

ARTGs have not been routinely updated by all sponsors when they have changed. Part of the reason for this is that a simple ARTG update can quickly turn into a full review. However, device sponsors need to commit to keeping ARTGs up to date and some consequence, such as delisting, should be considered for sponsors that do not make these changes within an agreed time period. Coupled with this, there needs to be a clearer alignment on what information genuinely needs review when an ARTG is updated, so that there is no more administrative burden either for the sponsor, the Department or advisory committees than is absolutely necessary.

Lookup database with device information

There has been a lack of clarity about what catalogue numbers (synonym with product codes or SKUs) sit under each billing code. While at various points in the past the Department has maintained a list of associated catalogue numbers, large numbers of these have been lost with system changes. In any case, there was never a complete list for legacy products. Clarity around how sponsors should address additional catalogue numbers that are added to the range but still conform to the ARTG has sometimes also been lacking. As noted, only recently have catalogue numbers been routinely shared with PLAC in the decision-making process.

One consequence of this is that insurers must sometimes guess whether a device claimed does in fact belong under the billing code. MTAA is committed to ensuring there is no ambiguity about the device range being sold under each billing code and that insurers have access to this for payment review purposes. This is also important to identify any misgrouping of products on the PL.

It should be clarified that catalogue numbers have no actual regulatory status. They are the manufacturer's way of organising the device range that is licenced for sale within the conditions of ARTG listing. The TGA doesn't necessarily have catalogue numbers on record although it can request them at any time. For Class III and AIMDs, the catalogue numbers are more likely to correspond directly with the UPI (Unique Product Identifier) that is assigned to each ARTG. Catalogue numbers appear on product brochures, instructions for use and specification sheets. In the case of the PL, catalogue numbers are primarily a way to identify what is actually sold by the manufacturer. There may be many catalogue numbers under a single billing code, corresponding to variations such as size or to different components that make up the single device.

It would be impractical and unwieldy to list catalogue numbers on the PL itself. Much more practical, and more effective, would be to use a look up database to which all sponsors, insurers and hospitals have access. This database could also include other information including product brochures as well as other relevant identifying numbers such as existing GTIN numbers.

The best candidate for this lookup database would be the proposed UDI database to be developed by the TGA. UDIs have long been used in the US and offer a uniform approach to product identification and a corresponding barcode. If there is a need for an interim solution, the National Product Catalogue or the Department's PL IT system (currently PLMS) could be candidates, depending on their flexibility.

Device sponsor disclosure obligations

Questions have been raised about whether a few device sponsors have benefitted from the ambiguity or vagueness about groups and products on the PL. While the vast majority of sponsors are highly ethical it is important that there is public and stakeholder confidence that sponsors are transparent at all times about their devices and selling products in full accordance with the PL requirements.

Sponsors need to:

- Fully disclose all information relevant to listing at the time of application
- Properly amend or seek to amend listing if relevant changes occur such as to the ARTG
- Ensure product descriptions on the PL are correct and in accordance with guidance (see above)
- Take responsibility to alert the Department if they believe their product may be wrongly grouped
- Make available all relevant information about products actually being sold and claimed under a billing code

MTAA proposes that there be clearer responsibilities outlined with the potential for penalties in certain circumstances if sponsors do not adhere to these requirements. One option would be to update the MTAA Code of Practice to reflect this and require sponsors to sign up to the Code.

Combined with other transparency initiatives, particularly the lookup database, this would allow competitors, insurers, the Department, and hospitals to more easily identify when there is an anomaly and, if there is sponsor responsibility, to have an avenue for sanctions.

MTAA expects that the prospect of this accountability would take away any presumed incentive that may exist for sponsors to take advantage of the PL system. MTAA reemphasises that cases of this are certainly rare, and far rarer than is alleged, but nonetheless recognises this measure is required to build confidence in the system.

Having a system of transparency and accountability also allows sponsor applications to have a much lighter touch review in many cases, as possible errors will be much more transparent and the opportunity for sanction exists.

This approach of requiring sponsors to assume ownership for accuracy under possible penalty is what currently exists for TGA registration in the case of devices Class IIB and below.

Structure and Transparency Summary

The above proposals mean that both *benefit groups* and *billing codes* can be better managed. Combined, the above measures should result in a PL that is transparent and more easily comprehensible. This increases accountability by all parties and MTAA recognises this must include accountability from sponsors. This also allows the Department to focus more on the management of groups, while sponsors take more ownership, with accountability, for their billing codes.

This would lead to lower administrative complexity and fewer errors, while maintaining a comprehensive list from which clinicians are free to choose that is efficiently priced.

Structure and Transparency Recommendations

- Consolidate benefit groups based on clinical interchangeability
- Add clearer guidance on product descriptions on the PL
- Create a lookup database with full product catalogue information preferably using the future TGA UDI database
- Strengthen sponsor information disclosure responsibilities, including keeping the ARTG up to date, potentially through strengthening and broadening the application of the MTAA Code of Practice

OPTIMISING UTILISATION

Many specious arguments have been made to suggest that utilisation on the PL is out of control. Unlike in the public sector, clinicians in private hospitals have autonomy over what they use in a procedure, precisely because there is a PL. Criticisms of high or growing utilisation rates are in effect criticisms of clinician decision making.

The DRG model confuses *curtailing* clinician decision making with *improving* clinician decision making on device choice. It is intended to introduce a system of controls.

While the option to create restrictions on the current PL exists and can always be considered as an option, the best approach to optimising utilisation in the private sector is to collaborate with the clinicians themselves. This may include improving the information flow and also increasing confidence that device manufacturers are at all times playing the correct role in the use of devices.

What is 'overutilisation'?

It is important to be clear what is meant by 'overutilisation' if it is to be properly addressed. As noted above, high utilisation or utilisation growth does not mean overutilisation and this suggestion should be avoided. The basic assumption should be that clinicians endeavour to make the best choices for their patients. Likewise, there are many situations where only a set number of devices can be used within the procedure. In view of this, overutilisation can fall into two possible categories:

- A higher priced product is used when a lower priced product would have been clinically as effective
- A product is used more often than is clinically warranted, either in a single procedure or across procedures

It is important to realise that while use outside of approved intended purpose of a device may often sit in one of these two categories, it could equally sit in neither. Nonetheless the presumption is that off label use is usually also not the best use of the product and certainly should not be promoted by any supplier.

In both cases above, the use is not considered *cost-effective* use. There may be other situations where a poorer outcome is being achieved due to the selection of an inferior device.

Importantly, imposing controls on clinicians through a DRG model doesn't guarantee better selection, it only guarantees lower cost selection.

Engaging Clinicians

The priority objective for improving utilisation is to better engage the clinicians using the devices. Primarily this should occur through the specialty groups. MTAA understands that there is a strong desire among specialty groups to retain the PL. They are best placed to evaluate usage and to advise their members on best practice approaches to utilisation that reflects the evidence.

Creating an annual report of utilisation for discussion with the specialty groups would be a welcome step. MTAA understands that at present the *Private Health Insurance Act* 2007 (the Act) makes it difficult to share data on prostheses use more widely. If this is a genuine barrier, then an amendment should be considered to allow sharing of data in a way that carefully protects confidentiality of patient data.

Creation of a representative specialty council to review PL utilisation and provide recommendations to clinicians practicing in the private sector would be highly beneficial. Various stakeholders could assist with communicating recommendations. There could be a particular focus on areas of concern such as wound closure. In particular, Clinical Advisory Groups (CAGs) that now play a gatekeeper role to the PL could increasingly play an advisory role in providing advice to clinicians on appropriate use of PL products.

Through this process, clinicians would not lose control of choice of device but be engaged to achieve better outcomes for patients while optimising value on the Prostheses List.

Registries

Registries such as the AOANJRR (National Joint Replacement Registry) provide valuable sources of data for assessing utilisation patterns and outcomes, and providing evidence-based guidance to clinicians on optimising device choice. MTAA would welcome further initiatives led by the AOA using the NJRR to maximise health outcomes and value for money on the PL. It should be noted that the NJRR is currently funded by law from industry fees collected through the PL. If this is abolished, another mechanism would need to be found.

MTAA also welcomes the Australian Government's National Clinical Quality Registry Strategy which aims to prioritise the establishment of national registries according to need and also to find equitable funding pathways for them that rely neither on governments or industry alone. Registries can also be considered as a major option to address specific questions that arise in relation to the best use of devices on the PL. Given the major investment involved, this would need to be considered carefully. Investment should come from insurers as well as from the device industry.

Restrictions, MBS codes and approved intended purpose

While increasing restrictions may be an attractive option to perceptions of overutilisation, it greatly increases the administrative burden of the system. Typically, restrictions should only be imposed where there is high risk of utilisation that will not be cost-effective and not merely its possibility.

Approved intended purpose should be a guide for clinician utilisation and is certainly essential for circumscribing promotional activity by device manufacturers. There is the opportunity to make the approved intended purpose more visible to all parties through the lookup database proposed above. There may also be opportunities to clarify the approved intended purpose with clinicians and hospitals where there is reason to think there is significant off-label prescribing.

The Act requires that a prosthesis listed on the PL has an MBS item number associated with its provision. Historically this has been seen as a threshold requirement, so that once an MBS number can be associated with the device, it becomes eligible for listing. However, the association of the MBS item number to the billing code could reasonably be taken further by pre-identifying the specific MBS item numbers in which the device can be used and only requiring payment by insurers if used with those item numbers. This would add administrative complexity for hospitals and clinicians and would need to be weighed against the perceived upside in limiting use that may otherwise be off-label or clinically not recommended. It would also add to the burden of evaluation. It would likely be better to allocate MBS item numbers to benefit groups, not to specific products.

Industry activity

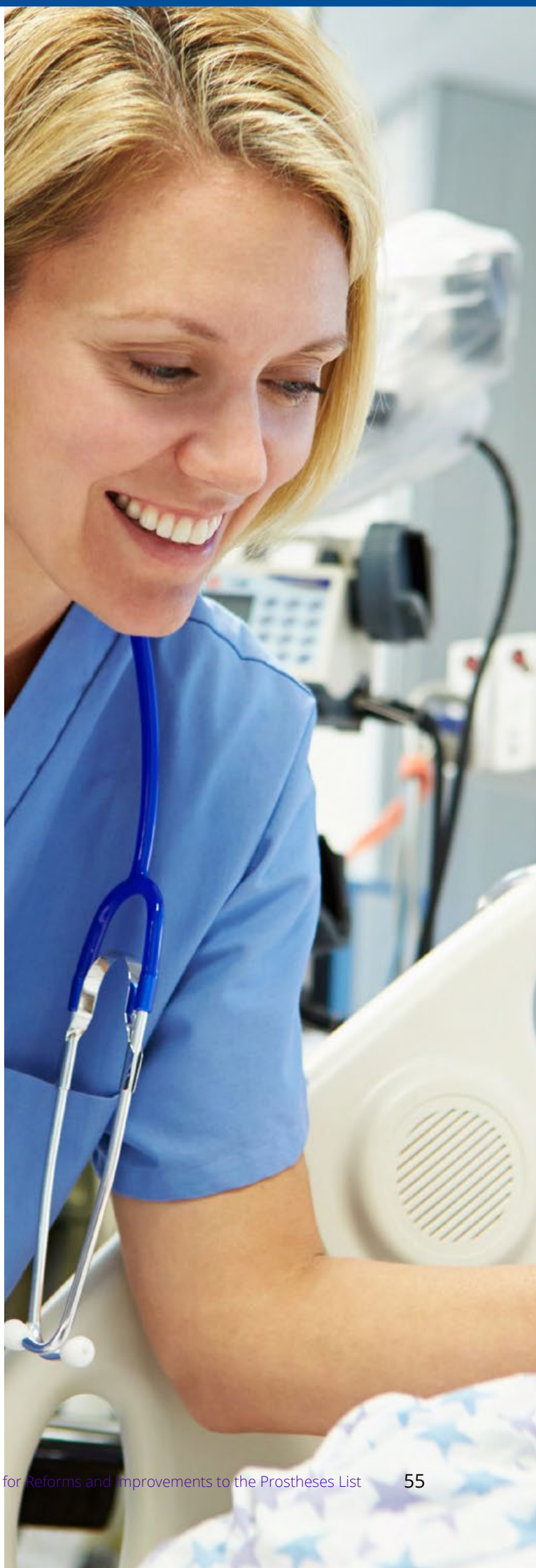
MTAA is confident that its members are largely responsible in their promotion of PL products. However, it is important that there is confidence in the behaviour of the device industry. It is important that company representatives promote according to the approved intended purpose and do not encourage use of products that are not clinically necessary. MTAA can review its Code of Practice with the PL in mind to ensure the provisions relating to promotion are sufficiently strong. However, this would only be effective if agreement with the Code of Practice was mandatory for all sponsors of products on the PL.

Utilisation summary

Promoting optimal use of devices on the PL without heavy controls that restrain clinician choice requires a cooperative effort led by clinicians and, in particular, the specialty groups who advise their members. MTAA supports specific measures to review utilisation and engage clinicians on best practice device use that is patient and outcomes focused. It is important that high utilisation does not automatically get branded as 'overutilisation'. MTAA supports industry taking further responsibility for the messages it provide to clinicians to ensure best practice use is encouraged.

Utilisation Recommendations

- Engage clinicians through colleges to conduct reviews of high utilisation groups on the PL to create recommendations for improved utilisation
- Develop and share a comprehensive database on PL utilisation to enable action across stakeholders
- Consider selective funding of additional registries to inform best practice utilisation
- Further disseminate information on device approved intended purpose and consider use of MBS item codes and, in selected cases, restrictions to promote optimal utilisation
- Strengthen sponsor promotion responsibilities, potentially through strengthening and broadening the application of the MTAA Code of Practice



IMPROVING LISTING PROCESSES

It is critical for the private sector and private patients that new innovation and new competition can be listed on the PL without any unnecessary barriers. Access to innovative medical technology should be at least as good, if not better, in the private sector. If this were not the case, it would be a clear sign that listing processes are not working.

Benefit setting for prostheses by DRGs under Option 1 favoured by the Department dispenses with centralised reviews of efficacy, safety and cost-effectiveness of the vast majority of products for reimbursement purposes. It is assumed that a DRG model will drive trade-offs at the hospital level rendering a centralised review unnecessary, at least for the purposes of establishing cost-effectiveness. The TGA's approval of a product for sale and the hospitals' purchasing decisions become the only barriers to entry. This has been suggested as an upside for improving access to new technologies with a DRG model.

The DRG model prompts consideration of what level of centralised review of efficacy, safety and cost-effectiveness is actually needed. A DRG model purports to control prices and to control volume and if these two factors are sufficiently addressed in a retained PL, it is questionable whether significantly more review is needed than under a DRG model. MTAA recognises that in retaining a PL some centralised review is needed. However, the question is what level and in what circumstances. The principle should be that any assessment should be, having regard to the risk, the minimum necessary to create confidence that the listing is appropriate, at the right price and under the right conditions.

Health technology assessment (HTA) is embedded as a method used by the Federal Government to inform decisions on public funding of the PBS and MBS. In recent years the Department has sought to extend the methodologies of HTA more extensively to devices on the PL, both in the name of consistency and to eliminate the perceived errors of past decisions.

Two points should be noted in relation to this. Firstly, the PL is not primarily a publicly funded system and decisions to list on the PL are not primarily decisions about societal opportunity cost. They are decisions about how to spend individual policyholders' funds that they have invested in their health via their insurer. The Government rebate does not change this but is designed to support it as a public good. It doesn't license a different kind of decision making more suited to public systems. Applying HTA to the PL needs to be considered in this context. It doesn't mean ignoring value but may suggest a different approach is warranted.

Secondly, most of the listing errors that have been promoted as examples of a broken system don't have anything to do with the assessment of value, but rather with accurately identifying and grouping products combined with a lack of confidence in the validity of the price of different groups and comparators.

MTAA's proposal has a clear method to create confidence that benefit setting across the PL is efficient. Similar to the application of a DRG model, this price will reflect the relative value placed on the product by a range of public health systems both in terms of the price itself and the volume used.

It also includes a proposal to create absolute transparency of devices on the PL and an approach to grouping them accurately, with built-in accountability mechanisms. Finally, it includes proposals to promote best practice use of devices through clinician-led initiatives.

With these in place, the question for assessing new or amended listings becomes:

1. Are additional efficacy and safety reviews required beyond TGA mechanisms?
2. What determination of value needs to be made including conditions of listing?

Answering these questions needs to have regard to the following:

- The TGA is a highly credible regulator of devices; if there are issues with their processes for assessing the risk/benefit profile of products these should be addressed there not replaced with a duplicate process
- Most devices or even groups of devices will have small sales in isolation so financial risk is generally low
- For reasons described earlier, clinician knowledge and experience rather than large data sets are sometimes the only and often the best source of information about the value of devices except for major new innovations and post-market registry data
- Many devices or device ranges will undergo minor changes during their lifecycle which don't impact the overall performance of the product but may provide incremental benefits or offer more choice
- Placing multiple restrictions on an array of devices to control utilisation is inefficient and largely unnecessary given their expenditure risk
- Issues with unexpected utilisation can be addressed through transparent sharing of utilisation data and discussions with clinicians using the devices

CAG/PoCE reviews

The Clinical Advisory Groups (CAGs) or the Panel of Clinical Experts (PoCE) supporting PLAC have been required until now to review every single new or amended application for the Prostheses List. They have played a heroic role in juggling many competing issues and datasets in this process. In doing this role they have answered two major questions. Firstly, whether the product qualifies for the PL and what group it belongs in. Secondly, whether the clinical impact justifies the listing. They may also make comments on the benefit proposed, but these are secondary to the major questions.

The workload in managing the CAGs/PoCEs and of the CAGs/PoCEs themselves is very significant. They are reviewing multiple applications that do not really require their expertise, which is better used on a core set of decisions.

MTAA believes that though other reforms: clarifying PL criteria, simplifying groupings, providing product transparency and sponsor accountability, and improving Department systems and capabilities, the first question addressed by CAGs/PoCEs can be answered by the Department for all risk levels of devices that are being added to existing groups, unless there is uncertainty, in which case only one clinician's advice out-of-session should be needed.

In the case of efficacy and safety reviews, CAGs/PoCEs should only be involved in these where there is some significant uncertainty, particularly for a proposed listing in a new group.

Consequently, MTAA recommends that for most new applications to list in the same group, or to make an amendment application, a CAG/PoCE review is not required. This can be managed by the Department, typically with a 'light touch' approach, which has until now been referred to as the Abbreviated Pathway. This has been piloted but not implemented on a wide scale.

Applications to create a new group require clinical assessment to evaluate both the merit of distinguishing the technology from existing groups and also the clinical performance of the devices if an HTA is to be applied. This is where CAG/PoCE expertise is most valuable.

By carefully reviewing the best role CAGs/PoCE can play in assessment this provides the opportunity to reduce the resources required for most assessments. Department resourcing will be discussed further below.

Application of HTA

An application to list on the PL by creating a new group that is priced differently to existing groups immediately raises the question of value. If there is utilisation in the public setting, in many cases the value question has already been answered, and once the new group is defined the benefit can be set immediately using the methodology proposed by MTAA for benefit review, if the sponsor requests this approach. Clearly, this would not be able to account for volume in the private market,

so this would be a decision for the sponsor.

Where this isn't the case, some sort of HTA will continue to be required. The Department's consultation paper proposes moving HTA to a responsibility of MSAC, which is gradually becoming a 'catch all' for every HTA process apart from PBS applications. MSAC is very suitable to reviews of devices that involve a new, previously unfunded procedure. In these cases, there should be a significant evidence base developed for assessment. This enables clinical and health economic experts not skilled in treating the condition with current procedures to comment on the value and how it fits within the overall healthcare system. However, for new devices with claimed improvements the lengthy MSAC process is rarely appropriate. At present, PLAC has sometimes referred applications for devices with markets of only a few hundred thousand dollars to MSAC for consideration. This is unnecessary, and if the Department imposes higher cost recovery, also cost prohibitive.

The MSAC process for PL devices needs improvement. At present there is significant disjuncture with PL listing processes which adds unnecessary time. Furthermore, applications that involve changes to MBS items can take years due to delays in the Budget process for approving MBS items. Finally, more device-specific guidance for both sponsors and MSAC would improve the evaluation process.

