Costing an arm and a leg

Making healthcare more affordable and accessible for Australians

Private Healthcare Australia
Better Cover. Better Access. Better Care.

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Contents

Executive summary

Australians depend on their health system to deliver effective and accessible care, but the affordability of this system is becoming increasingly challenging for consumers and the government. Healthcare spending has outpaced economic growth for years, increasing from 8.3 percent of GDP in 2003 to 9.4 percent in 2013. Private health insurance is an essential component to alleviate the burden on the public system, but is under financial strain: annual premium revenue growth has ranged from 7 to 9 percent in 2013-15[1], while participation has flat-lined at 47 percent of the population[2]. New measures are needed to keep healthcare within the means of all Australians.

Reforming the prostheses reimbursement model is a promising opportunity to contribute to the sustainability of healthcare in Australia. Prostheses represent a significant amount of expenditure, comprising over 10 percent of total reimbursements by private insurers[3]; and current pricing governance mechanisms for prostheses have led to benefit levels that are often twice as high as prices in comparable systems, both domestically and abroad.

As will be shown, by addressing the area of prostheses reimbursement, the Australian health system could save $800 million in annual expenditure while preserving quality of care. This could translate into a premium reduction of 4.5 percent, or a savings of over $150 per policy. Furthermore, lower premiums are estimated to enable a migration of 300,000 Australians towards private health insurance, creating up to $276 million in additional value for government and significantly reducing the burden on the public health system.

In order to improve the system, Australia's private health insurers developed a set of 11 potential reforms based on international case studies, a review of the literature, and expert interviews. These were evaluated in terms of both impact (i.e., ability to reduce value flowing out of the system while improving or preserving outcomes) and feasibility (i.e., magnitude of reform required and potential downside risks). Appendix A provides further detail on this evaluation.

Two options emerged as the most promising avenues for reform, diverging significantly in scope of impact and change required. The first avenue is reference pricing, which would enhance the current model with a stronger fact base of domestic and international benchmarks. Reference pricing may be relatively straightforward to accomplish, as it requires little reform, has widespread usage, and could lower benefits to benchmark levels (i.e., by 45 percent) within two or three years.

The second, and longer-term, opportunity is to integrate prostheses costs into an episode-based payment. Agreeing on a predetermined reimbursement per procedure (e.g., per MBS item) would create stronger incentives for manufacturers to compete on price and improve the sustainability of the overall health system.

For these or any potential improvements to the reimbursement of prostheses, three criteria should be carefully considered:

- **Improve or maintain clinical outcomes** – quality of care is the paramount objective of the entire prosthesis field, and any reforms undertaken should not compromise patient welfare.
- **Make healthcare more affordable and accessible for Australians** –by eliminating excess expenditure, reform can reduce private insurance premiums and alleviate the burden on the health system.
- **Align incentives towards financial sustainability** – the government can increase transparency into true costs and value to promote competition and set a sustainable course for prostheses expenditure in the future.

This report is divided into three sections: first, the case for change analyses the root causes and impact of current inefficiencies. Next, the proposed alternative – reference pricing – is presented. Finally, a perspective is offered on what longer-term evolutions to the value chain and complementary reforms should be considered as part of a holistic approach.

The case for change

The case for change is built on four key points:

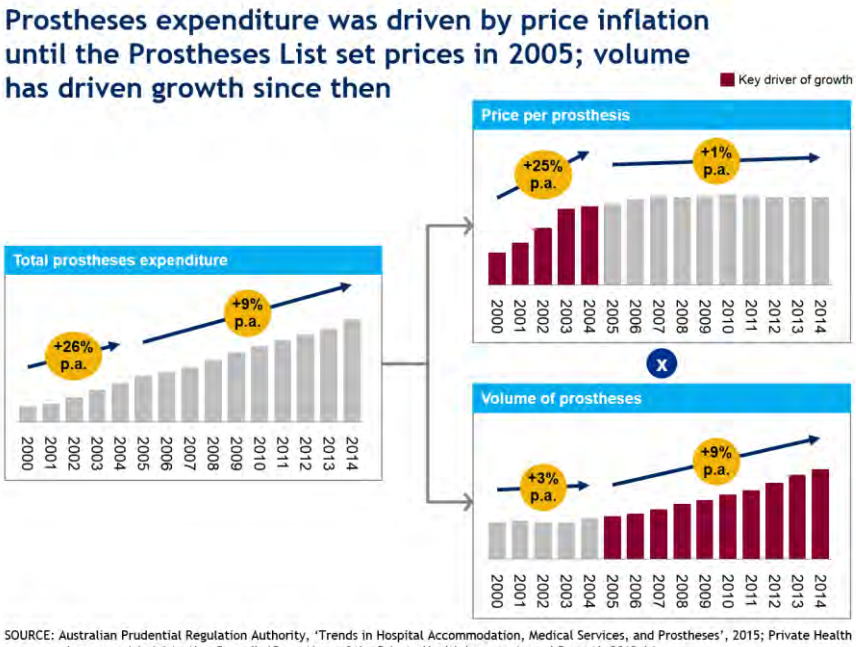
- Historical regulatory conditions have driven and then entrenched highly inflated prices in Australia's private prostheses market, and the current governance model in place to regulate these prices is flawed.
- International and domestic price benchmarks suggest that, on average, the Australian private health system is paying nearly twice the efficient benefit level for prostheses.
- There is an imbalance between who benefits and who pays in the current system, with the value tilted heavily towards the multinational shareholders of manufacturers and providers at the expense of Australian consumers and taxpayers.
- There is a lack of transparency into the true cost of prostheses in the health system and the extent of value disbursed through rebates or other incentives.

CHARTING THE HISTORICAL COURSE OF PROSTHESES EXPENDITURE

The regulation of prostheses in Australia has undergone a number of changes over the past two decades, which have driven and then entrenched heavily inflated prices.

Between 1985 and 2001, The Department of Health set the amount that health insurers were required to reimburse for medical prostheses in Australia. In 2001, the industry was partially deregulated, allowing insurers to negotiate benefit levels with providers and suppliers, but with the restriction that no gaps be charged to consumers. In this new environment, the market power of large, multinational medical device suppliers and clinician brand loyalty contributed to rapid benefit inflation that saw average prosthesis benefits skyrocket by approximately 150 percent in a four year period[4], driving up premium growth to 7-9 percent per annum[5]. During this same period, growth in the volume of prostheses was slow (see Figure 1).

FIGURE 1



SOURCE: Australian Prudential Regulation Authority, 'Trends in Hospital Accommodation, Medical Services, and Prostheses', 2015; Private Health Insurance Administration Council, 'Operations of the Private Health Insurers Annual Report', 2013-14.

In reaction to this price spiral, the government intervened in 2005 to set benefits using the Prostheses List, transitioning to a new model in a mostly cost-neutral way, thereby locking in reimbursements at inflated levels. A maximum reimbursement level was also set for each item, re-opening the possibility for providers to charge payment gaps, but was removed in 2010 as in practice it was not used. Currently, the Prostheses List continues to mandate a single minimum reimbursement benefit for each item on the list, benchmarked to groups of comparable items and set relative to the price of the year before. As a result, today's Prostheses List is winning the battle but losing the war: price inflation is under control, but reimbursement levels remain significantly higher than other comparable health systems – and each year, hundreds of millions of dollars of excess value are flowing to the shareholders of manufacturers and providers, at the expense of insurers, consumers, and government.

Regulating the Prostheses List

Today, the Prostheses List Advisory Committee (PLAC) deals with over 1,200 product submissions a year[6], mostly from medical device manufacturers applying to introduce a new or upgraded product into the market. While there is a focus on assessing and pricing new entries, many entries remain unchanged: close to half of all items on the Prostheses List retained the same benefit level from 2011 – 2015[7]. In order to add or update an item on the List, a 'sponsor' (the medical device company who owns the new technology) must submit an application, which is assessed by the PLAC's associated Clinical Advisory Groups (CAGs) to determine suitability of the device for inclusion on the list. Once the initial assessment has been passed, the PLAC will negotiate amongst themselves to arrive at a set benefit level to charge, based mostly on reimbursement levels of equivalent products already on the Prostheses List. The sponsor then has the right to appeal the set benefit level, triggering a review by external consultants with a clinical background to determine whether the case warrants reopening[8].

Despite the structured nature of the approvals process, the methodology used to review and assign benefit levels to Prostheses List items is limited in four key ways:

- PLAC does not systematically collect price point data from manufacturers, public hospitals or international benchmarking services. As a result, domestic or international benchmarks are rarely considered, leading to pricing 'in a vacuum'.
- New entrants have no incentive to compete on price, for two reasons. First, hospitals have no sensitivity to invoice price, so competitors gain no competitive advantage from a lower minimum reimbursement. Second, the minimum reimbursement level is set at the price offered by manufacturers comprising 25 percent of the market, so a new product cannot drive down prices until it gains significant share.[i,9]. The impact can be seen, for example, when patents expire: while competitors are quick to list 'me-too' products, they typically do so at the existing minimum reimbursement level, not at the expected 'generic' discount seen in pharmaceuticals and other systems. Rebates are not included, motivating providers and manufacturers to 'price shield' in contracts (i.e., agree to maintain a high invoice price and negotiate on opaque rebates.
- Manufacturers regularly do not provide all the data required by PLAC to build a robust view of cost base vs. clinical effectiveness, citing the information as 'commercial in confidence'.
- Comparative effectiveness is typically calculated using average outcomes, regardless of individual patient needs.

[i] Refers to private providers' current incentive to select Prostheses List items with the highest possible benefit level if benefits differ, to maximise rebates received given the cost will be passed on to insurers regardless. Therefore, a manufacturer looking to sell at a lower price (with a corresponding lower margin and less ability to provide rebates to providers) has few prospective customers, and cannot break into the market.

Hence, the 'average' superior product may be favoured even where an alternative would be more suitable.

