s 22

From: s 47F
Sent: Friday, 15 May 2020 1:56 PM
To: PLAC; s 47F
s 47F

Cc: s 47F ; Platona, Adriana; s 22 ; RYAN, Natasha;
s 22

Subject: RE: PLAC - Basket of 287 draft report [SEC=No Protective Marking]
Attachments: 20200302 - PHA - PL Basket - FINAL.pdf

Categories: s 22 Purple Category

All,

Please find attached a penultimate draft of a report we have commissioned from Evaluate on international pricing comparisons for the 287 most expensive items on the Prostheses List.

We are likely to release this next month. If you have any comments, I would be happy to pass along to the authors for consideration.

Please treat this report as a draft in confidence, we have it out for review with a couple of critical readers and it's not finalised yet.

Thanks

s 47F

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From: PLAC
Sent: Wednesday, 13 May 2020 12:22 PM
s 47F

Cc: s 47F ; Platona, Adriana ; s 22 ; RYAN, Natasha ; s 22 ;
PLAC
Subject: PLAC Meeting May 2020 - Late Paper [SEC=OFFICIAL]

Dear PLAC members,

Please find attached an additional late paper that will inform the Departmental Update agenda item. I apologise for any inconvenience caused by sending out the paper so close to the meeting date.

Kind regards,

s 22

Assistant Director
Prostheses Reform
Office of Health Technology Assessment | Technology Assessment and Access Division
Department of Health
PLAC@health.gov.au
I acknowledge the traditional custodians of the lands and waters where we live and work, and pay my respects to elders past, present and future.

Please note, I am currently working from home. I can be contacted via phone or email.

EVALUATE

Economics. Policy. Strategy.

The Prostheses List: Is it cost effective and what recommendations could improve its quality as a tool for reimbursement?

Private Healthcare Australia

2 March 2020

s 47F

DOCUMENT 32

Authors

s 47F

Evaluate

Evaluate was formed in September 2016, to bring fresh thinking to policy and economic questions, particularly those in the social sphere.

Our particular goal is to identify long-term solutions to ensuring the sustainability of Australia's admirable social compact, including universal access to healthcare and education, and the supply of aged care, housing and other social infrastructure.

Our approach is based on a traditional microeconomic toolkit, moderated by the knowledge that social services are accessed by people with a vast variety of experiences, needs and resources. Consequently, we have no bias towards either public or private supply of services, noting that the access and welfare needs of different Australians typically require a mix of both.

The Principals of Evaluate are experienced professionals, and we complement this with external expertise where appropriate.

www.evaluate.net.au

Funding

This research was requested and funded by Private Healthcare Australia.

www.privatehealthcareaustralia.org.au

Table of Contents

The Prostheses List: Is it cost effective and what recommendations could improve its quality as a tool for reimbursement?

Abstract

Objective: To compare the largest 283 billing codes on the Prostheses List (PL) by value against list prices for the same items from other first world markets.

Design: Using HCP1 data for the 2017/18FY (then current reimbursement level post-MTAA Agreement), Prostheses billing codes were ranked from highest reimbursed value to lowest. These billing codes were then translated into a range of expected high utilisation Manufacturer Product Codes (MPC) and compared against 3 data sources: NHS List Prices - UK (non-volume purchases); PHARMAC list prices recorded in New Zealand (NZ); and Product list and benefits payable in France. A fifth arm of Australian public state tender pricing was initially intended but this information was found to be commercial in confidence and not available.

Determination of appropriate MPC to billing codes: A multilayered approach was taken: in some cases the Manufacturer Product Code (MPC) is listed within the billing code (single product listing); alternatively supplier marketing materials and searches on the NHS website were employed to determine appropriate MPC comparator(s) to the billing code description. Where multiple size ranges of products were presented, the mid-point of sizing was selected on the assumption of utilisation following a natural distribution.

Limitations to model: The ability to provide like to like code match was restricted particularly with French and NZ pricing based on limited product groups reported through these published price lists. Statistically, this provides some limits to extrapolation and the greater matching of UK data is more reliable.