The focused HTA process introduced in late 2019 has not had good results for industry applications. Most have been rejected or accepted only at benefit levels well below the sponsor's application request. This has resulted in access in the private market potentially being worse than in the public market. There is a need to grow an understanding within the industry of the evidence required to satisfy even a more focused HTA process. However, the process itself also needs reconsideration if genuinely valuable technology is to be reimbursed on the Prostheses List. Once again, replacing the PL with a DRG model would lower the bar to entry by having no HTA requirements but merely a negotiation process with hospitals.

In light of this the focused HTA process needs reconsideration if more incremental innovation is to become available to clinicians and patients in the private setting. MTAA is willing to engage with the Department and other stakeholders on how to achieve this. However, MTAA recommends the following approaches:

- Evaluation of value should be proportioned in according with the financial and clinical risk of listing
- Advice of clinicians who routinely surgically treat the condition must be combined with available data to inform the assessment of value
- Use of a cost-consequence or multi-decision criteria analysis (MCDA) approach should be used in many cases to assess PL device value
- To use legal terminology, a 'beyond reasonable doubt' approach often applied in HTA should not be used a threshold for proof, which will exclude many devices whose value will only be demonstrated by experience
- Use of fit-for-purpose post-market reviews to assess utilisation and clinical performance of new groups should be used rather than high barriers to entry

In principle, any device available in the public sector should be available in the private sector unless there is evidence that public use is in error. A more pragmatic approach to innovation will help ensure that private access equals or, where appropriate, exceeds, the public sector.

As noted earlier, MTAA proposes that any new benefit group be excluded from benefit group reviews for a period of 4 years.

Listing process summary

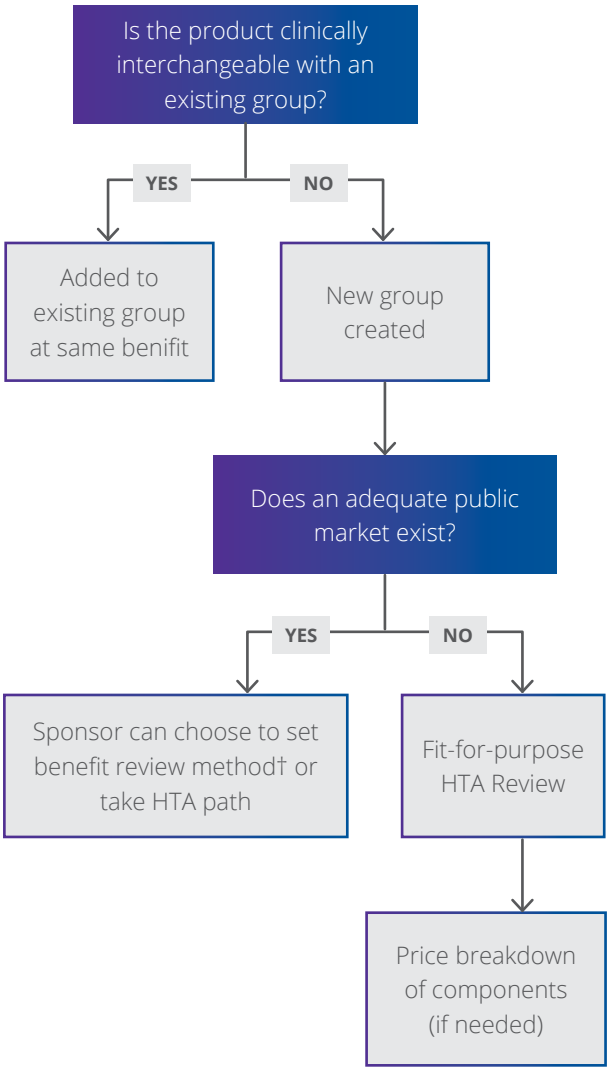
The move to a DRG model would abolish most central evaluation of devices at the price of removing choice for financial reasons. This should prompt a rethink about the level of central evaluation actually needed for new and amended listings on the PL. Proposals by MTAA for benefit review, transparency and utilisation improvements should create greater confidence that in-depth reviews can be undertaken only where needed. CAGs/PoCEs can be focused primarily on assessing new groups and informing HTA. MSAC processes should be reserved for high risk decisions and should be improved for PL devices. Focused HTA should be redesigned to take a pragmatic approach that is still more rigorous than the proposed DRG model but nonetheless does not overengineer the decision out of proportion to the risk.

Listing Process Recommendations

- Implement the Abbreviated Pathway listing process for all products that have an existing benefit group on the PL unless there is uncertainty or a specific issue of concern
- Clinical Advisory Groups and the Panel of Clinical Experts should be used primarily to assess applications for new groups i.e. higher benefits
- Sponsors of applications to form a new group should have the opportunity to use public benchmarking rather than an HTA process to set a price
- MSAC reviews of PL applications should be limited to high clinical and financial risk applications
- Focused HTA reviews should be continued with an emphasis on HTA reviews closely involving clinicians skilled in the use of relevant procedure

Figure 3 shows a summary of MTAA's proposed listing process for existing and new groups:

Figure 3: MTAA's proposed listing process



†Without private volume the public price + adjustment will set the benchmark

DEPARTMENT RESOURCE AND COST RECOVERY

Department resource

Adequate Department resourcing is one of the most important keys to reforming the PL. There isn't a need for an enormous bureaucracy and this proposal suggests ways in which resource intensive activities for evaluation and rectification of issues can be limited or avoided. However, there are two key improvements in resourcing that are needed:

- Staffing – there is a need to recruit and retain staff who have the technical capability to understand devices. While this has improved recently with recruitment of the Prostheses Section Director from the TGA, there are still significant misunderstandings that occur because of a lack of expertise whether acquired through tertiary qualifications, external experience, on-the-job training or preferably all three. This needs to be combined with a high level of competence to manage processes and communicate clearly with sponsors
- Information technology systems – It is acknowledged by the Department that the current Prostheses List Management System (PLMS) is not fit-for-purpose for managing the PL and needs improvement. The Department has expressed a preference to move to the Health Products Portal (HPP) system used for the PBS. It is unclear whether this is suitable for devices and this would need to be investigated. However, in the digital age there is no reason that a modern IT system could not allow efficient management and high user interoperability for the PL. While the 11,000 items on the PL is frequently cited as a problem, in fact this is not a particularly large database and can be managed effectively.

Cost recovery

The Department advises that, should the PL be retained, evaluation and compliance processes will be tightened and that these will be fully cost-recovered from industry. As noted above, MTAA has proposed a way in which administration of the PL can remain reasonable, recognising that some additional resource will be required and some proportionate additional fees are likely for listing and remaining on the PL. MTAA and its members would welcome the additional resourcing and process improvements that new cost-recovery arrangements should deliver.

However, device sponsors are not the only beneficiary of the listing process. The entire PL is run to deliver benefits to policyholders of insurance industry products. Therefore, the role played by the Department is partly one of delivering a service to the insurers themselves. For this reason, cost recovery should not be from device sponsors alone but also from the private health insurance industry.

Department Resource and Cost Recovery Recommendations

- Staffing in the Department to manage the PL should include greater technical expertise in devices
- The Department's IT system for managing the PL should be upgraded and the Health Products Portal should be assessed for this purpose
- Cost recovery should be levied from both the device sponsors and from the private health insurers

CONCLUSION

MTAA's proposal to reform the PL delivers savings and retains the characteristics of the PL as providing the choice of device suitable for a clinician-led private system.

It proposes clinician engagement as the best approach in this system to addressing concerns about utilisation growth. Furthermore, it offers a way in which the transparency of the PL can be further improved. Combined with improved reviews and accountability within the system, as well as bolstered Department resource, this offers the promise of a PL that is efficient and effective. MTAA's proposal includes an approach to ensure that access to technological innovation is as good as, if not better than, the public system.

MTAA looks forward to constructive engagement with the Government and other stakeholders on these solutions. A highly functional PL should be the ambition of all involved stakeholders and a shared commitment will enable it to protect patient access to valuable technology that improves their health into the future.

APPENDIX 1

KPMG

Cardiac Implantable Electronic Device (CIED) service valuation

Medical Technology Association of Australia

February 2021

Contents

Inherent Limitations

This report has been prepared as outlined with the Medical Technology Association of Australia in the Scope Section of the contract dated 23 December 2020. The services provided in connection with this engagement comprise an advisory engagement, which is not subject to assurance or other standards issued by the Australian Auditing and Assurance Standards Board and, consequently no opinions or conclusions intended to convey assurance have been expressed.

No warranty of completeness, accuracy or reliability is given in relation to the statements and representations made by, and the information and documentation provided by the Medical Technology Association of Australia consulted as part of the process.

KPMG have indicated within this report the sources of the information provided. We have not sought to independently verify those sources unless otherwise noted within the report.

KPMG is under no obligation in any circumstance to update this report, in either oral or written form, for events occurring after the report has been issued in final form.

Third Party Reliance

This report is solely for the purpose set out in the Scope Section and for the Medical Technology Association of Australia's information, and is not to be used for any purpose not contemplated in the contract or to be distributed to any third party without KPMG's prior written consent.

This report has been prepared at the request of the Medical Technology Association of Australia in accordance with the terms of the contract dated 23 December 2020. Other than our responsibility to the Medical Technology Association of Australia, neither KPMG nor any member or employee of KPMG undertakes responsibility arising in any way from reliance placed by a third party on this report. Any reliance placed is that party's sole responsibility.

Executive Summary

Cardiac implantable electronic devices (CIEDs) consist of pacemakers, implantable cardioverter-defibrillators (ICDs) and implantable loop recorders (ILRs). CIEDs require technical support during the implantation procedure as well as ongoing technical services for the life of the device once implanted. These services can range from providing technical advice about device features through to troubleshooting a device.

The provision of these services differs depending on whether it occurs in a public or private healthcare setting. Hospital staff typically provide these services in a public setting. However, in a private healthcare setting, *e.g.* private hospitals or clinics, staff at companies supplying CIEDs, also known as industry employed allied professionals (IEAPs), support physicians who conduct the implantation procedure or request for the follow-up consultation..

While IEAPs work closely with physicians to provide technical services for patients, these individuals are directly employed by companies supplying CIEDs. Even though public and private payers provide reimbursement for follow-up services, these payments go toward the physician's time only, rather than toward the services provided by IEAPs. As such, these technical services do not attract any further reimbursement to companies supplying CIEDs beyond the cost of providing the device at the point of implantation.

Demand for CIED services can often be unpredictable. As such, meeting this demand can be challenging. Companies supplying CIEDs are tasked with managing the delivery of services even if they occur concurrently across multiple locations without notice, or if the service is required in a remote area with limited air transport access. In the presence of such challenges, companies continue to provide timely and accessible services which ensure universal access and equity of care across Australia. The more responsive and the more accessible the level of service provided, the higher this estimated cost to provide CIED support services will be.

Scope

To inform discussions regarding revisions to the Prosthesis List, this report presents estimates of the resource requirements to provide these CIED services by companies supplying CIEDs in a private healthcare setting between 2019 – 2022 (2019/20 – 2022/23). The focus of the report is on the private healthcare setting *e.g.* private hospitals and clinics only, where, unlike the public healthcare setting, companies supplying CIEDs take on the delivery of CIED support services. This study:

- estimates the cost of the various components that are involved in providing timely and accessible CIED services, as provided by those companies supplying CIEDs in a private healthcare setting *e.g.* items that make up labour and travel costs, on an annual basis for 2019 – 2022 (2019/20 – 2022/23); and
- illustrates the value of these services, through the use of counterfactual scenarios, highlighting the resources that would be required from households and/or governments for the continued delivery of these services, if they were not provided by the companies supplying CIEDs.

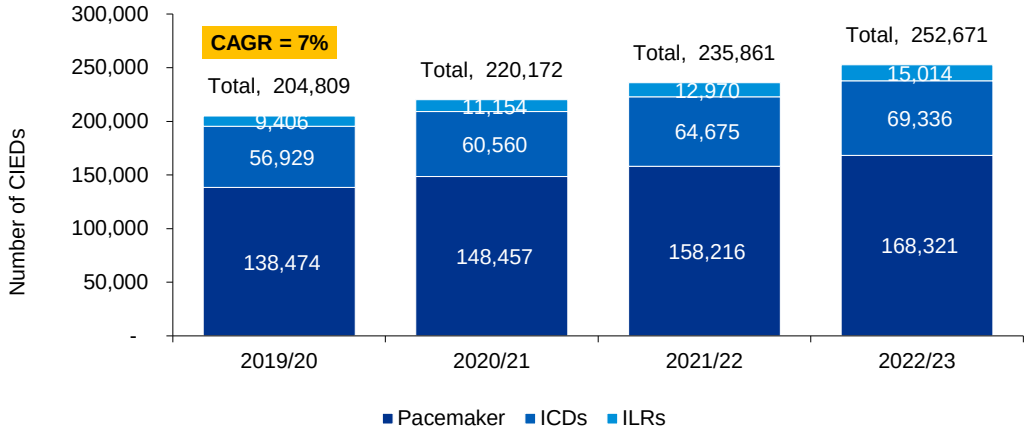
The analysis in this report does not include any assessment regarding the level or adequacy of existing funding under the Prosthesis List for the level of service currently being provided by companies supplying CIEDs. Without further information on the cost (and price margins) for each device, it is not possible to make a connection between the cost of CIED services estimated here on an annual basis and the cost of services bundled into the once-off reimbursement for the provision of a device at the point of implantation.

Inherent within the provision of CIED services by these companies is a value transfer from device manufacturers to patients and society more generally. This value is broader than just the costs required to provide these services. It is derived from several value drivers including, but not limited to, the responsiveness of CIED service delivery, patient experience, clinical outcomes, and clinician productivity. In the absence of more data, assessment of this broader value contribution is out of scope and, as such, the analysis relies on quantifying the *cost* of providing these services rather than the full *value* that they create.

Demand for CIED services

Every implanted CIED will require technical services over the life of the device. New insertions of CIEDs each year add to the prevalence of devices implanted while the number of deaths and removal of CIEDs reduce the prevalence of implanted devices requiring services each year. The number of new CIED insertions exceeds the number of removals (from death or scheduled ILR removals) by approximately 18,000 units on average each year, thus the prevalence of CIEDs is projected to grow by an average of 7% per year over 2019/20 – 2022/23.

Estimated Prevalence of CIEDs in the population, 2019/20 – 2022/23



Note: values are reported on a financial year basis

Based on data from the companies supplying CIEDs[1], the number of scheduled, unscheduled and remote monitoring services required per device each year is known:

- Each device will require on average 2 scheduled services per year; and
- For every scheduled service, each device will require on average, 0.087 unscheduled services and 0.77 remote monitoring services.

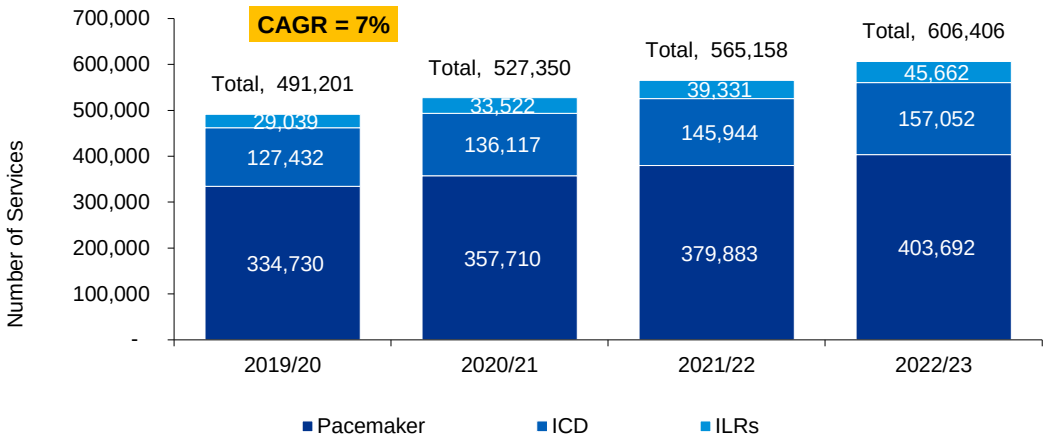
Based on the total number of services that are estimated to occur each year, a Productivity Commission (2009) report suggests that only 56% is provided in a private healthcare setting. With limited data, this share is assumed to hold over the projection period and that the current level of timeliness and accessibility of services is retained.[2]

[1] Internal data has been provided with information on the volume and type of services delivered over a 6-week period.

[2] Companies supplying CIEDs are required to provide services that may occur concurrently, across multiple locations with varying degrees of remoteness when they are needed, often without much notice.

The number of services that are provided in a private healthcare setting is estimated to be about 491,000[3] in 2019/20. This will likely grow to be over 606,000 by 2022/23.

Number of CIED services provided in a private healthcare setting, 2019/20 – 2022/23



Source: KPMG estimates
Note: values are reported on a financial year basis

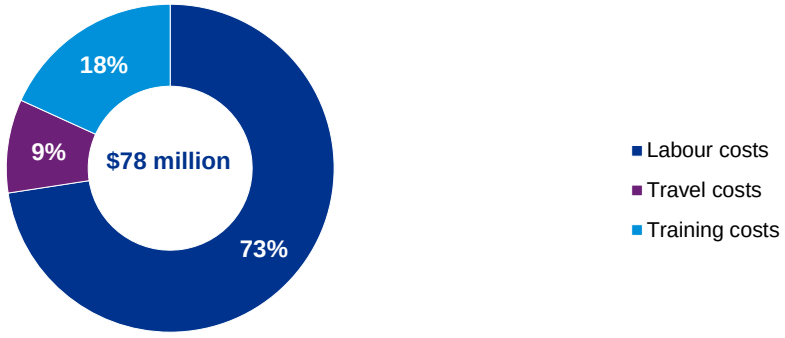
Cost of providing CIED services in a private healthcare setting

There are three main components that make up the resource requirements to provide CIED services in a private healthcare setting under the current arrangements and level of service: labour costs, travel costs and training costs. The estimated cost of these services in 2019/20 is expected to be about **$78 million**, with **491,201** services provided. This is anticipated to increase by **9%** to **$103 million** by 2022/23, where the volume of services is expected to be **606,406**. The estimates are provided in nominal terms. The growth in the cost of providing CIED services is made up of volume of services growth (7%) and Consumer Price Index (CPI) and Wage Price Index (WPI) increases each year (2%).

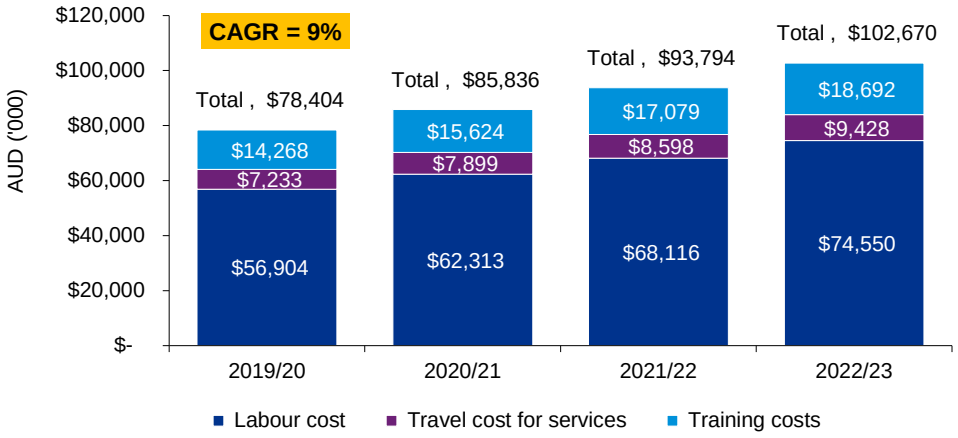
The labour cost component makes up almost three-quarters of the total cost of providing CIED services, largely due to the need for a buffer to ensure services are delivered in a timely and accessible manner.

[3] This number is estimated from a bottom-up approach based on the estimated number of devices in the population and includes the number of insertion support services for 2019. The Cardiac Internal Working Group Draft provided to KPMG by companies supplying CIEDs reports approximately 423,000 services in 2019 however this does not include the number of insertion support services and is based on an annualised estimate of follow-up services from a 6-week data snapshot collected by companies that is assumed to be a representative period. The discrepancy between the two estimates is due to a difference in data sources and methodology.