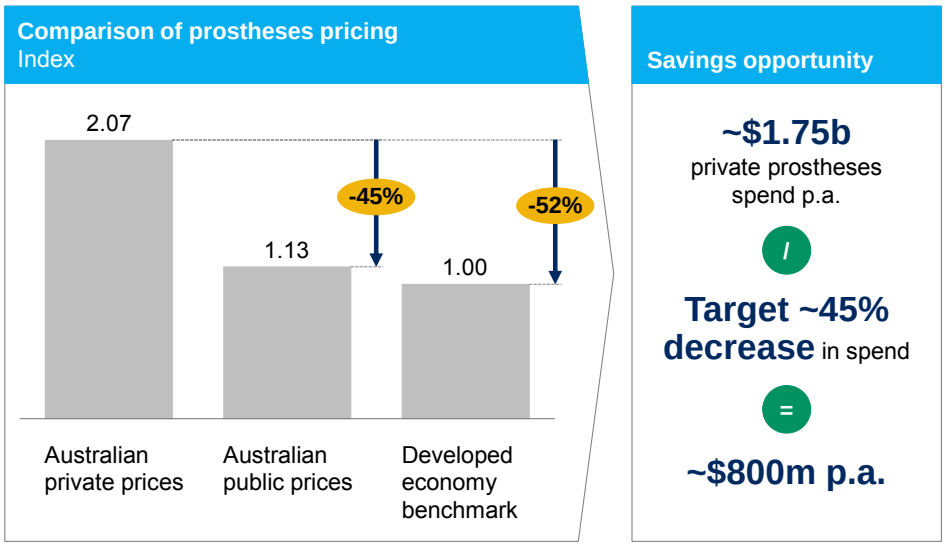
In summary, regulatory changes over the past two decades have first created, and then locked in highly inflated prostheses benefit levels in Australia's private health market. Furthermore, the current governance model that has been put in place to regulate the system is flawed, and unable to leverage the right price signals to bring costs down.

THE PRICE IS WRONG: SIZING THE MAGNITUDE OF CURRENT INEFFICIENCIES

Both international and domestic weighted price benchmarks suggest that the Australian private health system is paying twice as much as it should on average for prostheses, which would equate to approximately $800 million per annum in potential value caught up in the system (see Figure 2). Appendix B provides further detail on benchmarking sources.

FIGURE 2

Prices paid by Australian insurers are double those of domestic and international benchmarks



SOURCE: Australian Prostheses List 2015; WA Health pricing schedule; PHA Report 2014; International Federation of Health Plans Comparative Price Report, 2012; PwC Medibank Medical Devices Review, 2010

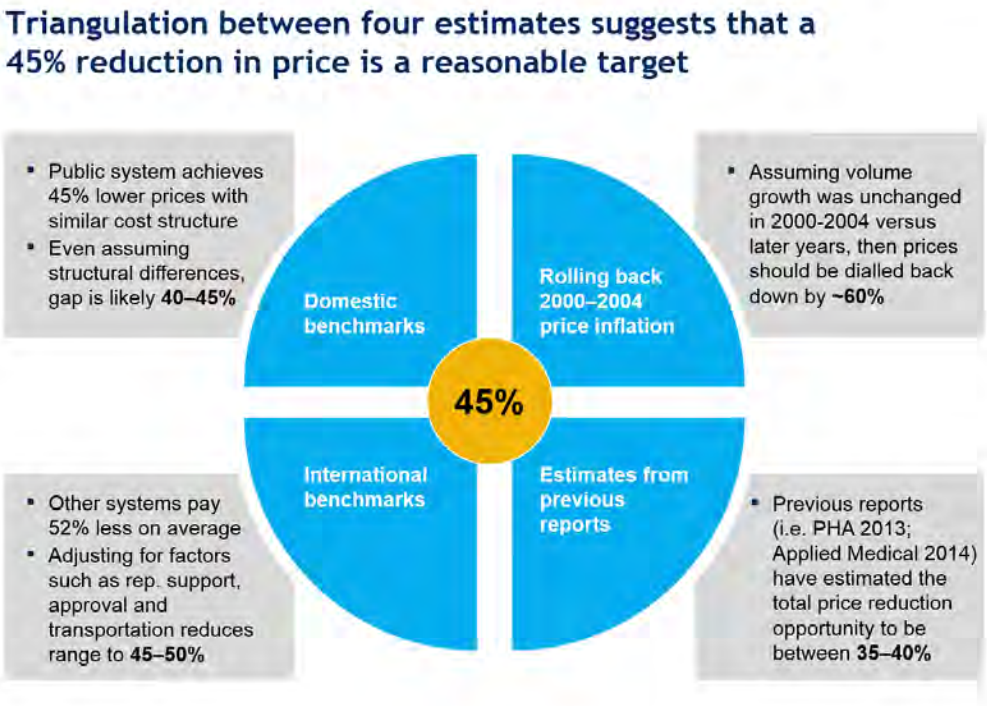
This sizing of the cost of current inefficiencies was determined by comparing four different estimates (see Figure 3):

- **Domestic benchmarking** of prostheses prices published by Western Australia Health for the cardiac, ophthalmic and orthopaedic categories shows that on average, public sector prices are approximately 45 percent below those set by the Prostheses List. To illustrate this gap, an uncemented Zimmer Trilogy cup costs Western Australia Health just under $1,000 less than the listed benefit on the Australian Prostheses List, at $1,939 and $2,900 respectively[10]. This closely matches the hospital-level benchmarking conducted by the Productivity Commission, which found

that public prices were 48 percent below those of the private sector[ii][11].

- **International benchmarking** using data from comparable economies such as France, Japan, New Zealand, the United States, Italy, and Spain lends weight to the domestic findings, with prices found to be roughly 50 percent below Prostheses List benefit levels. In France, for example, a Consulta CRT-P model C3TR01 triple-chamber pacemaker costs €4000 (approximately $5,840), compared with a cost of $13,520 on the Australian Prostheses List[12]. These benchmarks come from a range of sources, with France, Japan and Italy publishing public price lists (in a similar way to Australia), and other country comparisons made possible by price point data from suppliers and hospitals.
- These benchmarks triangulate with the **effects of the price inflation from 2000- 2004** discussed earlier in the chapter, as 2004 reimbursement levels would need to decrease by approximately 60 percent to reach 2000 levels.
- **Previous estimates** have also reached comparable conclusions; Deloitte Access Economics' 2014 report for Applied Medical quantified $592 million waste in the system (implying the potential for a 35 percent price decrease), and a 2013 submission to the National Commission Audit by the PHA estimated a total price reduction opportunity of $700 million (40 percent decrease)[13].

FIGURE 3

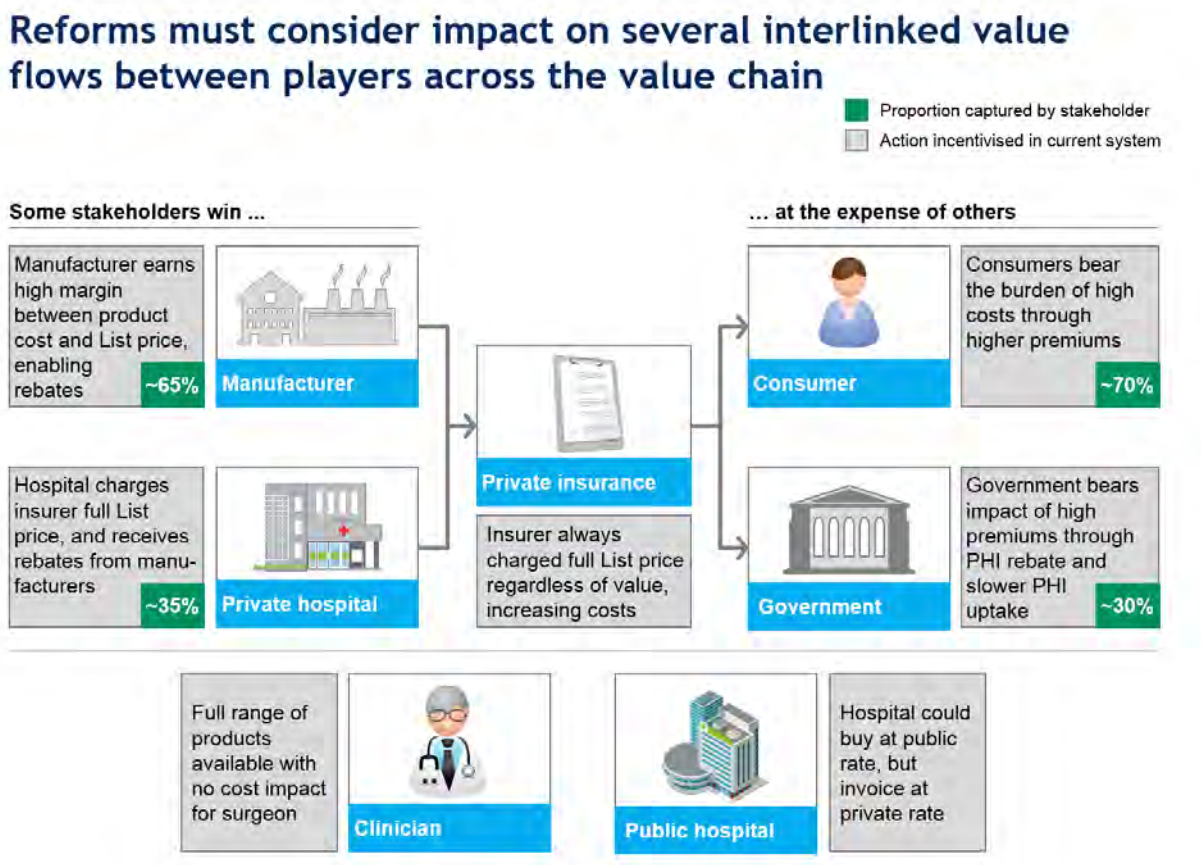


[ii] Refers to differential found between public and private hospitals for prostheses cost per casemix-adjusted separation, using only DRGs with an average prostheses cost over $30 per separation to account for potential differences in procedure mix.

WHO BENEFITS?

When assessing the efficacy of the current system, it is important to consider who wins and who loses under this model. In order to make such an assessment in a fact-based way, it is useful to think about the system in terms of the value flowing from product creation, through to final benefit settlement (see Figure 4).

FIGURE 4



As illustrated above, the prostheses value chain can be broken into a number of stakeholders, each of whom adds value, and captures value, to varying degrees. They include:

- **Manufacturers** add significant value via R&D, device production and logistics. However, they are disproportionately profiting by capturing an estimated 65 percent of the markup above benchmark.
- **Private hospitals** add limited value to the supply chain, primarily sourcing and managing inventory. They, too, are capturing inappropriate rents equaling approximately 35 percent of the markup above benchmark.
- **Insurers** add value by covering the benefit of the item via risk pooling and administering funding arrangements. Their profits are negligible, since device costs are

passed on to consumers through regulated premium increases.

- **Consumers** bear the bulk of the cost – approximately 70 percent – through insurance premiums, but are largely insensitive to the excess payments as they are blended into a single premium payment.
- **The Australian Government** subsidises roughly 30 percent of prostheses costs, regulates the system, and covers the healthcare costs of consumers who drop out of private health insurance because of unaffordable premiums.
- **Other stakeholders** also influence this flow. For example, clinicians often drive product choice, and public hospitals invoice insurers for private patients.