Outcome Measures: Main outcome measure was the comparative price on matched products across 4 first world health markets. Secondary outcomes included spread of pricing between markets and price variants between products (across various Clinical Advisory Groups [CAG]).

Results: The 283 largest PL billing codes out of ~11,000 on the 2017/18 full list represented $1.019 billion or 62.3% of data reported on HCP1 with HCP1 being the nearest approximation by code of full APRA data. The 283 billing codes represented an appropriate proxy for the full value PL with billing codes covering all major CAGs. Accurate matches could be found in 216 items on the NHS file, 99 on PHARMAC and 83 in France. This reflected only certain items or groupings being published in respective price sources and a small percentage of Australia only devices appearing in the 283 items.

68 of the 283 billing codes had a clearly established match across the Australian, UK, NZ and French pricing. The 68 codes recorded HCP1 value on the PL of $282,202,601 which represents 17.5% of PL value recorded on HCP1. These items equated to values of $202,460,785 (UK), $193,231,805 (NZ) and $133,525,481 (Fr). 216 had a match in UK representing PL $805,930,431 vs UK $664,881,926 or 49.3% of the full HCP1 PL data

value. 99 direct matches were seen with NZ data, equating to PL $364,221,112 and NZ equivalent at $266,358,269.

With a minimal PL coverage of 17.5% of total PL value across all 3 International markets, this data indicates that the Australian PL is priced around $562.8 million above NZ PHARMAC pricing when extrapolating out the 22.3% matched coverage of total PL value according to HCP1 data. In the case of the UK, with a stronger matched data set covering 49.3% of total PL spend by private insurance funds, there is an indicated premium on the PL of $366.5 million against the same volume of items rebated if charged at the UK NHS list price rate. In making these extrapolations a normal distribution of device costs is assumed together with relative consistency on high volume brands and devices between markets. Full price disclosure permitting complete indexation – at least against international list prices – would improve this data.

Overview

This paper reviews relative pricing between the Australian Prostheses List (PL) and comparable health systems in the UK, France and New Zealand. Further to this, it considers what drives disparity in prices and makes a series of recommendations for reform that would deliver savings across the Australian health system.

The appropriateness of prostheses (medical device) prices in the Australian private health sector has been in question for many years if not decades,[1,2,3,4,5,6,7,8] with a variety of entities and reviews attempting to generate an estimate of the scope of disparity between comparable markets.[9,10] This study is novel in its robust approach to clarifying this question against a significant percentage of the total sales value recorded on the PL.

Reliable market/list price information is limited, particularly when considering the depth and breadth of devices included on the PL. This extends to the Australian public health system where pricing agreements are held as *commercial in confidence* and offer no transparency to payers in the private system. From a policy perspective, this is curious.

Leaving aside differing Commonwealth-State responsibilities in direct healthcare finance, the lack of a single national market for prostheses is inefficient for both public and private sector consumers. Further, given the Commonwealth's contribution to private health insurance (PHI) via the PHI Rebate, this is a particular cost to efficiency in public funding for the private sector.

While the Medical Technology Association of Australia (MTAA)[11,12] and their members' commentary argues that price variation exists between markets for a variety of reasons, including regulatory, tax and reimbursement factors, this review found little evidence to support this claim. Prices of the 283 items reviewed varied from price parity (or slightly below) international benchmarks to up to five times international comparators. This indicates low levels of consistency to claimed factors driving price variations, which most likely reflects the historical pricing methodology employed in setting benefit levels on the PL.

One example of this is cementless vs cemented hip stems where the price variation, or premium on cementless, on the PL is inconsistent when compared to the other international markets. Another observation was the tight alignment on pricing between NZ and the UK. While both are predominately public markets, this should have no relationship to the list price of physical devices. New Zealand is also a smaller market with more substantive transport costs servicing two islands and a less urbanised population than Australia.