Breakdown of total costs by component, 2019/20



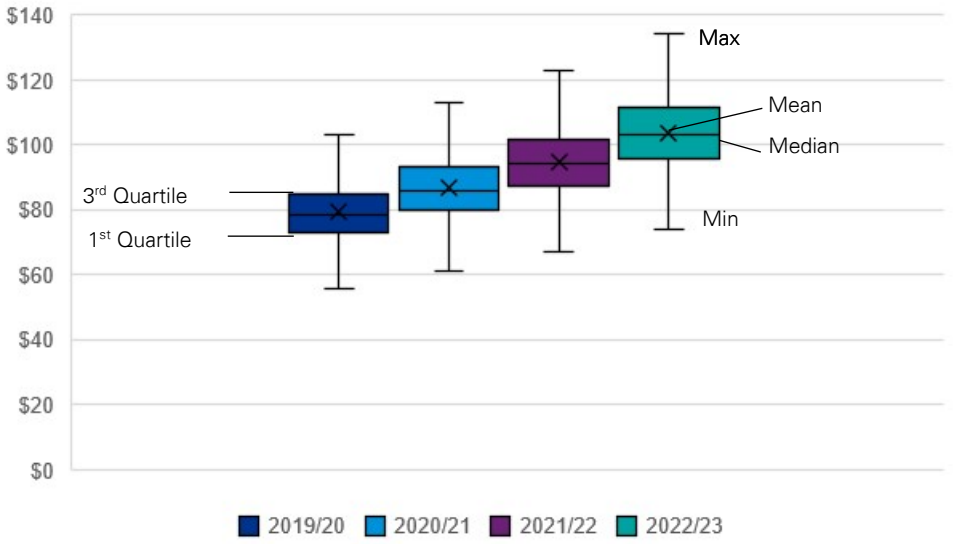
Total cost of CIED service delivery by companies supplying CIEDs, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported in nominal terms and on a financial year basis

The analysis is underpinned by several assumptions due to limited data available. To account for this, a Monte Carlo simulation with 1,000 iterations was used to assess the impact of uncertainty in key assumptions. Constructed 95% confidence intervals suggest that the total cost of services provided by companies supplying CIEDs in 2019/20 is expected to fall in the range of $66 million and $96 million, and between $86 million and $125 million in 2022/23.

Total cost of providing CIED services ($ million)

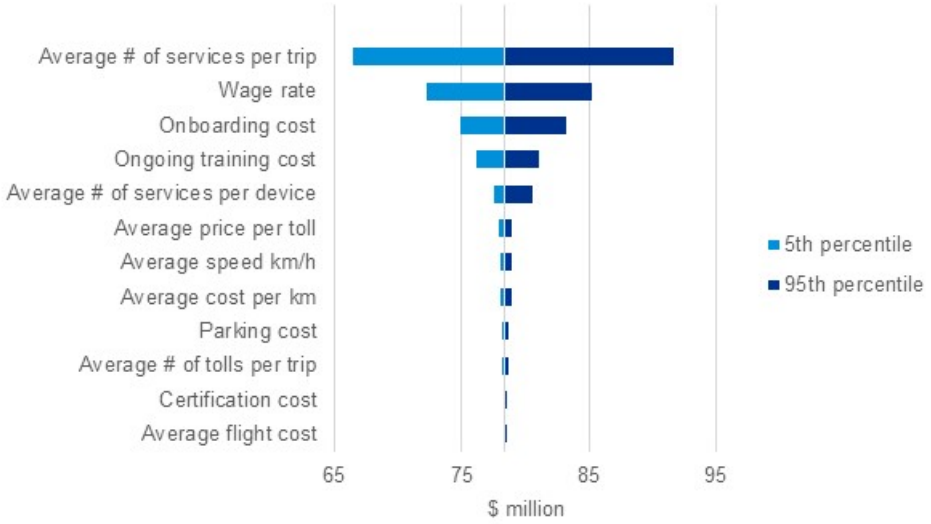


	2019/20	2020/21	2021/22	2022/23
95th percentile	$95.79m	$104.81m	$114.39m	$125.00m
5th percentile	$65.63m	$71.83m	$78.44m	$85.88m
Median	$78.59m	$86.06m	$94.08m	$102.98m

Note: all values are reported in nominal terms and on a financial year basis

The number of trips made by IEAPs depends on the number of services demanded each year and the number of services able to be delivered on a trip. Based on data from companies supplying CIEDs, the average number of services per trip is approximately 5 if provided in the metro areas, 6 in regional areas, and 8 in remote areas. Sensitivity analysis shows that uncertainty in the assumed average number of services required per trip has the largest impact on the cost of providing services. This was followed by uncertainty in the wage rate.

Uncertainty in assumed parameters on total cost of providing CIED services (2019/20)



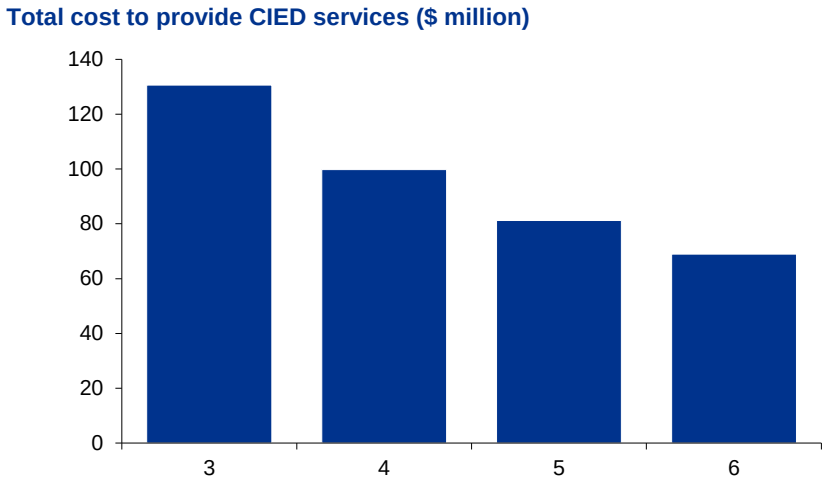
Note: all values are reported in nominal terms and on a financial year basis

The average number of services provided is based on internal estimates from companies supplying CIEDs.[4] This parameter helps capture the non-linear, concurrent and unpredictable nature of providing CIED services that these companies are faced with. In order to ensure that needed CIED services are delivered on-time and across multiple locations with varying degrees of remoteness, a buffer is required to deal with unforeseen circumstances that could range anywhere from traffic and appointment delays to a limited flight schedule to remote areas of Australia to provide a service.

The cost to provide this buffer was estimated to be $32 million in 2019/20 and is expected to rise to $42 million by 2022/23. As there is great uncertainty surrounding this parameter that could vary by type of service and also by location, a sensitivity analysis was also run on the average number of services able to be conducted per full-time equivalent (FTE) per day. While the value of this buffer does not change with this parameter, the cost of CIED services associated with providing the same level of service could fall between $69 million - $131 million if the average number of services per FTE per day were to vary between 3 and 6.

[4] Following industry validation of assumptions, a more conservative estimate was used based on data from one company as it is relies on data from more robust data collection practices.

Sensitivity analysis of the average number of services per FTE per day in 2019/20



	Total labour cost	Training cost	Total cost to provide CIED services
3 services per FTE per day	$98.63m	$24.73m	$130.60m
4 services per FTE per day	$73.97m	$18.55m	$99.76m
5 services per FTE per day	$59.18m	$14.84m	$81.25m
6 services per FTE per day	$49.32m	$12.37m	$68.91m

Note: all values are reported in nominal terms and on a financial year basis

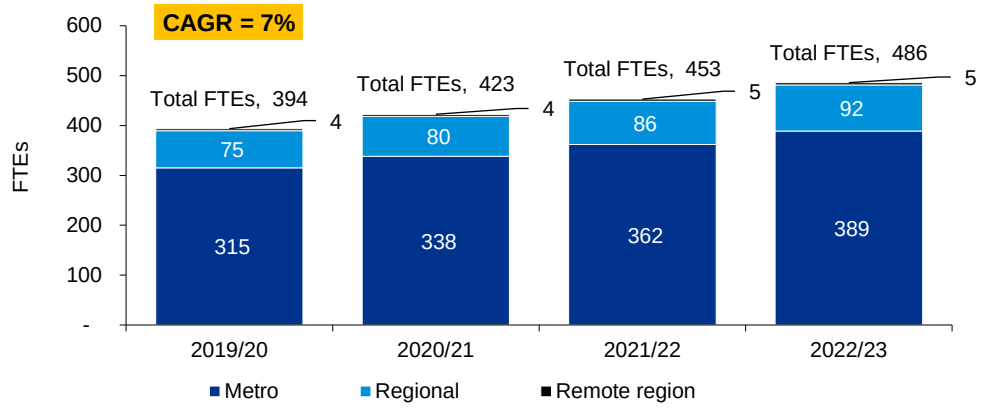
Implications if companies were to stop providing services

If reductions to the Prosthesis List were to reach a point where provision of CIED services became unviable for companies supplying CIEDs to continue to do so, the demand for these services would need to be met by either the public healthcare sector or potentially by private healthcare providers. Alternatively, companies supplying CIEDs that currently deliver these services would need to be further reimbursed under a different funding model to continue to provide these services.

Assuming an average of 5.2 services are able to be provided by each FTE per day[5], approximately **394 FTEs** will be required to provide the estimated number of CIED services demanded in 2019/20 at a cost of about **$57 million**. This is anticipated to increase to require **486 FTEs** by 2022/23 at a total labour cost of about **$75 million**. These estimates assume that there are no productivity gains over the projection period. The number of FTEs required are not the same as the number of employees (based on head count).

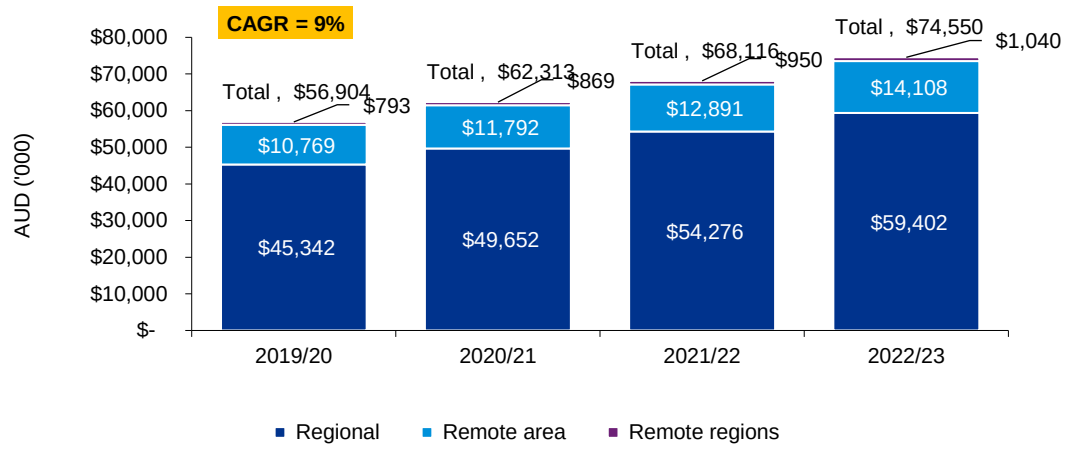
[5] Derived from internal data provided by companies supplying CIEDs. The average estimate across all companies was 4 services per FTE per day. Following industry validation of assumptions, a more conservative estimate of 5.2 services per day was used as it is based on data from more robust data collection practices.

Number of FTEs by region[6], 2019/20 – 2022/23



Source: KPMG estimates

Labour costs by region, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported in nominal terms and on a financial year basis

Limitations

There are limitations to the analysis in this report:

— There are significant gaps in the data. As such, the estimates are an approximation of the volume and cost of total CIED services provided by companies supplying CIEDs in a private healthcare setting. Where data or information is unavailable, subject matter experts and industry sources have been consulted to inform the assumptions. The uncertainty around key modelling assumptions are assessed through a sensitivity analysis to evaluate the possible range of final estimates.

— There are additional uncertainties with projecting into the future. The volume (and value) of service estimates are based on data e.g. population projections and mortality rates, that are likely to be

[6] NDIS zone definitions have been used to estimate the number of services conducted in metropolitan (metro), regional, and remote locations. Based on a postcode to MMM concordance, services provided in MMM 1 are classified as metro, MMM 2-5 as regional and MMM zone 6 and 7 as services conducted in remote areas.

revised in the future, and will impact on the estimates contained in this report. The estimates in this report do not include any impacts of new technologies nor changes in medical treatment for diagnoses that CIEDs are currently prescribed. They should be considered indicative only.

- The estimates in this report are intended to capture the average cost and level of service as currently provided. As such, the analysis does not incorporate clinic-specific requirements *e.g.* minimum number of IEAPs to be present if a certain number of patients require CIED services. As the distributions of key parameters are often long-tailed and right-skewed, the use of averages in the analysis may create some upward bias in the results. Through Monte Carlo simulations, the construction of 95% confidence intervals provide an indication of the range of values the final estimates are likely to fall.
- The analysis in this report does not include any assessment regarding the level of existing funding under the Prosthesis List for the level of service currently being provided by companies supplying CIEDs. Without further information on the cost (and price margins) for each device, it is not possible to make a connection between the cost of CIED services estimated here on an annual basis and the cost of services bundled into the once-off reimbursement for the provision of a device at the point of implantation.
- The analysis estimates the cost of services provided as it is currently delivered. It does not examine how efficiently these CIED services are, or could be, provided, whether by companies supplying CIEDs or by alternative providers. The cost of the provision of timely and accessible services could be much higher with a higher level of service, or lower with a lower level of service.
- The estimates in this study are an approximation that requires the use of several limiting assumptions owing to significant gaps and very limited data available.
- Data on each type of service provided over a 6-week period as well as internal estimates for each company have been provided by the companies supplying CIEDs to supplement the limited data available for the analysis. With no further information on services provided and without any way of verifying the impacts of seasonality, the 6-week snapshot is assumed to be a representative period of services provided over a full year.
- Although the use of survey data would have been beneficial, this is outside the scope of this report.

1. Introduction

Companies supplying Cardiac implantable electronic device (CIED) are involved with the provision of devices as well as any technical follow-up services required over the life of a device in a private healthcare setting. While the provision of the devices is covered by private health insurance as they are included in the Prosthesis List, any follow-up services over the life of the device is provided by companies supplying CIEDs without any further reimbursement. Reimbursement for these services is assumed to have been bundled into the price of a device at implant.

As the overall cost of healthcare grows in Australia, medical device providers, private healthcare providers and pharmaceutical manufacturers continue to face pressure from both public and private payers. Continued reductions to the Prosthesis benefits list, including CIEDs, may limit the ability of companies supplying CIEDs to sustain existing levels of support for device insertions and follow-up technical services in a private healthcare setting.

Scope

KPMG has been commissioned by the Medical Technology Association of Australia to determine and highlight the resource requirements of services currently provided in a private healthcare setting for CIEDs (pacemakers, implantable cardioverter-defibrillators, and implantable loop recorders) by companies supplying CIEDs. In particular, this study:

- estimates the cost of the various components that are involved in providing timely and accessible CIED services, as provided by those companies supplying CIEDs in a private healthcare setting *e.g.* items that make up labour and travel costs, on an annual basis for 2019 – 2022 (2019/20 – 2022/23); and
- illustrates the value of these services, through the use of counterfactual scenarios, highlighting the resources that would be required from households and/or governments for the continued delivery of these services, if they were not provided by the companies supplying CIEDs.

The analysis in this report does not include any assessment regarding the level or adequacy of existing funding under the Prosthesis List for the level of service currently being provided by companies supplying CIEDs. Without further information on the cost (and price margins) for each device, it is not possible to make a connection between the cost of CIED services estimated here on an annual basis and the cost of services bundled into the once-off reimbursement for the provision of a device at the point of implantation.

Inherent within the provision of CIED services by these companies is a value transfer from device manufacturers to patients and society more generally. This value is broader than just the costs required to provide these services. It is derived from several value drivers including, but not limited to, the responsiveness of CIED service delivery, patient experience, clinical outcomes, and clinician productivity. In the absence of more data, assessment of this broader value contribution is out of scope and, as such, the analysis relies on quantifying the *cost* of providing these services rather than the full *value* that they create.

Report structure

The structure of the report is as follows:

- This section (Section 1) has defined the scope and structure of this report;
- Section 2 describes how the demand for devices is estimated;
- Section 3 describes the estimation of demand for CIED services;
- Section 4 estimates the components that make up the cost of CIED services provided by companies supplying CIEDs;
- Section 5 summarises key findings from the sensitivity analysis;
- Section 6 presents a short discussion;
- Appendix A summarises the assumptions underpinning the analysis;
- Appendix B describes the modelling undertaken;
- Appendix C presents the sensitivity analysis; and
- Appendix D provides a bibliography list of references.

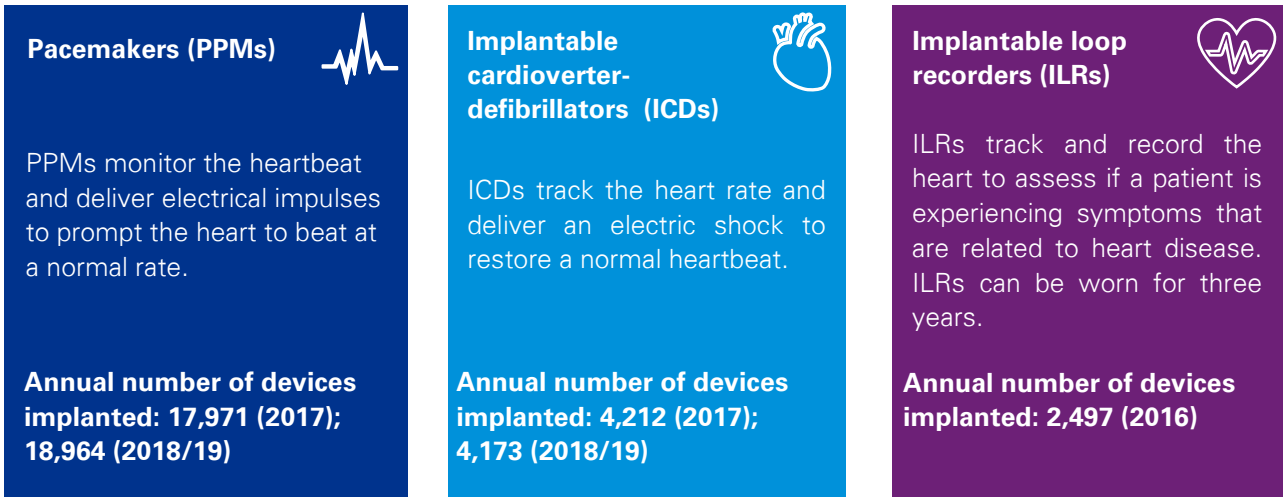
2. Demand for devices

Cardiac implantable electronic devices (CIEDs) are a group of medical devices used to increase life expectancy and enhance the quality of life of individuals with heart disease. CIEDs encompass pacemakers (PPM), implantable cardioverter-defibrillators (ICDs) and implantable loop recorders (ILRs).

According to Mond and Crozier (2019), there were 17,971 new pacemakers and 4,212 new ICDs implanted in Australia in 2017. In 2018/19, AIHW data shows that there were 18,964 new pacemaker and 4,173 new ICD insertions.[7] Castles et al (2018) report that just under 2,500 ILRs were inserted in 2016. These numbers are anticipated to grow with Australia's ageing population.

These are the latest estimates available on the numbers for CIED implants in published studies. Data on ICDs and PPMs implanted is available up to 2018/19 however, data for ILR insertions is only available up to 2016. Although MBS data on the number of insertions of each device is available, it does not fully capture all insertions and device follow-up services that occur each year.