Value is and should be distributed along the chain; however, the system currently tilts that value too heavily towards manufacturers, at the expense of consumers and the Australian Government.

Medical device manufacturer margins are extremely high. In FY15, the top five multinational manufacturers supplying Australian hospitals earned an average gross margin of ~70 percent on their products internationally[14], implying that they are earning a substantial markup even on already lucrative international benchmark prostheses prices. In Australia, manufacturers are also capturing at least part of the additional markup from international benchmark prices to Prostheses List reimbursement levels (with the other portion going to private hospitals in the form of rebates), making it likely that they are earning even higher margins on private procedures in Australia.

Private hospital margins are also high – for instance, a large Australian listed private hospital operator recorded EBITDA margins of 25 percent.[15] By comparison, the average operating margin for American hospitals has ranged between 3.1 and 3.4 percent for the last three years[16] .

One contributing factor to those margins is the sharing of the excess value created between international benchmark prices and Prostheses List benefits through the practice of rebates for providers in exchange for spend volume. While insurers are in theory able to request information on any direct rebates given for particular prostheses and subsequently claim back the value, there are myriad ways of accounting for rebates within a provider/supplier contract that are less overtly tied to particular items, and therefore highly unlikely to be picked up and claimed in practice.

The magnitude of the markup split cannot therefore be quantified exactly, however expert and field interviews have led to an approximation of ~35 percent going to providers (accounting for the wide variability in prevalence of rebates across different categories of prostheses spend), leaving ~65 percent for manufacturers. Private hospitals therefore have an incentive to always charge the List price to insurers and negotiate rebates connected with spend in other ways, and then to drive increased use of those products that attract the greatest rebate.

Some evidence suggests that **Public hospitals** also receive a marginal benefit under the current system, when they invoice private patient insurers for the full List amount, but only pay manufacturers public prices. However, this benefit is estimated to be relatively small, as manufacturers typically charge the full Prostheses List price for privately insured patients in public hospitals.

WHO PAYS?

The ultimate burden of a system that drives inflated prostheses spend is borne by consumers and taxpayers.

Consumers bear most of the excessive costs driven by the current system through higher premiums. Given private healthcare insurance premiums are a function of total benefit spend, an excess value of $800 million flowing out of the system equates to approximately 4.5 percent in premiums for the 11 million Australians who currently hold private health insurance, or $150 a year per insurance policy[17]. Effectively, this means that Australian private healthcare consumers are currently subsidising the corporate shareholders of multinational manufacturers and private hospitals.

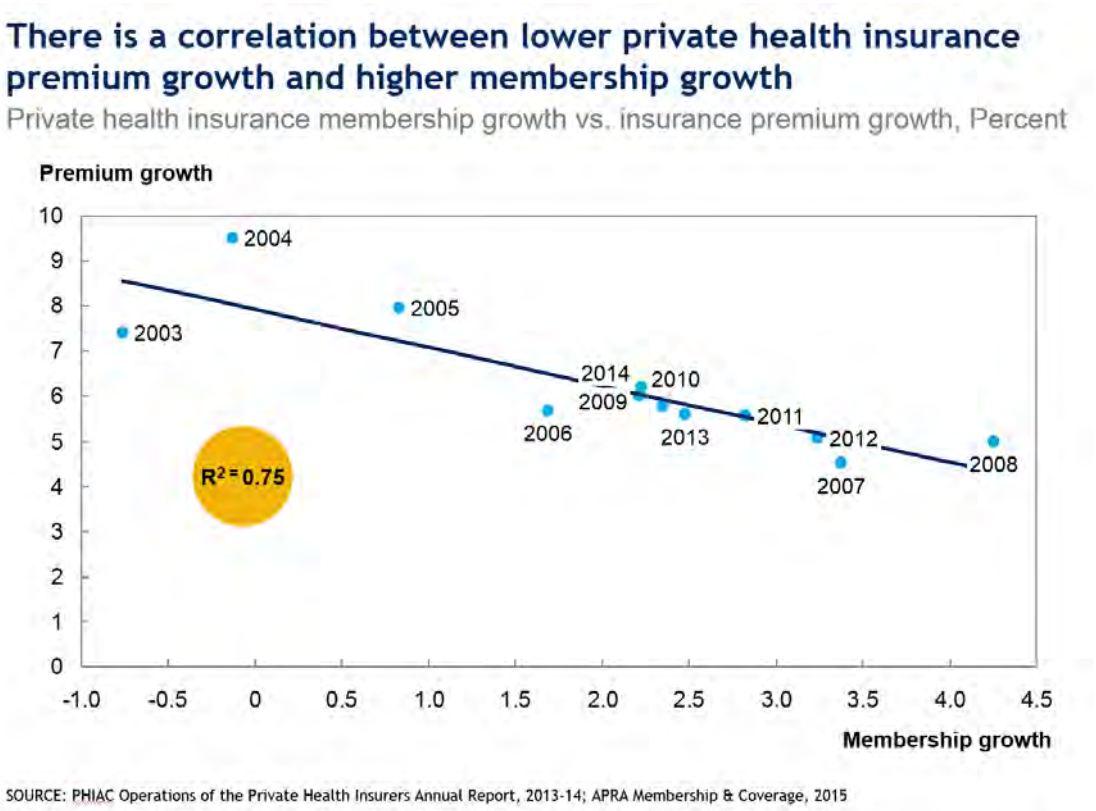
The **Federal Government** has also historically paid a heavy price for the inefficiencies of the current system. Since 1999, the Australian Government has offered a rebate of approximately 30 percent to all Australians with private health insurance, to encourage a shift from public to private healthcare. This means that nearly one third of the excess private healthcare spend that has been passed through to consumers in the form of higher premiums has in fact accrued to public purses. Over time, this additional spend has amounted to a considerable loss to the system – over the past decade, excess government spend on private health insurance rebates due to inflated prostheses costs alone equals $1.7 billion of taxpayer money.[18]

Premiums and PHI participation

Consumers are increasingly hard-pressed to bear these excess costs in Australia's constrained economic climate. For the first time in fifty years, personal disposable income has fallen for four quarters in a row. Debt-to-income ratios have tripled to 152 percent since the 1990s, and nominal wages and real disposable income have flattened, forcing many to tap into personal savings to maintain living standards.

In this environment, consumers are very sensitive to changes in the affordability of high-cost items such as private health insurance, and tend to vote with their feet. Comparative analysis of PHI premium and membership growth over the past decade indicates that a strong negative correlation ($R^2 = 0.75$) exists between premium growth rates and membership growth rates (see Figure 5). This reflects the experience of introducing the Government Rebate, where the 30 percent benefit introduced in 1999 was followed by 15 percent membership growth in just two years.[19] These two data points suggest that for a 4.5 percent decrease in premium growth, ~300,000 additional Australians will take up private health insurance.

FIGURE 5



This correlation highlights another cost borne by taxpayers under the current regime – namely, the cost of providing public healthcare benefits to Australians who would otherwise have taken up private health insurance, or upgraded their insurance to more comprehensive coverage, if premiums were lower. Saving 45 percent of prostheses spend would lower overall private health expenditure by approximately 4.5 percent, encouraging 300,000 additional Australians to take up private health insurance.

Such a shift would deliver two broad benefits to the Australian Government and taxpayers: reduced strain on the public health system, and greater healthcare choice for more Australians. This reduced strain would manifest in improved access to services. To take a simplified example[iii], 300,000 less Australians in the public system could lead to a decrease of over 13% in median wait times for elective surgery (from 36 to 31 days)[iv][20]. It follows that lower premiums would also prompt many existing private health insurance members to upgrade to more comprehensive policies: broader private coverage would further reduce the burden on the public system.

Increased participation in private health insurance could also create up to $276M in net value for government in Australia, via three changes: the avoided cost of treating 300,000 patients in the public system, less the cost of additional private health insurance rebates, and the revenue lost on the Medicare Levy Surcharge.

Assuming an average saving of $3,980 per hospital separation performed in the private system versus the public system[v] and an average of 410 separations per 1,000 Australians[21], 300,000 people shifting to the private health system equates to an additional $493M in avoided public costs. $135M in additional government expenditure due to the ~30% government rebate[22] and $82M in government revenue lost from Medicare Levy Surcharge on non-privately insured Australians (depending on income tier)[23] would then need to be subtracted, to arrive at the net value of $276M. It would then be the task of government to decide how the $493M in value created in the public system would be used: it could manifest as cost savings, or be reinvested to reduce burden on capacity.

In summary, a system that offers rents in excess of international benchmarks to certain stakeholders must necessarily be imposing an undue burden on other stakeholders, and under the current prostheses pricing and regulatory model, it is consumers and taxpayers who lose. Every year, Australians are paying $800 million in excess margins to profit the shareholders of largely multinational manufacturers and providers, and the Australian Government is bearing the burden of an additional 300,000 people relying on public health insurance who otherwise may have switched to private coverage if premiums were lower, estimated at up to $276M a year. It is time to re-evaluate the incentives and value flows in the system to ensure a more equitable distribution for all stakeholders.

[iii] Assumes that migration of patients from the public to private system manifests as a linear, one-off reduction in demand. In reality, the relationship between demand reduction and waiting times is non-linear, and conducting a full flow analysis would likely result in even bigger decreases in waiting times

[iv] Calculation based on 30 people per 1,000 population requiring elective surgery in any given year and approximately 700,000 elective surgeries being performed in the public system each year

[v] Based on AIHW $4,900 cost per separation, taking into account MBS coverage of 75% medical costs across both systems

Reference pricing: bringing benefits in line with domestic and international peers

OVERVIEW OF PROPOSAL

In this section, a reference pricing model is proposed which would adjust reimbursement levels for each clinical category of products to bring them in line with comparable health systems. By defining a basket of common products with domestic and international peers, and accounting for variances in delivery model, exchange rate, etc., this system can ensure that all stakeholders receive fair compensation for their value-add with little incremental overhead required.

Reference pricing is a well-accepted system which is currently used in several countries. For instance, Japan has employed international reference pricing for over a decade (see sidebar). France, Italy, the Czech Republic, Russia and the U.K. are other exemplars of domestic or international reference pricing. In applying this model to prosthesis pricing in the Australian health system, the proposed reform would closely resemble the recent reforms to the Pharmaceutical Benefits Scheme (PBS) where more stringent requirements on price disclosure and international references are expected to yield $3.1 billion in savings by 2018[24].

A concerted effort to introduce reference pricing could yield significant near-term impact; by setting a target of price parity with comparable benchmarks, the Australian Government could reduce expenditure levels by an estimated 45 percent, as described previously. In addition to reflecting external benchmarks, this objective would effectively undo the extreme price inflation of 2001-2004, when benefit levels rose by up to 27 percent every six months.