The structure of PHI device funding is currently under review with, among others, a multi-year cross-stakeholder Industry Working Group (IWG) initiated by the Department of Health formulating potential structural options post the conclusion of the MTAA Agreement. This paper indicates a number of actions that should be taken regardless of whether the Prostheses List is retained or some form of Diagnostic Related Group (DRG) procedure-based funding model is adopted. The recommendations in this paper

particularly focus on eliminating the gaming that appears rife across specific groups and codes as well as increased utilisation of Health Technology Assessment (HTA) for funding devices, both in their initial listing and on an ongoing basis where supported through outcomes data generated via Clinical Quality Registries (CQR).

What is apparent both in the raw data and summaries outlined below is that the traditional argument that Australia is simply a high-priced device market is not founded in evidence. With a number of high value devices being priced competitively to global market, while others are clearly excessive (up to five times the price in NZ).[13] These inconsistencies appear driven by the traditional method by which benefits were set, i.e., largely nominated by the device sponsor and without any link to HTA or comparative global data.

Sustainability and affordability of PHI remains a major concern for the Federal Government and Australians more generally. This review on substantial data, representing 62.3% of all PL funding, indicates Australian devices prices in the private sector are ~$400,000,000 over comparable first world markets.

Significantly there are substantial variations across technologies and suppliers and, for this reason, traditional blanket re-pricing at group level is not advised. Private Healthcare Australia and the PHI funds they represent have stated that any savings gained from device re-pricing would be passed on in full via premiums.[14] The sums involved would suggest a potential saving of around 1.5% on annual member premiums and would support retention of premium increases below 3% for a period of years.

In addition, tighter controls on gaming through changes to legislation, including the use of conditional listing, may reduce costs further. Evaluate advocates stakeholders, in particular the Department of Health and Health Minister's office, assess these proposed actions and the benefits they would provide to Australians.

Glossary of Terms

PL	Prostheses List
NJRR	Australian Orthopaedic Association National Joint Replacement Registry
MTAA	Medical Technology Association of Australia
HTA	Health Technology Assessment
CQR	Clinical Quality Registry
IWG	Industry Working Group
PHI	Private Health Insurance
DRG	Diagnostic Related Group
HCP1	Hospital Casemix Protocol data
MPC	Manufacturers Product Code
UDI	Unique Device Identifier
TGA	Therapeutic Goods Administration of Australia
Pharmac	Pharmaceutical Management Agency (NZ)
NHS	National Health Service (UK)
CAG	Clinical Advisory Group
PLAC	Prosthetic Listing Advisory Committee
APRA	Australian Prudential Regulation Authority
GTIN	Global Trade Item Number
SCP	Superior Clinical Performance
AOA	Australian Orthopaedic Association
HTARR	Higher than anticipated revision rates

Method

A known limitation of the PL framework is an inability for payers to identify what items are funded under a billing code. In some cases, this may be a single product and, in other cases such as basic trauma wires, hundreds of products from a manufacturer may be sitting under a single billing code. While previous published reports were criticised by device suppliers for using a small dataset of codes to generate projections on price variations, [15] the approach taken in this review utilises a systematic approach starting from the highest reimbursed item downwards.

The 80/20 rule is often commercially referenced, in the case of the PL just 6.4% of billing codes from a total of nearly 11,000 generate 80% of dollars expended. This review considers the largest 283 billing codes recorded for 2017/18 sales. These represent 62.3% of the total value of the PL as reported on HCP1 data. HCP1 is known to under-report total APRA data by between 10 and 12%. APRA reported the total PL sales for 2017/18 at $2.094 billion. The deviation to APRA totals is not a driver to this review given it looks at macro volumes against known prices in markets on those volumes.

A small selection of billing codes are for a single device and often reference this in the device description. For the remainder, identification of appropriate Manufacturer Product Codes (MPC) were required. This was done through a combination approach of searching the NHS database for key brand and product descriptors combined with reviewing supplier TGA registrations, marketing materials, press releases, historical public tenders and surgical techniques. Wherever possible, the most commonly used device(s) within a size range was selected as reference MPC. This allows the model to be used with ongoing price datasets from other countries or the Australian public system (where this is accessible).

Three lists were available for comparison. These were the NHS (UK) supply chain website, PHARMAC (NZ) Device pricing and the product and benefit refundable list from France. The NHS and PHARMAC lists are exclusively reported as Manufacturer Product Code (MPC) prices submitted per product while the French list is a combination of supplier-submitted MPC and some grouped (category) pricing in areas such as joint replacement.