Figure 1: Summary of CIEDs



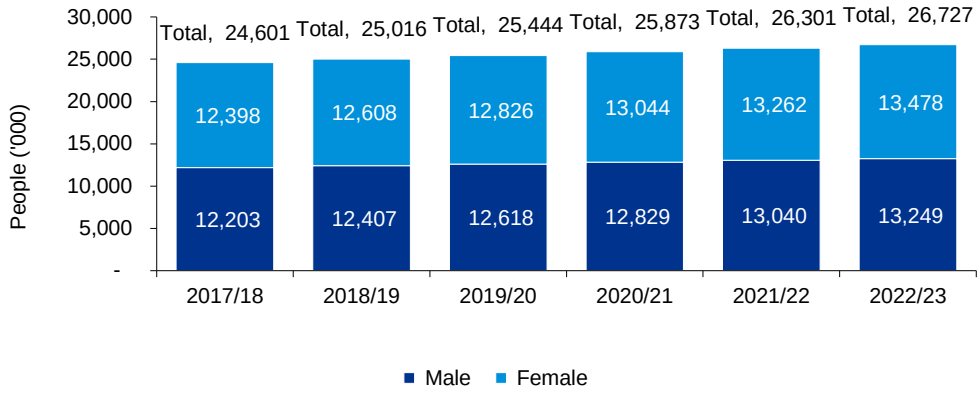
Source: NHLBI, American Heart Association and St Vincent's Hospital Heart Health for descriptions; Mond and Crozier (2019), AIHW (2020) and Castles et al (2018) for annual number of implants

Demographic drivers

The population of Australia is forecast to reach just under 27 million by 2022/23, averaging growth of approximately 1.7% per year between 2019/20 and 2022/23 (Figure 2). This growth is primarily driven by key demographic trends as a larger portion of the population moves into the older age cohorts.

[7] ACHI code for pacemaker and ICD insertions are 38350-00 and 38393-00, respectively.

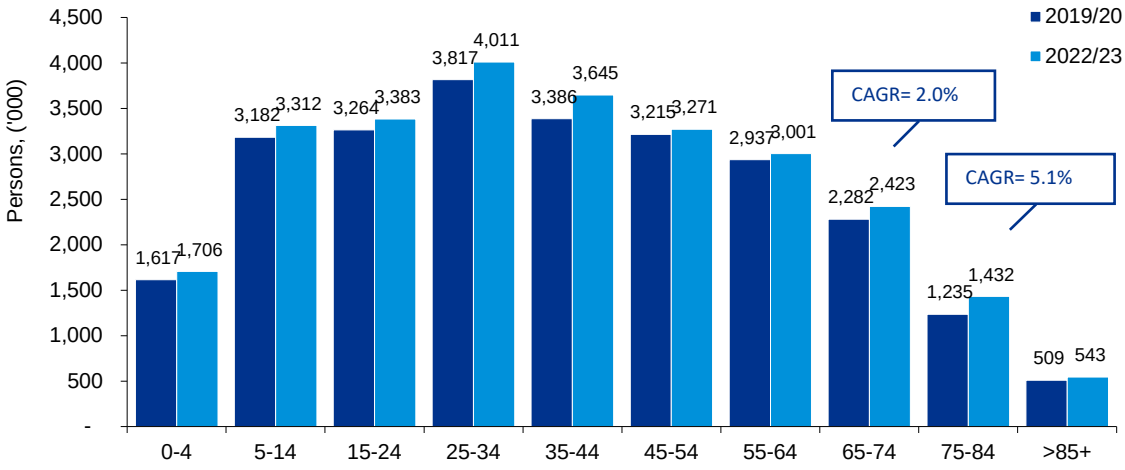
Figure 2: Population projections, 2017 – 2022



Source: ABS Cat. No. 3222.0 Table B9

Figure 3 shows that growth in the 65-74 year old and 75-84 year old age brackets will contribute the most to the overall population growth rate. Growth in these two age brackets is expected to be higher than the total population growth rate of 1.7%, to average 2% and 5% per year respectively, for the next 3 years.

Figure 3: Population projections, 2019/20 and 2022/23



Source: ABS Cat. No. 3222.0 Table B9

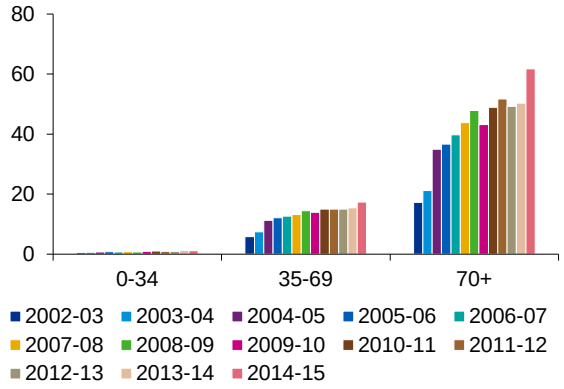
Incidence rates

Incidence rates per 100,000 population between 2019/20 – 2022/23 have been calculated using trend growth for the respective devices. Based on available data from published studies, incidence rates for new CIED implants for the older age brackets currently are, and are also expected to continue to be, higher relative to the incidence rates for younger age brackets for all three devices.

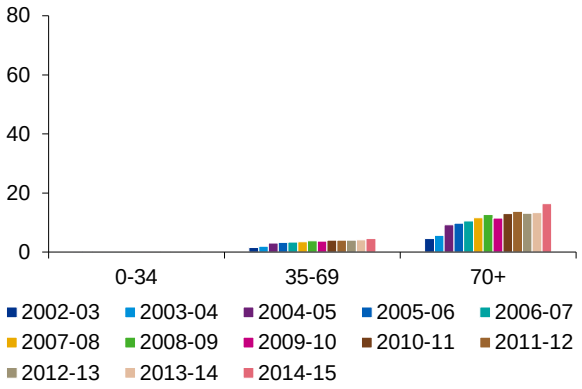
ICDs: Historical average annual growth in the incidence rates of new ICD insertions by age in Blanch et al (2018) were used. Males accounted for 79% of the total ICD insertions.

Years: 2002/03-2014/15	Total
0-34	6.7%
35-69	9.5%
70+	11.2%

Incidence rate for ICDs insertions - male



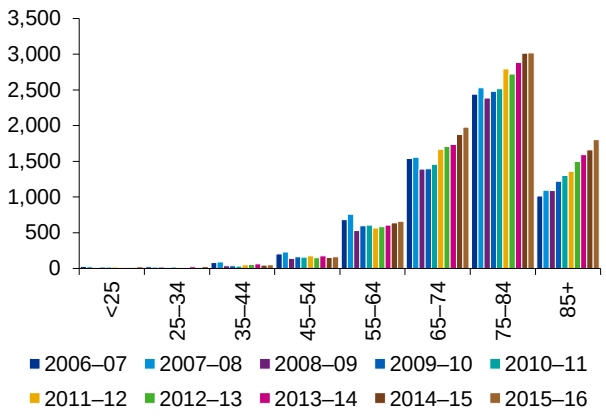
Incidence rate of ICDs insertions - female



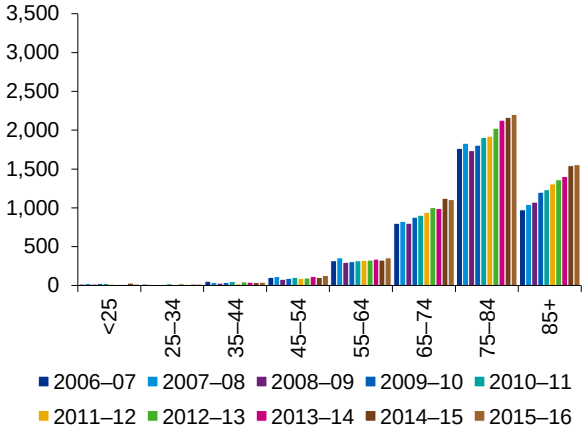
Pacemakers: Historical average annual growth rates for the number of insertions by gender and age from AIHW (2019) were used to inform the incidence of new pacemaker insertions in 2019/20. Following which, incidence rates per 100,000 population were calculated using ABS's population data.

Years: 2006/07-2015/16	Male	Female
<25	-1.7%	0.0%
25–34	1.3%	-0.6%
35–44	-5.4%	-2.2%
45–54	-2.4%	2.2%
55–64	-0.4%	1.2%
65–74	2.9%	3.7%
75–84	2.4%	2.5%
85+	6.6%	5.3%

Number of pacemaker insertions - male



Number of pacemaker insertions - female



ILRs: Historical average annual growth rates by age and gender from MBS data on the number of ILR insertions were used to estimate the incidence of ILR insertions in 2019/20.[8] The incidence rates per 100,000 population were then calculated using ABS's population data (ABS Cat. No. 3222.0, Series B).

Years: 2016-2019	Male	Female
0-4	0.0%	0.0%
5-14	0.0%	0.0%
15-24	3.5%	-6.5%
25-34	18.2%	6.4%
35-44	3.1%	7.0%
45-54	8.3%	8.0%
55-64	15.9%	13.9%
65-74	20.9%	16.1%
75-84	21.7%	15.9%
>=85	17.2%	9.4%

Number of ILRs inserted in 2016 (Castles et al 2018)

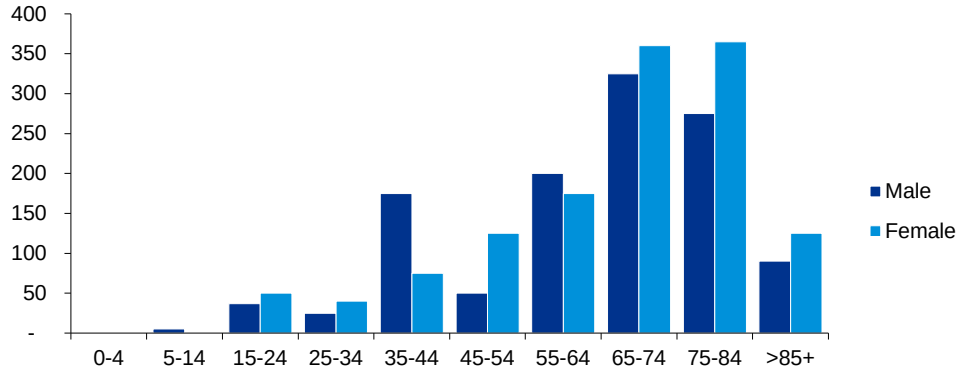
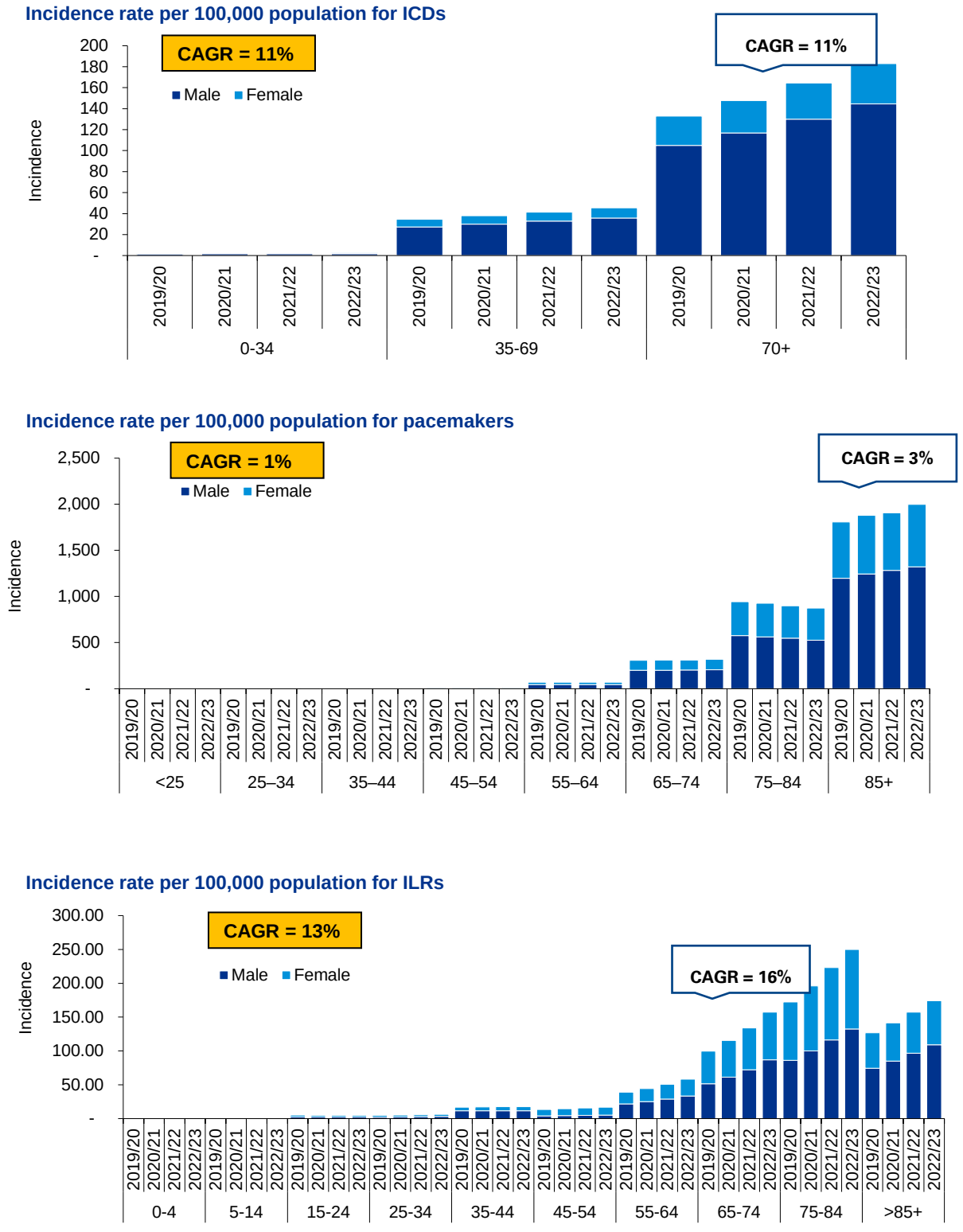


Figure 4 summarises the incidence rates, number of new insertions per 100,000 population, that were used in the analysis, calculated using the abovementioned growth rates. Across all three devices, the incidence rates were highest in the older age cohorts.

[8] We assume that the growth rates in the MBS data holds even if the actual number of insertions may be incomplete.

Figure 4: Incidence rates for new CIEDs by age bracket, 2019/20 – 2022/23

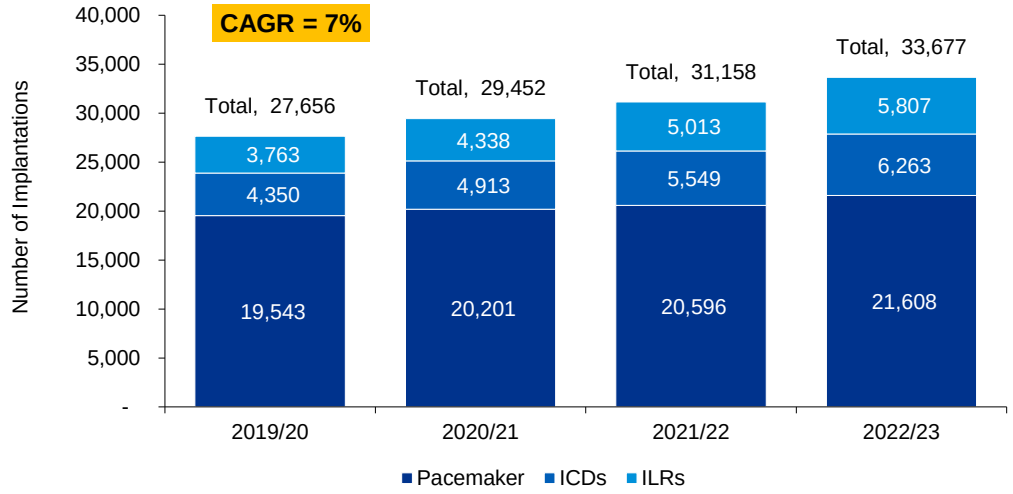


Source: KPMG estimates; AIHW (2019) – pacemakers; Blanch et al (2018) – ICDs; Castles et al (2018) – ILRs; ABS Cat No. 3222.0.

The number of new insertions is anticipated to grow by 7% each year between 2019/20 – 2022/23. It is estimated that 27,656 new CIEDs were inserted in 2019/20 and this will increase to be 33,677 by 2022/23

(see Figure 5). Growth in the overall incidence rate is approximately 3%, with the remaining 4% increase due to population growth in the older cohorts.

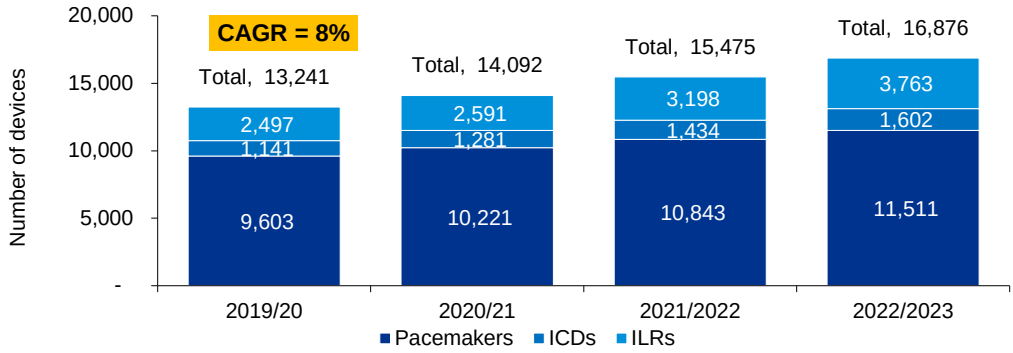
Figure 5: Number of new insertions by device, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported on a financial year basis

Unlike PPMs and ICDs that are intended to be permanent devices, ILRs are required to be removed three years after insertion (Vijapurapu et al 2019). These removals reduce the number of existing devices which require CIED services each year. Both the incidence of implanted CIEDs and the mortality rate increases with age *e.g.* the mortality rate of males between 65-74 is 2% and increases to 4% and 13% in the 75-84 and 85+ age cohorts, respectively. Together, the rate of removals owing to the mortality of individuals and ILR removals increases by 8% each year on average, between 2019/20 – 2022/23. 13,241 devices were estimated to be removed in 2019/20 and is expected to rise to reach 16,876 device removals by 2022/23.

Figure 6: Number of deaths and ILR removals, 2019/20 – 2022/23



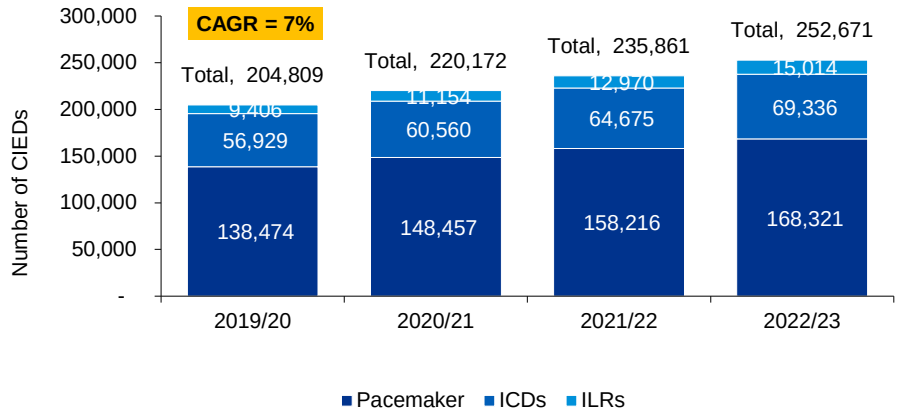
Source: KPMG estimates
Note: all values are reported on a financial year basis

Estimated prevalence of devices

New insertions of CIEDs add to the number of existing devices while deaths of individuals with CIEDs and removals, such as in the case of ILRs, reduce the number of devices in use. Overall, the number of new insertions each year exceeds the number of removals (from deaths or as ILR removals), thus increasing the number of existing devices. We estimate that there were 204,809 CIEDs in use in 2019/20.

This is expected to increase to 252,671 by 2022/23, following an average annual growth rate of 7%. This growth is mainly driven by the increase in the prevalence of ILRs. Figure 7 summarises the estimated prevalence by device type for 2019/20 through to 2022/23.