A 3-year sequence of price revisions is recommended, in order to bring benefit levels in line with benchmark levels as rapidly as possible, while providing adequate time for stakeholders to update their business models and contract terms. To maximise impact, the Australian Government should consider setting the largest decrease in the first year, for example, aim for a 25 percentage point price reduction in that time frame, if data permits.

It is therefore proposed that the Australian Government develop a reference pricing scheme to reduce prostheses expenditure by approximately 45 percent, or $800 million p.a., over three years. The following sections outline the expected benefits of this approach, analysis of risks and considerations, and one potential implementation design based on six key parameters.

Case study of international reference pricing – Japan

Japan uses a prostheses list to control prices for complex or innovative prostheses. Commoditised prostheses, such as sutures or gauze, are included in the cost of the procedure.

Price-setting for a new prosthesis incorporates reference pricing as a part of a multistage process. At the initial stage, a prosthesis is categorised as one of two types – devices that develop existing products and devices with innovative technologies. Prostheses that fall into the first category are benchmarked against existing comparable devices, with premiums for added value. The price of the second category is determined through zero-based pricing which breaks down manufacturer costs.

It is only at this stage that international reference pricing is applied. The price generated by the first stage is compared against those of the US, UK, Germany, France and Australia. If the initial price is more than 1.5 times the international average, it will be reduced by up to 25 percent.

Finally, Japan mitigates against the risk that manufacturers will delay or decline to release new products on the market by applying an additional premium to products that launch in Japan within 180 days of their US release.

Japan has successfully utilised international reference pricing alongside other pricing strategies. The Ministry has cut prices every two years (e.g., by 5.6 percent in 2012) which has held prostheses price growth below health inflation.[25]

EXPECTED BENEFITS FOR CONSUMERS AND GOVERNMENT

As described earlier, a 45 percent average reduction in prosthesis prices would yield significant benefits for the Australian consumer. Premium growth would be curtailed – for instance, if the reduction had been distributed across the past three years, annual premium growth rates would have been lowered by an average of ~1.5 percent per annum. This translates into total run-rate savings of ~4.5 percent per year on private health insurance premiums.

The Australian Government would also greatly benefit from increasing consumer demand for private insurance. The correlation described earlier indicates that a 4.5 percent reduction in premiums could encourage roughly 300,000 Australians to switch to private insurance. Based on this migration, the financial burden on the public system could be reduced by up to $276 million. Additional gains would be derived from consumers upgrading their insurance products, and hence consuming fewer high-cost public hospital resources.

In addition to these direct financial gains, the proposed reform would also yield secondary benefits across the system. New manufacturers will more easily introduce low-cost alternatives into the market, fostering competition. Quality of care is likely to improve with more appropriate provider incentives – the risk of physician influence and unnecessary product usage could decrease as providers receive less excess profit per procedure. Finally, the resources expended in negotiation between the PLAC and manufacturers can be repurposed, as reimbursement levels are set based on an objective fact base.

ANALYSIS OF POTENTIAL CONCERNS AND RESPONSES

The proposed reforms would have significant implications for manufacturers, providers, consumers and the Australian Government. As such, these stakeholders should be involved in all phases of the design, and potential unintended consequences must be carefully examined. A risk

analysis was conducted, divided into structural and clinical downsides.

Structural risks

Three structural risks were identified which could limit the reform's ability to achieve its stated aims: manufacturer exit, increasing gap payments, and price hikes for public hospitals.

Manufacturers will feel the greatest margin pressure, and may threaten to exit the market. While care must be taken to maintain a viable industry for medical technology players, three facts suggest that the risk of supplier flight is relatively low. First, the proposed reform would not reduce prices below comparable benchmarks. There are no evident reasons why prices should be higher in Australia, since transportation costs have been lowered by the shift to Asian production, product representatives assist to a similar degree in other systems, and Australia's distributor network is also comparable. Hence, suppliers should still attain the same margins in the private Australian market as elsewhere. Second, a scan of twelve developed countries did not reveal any instances where healthcare reform, including shifting to a reference pricing model for prostheses, spurred a major supplier exit, nor of disruption to supply. Finally, Australia's exposure to individual suppliers is quite low, with only 1.3 percent of prostheses spend in categories with only one supplier.[26] Thus, manufacturer exit appears to be an acceptably small risk to product supply.

The uncontrolled growth of gap payments could be another adverse consequence, if the current regulation prohibiting manufacturers from charging prices above the Prostheses List benefit levels were loosened. This could adversely impact consumers via growing out-of-pocket expenses, as well as potentially reducing the efficiency of providers and clinicians, who would spend more time discussing product choice with patients. However, 20 percent of prostheses included gaps as recently as 2011[27], suggesting that a moderate level of gap payments could motivate consumers to participate more actively in selecting the right prosthesis. The Australian Government may wish to establish protective measures such as requiring manufacturers to agree to no-gap pricing as a condition of listing.

Potential cross-subsidisation between public and private systems was also examined; manufacturers could claim that the high prices paid by private patients are effectively subsiding low prices in the public system. This is directly contradicted by domestic and international benchmarks (see Figure 2), which have demonstrated that Australia's public system has prices in line with several other countries. Hence there is no evidence to suggest that a decline in private prices should entail a commensurate rise in public prices. In fact, public buyers may benefit from the increased transparency afforded by international benchmarks in their negotiations.

Clinical risks

Three clinical risks were identified: surgeon throughput may be reduced if manufacturers reduce product representative levels in theatres, choice of prostheses may be curtailed by providers, and innovative products could be slower to reach the Australian market.

Manufacturers' product representatives now attend the great majority, perhaps 90 percent, of orthopaedic surgeries. If lower revenues cause manufacturers to reduce their sales force, surgeons may no longer receive the same degree of support. However, interviews with surgeons and international experts indicate that product reps do attend in genuinely necessary cases even in systems with lower price points. Hence, any cutbacks in representative support would likely be limited to 'bread-and-butter' operations, where the surgeon's product knowledge is expected to be more than adequate.

Providers may assert that the loss of revenue from manufacturer rebates creates a financial pressure to constrain physician choice. This logic seems flawed, since the Prostheses List aims to flow payment through providers, eliminating any incentive to narrow suppliers. Furthermore, many private hospitals are already narrowing choice, for instance, nearly 50 percent of private providers purchase knees from only one or two manufacturers.[28]

Finally, manufacturers may claim that lower reimbursements will choke the supply of next-generation technology. While it is important to preserve access to such products, other countries are doing so at lower prices – matching their reimbursement levels, if carefully managed, can maintain a flow of innovative products without overpaying for their benefits.

KEY PARAMETERS OF THE PROPOSED DESIGN

The success of the proposed reference pricing reform will largely depend on the quality of its design and implementation. Six key parameters have been analysed below in order to permit a more comprehensive evaluation of the proposal and to accelerate progress towards a more sustainable pricing model (see Figure 6).

FIGURE 6

Six key parameters of the proposed reference pricing model

	Recommended solution
Data source	▪ **Combine domestic and international benchmarks** from high-performing, comparable healthcare systems with reliably available data
Calculation methodology	▪ **Set target levels as the best-practice** of product prices in reference health systems, extending to clinically equivalent products where necessary
Integration with current criteria	▪ **Gradually increase weight** of benchmark pricing to create a predictable transition period for business models and industry dynamics
Operating model	▪ **Codify a more transparent price-setting process** for an independent body, including clear points of interaction for each stakeholder with vested interests
Governance structure	▪ **Ensure appropriate involvement** of clinical, policy and industry bodies in each phase of managing prostheses, from overseeing the price-setting reform to evaluating and delisting products
Sequence of roll-out	▪ **Parallel-process** all categories where data is available over three years from May 2016 (as opposed to category-based sequential roll-out)

1. Data sources. To ensure that prostheses benefit benchmarks remain accurate and relevant, the Australian Government could consider adopting a PBS-style approach, wherein manufacturers must provide reference price points from other countries as part of their submission to the TGA or PLAC. The PLAC should define confidence criteria to determine when a benchmark may be used, and assess this independent of industry input. The inclusion of manufacturer catalogue numbers for each item in the Prostheses List would also facilitate cross-referencing.

If a PBS-style approach is unachievable, a secondary method of determining benchmarks would be to identify target systems by evaluating three criteria: their performance in achieving best-in-class benefit levels, their degree of comparability with the Australian health system, and the availability of comprehensive data. An initial assessment suggested that high-potential

systems include the Australian public system, the U.K., France, Spain, Japan, large U.S. health systems, and/or Sweden. Appendix B includes a case study illustrating the availability of comparable data for France.

As next steps, it is proposed that the Australian Government explore the PBS model of soliticing reference data from manufacturers, as well as looking into public and private sources of benchmark data.

2. Calculation methodology. Several formulae are employed for reference pricing worldwide, typically at the product level. The most common are average, median, or minimum prices from the benchmark set. It is proposed that reimbursement levels be set to the minimum benchmark price achieved in comparable systems, in order to ensure that consumers are paying efficient prices for prostheses. Where data is not available for a given product, three options exist: either the manufacturer can supply reference prices as described above, or prices of clinically equivalent products can be used, or similar products may be used as a starting point, with the supplier asked to justify any price premium. A mechanism should be added to adjust for currency fluctuations. The experience of other international reference pricing systems indicates that average exchange rates from the past three years should be used.[29]

As a next step, the Australian Government could define the formula which will be employed – potentially adopting the common minimum-of-comparable-systems formula.

3. Integration with current pricing levels. To smoothly progress towards full benchmark pricing, it is proposed that the PLAC define both current and target reimbursement levels for each product. A simple step-down mechanism can then be used to define interim reimbursement levels during the transition period. For instance, the first change to reimbursement levels could close half of the gap between current and target reimbursement levels, with the second half closed over the following one to two years. Exceptional cases, such as brand-new products, may be assessed separately, although clear guidelines should be set to ensure that this channel is limited to less than 5 percent of submissions.

As a next step, the Australian Government could define the step-down function to smoothly move reimbursement levels to benchmark in the near-term.

4. Operating model. Under a reference pricing scheme, the PLAC would function with a narrower focus of activities. Its price-setting functions would be simplified to administer reference pricing and rule on exceptional cases. The PLAC's composition and interaction points with industry could be restructured to ensure that reimbursement levels are set objectively as intended. This would involve a rebalancing to ensure equal representation of insurers to combined manufacturers and providers (who are frequently aligned), with a dominant representation of health economists and clinicians. Manufacturers would be invited to contribute input to the process via three clear steps – first by providing information during the submission, then by presenting to the PLAC prior to price-setting for high-spend products, and finally by choosing whether or not to accept the set benefit level.