While 283 Billing codes were reviewed, limitations existed to determining a match for some codes. This was largely due to coverage in device groupings under the various mechanisms, i.e., Ophthalmics and Plastics were not covered under any other international price files, while areas including glues, sealants and endoscopic stapling were poorly represented in NZ and France. A small number of codes (4 of the 283 reviewed) were Australian manufacturers only listed in Australia.

The summary below confirms the specific number of matched equivalents found across each price file. Notably all prices were calculated/assumed as list prices. While, in the case of the NHS, suppliers have the opportunity of offering bulk purchase discounts, for this review only single unit prices were used. It is likely other hospital site and volume agreements may exist in these markets and it is also likely that discounts are built into public tenders in Australia. However, these were also excluded for the purpose of this review, for purposes of caution as well as the fact that bulk discounts would only increase the observed Australian

premium against international markets. Discounted pricing may be able to be included should a large hospital or procurement network's prices be available to test within the model.

Results

Among the 283 largest value items on the PL, all procedural Clinical Advisory Groups (CAG) are represented at some level. The largest representations are consistent with the largest CAG categories and represent 62.3% coverage of the PL from these 283 codes. As noted, direct market comparators were not available for Ophthalmic items and Plastics. No conclusions can be drawn for these two categories.

Clinical Advisory Group	283 PL items	PL/UK/NZ/Fr	PL/UK	PL/NZ
01 – Ophthalmics	16	-	-	-
02 – Ear, Nose & Throat	6	-	6	-
03 – General/Miscellaneous	36	-	20	2
04 - Neurosurgical	11	-	11	-
05 – Urogenital	6	-	3	-
06 – Specialty Othopaedics	27	2	20	14
07 – Plastic & Reconstructive	3	-	-	-
08 – Cardiac	54	6	47	7
09 – Cardiothoracic	4	-	4	-
10 – Vascular	9	-	8	3
11 – Hip	40	22	38	23
12 – Knee	52	35	45	41
13 – Spinal	19	3	14	9
TOTAL	283	68	216	99

68 of 283 billing codes were matched on all 4 datasets, representing 17.5% of all PL FY2017/18 value

PL value	UK value*	NZ value*	French value*
$282,202,601	$202,460,785	$193,231,805	$133,525,481
PL premium	39.4%	46.0%	111.3%

* Exchange rate used £1:A$1.82, NZ$1:A$0.94, €1:A$1.58

216 of 283 billing codes were matched on the UK NHS, representing 49.3% of all PL FY2017/18 value

PL value	UK value*
$805,930,431	$664,811,926
PL premium to NHS (UK)	39.4%

* Exchange rate used £1:A$1.82

99 of 283 billing codes were matched on NZ PHARMAC, representing 22.3% of all PL FY2017/18 value

PL value	NZ value*
$805,930,431	$266,358,269
PL premium to PHARMAC	36.7%

* Exchange rate used NZ$1:A$1.82

Using the data for the UK and NZ as the two strongest data sets, representing one close to the Australian market and one major European one, this data can be extrapolated as proxy for the total recorded APRA figures for the UK at a market value of $1,727,876,717 and New Zealand at $1,531,675,789.

In making these calculations, it is noted that a normal distribution is assumed and it is further acknowledged that the true figure will be affected by variance between different DRGs. Obviously full price disclosure permitting complete indexation – at least against international list prices – would improve this data.

Further, it should be noted that all of these calculations are based upon single purchase unit prices and do not reflect the likely significant discounts and rebates afforded to payers in these systems on many of the high volume consumable items on the PL, including haemostats and glues. Therefore, this review finds the current PL to be overpriced against the NHS (UK) by $366,552,944 and to PHARMAC (NZ) by $562,753,872.

Intrinsic flaws in the current model

It is uncommon for a payer in any commercial market to be unaware of what products they are paying for, let alone when their aggregate cost exceeds $2 billion annually. Yet this is the model presented by the Prostheses List and the primary impetus for this review being undertaken.