Figure 7: Estimated prevalence of devices implanted in the population, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported on a financial year basis

3. Demand for CIED services

Provision of CIED services

Every CIED in use is associated with scheduled follow-up services and unscheduled technical services that will be required over the life of the device. The provision of these services differs depending on whether it occurs in a public or private healthcare setting. Hospital staff typically provide these services in a public setting however staff at companies supplying CIEDs, also known as industry employed allied professionals (IEAPs), support physicians in a private healthcare setting.

While IEAPs work closely with physicians to provide technical services for patients, these individuals are directly employed by the companies supplying CIEDs. Even though public and private payers provide reimbursement for follow-up services, these payments go toward the physician's time only, rather than toward the services provided by IEAPs. As such, these technical services do not attract any further reimbursement for companies supplying CIEDs beyond the cost of providing the device at the point of implantation.

The services provided by IEAPs involve a range of activities such as trouble-shooting of device, algorithm optimisation, or providing technical advice about the device or its features. [9]

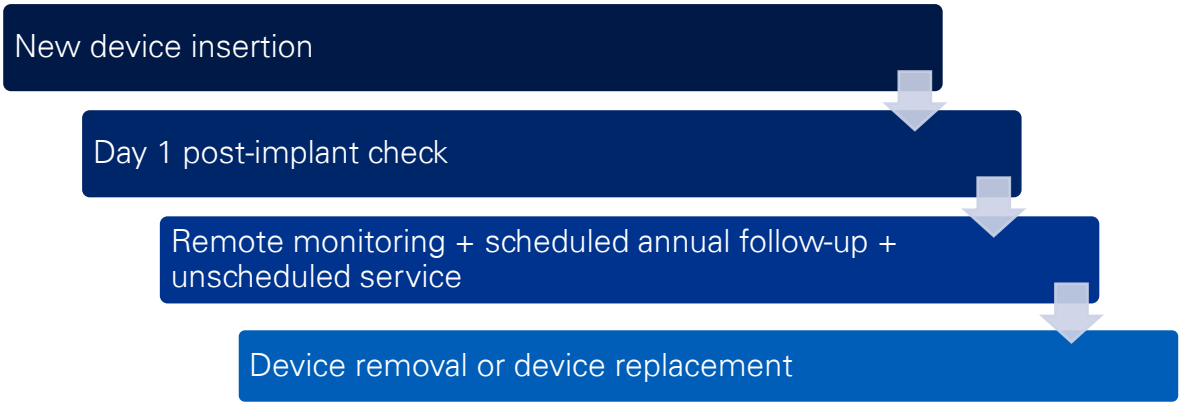
Figure 8: Services provided by IEAPs

Source: Cardiac Internal Working Group Draft report provided by companies supplying CIEDs

Figure 9 summarises a typical life cycle of services required by a CIED. CIED services are required at the point when the device is implanted. This is followed by a day 1 post-insertion service.

[9] Cardiac Internal Working Group Draft provided by companies supplied CIEDs

Figure 9 Typical life cycle of a CIED device



According to industry sources, CIEDs such as pacemakers and ICDs have an expected battery life of between 6 – 15 years. At the end of the life cycle of the device, the patient will require the device to be replaced. Unlike pacemakers and ICDs that are more permanent, ILRs are often used to monitor a patient for heart disease and are implanted for up to 3 years before being removed (Vijapurapu et al 2019).

Number of follow-up services required

CIEDs require regular post-implantation checks to ensure the devices continue to function properly with regards to their diagnostic and therapeutic functions. Patients' underlying cardiac disease is subject to changes or deterioration. Regular review of diagnostic information collected by the CIED and testing of the heart's electrical response to the programmed therapy ensures the device therapy is regularly adjusted to each patient's changing requirements.

There are approximately 1 – 4 scheduled annual follow-up checks that occur each year, based on recommended guidelines by the Cardiac Society of Australia and New Zealand (CSANZ). This occurs every 3 – 6 months for both PPMs and ICDs, and 6 – 12 months for ILRs. The modelling assumes that there are 2 follow-up (scheduled) services required per year per device.

While remote monitoring could reduce the need for in-person services, industry sources have advised that they are often conducted alongside in-person services. IEAPs are still required to assist with relaying technical information to physicians and/or patients even with remote monitoring available.

Unexpected onset of symptoms may prompt unscheduled follow-ups. Similarly, information transmitted via a home monitoring system (remote monitoring) may give cause for a closer review in an unscheduled follow-up.

Technological advancements are ongoing in CIEDs. They do not however, reduce the number of services required. Rather, the type of service received with newer devices changes instead, with the aim of a higher level of care potentially received by the patient.

Number of services based on number of implanted devices

Each device in use will require a combination of scheduled, unscheduled and remote monitoring services. Data on each type of service provided over a 6-week period as well as internal estimates for each company has been provided by companies supplying CIEDs to supplement the limited data available. The analysis assumes that the 6-week snapshot is a representative period of services provided over a full year to translate the new and existing number of devices each year into the number of CIED services required each year. Figure 10 summarises the CIED services assumed to be required that are related to new insertions and those that are required for the existing number of CIEDs in use.

Figure 10 Summary of services required by status each year

Each **new insertion** in a given year is assumed to require both an insertion procedure service as well as a Day 1 post-insertion service.

According to industry sources, devices typically last between 10-15 years and will need to be replaced at the end of their life. Each **replacement** is also associated with an insertion procedure service and Day 1 post-insertions service. Replacements are assumed to only occur in ICDs and PMs and are based on a historical ratio of 0.30 and 0.18 replacements per new insertion, respectively.

Existing devices and new insertions are assumed to require 2 scheduled follow-up services e.g. doctor's room clinic or hospital device follow-up clinic per year.

Unscheduled checks e.g. MRI or Emergency department checks, are also accounted for as a ratio to scheduled services per year. Based on internal data from companies supplying CIEDs, it is assumed that there are 0.087 unscheduled checks and 0.77 remote monitoring services required for every one scheduled service.

Number of services provided in a private healthcare setting

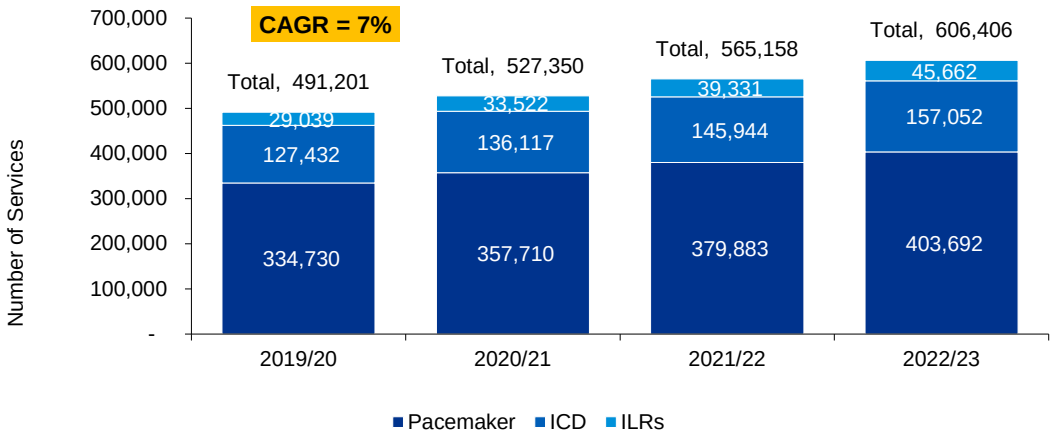
As CIED services are provided in both public and private hospitals, only a portion of the total number of services demanded each year are provided by companies supplying CIEDs. It is assumed that approximately 56% of CIED services are provided in a private healthcare setting and are therefore provided by these companies.[10] Without any further information, this is assumed to stay the same over the projection period and be provided at the same level of service.

In a private healthcare setting, this comes up to approximately 606,000 CIED services across all devices that will be required by 2022/23, up from over 491,000[11] in 2019/20.

[10] This is based on the share of private to public services reported in Productivity Commission (2009).

[11] This number is estimated from a bottom-up approach based on the estimated number of devices in the population and includes the number of insertion support services for 2019. The Cardiac Internal Working Group Draft provided to KPMG by companies supplying CIEDs reports approximately 423,000 services in 2019, however this does not include the number of insertion support services and is based on an annualised estimate of follow-up services from a 6-week data snapshot collected by companies that is assumed to be a representative period. The discrepancy between the two estimates is due to a difference in data sources and methodology.

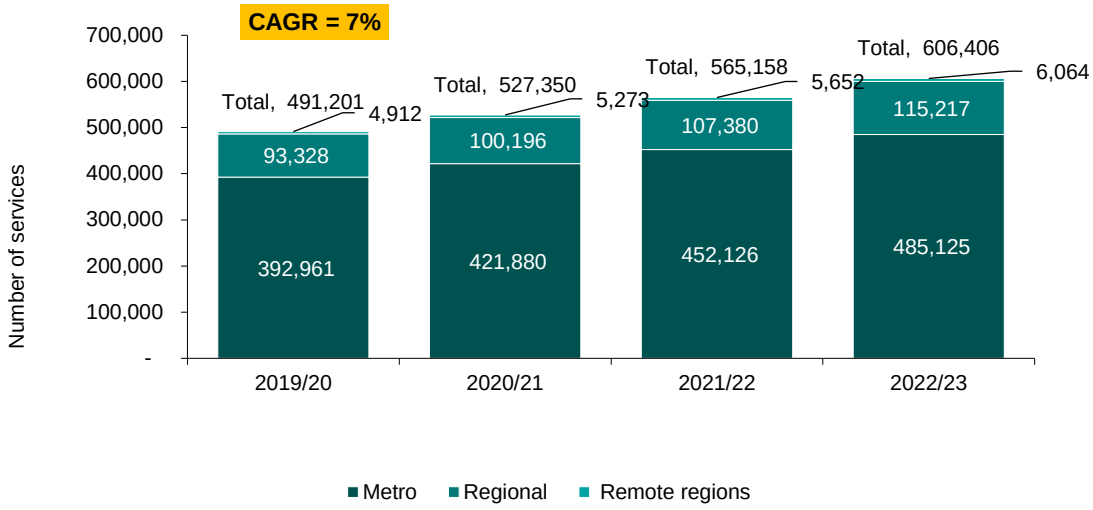
Figure 11: Number of CIED services provided in a private healthcare setting, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported on a financial year basis

Based on internal data from companies supplying CIEDs, the bulk of services are provided in the metro region, with about a fifth of services occurring in regional areas.[12] The volume of services in remote areas make up a very small share of the total services that occur each year (~1%).[13]

Figure 12: Volume of Services by region, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported on a financial year basis

[12] Virtual remote monitoring services have been assumed to occur in the metro area as it does not include the remote loading.

[13] NDIS zone definitions have been used to estimate the number of services conducted in metropolitan (metro), regional, and remote locations. Based on a postcode to MMM concordance, services provided in MMM 1 are classified as metro, MMM 2-5 as regional and MMM zone 6 and 7 as services conducted in remote areas.

4. Cost of CIED service provision in a private healthcare setting

This section details each component that constitutes the resources required to provide CIED services in a private healthcare setting under the current arrangements and level of service. To note, the cost of providing these services contributes to the value of CIED services received by patients however, there are other drivers of value that are not captured by measuring costs alone. Some examples include, the responsiveness and universal accessibility of needed services, patient experience, clinical outcomes or clinician productivity. However, the contribution of these other drivers to the total value of CIED services in the private healthcare setting is beyond the scope of this report.

The analysis is conducted in three stages. First, the volume of services in a private healthcare setting is estimated. Using a bottom-up approach, the model projects the number of new insertions, existing devices and removals required between 2019/20 – 2022/23. The projections are based on available information from the literature regarding the incidence rate of CIED insertions, population projections, mortality data and any available information on prevalence of existing devices.

Second, the number of scheduled and unscheduled services required by each device is assumed and applied on the number of existing devices estimated in the first stage. Internal data from companies supplying CIEDs help to inform the distribution of service types and location that services are provided in.[14] Data over a 6-week period on each type of service as well as internal estimates for each company have been provided to supplement the limited data available for the analysis. The 6-week snapshot is assumed to be a representative period of services provided over a full year. The lack of additional information, however, prevents any seasonal adjustments.

Finally, the cost of services is then determined by overlaying the relevant price and cost information on the number of services that are forecast to occur each year. Further details about the modelling can be found in Appendix B.

As the estimates of the cost of services are based on assumptions with limited data, sensitivity analysis using a Monte Carlo simulation was undertaken to assess the uncertainty around these key modelling assumptions. A Monte Carlo simulation is based on the probabilities of possible values in parameters to assess the associated uncertainty surrounding the assumptions required. This simulation helps to provide a range of values that the final results could take on *i.e.* 95% confidence intervals. More information on the sensitivity analysis can be found in Appendix C.

There are three main components that make up the resource requirements to provide CIED services under the current arrangements and level of service: labour cost; travel cost; and training cost. The assumptions underpinning the modelling are listed below with further details provided in Appendix A.

The estimates are provided in nominal terms. Growth in the total cost to provide services are made up of changes in the volume of services and prices. From the previous section, the volume of services is estimated to grow by 7% while price changes are approximated by the Consumer Price Index (CPI) and Wage Price Index (WPI). Both the CPI and WPI are assumed to be 2%. Together, the total cost to provide CIED services in a private healthcare setting by companies supplying CIEDs is expected to increase by 9% each year, on average.

[14] All remote monitoring services are assumed to be performed from metro and does not require travel nor incur a remote region wage loading.

Travel cost

Companies supplying CIEDs incur the cost of transportation to ensure that IEAPs are able to get to the clinics or hospitals where CIED services are required. These include items such as: the cost associated with running a vehicle, tolls, and parking fees.

The regions where services are provided are based on the NDIS Modified Monash Model (MMM) classification. This helps guide assumptions regarding costs and allowances by region.

Assumptions:

- Multiple scheduled[15] services are able to be delivered in a single trip. Based on internal data from companies supplying CIEDs, 5 scheduled services per trip for metro, 6 scheduled services per trip for regional and 8 scheduled services per trip for remote are possible. Each unscheduled service is however, assumed to require a trip each;
- 0.5 hour for metro trips, 0.75 hours for regional trips and 1 hour remote trips, according to the NDIS Price Guide 2020-21[16] allowance;
- Average speeds of 65 km/h for metro trips, 67 km/h for regional trips and 70 km/h for remote area trips;
- $0.85 per kilometre, in line with the allowance for NDIS service providers to cover fuel, registration and depreciation costs related to running a vehicle;
- $10 parking fee per trip;
- Tolls required are only incurred in metro areas: 2 tolls per trip at a cost of $5 on average;
- 57% of regional services[17] will require additional travel allowance of $150 (for a return flight or additional driving of up to 175 kms return trip); and
- IEAPs travelling to remote regions require a return flight at a cost of $500.

$7.2m in 2019/20

$9.4m by 2022/23

Travel cost (2019/20)

Metro: $4.1 million

Regional: $2.7 million

Remote region: $0.5 million

Number of trips (2019/20)

Metro: 85,308

Regional: 18,714

Remote region: 883

Note: all values are reported in nominal terms and on a financial year basis

[15] These include Doctor's room clinic checks and Hospital device follow-up clinic checks only.

[16] NDIS Price Guide 2020-21. Metro is defined as MMM1, regional areas encompass MMM2-5, and remote areas are MMM6-7.

[17] Share of MMM3-5 as a proportion of MMM2-5 defined as regional areas based on data from companies supplying CIEDs

Labour cost

IEAPs are employed directly by the companies supplying CIEDs. As such, these companies cover the wages and salaries for IEAPs to provide technical follow-up services.

Assumptions:

- The hourly wage rates in metro and regional areas are $80 based on QLD Health, NSW Health wages/salaries for experienced cardiac technologists, and input from companies supplying CIEDs on a sensible adjustment to reflect private healthcare sector wages.[18] Wage rates in remote areas are assumed to have a loading of 40% to reflect higher wages in remote areas relative to metropolitan and regional areas. This wage loading is in line with the NDIS price guide 2020-21.
- The number of full-time equivalent employees (FTEs) required are calculated on the basis of 48 work weeks, 5 days of work per week and 7.5 working hours per day (1,800 work hours per year). To note, the number of FTEs is not the same as the number of employees (on a head count basis).
- Average number of services able to be provided per FTE per day is assumed to be 5.2. This is based on internal data provided by companies supplying CIEDs. The number of FTEs have been adjusted to capture the concurrent nature of providing services across multiple locations.
- The average number of services provided per FTE per day attempts to quantify the buffer required to accommodate appointment and/or travel delays e.g. limited flights to remote regions, appointments being cancelled or appointments requiring more time than scheduled. The cost of this buffer is estimated to be $32 million in 2019/20.

$56.9m in 2019/20

$74.5m by 2022/23

Labour cost (2019/20)

Metro: $45.3 million

Regional: $10.8 million

Remote region: $0.8 million

Number of FTEs (2019/20)

Metro: 315

Regional: 75

Remote: 4

Note: all values are reported in nominal terms and on a financial year basis

[18] An experienced cardiac technologist employed by QLD Health or NSW Health can expect to earn approximately $60 - $80 per hour. Input from companies supplying CIEDs suggest that this range is $70 - $90 in a private healthcare setting.

Training cost

Industry sources advise that CIED services are typically performed by highly trained personnel with a relevant bachelor's degree, at a minimum, or postgraduate university degree. While there is no formal accreditation process, many opt to attain qualifications from the Cardiac Electrophysiology Institute of Australasia (CEPIA) or the International Board of Heart Rhythm Examiners (IBHRE). However, these minimum qualification requirements mean that additional on the job training over a period of time is required for new IEAPs to be able to provide these technical services.

Industry sources advise that the usual onboarding process requires on-the-job supervision of new IEAPs until they are able to conduct services independently. This process can take up to a year. Training by the companies supplying CIEDs also occurs on an ongoing basis for all IEAPs to understand the requirements of the different models (specific to each brand) and variety of services requested.

There are training requirements in order to ensure that IEAPs are able to meet the service requirements of various device models such as ongoing annual updates on the latest technology and devices, and certification and onboarding of new IEAPs each year.

Assumptions:

— $15,000 per employee each year to update all IEAPs with the relevant information and service requirements of the latest devices.

— 10% of total staff base will turnover each year, requiring new replacement IEAPs to be onboarded at a cost of $200,000 per new employee and further support given for them to receive CEPIA/IBHRE certification at a cost of $12,500 per new employee. The onboarding cost quantifies the cost of time and wages it takes to fully train up employees to the point where supervision is no longer required and so includes wages/salaries for new IEAPs and experienced supervising IEAPs.

$14.3m in 2019/20

$18.7m in 2022/23

In 2019/20

Annual ongoing: $5.9m

Certification: $0.5m

Onboarding: $7.9m

By 2022/23

Annual ongoing: $7.7m

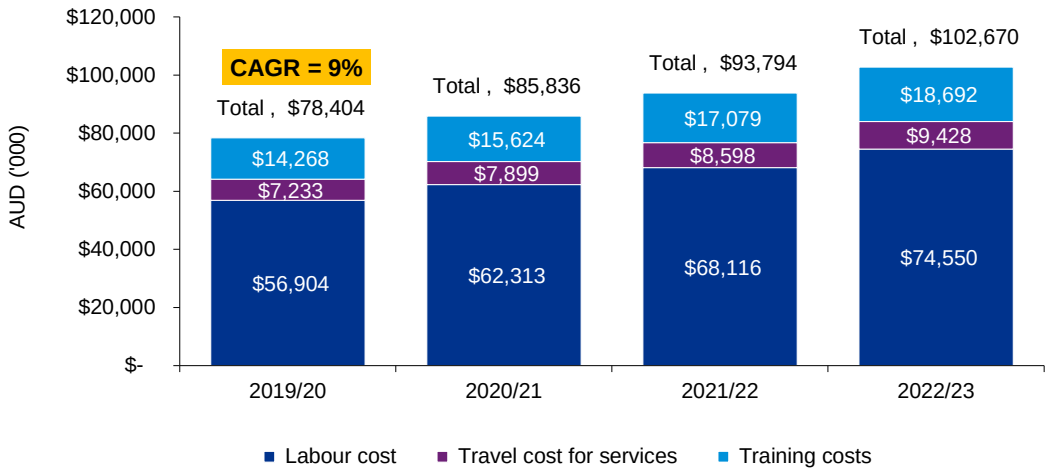
Certification: $0.6m

Onboarding: $10.3m

Note: all values are reported in nominal terms and on a financial year basis

Figure 13 presents a breakdown of these components that make up the total cost of services provided by companies supplying CIEDs between 2019/20 and 2022/23. The cost of CIED services in 2019/20 is estimated to be over $78 million, increasing at an average growth rate of 9% annually, to reach about $103 million by 2022/23.