The final proposed change would be to strengthen the delisting role of the PLAC. Under the current model, products are rarely delisted and outcomes may be compromised by clinicians continuing to use obsolete products. This is discussed further in the 'Complementary recommendations' section below. Patent expiration could be another trigger for review of relative clinical effectiveness and reimbursement level-setting.

As a next step, the Australian Government could refine the mandate, composition and processes of the PLAC in collaboration with affected stakeholders.

5. Governance structure. A steering committee of five members (three senior policymakers and representatives from the Medical Technology Association of Australia and Private Healthcare Australia) should be

established to review progress 2 months before the release of each Prostheses List. A balanced scorecard of performance metrics should be established to assess progress on average reduction of benefit levels, maintenance of adequate supply, control of gap payments, PLAC backlog, overhead cost of PLAC, and delisting of obsolete products.

As a next step, the Australian Government could establish this body, including a charter and performance scorecard.

6. Sequence of roll out. It is proposed that the 3-year timeline described above commence in May 2016, via inclusion in the national budget. Reimbursement levels should be adjusted as of the August 2016 Prostheses List for all products with reference prices meeting the defined confidence criteria. The benchmarking should initially focus on setting the right prices for the 500 prostheses that comprise 75 percent of total expenditure. The set of products with reference prices should be re-evaluated six weeks before the release of each Prostheses List to ensure that benchmarks are incorporated as soon as possible.

As a next step, the Australian Government could lay out a timeline of key milestones, objectives and priorities for the implementation of reference pricing.

To summarise, we propose that the Australian Government develop a reference pricing scheme based on domestic and international benchmarks from May 2016 to 2019. The key success factors include a robust methodology to obtain and calculate reference prices, a more objective process and team composition for price-setting, and a clear roll-out plan for smooth and predictable change. This investment would be amply justified by the benefits to consumers and government, and would bring Australia's pricing practices and performance in line with other developed countries.

Broader vision of a best-in-class health system

RATIONALE FOR BROADER REFORM

While the reference pricing model outlined above addresses the primary challenge of price disparities between Australia and peer health systems, three major inefficiencies would remain unresolved:

- Manufacturers would continue to operate with limited incentives for price competition. Central determination of benefit levels would lead manufacturers to negotiate with the Australian Government for higher prices, but to otherwise maximise pricing to providers.
- Knowledge would remain asymmetrical regarding the relative merits of the prostheses available, limiting providers' ability to choose the optimal prosthesis for any given situation.
- Providers would have no incentive to ensure that cost-effectiveness is factored into prosthesis selection.

A value-based reimbursement model can more effectively align incentives around selecting the right product for the right patient. Numerous health systems around the world have integrated the cost of prostheses into a broader episode of care, creating strong incentives for providers to improve both outcomes and cost-effectiveness.

Broadly speaking, two types of 'value-based reimbursement models' can be considered: reforms can target episode/unit cost management, or take on the holistic management of utilisation and total cost of care. As presented earlier (Figure 1), the market appears to have responded to fixed reimbursement levels by increasing volume utilisation following the re-introduction of the Prostheses List. This suggests that the Australian healthcare system could benefit from a holistic solution to address the utilisation of healthcare resources. However, this paper will focus on potential reimbursement mechanisms to control unit costs within each episode of care, as these measures are likely to be more readily implemented and drive near-term impact.

Various models have been adopted abroad. For instance, France, Germany, the US and the UK all generally embed prosthesis reimbursement into Diagnosis-Related Group (DRG) episodes (see the France example in sidebar). More recently, American bundled payment programs are integrating prostheses payments into an episode of care, negotiated by HMOs, providers and GPOs. Spain includes prostheses costs into hospitals' global budgets. Sweden has instituted a centralised program for value-based reimbursement, including significant narrowing of reimbursed products and standard follow-up on orthopaedic cases.

ONE VISION FOR VALUE-BASED REIMBURSEMENT

The basic concept of 'paying for the package, not for the piece' is well-established; labour and other costs are already integrated into a single DRG-based reimbursement for procedures involving prostheses, and DRG service weights are widely used in the public sector for budgets and funding allocation.

Integrating prostheses devices into a bundled payment could unlock value by encouraging competition among manufacturers, since providers would no longer pass on product-specific prices to insurers and would therefore be incentivised to control procedure costs.

With the management of costs in the hands of the providers, those providers that can both control product proliferation and optimise clinician needs in the context of medical device costs would benefit. Hospitals that failed to control product proliferation and/or struggled to engage clinicians and manufacturers would see their financial competitiveness decline. Critically, hospitals would be required to engage more actively with surgeons to balance the best outcomes for their patient with their individual accountability for cost to the hospital. The hospital would be required to shift from being passive cost centres

(or even misaligned operators). The ensuing clinical dialogue would be likely to improve costs and patient outcomes.

Operationalising this solution appears very feasible. Instead of relying on a Prostheses List to set the minimum benefit per product, the Australian Government could limit regulation to requiring suppliers to agree to low- or zero-gaps for patients on items that are listed. By legislating this requirement, hospitals and manufacturers would be pressed to agree on mutually satisfactory prices and protect against consumer cost inflation. The role of the PLAC would thus be limited to obtaining agreement on gap conditions, and identifying the link to a valid MBS item number. Application for listing would be predicated by approval by the TGA.

MBS item numbers seem preferable to DRGs as a basis for prosthesis value funding. Some DRGs contain several subtypes of procedures, which may differ significantly in prosthetic device needs. Hence, a single blended reimbursement level per DRG for prostheses would be complex to calculate, and some hospitals may 'cherry pick' subtypes with low prosthesis outlays. MBS items, however, are much more granular and better-suited to match prosthesis needs to a given procedure. Furthermore, the Prostheses List already includes a valid MBS item for each prosthesis on the list.

The Australian Government may have a role to play in ensuring fair determination of the prosthesis value assigned to each MBS item. These price points should be connected to comparable benchmarks, while ensuring that surgeon's product choice is not unduly inhibited. Regulation may also be required to determine the regular revision of these values (e.g., refresh benchmarks every two years) and to ensure that procedures do not result in multiple MBS numbers with prosthesis costs. Once the system stabilises, a further de-regulation could see insurers and providers independently negotiating prosthesis values for each MBS item.

Such changes could also support the Australian Government's broader reform agenda. For instance, the ongoing MBS review aims to transform Medicare reimbursement into 'a contemporary tool for helping drive best practice in healthcare, not just in primary care but across the system ... it could potentially change the way treatment is organised for patients', according to Dr. Bruce Robinson, the review lead.[30]

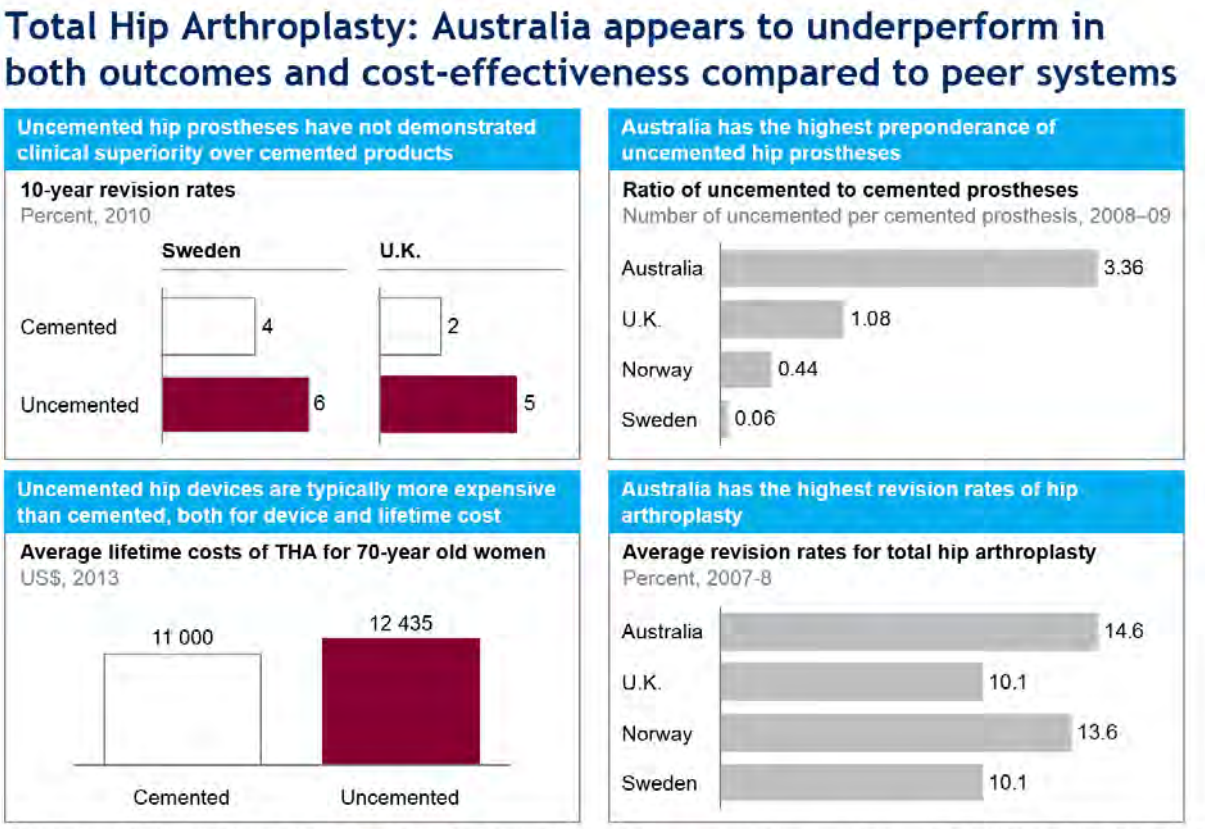
POTENTIAL ADDITIONAL BENEFITS OF EPISODE-BASED REIMBURSEMENT

Value-based reforms have been proven to improve outcomes and cost-effectiveness by aligning incentives in numerous health systems. For instance, a Swedish university hospital reduced waiting times by half, increased patient satisfaction from 85 to 91 percent, and reduced complications by 20 percent.[31] The American CMS is also building on successful pilots to mandate bundled payments for hip and knee replacements in 75 major geographies.[32] Leading providers, such as Brigham and Women's, have collaborated with surgeons to agree on three low-cost knee prostheses, with only a few, clinically-justified exceptions, reducing knee-implant costs by half.[33]

To illustrate the potential benefits for Australians, two examples are developed below. First, a comparison of hip prosthesis selection, and second, an analysis of stent usage in Australia versus international benchmark. In both cases, incentives could more effectively motivate decisions that improve both outcomes and cost-effectiveness to bring Australian performance in line with clinical benchmarks on product selection. It is important to note that these examples are illustrative and the impact of such unit cost-based reimbursement reforms would depend on the local patient population and latest evidence-based treatment standards.