The principles of the MTAA agreement state that there is to be "transparency of decision-making for all stakeholders that is informed by sharing of high quality data." The reality from a payer's perspective is very different with no access to the MPCs that sit behind Billing Code data and no access to comparable public pricing in Australia due to this being covered by commercial-in-confidence agreements. Even with access to state based tender pricing that utilise supplier MPCs, the need would still exist to translate these MPC into billing codes. This activity was a core - and lengthy - part of conducting this review.

A second observed flaw in the model is the lack of alignment between what procedure(s) a device is approved for by the TGA and the operations for which these devices are actually utilised and billed. This has been shown to create significant cost leakage through what is known in the pharmaceutical space as 'off-label use.' In the recommendations below, a potential solution to this leakage is identified through alignment with the Medicare Benefits Schedule (MBS).

The third flaw identified flows from the second, in that suppliers seeking PL listing generate their own submissions identifying the procedures where the device will be employed as well as expected volume of utilisation. While the issue of where a device is used compared to for what it is claimed is noted above, the question of volume expected is a critical one for the Department of Health and payers and, where the device is projected to significantly add cost to an existing procedure or group, then it is reviewed through MSAC or potentially an independent third party HTA assessor for impact. For this reason, it is in supplier's best interests to understate the device's potential uptake in order to avoid such evaluation, particularly if there is already a comparator on the PL. With hundreds, if not thousands, of codes applied for or amended each year, it becomes challenging for gatekeepers in the system, including Department of Health staff and

CAGs, to identify these outliers. For payers, this presents as a significant problem resulting in unexpected cost and was highlighted in FY2018/19 where unit growth on the PL was 8.6%, while hospital admissions growth was just 0.3%[16].

Cementless hips prices are routinely 20-50% higher than cemented globally, but in Australia they are more than double, reflecting historical flaws in the pricing of the Prostheses List model

Billing code	CAG	Supplier	Item	$A PL	NHS£	NZ$	France €
DP943	Hips	Johnson & Johnson	Corail	$3,779.00	£1,345.80 $2,519.93	$2,312.50 $2,173.75	€808.42 $1,293.47
MU003	Hips	Medacta	Quadra H	$3,779.00	£772.50 $1,436.85	N/A	€808.42 $1,293.47
SM122	Hips	Smith & Nephew	Polarstem	$4,394.00	£1,018.32 $1,894.08	$2,000.00 $1,880.00	€808.42 $1,293.47
HW529	Hips	Stryker	Accolade II	$4,394.00	£1,572.47 $2,924.81	$2,500.00 $2,350.00	€808.42 $1,293.47

Historical pricing which has not been benchmarked to global market movements has created substantial inconsistencies across PL groups. Many of these groups – including joint replacements – date back to the inception of the PL when suppliers played an active role in setting their benefits. While, over time, groups have been consolidated – often under the highest utilisation device – this still offers no evidence-based or market-informed decision making.

Further, many groupings, such as joint replacement, stents, pacemakers and trauma, have seen significant global price declines in recent years as a result of increased competition. While the PL has remained largely static for a decade, most major global markets have seen declines. This was shown in a paper by Wenzl & Mossialos, London School of Economics (2018) titled *Prices for Cardiac devices may be up to six times higher in the US than in some European countries*.[17] Utilising the Australian PL price and currency conversion to compare these key product groups, the Australian private reimbursed price remains well above the benchmark not just for Europe but the US as well.

EXHIBIT 1

Estimated mean prices, in US dollars, of drug-eluting stents in the US and four European countries, 2006–14