Figure 13: Total cost of services provided by companies supplying CIEDs, 2019/20 – 2022/23

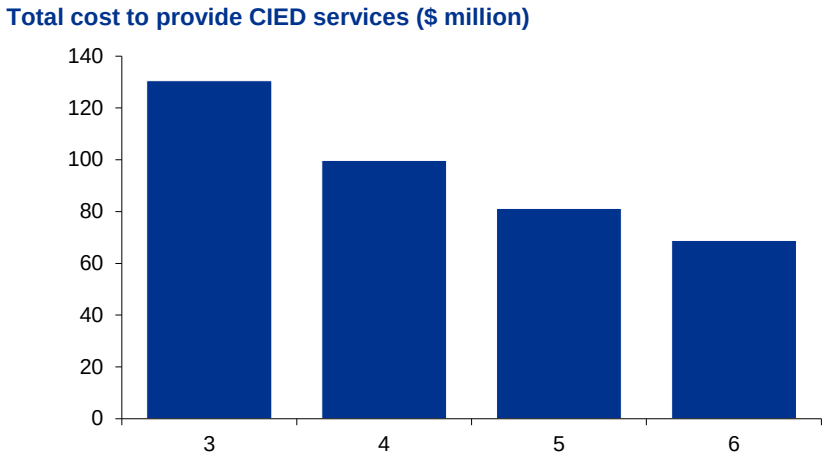


Source: KPMG estimates
Note: all values are reported in nominal terms and on a financial year basis

The resource requirements to provide CIED services in a private healthcare setting under the current arrangement and level of service comprises three main components: labour costs, travel costs and training costs. The largest component contributing to the cost of companies supplying CIED services comes from labour costs. Labour costs in 2019/20 were estimated to be about $57 million. This is largely due to a buffer that companies supplying CIEDs need to have to ensure demand for CIED services are met. The demand for these services can be unpredictable in nature and a buffer is needed in order to allow for responsive and accessible services. The cost of this buffer is estimated to be approximately $32 million in 2019/20 and $42 million in 2022/23.

To note, the cost to provide CIED services is sensitive to this parameter. If this average assumed were to fall to 3 services per FTE per day on average, the cost associated with providing CIED services would increase to $131 million in 2019/20. However, if the average number of services per FTE per day were to increase to 6 instead, the cost would fall to $69 million in 2019/20.

Sensitivity analysis of the average number of services per FTE per day in 2019/20

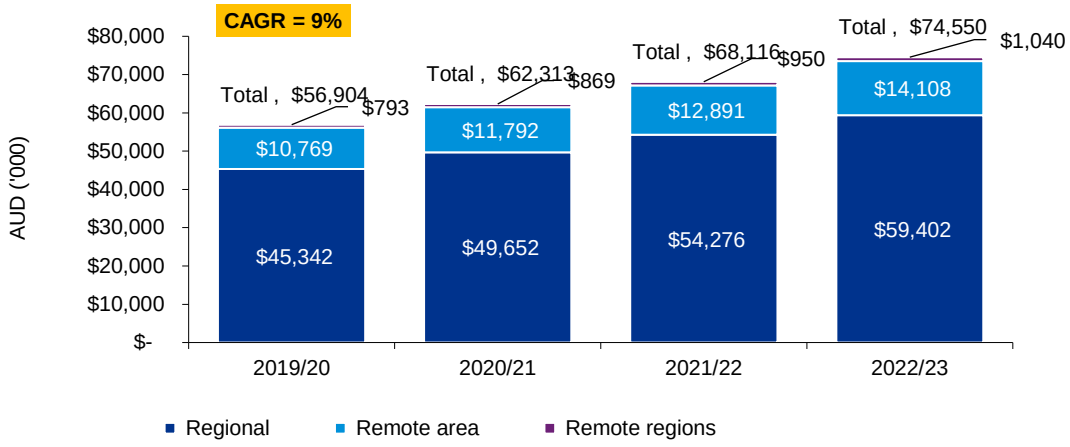


	Total labour cost	Training cost	Total cost of CIED services
3 services per FTE per day	$98.63m	$24.73m	$130.60m
4 services per FTE per day	$73.97m	$18.55m	$99.76m
5 services per FTE per day	$59.18m	$14.84m	$81.25m
6 services per FTE per day	$49.32m	$12.37m	$68.91m

Note: all values are reported in nominal terms and on a financial year basis

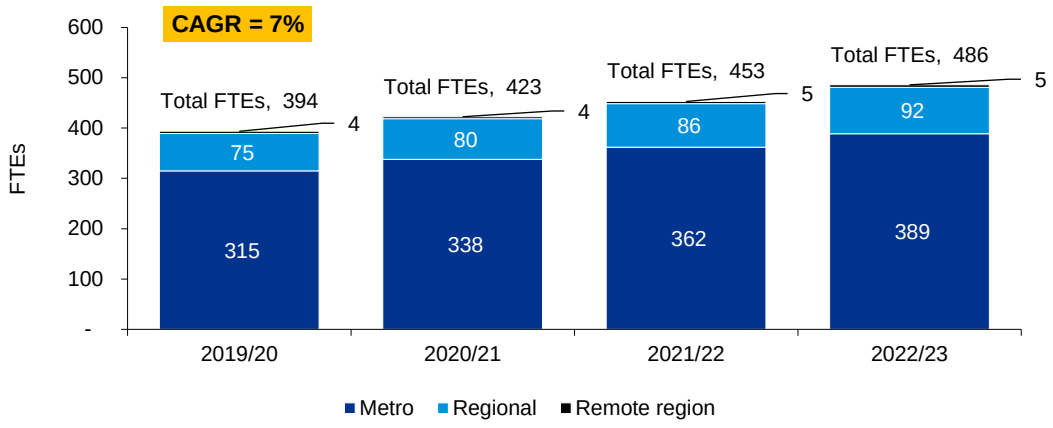
Approximately 394 FTEs were required to provide the estimated number of CIED services demanded at a cost of about $57 million. This is anticipated to increase to require 486 FTEs by 2022/23 at a total labour cost of about $75 million.

Figure 14: Labour costs by region, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported in nominal terms and on a financial year basis

Figure 15: Adjusted FTEs by region, 2019/20 – 2022/23

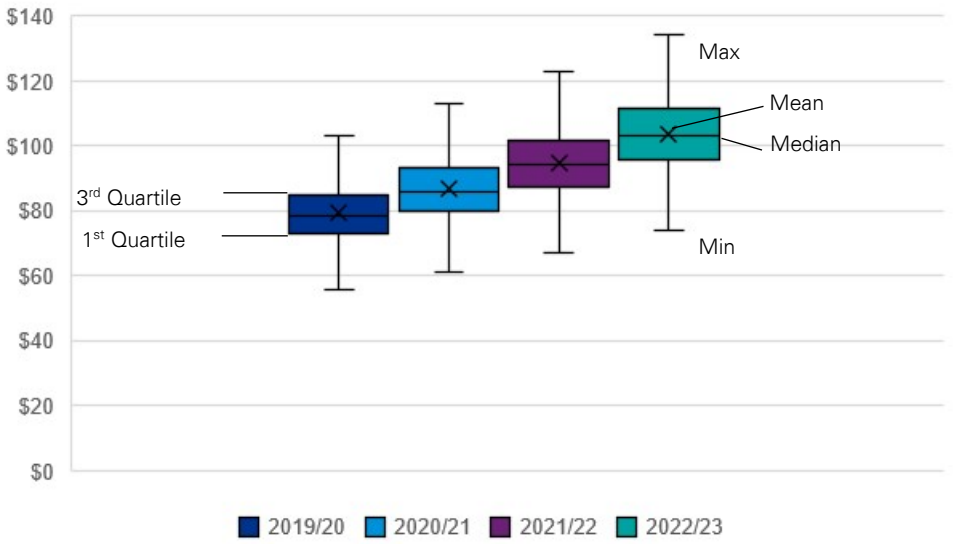


Source: KPMG estimates
Note: all values are reported in nominal terms and on a financial year basis

5. Sensitivity Analysis

A Monte Carlo simulation with 1,000 iterations was used to assess the impact of uncertainty in key assumptions. 95% confidence intervals were constructed, indicating that the total cost of services provided by companies supplying CIEDs in 2019/20 is expected to fall in the range of $66 million and $96 million, and between $86 million and $125 million in 2022/23.

Figure 16: Total cost of CIED services ($ million)

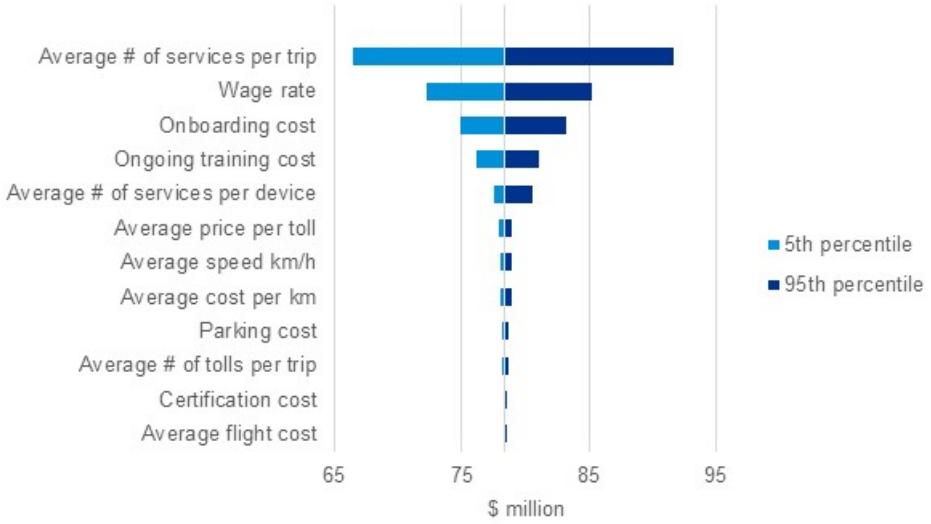


	2019/20	2020/21	2021/22	2022/23
95th percentile	$95.79m	$104.81m	$114.39m	$125.00m
5th percentile	$65.63m	$71.83m	$78.44m	$85.88m
Median	$78.59m	$86.06m	$94.08m	$102.98m

Note: all values are reported in nominal terms and on a financial year basis

Uncertainty in the assumed average number of services able to be serviced each trip has the largest impact on the cost of services provided by companies supplying CIEDs. This was followed by uncertainty in the wage rate (see Figure 17). The impact of uncertainty in key parameters on the labour cost, travel and training components that make up the total cost of CIED services can be found in the next chapter.

Figure 17: Uncertainty in assumed parameters on total cost of CIED services (2019/20)



Note: all values are reported in nominal terms and on a financial year basis

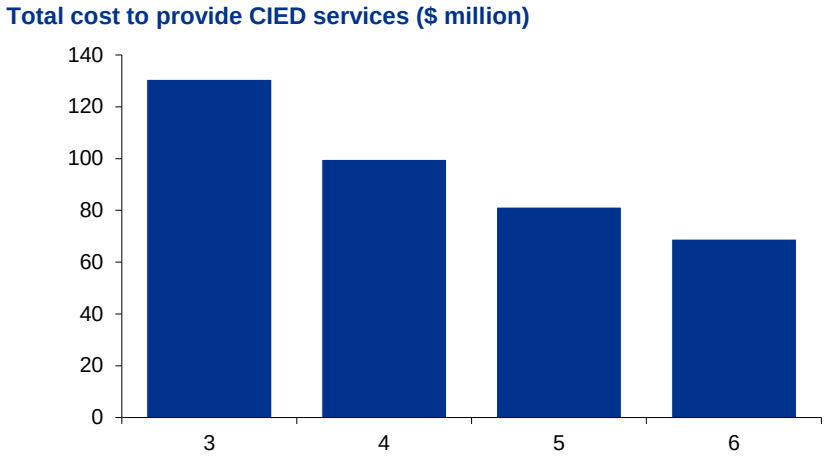
Labour costs are the largest component of the cost of CIED services provided by companies supplying CIEDs. Allowing for uncertainty in the assumed parameters such as wage rates, labour costs in 2019/20 are estimated to fall in the range of $47 - $70 million[19].

Demand for CIED services can often be unpredictable and attempting to deliver CIED services that are universally accessible and that ensures equity poses a number of operational challenges for CIED service providers. The unpredictable nature of CIED service provision can be captured in the average number of services able to be provided per FTE per day.

The number of FTEs required to provide the estimated number of services each year was adjusted based on the assumed average number of services per FTE per day informed by internal estimates from companies supplying CIEDs. This measure is likely to vary by location of services provided and a range of other factors. As such, a sensitivity analysis is also run to assess how it impacts on the total cost of services provided. If the average varies between 3 to 6 services per FTE per day, the cost of CIED services in 2019/20 would likely fall in the range of $69 million – $131 million and require between 341 – 682 FTEs, as summarised in Figure 18. These estimates assume no change in the level of service.

[19] This is based on constructed 95% confidence intervals from the sensitivity analysis (see Appendix C)

Figure 18: Sensitivity analysis of the average number of services per FTE per day in 2019/20



	Total labour cost	Training cost	Total cost of CIED services
3 services per FTE per day	$98.63m	$24.73m	$130.60m
4 services per FTE per day	$73.97m	$18.55m	$99.76m
5 services per FTE per day	$59.18m	$14.84m	$81.25m
6 services per FTE per day	$49.32m	$12.37m	$68.91m

Note: all values are reported in nominal terms and on a financial year basis

Number of FTEs required if assume:	2019/20	2020/21	2021/22	2022/23
3 services per FTE per day	682	732	785	842
4 services per FTE per day	512	549	589	632
5 services per FTE per day	409	439	471	505
6 services per FTE per day	341	366	392	421

Note: all values are reported on a financial year basis

The analysis assumes that 56% of the total services each year occur in a private healthcare setting[20] and are provided by IEAPs employed by companies supplying CIEDs. In most private healthcare settings, IEAPs provide support to individual private physicians, practices or hospitals. In the public health system, hospital employed cardiac physiologists are the primary provider of technical support services. Occasionally, cardiac physiologists may require further technical support or assistance from IEAPs. Whilst IEAPs occasionally support public follow-up clinics, their role is more educational and of a facilitative nature. Based on internal data from companies supplying CIEDs, the service delivery spillover into the public health system makes up approximately 2% of total services demanded each year.

[20] From Productivity Commission (2009)

Sensitivity analysis is conducted around the assumed share of CIED technical services provided by companies each year. The base case assumes that there is no spillover of services. Every one percentage point increase in the share of services provided by IEAPs in the public health system raises the cost of providing CIED services by $1.4 million in 2019/20. Though IEAPs may play different roles in public versus private healthcare settings, the sensitivity analysis assumes that the distribution of additional services provided remains consistent with the distribution in overall services provided each year.

Share of services provided by companies supplying CIEDs	2019/20	2020/21	2021/22	2022/23
No spillover (companies provide **56%** of all services each year)	$78.40m	$85.84m	$93.79m	$102.67m
Additional 1% of services in public sector (companies provide **57%** of all services each year)	$79.80m	$87.37m	$95.47m	$104.50m
Additional 2% of services in public sector (companies provide **58%** of all services each year)	$81.20m	$88.90m	$97.14m	$106.34m

Note: all values are reported in nominal terms and on a financial year basis

6. Discussion

The results of our modelling estimate that over 491,000 CIED services were provided in a private healthcare setting in 2019/20, with an estimated cost of $78 million. The demand for CIED services is expected to increase to approximately 606,000 services by 2022/23. The associated cost of providing these services is estimated to be over $103 million by 2022/23. The analysis is based on the existing level of service provided by companies supplying CIEDs and does not consider the efficiency by which it is being provided or could be provided. Due to the significant gaps and limited data available, the analysis relies heavily on input and internal data from companies supplying CIED.

Implications if companies supplying CIEDs were to stop providing services

If reductions to the Prosthesis List were to reach a point where provision of CIED services becomes unviable for companies supplying CIEDs to continue to do so, the demand for these services would need to be met by either the public healthcare sector or potentially by private providers. Alternatively, companies supplying CIEDs that currently deliver these services would need to be further reimbursed under a different funding model to continue to provide these services.

Policy implications

A significant portion of the cost of CIED services being provided lies in ensuring that patients are able to access required cardiac technical services in a timely manner, regardless of their location. While cost-savings may be found by centralising and only providing these services in metropolitan or regional centres, this would be a cost-shifting onto patients and households in regional and remote areas as they would have to incur the costs of transportation to access these services in metropolitan or regional centres.

Conclusion

Companies supplying CIEDs rely on the reimbursement for the provision of CIEDs at the point of implant or replacement to provide the required follow-up technical services over the life of the device.

The volume of CIED services each year is estimated through a bottom-up approach based on the number of insertions per 100,000 population from published studies and assumed service requirement per device. The total cost of CIED services in 2019/20 was estimated to be $78 million, growing to be $103 million by 2022/23. A significant portion of the cost comes from the cost of labour for companies supplying CIEDs to provide these services in a reasonably timely and accessible manner.

The estimates presented in this report are a first approximation of the cost to provide CIED services by companies supplying CIEDs in a private healthcare setting. The analysis does not consider what the most efficient way of providing these services might be. The level of efficiency related to providing CIED services in a timely and accessible manner may differ depending on whether companies supplying CIEDs, third party service providers or the public healthcare sector were to provide these services.

If reimbursement is reduced to a point where it is no longer viable for these companies to continue to provide these services, it would likely fall to the public health system to meet demand. Such a scenario could potentially be shifting the cost of provision from companies supplying CIEDs currently, to government and/or patients.

Limitations

There are limitations to the analysis in this report:

- There are significant gaps in the data. As such, the estimates are an approximation of the volume and cost of total CIED services provided by companies supplying CIEDs in a private healthcare setting. Where data or information is unavailable, subject matter experts and industry sources have been consulted to inform the assumptions. The uncertainty around key modelling assumptions are assessed through a sensitivity analysis to evaluate the possible range of final estimates.
- There are additional uncertainties with projecting into the future. The volume (and cost) of service estimates are based on data e.g. population projections and mortality rates, that are likely to be revised in the future, and will impact on the estimates contained in this report. The estimates in this report do not include any impacts of new technologies nor changes in medical treatment for diagnoses that CIEDs are currently prescribed. They should be considered indicative only.
- The estimates in this report are intended to capture the average cost and level of service as currently provided. As such, the analysis does not incorporate clinic-specific requirements *e.g.* minimum number of IEAPs to be present if a certain number of patients require CIED services. As the distributions of key parameters are often long-tailed and right-skewed, the use of averages in the analysis may create some upward bias in the results. Monte Carlo simulations help with the construction of 95% confidence intervals to provide an indication of the range of values the estimates are likely to fall.
- The analysis in this report does not include any assessment regarding the level of existing funding under the Prosthesis List for the level of service currently being provided by companies supplying CIEDs. Without further information on the cost (and price margins) for each device, it is not possible to make a connection between the cost of CIED services estimated here on an annual basis and the cost of services bundled into the once-off reimbursement for the provision of a device at the point of implantation.
- The analysis estimates the cost of services provided as it is currently delivered. It does not examine how efficiently these CIED services are, or could, be provided, whether by companies supplying CIEDs or by alternative providers. The cost of the provision of timely and accessible services could be much higher with a better level of services, or lower with a lower level of service.
- The estimates in this study are an approximation that requires the use of several limiting assumptions owing to significant gaps and very limited data available.
- Data on each type of service provided over a 6-week period as well as internal estimates for each company have been provided by the companies supplying CIEDs to supplement the limited data available for the analysis. With no further information on services provided and without any way of verifying the impacts of seasonality, the 6-week snapshot is assumed to be a representative period of services provided over a full year.
- Although the use of survey data would have been beneficial, this is outside the scope of this report.