Australia's current system aims to maximise quality of outcomes by eliminating cost considerations from prosthesis selection. However, the example of total hip arthroplasty (see Figure 7) illustrates how misaligned incentives may be leading to suboptimal quality and cost-effectiveness performance.

FIGURE 7



SOURCE: Swedish Hip Arthroplasty Register 2010, R. Kallala, et al, 'The cost analysis of cemented vs cementless total hip replacement operations on the NHS' (2013) 95 *Bone Joint Journal* B; F. Malassi, et al, 'Cemented versus cementless fixation in total knee arthroplasty' (2013) 1 *Joints* 121, E.J. Griffiths, et al, 'Cost savings of using a cemented total hip replacement: an analysis o the National Joint Registry data' (2012) 94 *Journal of Bone and Joint Surgery* 1032

A comparative assessment of joint registries found that Australian surgeons favour uncemented hip prostheses to an unusually high degree. While these enable higher throughput by reducing operating time by up 20 minutes[34], they tend to have significantly higher price points than cemented prostheses: a 2013 study in the BMJ found average costs in the UK of £739 for a cemented prosthesis versus £1697 for a cementless prosthesis.[35] Furthermore, most research has found higher rates of revision in uncemented prostheses.[36] This may contribute to the measured outcomes: Australia has higher revision rates than available peers.[37] This may be partly due to the current incentive system, which rewards surgeons for increasing procedure volume, but not for achieving lower revision rates or optimising cost.

Researchers have found that increasing usage of uncemented prostheses may be due to 'intensive marketing of more expensive uncemented implants.'[38] Hence, the frequent presence of manufacturer reps in Australian theatres may help explain the high usage rates of these devices. While a scan of European countries indicates that medical device reps traditionally attend the majority of procedures, the United States is notable for its recent efforts to limit the influence of reps; most hospitals now only allow medical device reps to interact with the purchasing department.[39]

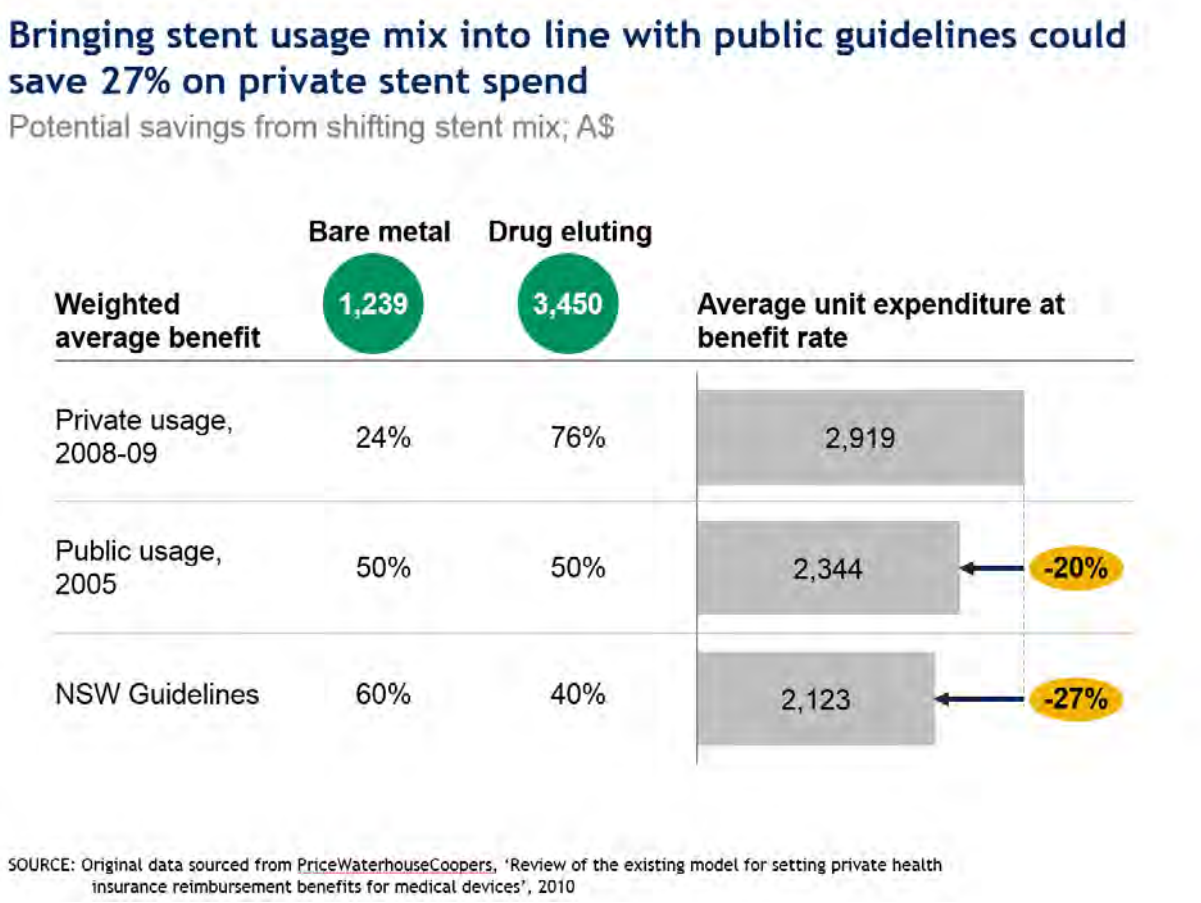
As a second example, drug-eluting stents are significantly more prevalent in Australia than in other countries that have different reimbursement models.

Drug eluting stents are often two or three times more expensive than bare metal stent alternatives.

When first introduced into the market, they appeared to bring benefits that sometimes justified the price difference, however more recent evidence suggests that these benefits were at least overstated, and that they may even be less effective than bare metal stents in certain situations. A 2006 UK study found that drug-eluting stents were acceptable on a cost/utility basis in only 4 percent of cases.[40]

However, drug-eluting stents account for ~76 percent of stents used in Australian private hospitals – above the public domestic benchmark of 50 percent, and almost double the NSW Guidelines of 40 percent.[41] Based on the weighted average difference in benefits, private stent spend could be reduced by 20 to 30 percent if price signals were introduced into the private market that brought stent usage in line with public practice (see Figure 8).

FIGURE 8



SOURCE: Original data sourced from PriceWaterhouseCoopers, 'Review of the existing model for setting private health insurance reimbursement benefits for medical devices', 2010

Case study of value-based prostheses reimbursement – France

In France, prostheses costs are reimbursed as part of an episode of care or diagnostic related grouping (DRG). In arriving at the appropriate price level for a DRG, the Ministry considers average prostheses costs across comparable French hospitals. As pricing data is reported on a voluntary basis, gathering reliable data remains a key challenge. In 2012 for example, 16 percent of hospital cases formed the basis of domestic benchmarks. However, participation is increasing.[42]

Hospitals are ultimately responsible for the overall cost of a DRG. They are therefore incentivised to negotiate the best possible price for prostheses. Any savings from price reductions beyond benchmark levels are shared evenly between providers and insurers, although adherence to this policy is inconsistent.

The DRG system has encouraged hospitals to make cost-effective clinical decisions. A comparison of French and Australian list prices indicates that, on average, similar prostheses are 40 percent less expensive in the French market.

Complementary recommendations

While this report focuses on mechanisms to ensure benefit levels are set fairly and efficiently, a cohesive reform package could also include the following measures to improve clinical safety, competition, and decision-making. Three categories of complementary recommendations are presented, addressing removal of underperforming products, refining the scope of the Prostheses List, and improving decision-making processes, outlined below.

Remove underperforming products from the Prostheses List

Products with poor clinical outcomes should be removed from the Prostheses List. However, currently the list does not adequately safeguard clinical safety and patient outcomes beyond the initial listing stage. The following measures would allow better assessment of the efficacy of products:

- Clinical effectiveness measures need to be monitored, re-evaluated, and acted upon
  - Items should be regularly reviewed to ensure clinical safety and patient outcomes
  - A registry, similar to the National Joint Replacement Registry, should be established for high risk prostheses[vi]
  - Underperforming prostheses (e.g. those with higher than acceptable revision rates) should have their Australian Register of Therapeutic Goods (ARTG) certificate revoked
  - Patients and surgeons should be better informed through the establishment of publicly-accessible comparative effectiveness reviews
- Costs associated with product failures should be met by manufacturers
  - If a product fails or is recalled during the guarantee or recall period, any associated costs should be met by manufacturers. Currently, hospitals have little incentive to follow up product guarantees and tend to bill insurers for all revisions, regardless of failure reason.
  - Manufacturers should be required to have appropriate levels of insurance to meet these costs in order to receive an ARTG number or be registered on the Prostheses List. This recommendation responds to the recent high profile example of the liquidation of Medical Vision following the recall of PIP breast implants.

Refine the scope of the Prostheses List

The Prostheses List needs to be better aligned with its initial aim of regulating the benefit levels for a specific category of medical products. It should provide adequate information, on items that are clearly defined as qualifying prosthesis items (see Appendix C for suggested revisions to the definition):

- Commoditised items which are subject to a high degree of competition should be removed from the Prostheses List
  - The current Prostheses List includes over 10,000 items, many of which sit outside the generally accepted definition of 'prostheses'
  - The original intent of the List was to regulate only those products which were 'advancing the edge of their discipline', 'surgically implanted', and 'expensive',

[vi] "High risk" refers to class 2A devices, class 3 devices, and active implantable cardiac devices.

however the List has expanded to include items that do not require strictly regulated pricing

  - As a result, market forces are constricted for many commodity products (e.g. gauze or sutures) that would benefit from increased competition

  - Furthermore, some products are already included in theatre fees/episodic payments/other hospital payments, yet are also included on the Prostheses List. This results in private health insurers paying for the same item twice

- All relevant information, including catalogue numbers and warranties should be included on the List to better identify the prostheses covered by a billing code

  - Manufacturer catalogue numbers would be of particular utility in facilitating reference pricing

  - Hospitals should be able to identify when product failure falls within manufacturer warranty periods

Improve the decision making process

The structure and processes of PLAC decision-making should be fair and efficient – it needs to respond to changing markets and technological innovation. Steps towards such improvement could include:

- The same clinical assessment process should be applied to incremental changes to currently listed items as to new items for listing

  - The current system creates unfair advantages for established manufacturers over manufacturers attempting to create a generic version of an existing product

- Private health insurers' representation on the PLAC should be increased from two to four members

  - There are currently 16 PLAC members. Alongside PHI representatives, there are two hospital representatives, four doctors, two sponsor representatives, one consumer representative, two Department of Veterans' Affairs representatives, two health economists and the chair

  - It is appropriate for private health insurers to have greater input into the pricing of prostheses given that they ultimately bear the cost of PLAC decisions

CONCLUSION

Now is the time to reform prostheses pricing. Private health insurance is becoming increasingly unaffordable in a challenging financial environment, putting more pressure on the public system. Australians are paying nearly twice the benchmark price for prostheses, reducing consumers' disposable annual income by $800 million. Furthermore, setting efficient benefit levels for prostheses could also alleviate up to $276 million in financial pressure on the public system by making private insurance more affordable. All that is needed to unlock this potential is to enhance the PLAC with a fair and effective reference pricing scheme, bringing Australia in line with other health systems.