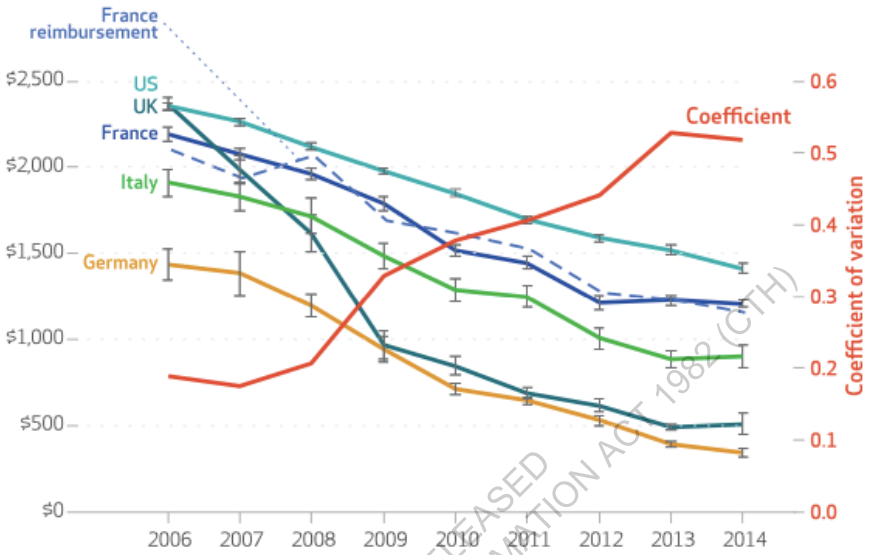
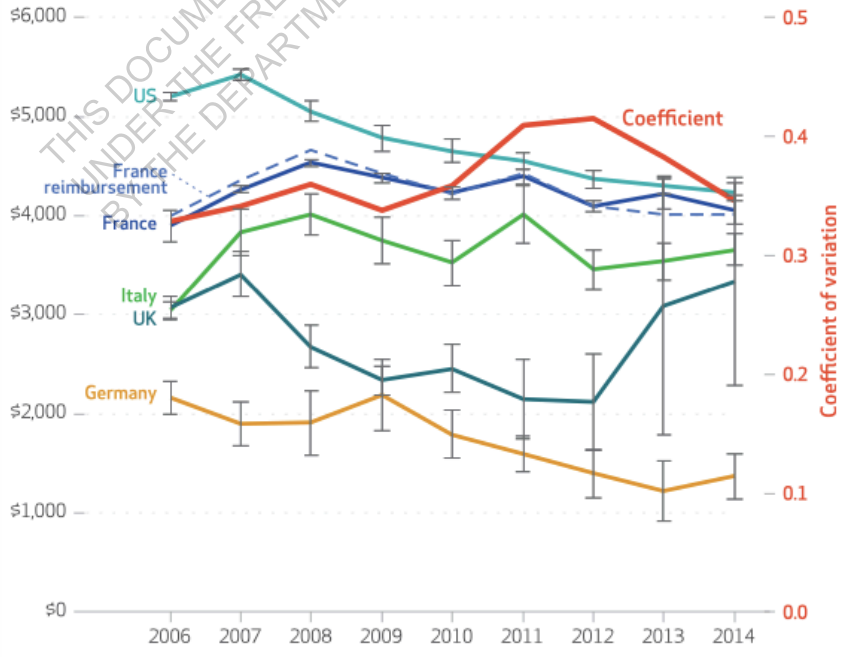


EXHIBIT 3

Estimated mean prices, in US dollars, of dual-chamber pacemakers in the US and four European countries, 2006–14



A continuing theme from the devices industry, noted in the MTAA agreement, is the increased need for evidence- and value-based decision making, often referenced as Health Technology Assessment (HTA). This is a credible approach and is discussed further in the recommendations section.

Clinical Quality Registries (CQR) remain the gold standard in assessing cost-efficiency and value, both in devices and surgical choices. The Federal Government is looking to expand funding in a number of these over the next decade. Australia already has one world class CQR in the Australian Orthopaedic Association's *National Joint Replacement Registry* (NJRR). While containing over 20 years' data and informing the Department of Health and TGA on devices for removal, it is yet to be used in valuing device outcomes. In their 2017 Annual Report[18] and later paper,[19] the NJRR indicated that there were differences between private and public patient outcomes, with a higher rate of revision in the private system. Through their analysis, they determined this was largely due to the differences in prostheses used. When the best 10 devices were used there was minimal difference between outcomes. Effective deployment of HTA overlaid on the NJRR would most likely result in significant reimbursement realignment driven by historical device performance.