Appendix A: Assumptions

The following table summarises the assumptions used in the model and provides information on the rationale and source for the assumption.

Components	Values	Sources
Insertions and Replacement of Devices		
Insertions	New device insertions are based on incidence rates informed by data from the literature. Rates are grown in line with historical trend growth. In the case of ILRs, growth trends of the MBS data were used as historical incidence rates were not available in published studies.	Published rates from Blanch et al (2018) for ICDs; Castles et al (2018) for ILRs and AIHW (2019) for pacemakers
Replacements	Device replacements are factored in as a share of insertions in a given year. There are on **average 0.30 replacements for every one ICD insertion** and **0.18 replacements for every one pacemaker insertion** every year	This is based on published data from Mond and Crozier (2019)
ILR removals rather than replacement	ILRs are assumed to be **removed after 3 years** rather than replaced. Patients often require an alternative device and will also require ongoing follow-ups. 2019/20, 2020/21 and 2021/22 removal services are based on the number of insertions in 2016/17, 2017/18 and 2018/19 insertions, respectively. 2022/23 removals are based on our estimate of insertions for 2019/20. Volume of annual ILR removals are net of device removals associated with ILR patient mortality.	MBS insertions for 2016, 2017, 2018. St Vincent's Heart Health and Vijapurapu et al (2019) on ILR removals
Average number of annual scheduled services per existing and newly inserted device	This is currently assumed to be **2 scheduled (Doctor Room Clinic/Check and Hospital Device Follow-Up Clinic) services for ICDs, pacemakers and ILRs**, per new and existing device annually**.**	Assumptions informed by minimum number of scheduled follow-up services from: Cardiac Society of Australia and New Zealand (CSANZ) guidelines.

Composition and Type of services		
Ratio of Unscheduled to scheduled services	Our calculations show that for every one scheduled service, **0.087 unscheduled services** are provided.	These estimates are based on internal data from companies supplying CIEDs.
Ratio of Remote monitoring services to scheduled services	Our calculations show that for every one scheduled service, **0.77 remote monitoring services** are provided.	These estimates are based on internal data provided from companies supplying CIEDs.
Distribution of scheduled and unscheduled services	**Scheduled services** Doctor Room Clinic/Check 77% Hospital Device Follow-up Clinic 23% **Unscheduled services** Ward Check 41% Emergency Department Check 19% MRI Check 17% Radiation Oncology Check 7% Pre-Op/Theatre Check 8% ICU Reprogramming 2% EP Procedure Reprogramming 4% Nursing Home Check 1% Palliative Reprogramming 1%	These estimates are based on internal data provided from companies supplying CIEDs. Definition of scheduled versus unscheduled services based on discussion with companies supplying CIEDs.
Public and Private split	Approximately **56%** of services are conducted in **private healthcare setting** with 44% occurring in public sector.	From Productivity Commission's hospital report 2007-08 (Productivity Commission 2009). Private and public split on Prosthesis costs and separations for top 20 Diagnosis related groups.
Regional Split	Metropolitan: **80%** Regional: **19%** Remote and very remote: **1%**	Using **Modified Monash Model (MMM)** definitions on internal postcode data from companies supplying CIEDs. MMM 1 is defined as a metropolitan region, MMM 2-5 as regional areas and MMM 6-7 are classified as remote areas.

Labour Cost		
Number of FTEs (adjusted)	Metro: **315** Regional: **75** Remote: **4**	Estimated number of full-time equivalents (FTEs) from the model have been adjusted using the average number of services provided per FTE per day.
Average number of services able to be provided per FTE per day	**5.2** services per FTE per day	Derived from internal data provided by companies supplying CIEDs. The average estimate across all companies was 4 services per FTE per day. Following industry validation of assumptions, a more conservative estimate of 5.2 services per day was used as it is based on data from more robust data collection practices. This measure accounts for a required buffer to provide CIED services in a timely and accessible manner as variations occur frequently *e.g.* limited flights to remote regions, flight and traffic delays, appointments being cancelled or requiring more time than scheduled.
Wage rate per hour	Metropolitan: **$80** Regional: **$80** Remote: **$112**	This is based on QLD Health, NSW Health wages/salaries for experienced cardiac technologists, and input from companies supplying CIEDs on a sensible adjustment to reflect private healthcare sector wages. An experienced cardiac technologist employed by QLD Health or NSW Health can expect to earn

			approximately $60 - $80 per hour. Input from companies supplying CIEDs suggest that this range is $70 - $90 in a private healthcare setting.
Remote wage loading	**40%**		NDIS price guide does not provide a regional loading but recommends 40% and 50% for *remote* and *very remote loading*, respectively. As *very remote* services are less likely to be provided, the loading is assumed to be 40% for remote areas.
Time required for each service in hours	**Scheduled services**	Time (hours)	This information has been sourced from the Cardiac Internal Working Group draft data and re-confirmed with companies supplying CIEDs. The information relies on input that was collected by one company but subsequently validated by industry stakeholders.
	Doctor Room Clinic/Check	0.50	
	Hospital Device Follow-up Clinic	0.50	
	Unscheduled services		
	Day 1 Post-Implant Check	1.00	
	Ward Check	1.00	
	Emergency Department Check	1.00	
	MRI Check	2.00	
	Radiation Oncology Check	2.00	
	Pre-Op/Theatre Check	2.00	
	ICU Reprogramming	1.50	
	EP Procedure Reprogramming	3.00	
	Nursing Home Check	1.00	
	Palliative Reprogramming	1.00	
	Morgue/Funeral Check	1.00	
	Remote Transmission Review (no loading)	0.25	
	Implant/Replacement - Pacemaker	2.00	
	Implant/Replacement - ICD	3.00	
	Implants only - ILRs	1.00	

Travel cost		
Number of services per trip	Metropolitan: **5** scheduled services per trip Regional: **6** scheduled services per trip Remote: **8** scheduled services per trip Each unscheduled service is assumed to require a single trip.	Average estimates are based on internal data collected by one company and validated by stakeholder companies.

Average travel cost per km	**$0.85** per km	Based on travel cost allowance from NDIS Price Guide 2020-21.
Travel time required	Metropolitan: **0.5** hours Regional: **0.75** hour Remote: **1** hour	This is based on NDIS Price Guide 2020-21. The maximum amount of travel time that can be claimed is 30 minutes for the MMM 1-3 region, and 60 minutes for the MMM 4-5 areas. As the regional area encompasses MMM2-5, we take the average of the allowance. We have currently assumed 1 hour for remote travel as well.
Average speed (km per hour)	Metropolitan: **65** km/h Regional: **67** km/h Remote: **70** km/h	Average speed estimates have been taken from *Road Congestion in Australia* report produced by Australian Automobile Association in 2019. For remote areas, a speed limit of 70 has been assumed.
Average parking cost per hour	Metropolitan: **$10** Regional: **$10** Remote: **$10**	This has been taken from *Global Parking Index* report produced by Parkopedia, 2017. Parking cost for all three regions have been assumed to be consistent.
Average tolls cost (metro and regional only)	An average full trip charge of tolls is estimated at **$5**. Tolls are only located in metro areas so regional or remote travel assumes that metro IEAPs travel out to regional areas. Tolls are not included for remote services as it is assumed that IEAPs catch a flight to their remote destination and drive locally.	This estimate has been calculated from full trip toll charges provided by *Toll Roads in Australia* report, BITRE, 2016.
Average number of tolls per trip	An average number of tolls per trip is estimated at **2**.	Assumed that one toll is taken per leg of a return trip.
Average return flight cost to remote areas	**$500**	Regional Express return flight between Adelaide

		and Broken Hill as reference.
Average additional travel cost for regional trips (i.e. additional kms needed for car travel or a return flight)	Assumed that **57%** of regional services provided require flights or additional car travel, at an average return cost of **$150.**	Share of regional services requiring flights assumed to be MMM3-5, derived from internal data of companies supplying CIEDs. Flight cost is based on a Regional Express flight between Sydney and Wagga Wagga. Alternatively, this accounts for approximately 175 km additional driving allowance at $0.85 per km.
Training and accreditation		
Onboarding cost	$200,000 per new employee	Median estimate of internal data of companies supplying CIEDs. This captures the cost of onboarding a new IEAP to the point where they no longer require any supervision when conducting technical services. This measure includes the cost of time to train up a new IEAP as well as time towards supervision.
Percent of staff requiring onboarding and certification each year	10%	This is the proportion of the IEAP staff base assumed to be new in a company that provides CIED services hires in a given year and will require onboarding and certification training to provide CIED services. Informed by average staff turnover rate in Australia in 2018. AHRI (2018) specifies 18% in staff turnover across Australia.

Certification help (IBHRE)	$12,500 per employee per year	Median estimate of internal data from companies supplying CIEDs.
Annual update and training for all IEAPs	$15,000 per employee per year	Median estimate of internal data from companies supplying CIEDs.
CPI and WPI	Assumed to be 2%	

Appendix B: Model

The modelling approach consists of three stages.

1 Establish the number of new insertions, removals and prevalence of each device in a given year using a population projection model.

2 Estimate the volume of services based on the number of existing and new devices each year, assuming the services required by each device over a typical device life-cycle.

3 Estimate the costs associated with the number of services and service type provided each year.

The following sections describe each of these stages in more detail.

1 Population projection model

KPMG adopted a bottom-up approach to estimating the prevalence of CIEDs. This approach uses population projections and mortality data from the Australian Bureau of Statistics (ABS) coupled with published estimates on the incidence rate by age and gender to determine the prevalence of CIEDs for 2019/20 – 2022/23.

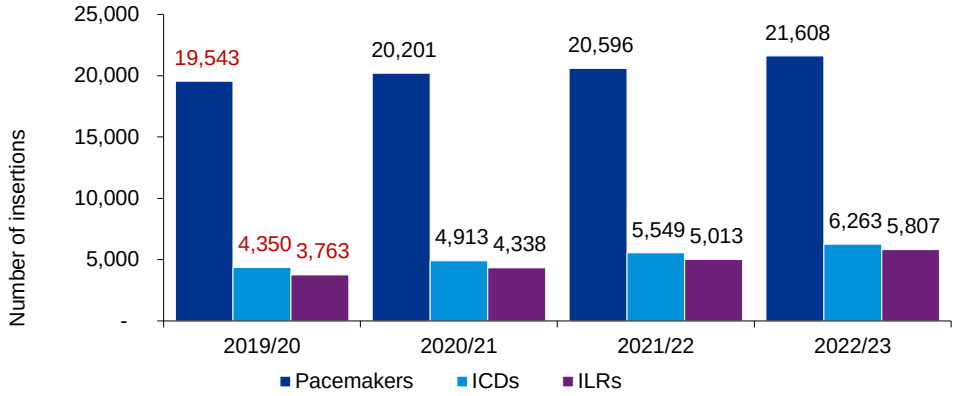
Incidence

For each of these years, the number of new device insertions, number of individuals with existing devices and the number of deaths of individuals with devices for a given year can be estimated. Newly inserted devices add to the prevalence of existing devices each year while deaths of individuals with devices or ILR removals reduce it. Therefore, the difference in the number of existing devices between each year is equal to the number of new insertions, net the number of removals that year.

Incidence rates for PPMs, ICDs and ILRs by age and gender were used. The PPM incidence information was based on reported information from the AIHW (2019), ICD incidence rates were sourced from Blanch et al (2018) and ILR incidence rates were based on Castles et al (2018). As historical information is not available for ILRs, historical trend growth from the MBS data was used instead.

The number of insertions for PPMs and ILRs were projected forward and the rate calculated by using ABS's population projections (ABS Cat. No. 3222.0 Series B). As historical incidence rates for ICDs were available, ICD projections for 2019/20 – 2022/23 were based on the average annual growth. To validate the estimates in the model, the number of new devices inserted (excluding replacements) were anchored against the known number of new insertions in 2016 (ILRs) and 2017 & 2018/19 (pacemakers and ICDs) from Castles et al (2018), Mond and Crozier (2019) and AIHW (2020), respectively. Estimated new insertions by device are summarised in the chart below.

Figure 19: Total number of new insertions by device



Source: KPMG estimates
Note: all values are reported on a financial year basis

Prevalence

Estimates on the number of individuals living with CIEDs are severely limited in the literature. The prevalence of PPMs relied on in the model was based on a 2009 estimate from Bradshaw et al (2014) that cites approximately 7,739 adults living with pacemakers. The prevalence of ICDs in the model is based on Blanch et al (2019) that reports 39,410 ICD insertions were conducted between 2002 - 2014. Information on the prevalence of ILRs were not available. The number of ILRs inserted in 2016 from Castles et al (2018) was used as a base to help approximate the prevalence of ILRs in 2019/20 as ILRs are removed within 3 years of implantation.

From these starting prevalence estimates, the number of new insertions determined earlier, and the aggregate mortality rate were applied each year to accumulate an estimate for the prevalence at the start of 2019/20. Projections of the number of new insertions and prevalence of existing devices were estimated for 2019/20 – 2022/23.

2 Estimating the volume of services

As each CIED requires a certain number of technical services in any given year, the prevalence of CIEDs in a given year help establish the volume of services demanded. The number of new devices, existing devices and removals (from mortality or ILR removals) help establish the number of total CIED services required.

Data on each type of service provided over a 6-week period as well as internal estimates for each company has been provided by companies supplying CIEDs to supplement the limited data available. The analysis assumes that the 6-week snapshot is a representative period of the type of services provided over a full year.

Summary of services required by status each year

Each **new insertion** in a given year is assumed to require both an insertion procedure service as well as a Day 1 post-insertion service.

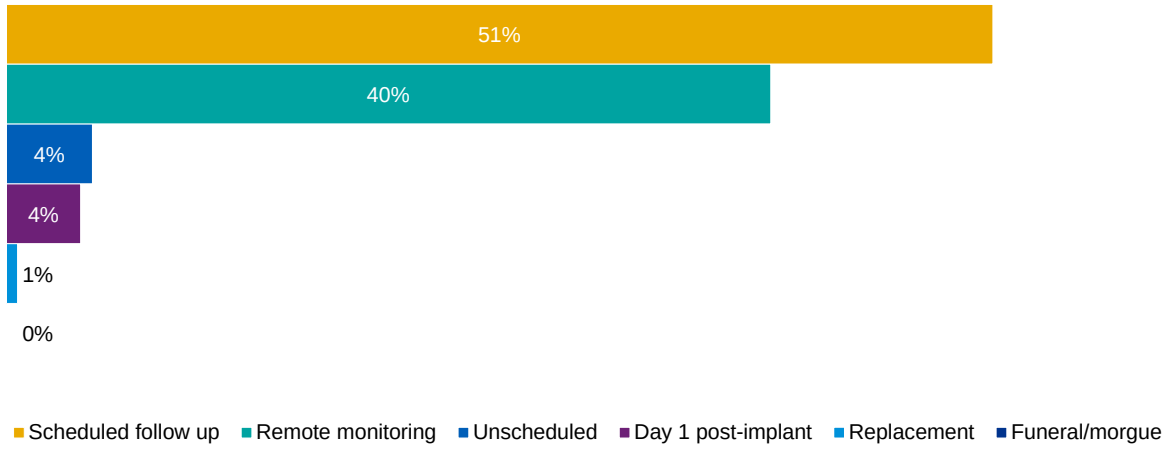
According to industry sources, devices typically last between 10-15 years and will need to be replaced at the end of their life. Each **replacement** is also associated with an insertion procedure service and Day 1 post-insertions service. Replacements are assumed to only occur in ICDs and PMs and are based on a historical ratio of 0.30 and 0.18 replacements per new insertion, respectively.

Existing devices and new insertions are assumed to require 2 scheduled follow-up services e.g. doctor's room clinic or hospital device follow-up clinic per year.

Unscheduled checks e.g. MRI or Emergency department checks, are also accounted for as a ratio to scheduled services per year. Based on internal data from companies supplying CIEDs, it is assumed that there are 0.087 unscheduled checks and 0.77 remote monitoring services for every one scheduled service.

It is assumed that there are two scheduled services (Doctor Room Clinic/Check and Hospital Device Follow-Up Clinic) for each existing device each year.

Figure 20: Types of services provided by companies supplying CIEDs



Source: KPMG estimates, companies providing CIEDs data

As CIED services are provided in both public and private hospitals, only a portion of the total number of services estimated are provided by companies supplying CIEDs. It is assumed that approximately 56% of CIED services are provided in a private healthcare setting and are therefore provided by these companies.[21]

[21] Productivity Commission (2009)

The shares of metro, regional and remote services are based on internal data provided from companies supplying CIEDs. They are 80% in Metro, 19% in Regional and about 1% in Remote regions. The total volume of services each year are apportioned accordingly. Doing so allows for the costs to be overlaid appropriately as wages and travel requirements to provide services vary with location.

There may be some savings in some instances where multiple scheduled services could be provided with a single trip. These are assumed to only be feasible for scheduled services. Given the unpredictable nature of unscheduled services, each unscheduled service will likely require an individual trip by IEAPs, based on advise by companies supplying CIEDs. The analysis estimates the number of trips required based on the number of scheduled trips and unscheduled trips forecast each year (see Table 1 for the total number of annual trips estimated in 2019/20).

Table 1: Estimated number of services and trips supported by companies supplying CIEDs in 2019/20

	Metro	Regional	Remote	Total
Number of Services	392,961	93,328	4,912	491,201
Annual number of trips (scheduled only)	39,075	7,734	305	47,113
Annual unscheduled trips	46,233	10,980	578	57,792
Total Annual trips	85,308	18,714	883	104,905

Source: KPMG estimates
Note: all values are reported in nominal terms and on a financial year basis

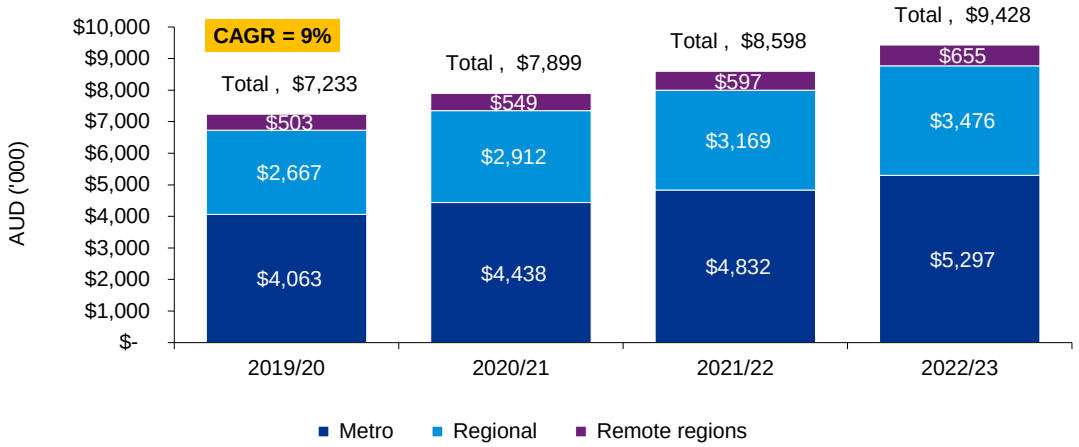
3 Estimating the cost of services

Travel costs are estimated based on the distance travelled that is calculated from the average speed and travel time required, the cost associated with running a vehicle (cents/km), distance travelled, tolls, parking costs, flight costs for a single trip. The total travel costs are then calculated for the number of trips required to provide the estimated number of services each year.

The cost of labour is estimated based on assumptions regarding the wage rate and the time required for services and travel. Based on data from companies supplying CIEDs, the average number of services able to be provided by an FTE each day is derived. This estimate attempts to capture the non-linear, concurrent and unpredictable nature of providing these CIED services across multiple locations. This is reflected in the FTE requirements to provide the estimated number of services each year.