In the longer term, Australians may also benefit from the aligned incentives and increased competition of a value-based reimbursement model. Manufacturers, providers, surgeons, insurers and patients alike could better partner to ensure that the right prosthesis is being implanted into the right patient at the right price. Embarking on such a reform would require significant consultation with all stakeholders, to ensure that quality of care remains at the heart of clinical decision-making and that the desired outcomes are achieved.

By rapidly implementing an effective reference pricing scheme in the short-term, and creating a shared long-term vision for reform, the Australian Government can take a significant and low-risk step towards making healthcare more affordable for all Australians.

Appendix A: Prioritisation of potential reforms

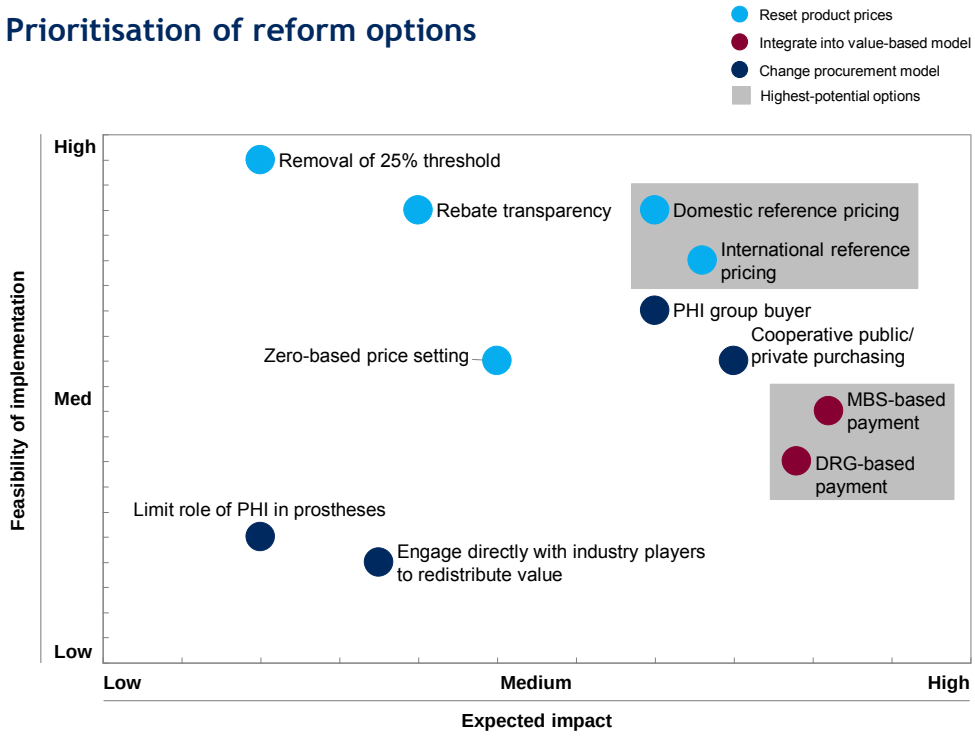
SELECTION AND EVALUATION OF POSSIBLE MODELS FOR REFORM

An international survey of prostheses pricing mechanisms revealed 11 potential options for reform. The relative strengths and weaknesses of each option were evaluated in the context of the Australian market. Each option was assessed against seven criteria along two dimensions: first, its potential to deliver significant impact (including magnitude, fairness, creation of incremental value, and timing), and second, the ease of implementation (including viability for all stakeholders, operational complexity and downside risk) The results of this exercise are illustrated in Figure 9, below.

These models should not be considered mutually exclusive alternatives. Different models can be complementary, either simultaneously or as part of a gradual timeline for broader reform.

The strengths and limitations of the most promising avenues for reform – reference pricing and value-based pricing – are discussed above. Each of the alternative models for reform is briefly evaluated below.

FIGURE 9



ZERO-BASED PRICING

Zero-based pricing would retain the Prostheses List while re-setting benefit levels based on a close interrogation of manufacturer costs. This mechanism has the potential to significantly reduce prostheses benefit levels, limiting the scope for rebates to providers and excess margins for manufacturers.

However, this model would be difficult to operationalise as it depends on manufacturers to divulge their cost of production. The burden of securing accurate cost data would primarily fall on the PLAC which is already tasked with a significant workload. Furthermore, there is a significant downside risk to this proposal. Manufacturers would have a strong incentive to overstate costs, effectively 'padding' the minimum benefit amount and concealing their actual cost base to maximise profitability.

PRICE TRANSPARENCY

Price transparency requires providers to disclose the actual prices paid for prostheses. Although this model does not address inflated manufacturer margins, hospitals would no longer be able retain excess value in the form of rebates. If hospitals regularly negotiated discounts on Prostheses List benefit levels, the PLAC would be expected to use this disclosed information to gradually reduce minimum benefits.

In practice, providers would be unlikely to reveal the full extent of discounts on minimum benefit amounts. Due to the prevalence of block purchasing arrangements, it would be difficult to identify savings on any particular list item. Furthermore, excess margins to providers may take the form of non-cash incentives such as free consumables and product representative support in the operating room.

REMOVAL OF THE 25 PERCENT MARKET SHARE THRESHOLD

Removing the 25 percent threshold would allow reimbursement levels to reflect the prices of small, low-cost manufacturers. Currently the PLAC uses the prices of manufacturers with a minimum 25 percent market share to determine the minimum insurer reimbursements. This threshold is designed to ensure that benefits are set at a level where the market will be supplied. However, the threshold currently operates to entrench large, incumbent manufacturers and prevent newer, low-cost manufacturers from putting downward pressure on benefit levels.

This measure may be a worthwhile complement, but alone is unlikely to close the gap to benchmark systems. Research and interviews indicate that there are a limited number of manufacturers who are attempting to compete on price. The price impact of low cost manufacturers entering the market would also be moderated by the need to reliably supply the market and ensure equivalent quality.

FORMATION OF COOPERATIVE PURCHASING AGREEMENTS BETWEEN PUBLIC AND PRIVATE HOSPITALS

Allowing public hospitals to purchase on behalf of their private counterparts would allow private patients to share in the discounts negotiated by the public system. Given that prostheses purchased by the public system are approximately 40 percent less expensive than Prostheses List benefit levels, this would offer significant savings to consumers. Additional savings could be driven by the combined bargaining power of the public and private system.

However, this course of action is unlikely to garner the necessary support from the public system. By adding high-price private volumes to low-price public volumes, manufacturers could demand higher average prices than current public levels. One potential path forward would be for motivated public buyers to explore the incremental discounts that manufacturers would be willing to offer for the additional volume of private insurers.

FORMATION OF GPO BY PRIVATE HEALTH INSURERS

The formation of a group purchasing organisation (GPO) by private health insurers would better

align incentives by placing purchasing decisions in the hands of payers. This proposal addresses the core structural disadvantage of the current model, which creates little incentive to reduce costs by those who control purchasing decisions (clinicians and hospitals).

There is, however, a sound rationale for the current basic purchasing structure. First, hospitals are better able to respond to the clinical needs of doctors and negotiate appropriate product choice. Product purchasing that is further removed from practitioners may face resistance from doctors. Secondly, there are potential legal complications to this model. PHIs would need to mobilise their combined purchasing power to avoid the rise in benefit levels that occurred in 2001-2004 (where PHIs negotiated individually with large multi-national manufacturers). This would require active collaboration with regulators to ensure that Competition Law is fully respected.

LIMIT ROLE OF PRIVATE HEALTH INSURANCE REIMBURSEMENT IN PROSTHESES

Given that prostheses tend to be less expensive in public hospitals, prostheses spending could be reduced by shifting an increasing share of prosthesis activities to the public system. However this reform would likely have wide-reaching, negative effects on the health system. Lengthy waiting times for elective procedures would only increase, private hospitals would lose a source of revenue, public healthcare expenditure would increase, and private insurance would become less attractive for many consumers.

ENGAGE WITH OTHER INDUSTRY PLAYERS FOR A MORE EQUITABLE DIVISION OF VALUE

Cooperation between private health insurers and manufacturers could reduce excess margins and pass on savings to consumers. For example, manufacturers could agree to pass on a proportion of costs savings to insurers, rather than providing rebates to hospitals.

However, any savings would be limited to excess margins currently flowing to providers. There would be little incentive for manufacturers to voluntarily reduce their own margins. This is only exacerbated by the fact that individual health insurers with no control over product choice would be in a weak bargaining position relative to manufacturers.

Appendix B: Benchmarking methodology

Given the important consequence to the industry and government of any price benchmarks published in this report, every effort was made to take a rigorous and data-driven approach. Further detail is provided below on the sources and methods used for each stage of the benchmarking analysis.

AUSTRALIAN PRIVATE BENEFITS

Prices paid by private health insurers in Australia were drawn from the August 2015 Australian prostheses list, available online at: http://www.health.gov.au/internet/main/publishing.nsf/content/prostheses-list-pdf.htm.

WEIGHTING BY SPEND

In order to arrive at an accurate comparison, each item's minimum benefit was weighted by the overall spend on that item, as measured through aggregated 2014 Australian private health insurer claims data. This process ensured that items could not be deliberately selected to bias the results towards products with extreme price differentials.

DOMESTIC BENCHMARKS

Western Australia Health public hospital procurement data was used as an indicator of prostheses prices in Australian public hospitals. Spend-weighted prices for a basket of 41 prostheses SKUs were compared, to arrive at an average benchmark. Of the 41 SKUs, Prostheses List process were lower for only two SKUs and higher for the other 39 – ranging from being 0.9 to 5.2 times the level of the Western Australia Health price points. As publicly available Western Australia data is limited to particular categories, only cardiac, ophthalmic and orthopaedic prostheses were examined. These three categories represent approximately 34% of overall private health insurance prostheses expenditure. It should be noted that the data is currently limited to Western Australia Health. It is possible that public hospital buying groups in more populous states (e.g. Health Purchasing Victoria) have different - and potentially lower - prices, but information is not yet publically available for these groups.