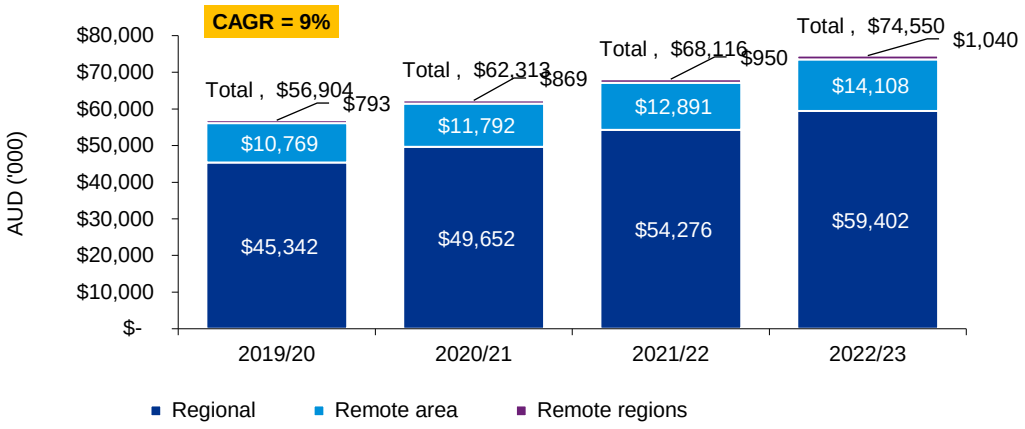
Annual training costs to facilitate CIED services in a private healthcare setting are also based on internal data from companies supplying CIEDs. Three types of training costs were considered: annual ongoing update/training for all staff, and onboarding and certification costs for new staff only. It is assumed that approximately 10% of total staff are new each year. These estimates are calculated based on the total number of FTEs of IEAPs each year. The cost of each of these components for 2019/20 – 2022/23 are summarised in Figure 21 to Figure 23.

Figure 21: Travel costs by region, 2019/20 – 2022/23



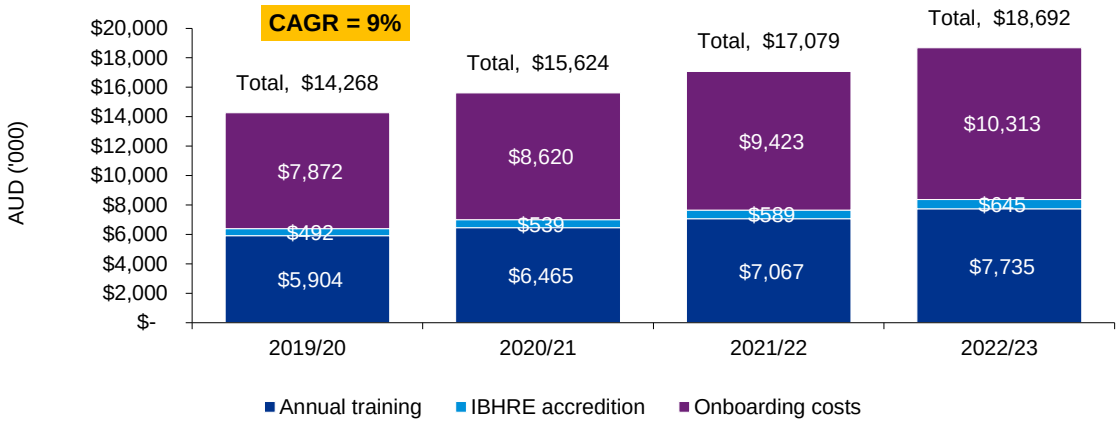
Source: KPMG estimates
Note: all values are reported in nominal terms and on a financial year basis

Figure 22: Labour costs by regions, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported in nominal terms and on a financial year basis

Figure 23: Total value of training costs, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported in nominal terms and on a financial year basis

Appendix C: Sensitivity Analysis

Due to the uncertainty around several assumptions needed in the modelling (Appendix A), a Monte Carlo simulation over 1,000 iterations was run to provide some sensitivity analysis surrounding the cost of CIED services provided.

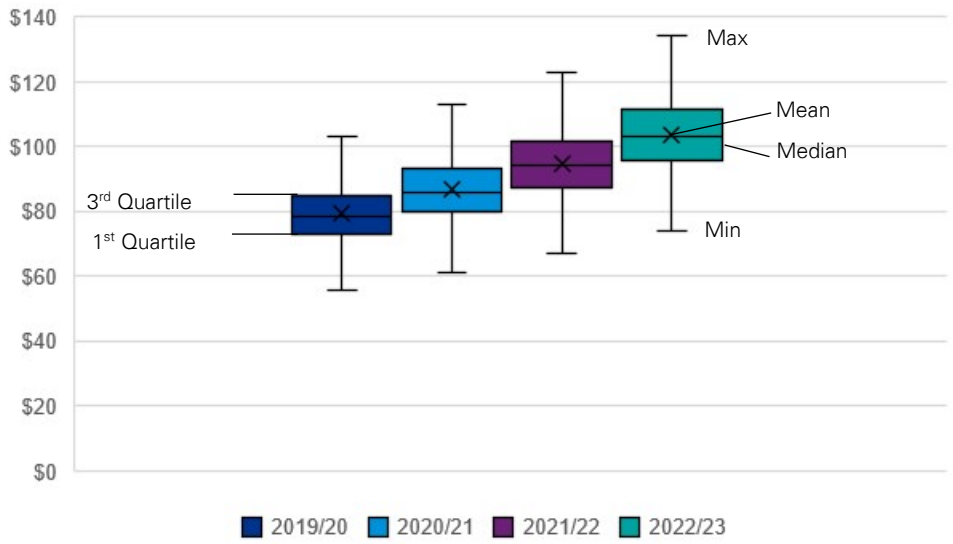
A key benefit of the Monte Carlo simulation is that it draws from a probabilistic distribution to inform the range of estimates possible through confidence intervals. Uncertainty in the following parameters were accounted for in the sensitivity analysis. All standard errors were calculated using the method from Wan et al (2014) that is based on maximum and minimum values that are expected for each of the assumed parameters.

Wage rate (per hour)	Mean = $80	Max = $90 Min = $70	Based on QLD Health and NSW Health wage rates per hour across different levels of experience, and input from industry source regarding adjustment for private healthcare sector.
Average number of services per trip in Metro, Regional and Remote areas	Mean = 5 (metro), 6 (regional); 8 (remote)	Range derived from internal data from companies supplying CIEDs	
Average number of services per device per year	Mean = 2	Max = 2.5 Min = 1.5	Based on CSANZ guidelines, there may be anywhere from 1-4 follow-up services each year.
Average travel cost per km	Mean = $0.85	Max = $0.98 Min = $0.72	Based on ATO's allowance of 72c as a minimum and NDIS's 85c allowance.
Average speed (km/h) in Metro	Mean = 65 km/h	Max = 73 km/h Min = 55 km/h	Based on the speed limit from AAA's Congestion report 2019 for average speed across capital cities. Max and min are based on the range of average speeds in the report. Average speeds for regional and remote trips are fixed at a factor of 1.03 and 1.07 to the average speed for Metro trips, respectively. The fixed factor is intended to reflect the ratio in the baseline where average speeds for regional and remote trips are expected to be faster than for metro trips.
Parking cost per trip	Mean = $10	Max = $15 Min = $5	

Average tolls per trip	Mean = 2	Max = 2.5 Min = 1.5	Assumed that one toll is taken per leg of a return trip.
Average price per toll	Mean = $5	Max = $8.70 Min = $2.70	Based on BITRE publication on the range of toll prices in Australia
Average return flight cost per remote trip	Mean = $500	Max = $600 Min = $400	
Ongoing training costs per employee	Mean = $15,000	Range derived from internal data from companies supplying CIEDs	
Onboarding costs per new employee (10% of total employees each year)	Mean = $200,000	Range derived from internal data from companies supplying CIEDs	
Certification costs per new employee (10% of total employees each year)	Mean = $12,500	Range derived from internal data from companies supplying CIEDs	

The following figures summarise the results from the sensitivity analysis indicating the range of values that are possible for the total cost of CIED services and its components (labour, travel and other costs) from 2019/20 – 2022/23. All values here are reported on in nominal terms.

Figure 24: Total cost to provide CIED services ($ million)

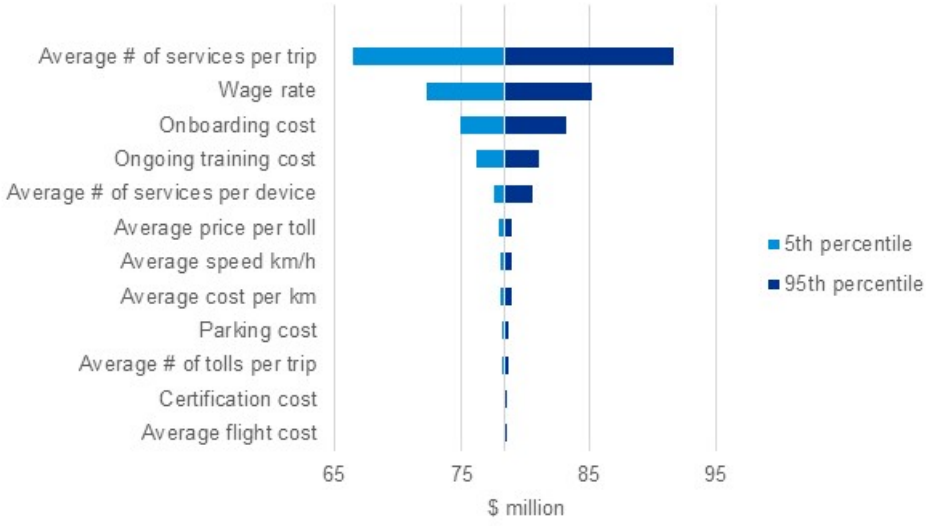


	2019/20	2020/21	2021/22	2022/23
95th percentile	$95.79m	$104.81m	$114.39m	$125.00m
5th percentile	$65.63m	$71.83m	$78.44m	$85.88m
Median	$78.59m	$86.06m	$94.08m	$102.98m

Note: all values are reported in nominal terms and on a financial year basis

The uncertainty in the average number of services able to be met per trip affects the number of trips required, and as a result the total value of CIED services, through the travel cost component. This is followed by the wage rate that influences the labour cost component of the value of CIED services in 2019.

Figure 25: Uncertainty in assumed parameters on total cost to provide CIED services (2019/20)



Note: all values are reported in nominal terms and on a financial year basis

The analysis assumes that 56% of the total services each year occur in a private healthcare setting[22] and are provided by IEAPs employed by companies supplying CIEDs. In most private healthcare settings, IEAPs provide support to individual private physicians, practices or hospitals. In the public health system, hospital employed cardiac physiologists are the primary provider of technical support services. Occasionally, cardiac physiologists may require further technical support or assistance from IEAPs. Whilst IEAPs occasionally support public follow-up clinics, their role is more educational and of a facilitative nature. Based on internal data from companies supplying CIEDs, the service delivery spillover into the public health system makes up approximately 2% of total services demanded each year.

Sensitivity analysis is conducted around the assumed share of CIED technical services provided by companies each year. The base case assumes that there is no spillover of services. Every one percentage point increase in the share of services provided by IEAPs in the public health system raises the cost of providing CIED services by $1.4 million in 2019/20. Though IEAPs may play different roles in public versus

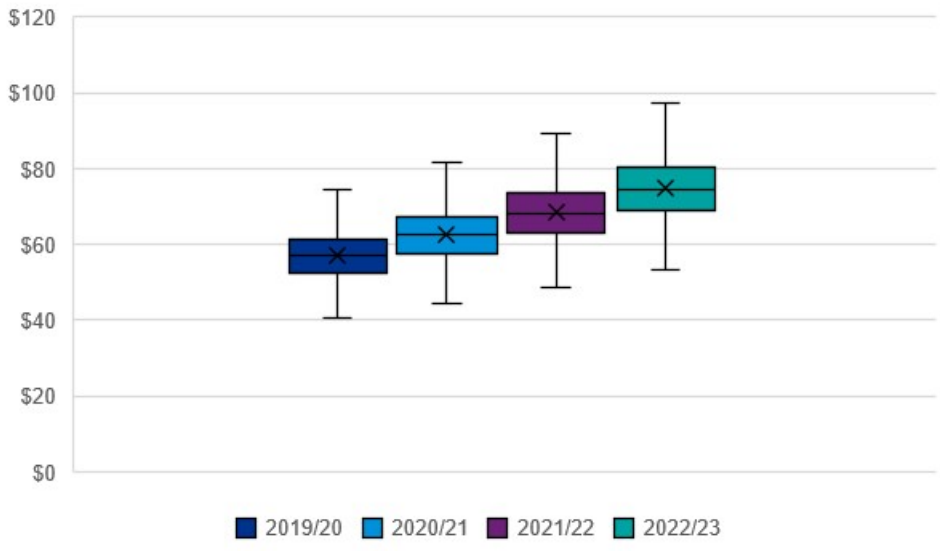
[22] From Productivity Commission (2009)

private healthcare settings, the sensitivity analysis assumes that the distribution of additional services provided remains consistent with the distribution in overall services provided each year.

Share of services provided by companies supplying CIEDs	2019/20	2020/21	2021/22	2022/23
No spillover (companies provide **56%** of all services each year)	$78.40m	$85.84m	$93.79m	$102.67m
Additional 1% of services in public sector (companies provide **57%** of all services each year)	$79.80m	$87.37m	$95.47m	$104.50m
Additional 2% of services in public sector (companies provide **58%** of all services each year)	$81.20m	$88.90m	$97.14m	$106.34m

Note: all values are reported in nominal terms and on a financial year basis

Figure 26: Total labour costs ($ million)



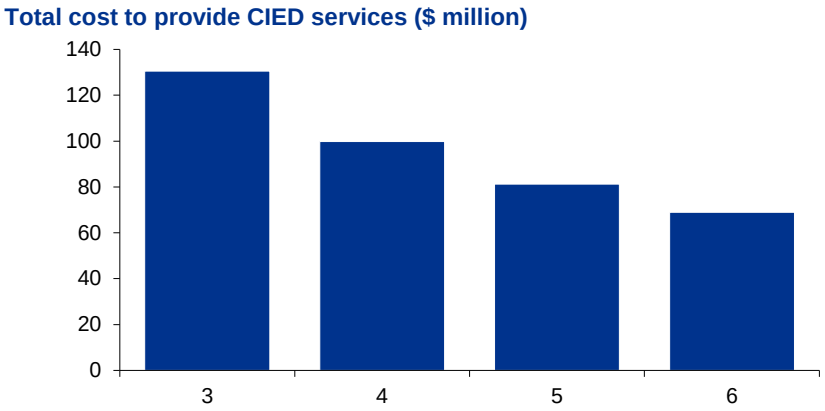
	2019/20	2020/21	2021/22	2022/23
95th percentile	$69.99m	$76.61m	$83.65m	$91.40m
5th percentile	$46.51m	$50.89m	$55.73m	$61.06m
Median	$57.00m	$62.41m	$68.21m	$74.62m

Note: all values are reported in nominal terms and on a financial year basis

The average number of services able to be provided per FTE each day is assumed based on estimates from companies supplying CIEDs. This measure attempts to capture the unpredictable nature inherent in CIED service provision that these companies are faced with. With the same level of service maintained, a lower number of average services able to be provided by each FTE each day captures a greater level of unpredictability and need for concurrency in CIED service provision. Thus, more FTEs are required to provide the same number of services demanded per year relative to if the situation were less unpredictable and linear, captured by a higher average number of services per FTE per day. This is done relative to a hypothetical situation where all services are able to be delivered whenever it is demanded.

The cost to provide this buffer was estimated to be $32 million in 2019/20 and is expected to rise to $42 million by 2022/23. As there is great uncertainty surrounding this parameter that could vary by type of service and also by location, a sensitivity analysis was also run on the average number of services able to be conducted per FTE per day. While the value of this buffer does not change with this parameter, the cost of CIED services associated with providing the same level of service could fall between $69 million - $119 million if the average number of services per FTE per day were to vary between 3 and 6.

Figure 27: Sensitivity analysis of the average number of services per FTE per day in 2019/20

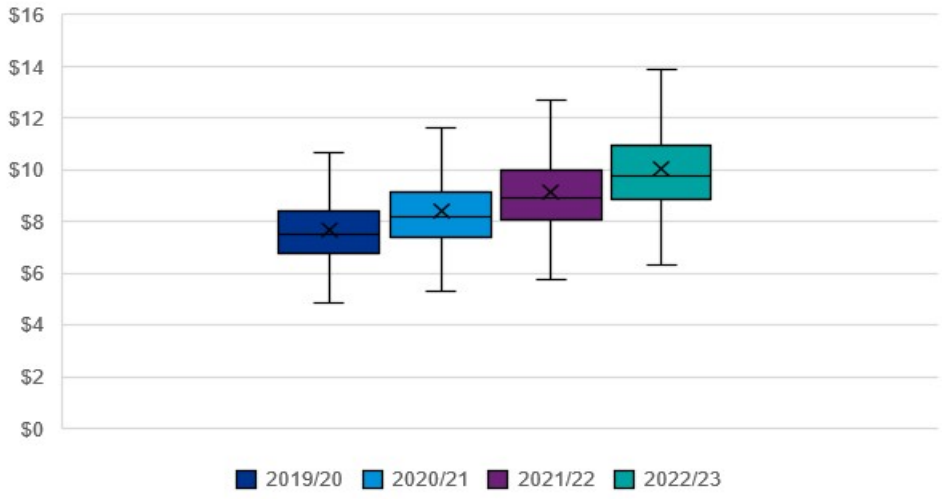


	Total labour cost	Training cost	Total cost to provide CIED services
3 services per FTE per day	$98.63m	$24.73m	$130.60m
4 services per FTE per day	$73.97m	$18.55m	$99.76m
5 services per FTE per day	$59.18m	$14.84m	$81.25m
6 services per FTE per day	$49.32m	$12.37m	$68.91m

Note: all values are reported in nominal terms and on a financial year basis

Number of FTEs required if assume:	2019/20	2020/21	2021/22	2022/23
3 services per FTE per day	682	732	785	842
4 services per FTE per day	512	549	589	632
5 services per FTE per day	409	439	471	505
6 services per FTE per day	341	366	392	421

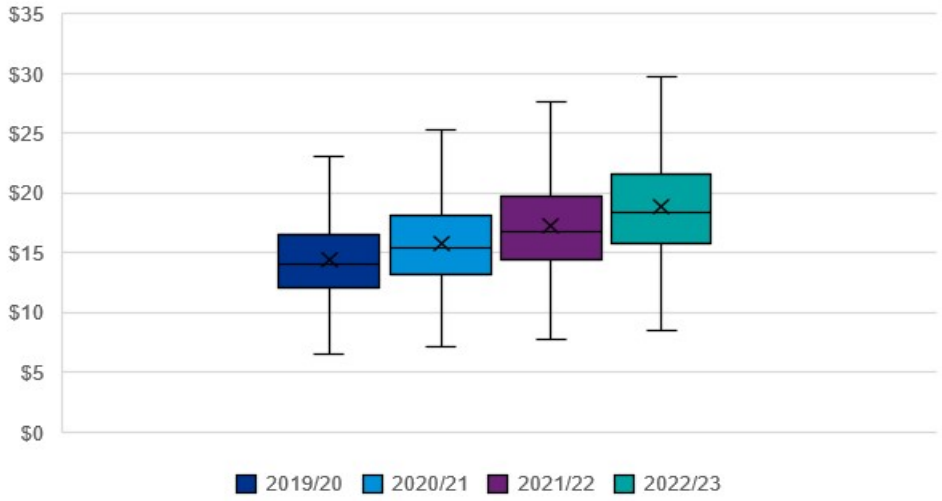
Figure 28: Total travel costs ($ million)



	2019/20	2020/21	2021/22	2022/23
95th percentile	$9.89m	$10.82m	$11.80m	$12.93m
5th percentile	$6.04m	$6.60m	$7.18m	$7.87m
Median	$7.49m	$8.19m	$8.92m	$9.78m

Note: all values are reported in nominal terms and on a financial year basis

Figure 29: Training cost ($ million)



	2019/20	2020/21	2021/22	2022/23
95th percentile	$20.07m	$21.97m	$23.99m	$26.22m
5th percentile	$9.70m	$10.61m	$11.60m	$12.71m
Median	$14.05m	$15.39m	$16.82m	$18.40m

Note: all values are reported in nominal terms and on a financial year basis

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