INTERNATIONAL BENCHMARKS

Prostheses pricing data from the United States, New Zealand, Spain, Japan, France and Italy was used to determine an international benchmark of prostheses prices. A spend-weighted basket of 50 prostheses SKUs from hip, cardiac, and general miscellaneous categories was analysed, representing 42% of total prostheses spend. A rolling 12-month average was used to determine each exchange rate used in the analysis. Of the 50 SKUs, Prostheses List prices were only lower for one SKU and higher for the other 49 – ranging from being 0.8 to 5.3 times the level of international price points. Given the benchmarks across the countries provided a wide range of data points, a weighting was assigned to each based on the number of items making up the sample, the representation of prostheses categories in the sample, and the country's level of comparability with Australia, to arrive at an overall benchmark.

Case example: Referencing the French Prostheses List

France provides both comparable and accessible data that could be used in international reference pricing. The French system employs a DRG model for financing medical devices, informed by a publically available benchmarked price list called the SPP. The list includes both general items (for commodities), and manufacturer-specific items (for products that are demonstrated to be materially distinct from the closest device in their category). It is available online - searchable by unique code and category - as well as being downloadable in full.

The SPP is divided into four overall sections, of which section 3 is a direct match to the Australian Prostheses List:

Title I: Medical devices for treatments and devices for life care, dietetic food and dressing articles

Title II: External prostheses and orthotics

Title III: Implantable medical devices & human tissue

Title IV: Physical handicap vehicles

Under Title III, items are first categorised by material type (ie. disposable synthetic; disposable derivatives and animal tissue; human tissue; active devices), then divided by area of medical specialty. This categorisation differs slightly from the Australian Prostheses List, which divides directly by area of medical specialty (see Figure 10), but is similar enough to enable relatively straightforward matching of items using the French online category sorting tool, and/or keyword searches. While neither the French nor the Australian list uses a common internationally recognised manufacturer code, once a match is found then the French and Australian unique codes can be linked, to enable continued tracking and comparison.

For any group looking to compare French and Australian item prices, the suggested process to follow would be:

1. Search for each item by manufacturer name and description in the French list. If a particular manufacturer item line is included, use this price.
2. If there is no manufacturer-specific item, search for only the generic description match, and use this price.
3. Once a match has been found, link the unique French code with the unique Australian billing code, to allow for continued tracking and comparison.

It is recommended that the initial matching process outlined above be completed by someone with both French and English skills, and medical knowledge (such as a bilingual physician)

FIGURE 10

Comparing the French and Australian Prostheses List structure

French List	Australian List
Liste des produits et prestations remboursables	**Prostheses List**
▪ Title III: implantable medical devices & human tissue – Chapter 1: Disposable - synthetic origin ▫ Section 1: Cardiac ▫ Section 2: Ophthalmic ▫ Section 3: Orthopaedic ▫ Section 4: Ear, Nose & Throat ▫ Section 5: Hearing Aids ▫ Section 6: Urogenital ▫ Section 7. – Supporting implants (digestive, cardiac, pleuropulmonary, orthopedic, gynecological, urological, in particular) ▫ Section 8: Plastic and Reconstructive - Breast ▫ Section 9: Plastic and Reconstructive – Liposuccion – Chapter 2 – Disposable - from derivatives or animal tissue – Chapter 3 – Human tissue implants – Chapter 4 – Active implantable devices	▪ Part A – Category 1: Ophthalmic – Category 2: Ear, Nose & Throat – Category 3: General Miscellanous – Category 4: Neurosurgical – Category 5: Urogenital – Category 6: Specialist Orthopaedic – Category 7: Plastic and Reconstructive – Category 8: Cardiac – Category 9: Cardiothoracic – Category 10: Vascular – Category 11: Hip – Category 12: Knee – Category 13: Spinal

Appendix C: Suggested definition of prostheses

The following definition was agreed by all parties in 2003. However, it was not adopted by Government. [43]

To be included on the list of prostheses, prosthesis must be:

1. Approved by the TGA;
2. Implanted in the course of hospitalisation, including day surgery (admitted patients);
3. Permanently or semi-permanently implanted, such that it must leave the hospital with the patient;
4. A partial or total replacement for a body part or function;
5. Limited to being able to be used on one single patient only by nature of its function and not because it is possible to design a product with a specification that it is a single use item; and
6. Medically necessary.

Prostheses do not include devices which are:

- Temporarily or permanently implanted or applied in the patient which does NOT replace a body part or function (e.g. all implanted drug and radiation source delivery devices);
- Non-implantable drug infusion devices or a non-implantable high cost items or devices, largely used and/or provided in the outpatient setting;
- Not permanently implanted e.g. tissue expanders;
- High cost single use devices which do not remain with the patient at discharge, which are not used routinely in each procedure of the type for which they are used and whose cost is not included in theatre banding;
- Nerve stimulators other than cardiac pacemakers and defibrillators;
- Consumables for which there may be repetitive requirements (such as dressings, catheters, batteries, etc);
- Re-usable devices including equipment which may be applied to more than one patient;
- Drugs; or
- Items funded by any other means.

Appendix D: Protocol for interaction between competing funds

The authors of this report are competitors in the private health insurance industry. As a result, the following procedures were observed to ensure legal compliance:

- All meetings were conducted in the presence of an independent third party;
- An agenda was circulated to all participants in advance of each meeting and minutes were taken of every meeting;
- No 'commercially sensitive' information was shared between participants;
- All communications between private health insurance funds were supervised by an independent third party;
- An independent third party collected all relevant data relating to the relevant entities and did not disseminate any identifiable data (including any 'commercially sensitive' information) of any relevant entity or any third party to any other relevant entity or third party.

Bibliography

1 Private Health Insurance Australia, 'Quarterly Statistics', June 2015, June 2014, June 2013.

2 Australian Prudential Regulation Authority, 'Private Health Insurance Membership and Coverage', 2015.

3 Australian Prudential Regulation Authority, 'Trends in Hospital Accommodation, Medical Services, and Prostheses', 2015.

4 Ibid.

5 Private Health Insurance Administration Council, 'Annual Report', June 2003, June 2004, June 2005, June 2006, June 2007, June 2008, June 2009, June 2010, June 2011, June 2012, June 2013, June 2014.

6 Expert interviews.

7 Private Healthcare Australia, 'Past Prostheses Lists', August 2011, August 2012, August 2013, August 2014; Department of Health, 'Australian Prostheses List', August 2015.

8 Department of Health, 'Prostheses List: Guide to listing and setting benefits for prostheses', 2010.

9 Applied Medical, 'Submission to competition policy review', 2014.

10 Western Australia Health, prostheses pricing list; Australian Prostheses List, August 2015

11 Productivity Commission Research Report, 'Public and Private Hospitals', 2009.

12 L'Assurance Maladie, 'Liste des produits et prestations remboursables', 2015; Australian Prostheses List, August 2015

13 Applied Medical, 'Submission to competition policy review', 2014; Private Healthcare Australia, 'Submission to the National Commission of Audit', 2013.

14 Medtronic, 'Annual Report', 2014-15; Johnson & Johnson, 'Annual Report', 2014-15; Stryker, 'Annual Report', 2014-15; Zimmer, 'Annual Report', 2014-15; St Jude Medical, 'Annual Report', 2014-15.

15 Healthscope, 'Financial Report Investor Presentation', 2014-15.

16 Modern Healthcare Financial Database.

17 Calculation based on ~5.33 million private healthcare policies in Australia, sourced from Private Health Insurance Administration Council, 'Operations of the Private Health Insurers Annual Report', 2013-14.

[18] Calculation based on 30 percent rebate on 45 percent saving off of annual private prostheses benefit spend, sourced from Private Health Insurance Administration Council, 'Operations of the Private Health Insurers Annual Report', 2013-14.

[19] Private Health Insurance Administration Council, 'Statistical Trends', June 2015.

[20] Australian Institute of Health and Welfare, 'Australian Hospital Statistics 2013-14: Elective surgery waiting times', 2014.

[21] Australian Institute of Health and Welfare, 'Australian Hospital Statistics', 2013-14.

[22] Private Health Australia, 'Australian Government Private Health Insurance Rebate', 2015.

[23] Private Health Australia, 'Medicare Levy Surcharge', 2015.

[24] Victoria University, 'The Impact of PBS Reforms on PBS Expenditure and Savings', 2009.

[25] Japanese Ministry of Health, Labour and Welfare, 2012.

[26] Calculation based on the 'Product Group' of the Australian Prostheses List August 2014 and private health insurers' claims data, 2014.

[27] Private Health Insurance Administration Council, 'Trends in Hospital Accommodation, Medical Services and Prostheses', 2015.

[28] Private health insurers claims data, 2014.

[29] RAND, 'Pharmaceutical pricing: the use of external reference pricing', 2013.

[30] S. Parnell, 'Medicare review chief says 30pc of treatments of little benefit', *The Australian*, 16 September 2015.

[31] Sahlgrenska University Hospital, Halverade väntetider med värdebaserad vård. 2015.

[32] Centers for Medicare and Medicaid Service, 'Comprehensive Care for Joint Replacement', 2015.

[33] A. Gawande, 'Big Med', 2012.

[34] R. Kallala et al., 'The cost analysis of cemented vs cementless total hip replacement operations on the NHS' (2013) 95 *Bone and Joint Journal* 874.

[35] M. Pennington et al., 'Cemented, cementless, and hybrid prostheses for total hip replacement: cost effectiveness analysis' (2013) 346 *British Medical Journal* 1026.

[36] N.B. Kandala, 'Setting benchmark revision rates for total hip replacement: analysis of registry evidence' (2014) 350 *British Medical Journal* 756.

[37] Ibid.

[38] Ibid.

[39] Eucomed, 'Access to the Operating Room for Medical Device Representatives', 2011; LEK, 'Hospitals adopt new strategies to boost profitability, but still face deep challenges: A new imperative for MedTech', 2013; expert interviews.

[40] M. Thomas, 'Are drug eluting stents really worth the money?' (2006) 92 *Heart* 5.

[41] PriceWaterhouseCoopers, 'Review of the existing model for setting private health insurance reimbursement benefits for medical devices', 2010.

[42] Z. Or, 'Implementation of DRG Payment in France: Issues and recent developments' (2014) 117 *Health Policy* 146, 147.

[43] Private Healthcare Australia, 'The Proposed Reform of Prostheses Management Version 3', 2014.