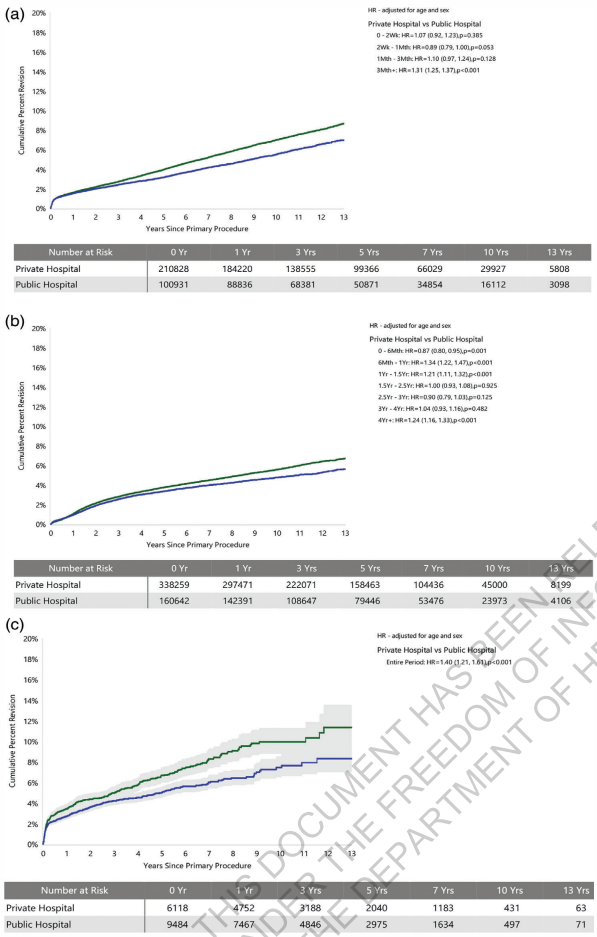


Fig. 3. (a) Cumulative percent revision for primary total hip replacement performed for osteoarthritis by hospital type. (b) Cumulative percent revision for primary total knee replacement performed for osteoarthritis by hospital type. (c) Cumulative percent revision for primary total hip replacement performed for fractured neck of femur by hospital type. (——) Private hospitals; (——) public hospitals.

The lack of PL pricing alignment with performance generates a perverse incentive highlighted in an ABC documentary,[20] where hospitals participating in rebate agreements with suppliers can be motivated from the fixed price and guaranteed payment mechanism of the PL[21] to have more items included per patient event and the use of the most expensive items within a category. While the authors understand variations in rebate models exist, these are largely based around the notion of the more items and value purchased by a private hospital group from a single device supplier, the greater the rebate amount or "kicker %" achieved. In this way, by buying more from the single supplier, the hospital can achieve a higher percentage rebate on all purchases with that supplier. This often relates to non-PL items as well which has the added effect of creating market failure in this area as well.

In this way the fixed and premium priced PL structure encourages hospitals to limit suppliers to those that can offer the largest range coverage across both PL and non-PL items. The outcome of these rebates clearly favours the largest multinational suppliers with the widest product coverage, enacting anti-competitive behaviours on smaller suppliers, many of which are Australian based. In the case of some multinational hospital providers, these rebate agreements with global manufacturers are believed to extend beyond Australia and benefit from the premium pricing on the PL. This anti-competitive blocking behaviour was reported by Applied Medical in the 2017 Senate Reviews.[22]

Drug Eluting Stent prices vary dramatically to International Comparators

Billing code	CAG	Supplier	Item	$A PL	NHS £	NZ$	France €
MI289	Cardiac	Medtronic	Resolute Onyx	$2,484.00	£435.46 $823.02	$950.00 $893.00	€760.00 $1,238.80
AY044	Cardiac	Abbott Medical	Xience Alpine	$2,484.00	£426.80 $806.65	$750.00 $705.00	€840.00 $1,369.20
BS272	Cardiac	Boston	Synergy	$2,484.00	£705.16 $1,332.75	$1,600.00 $1,504.00	€840.00 $1,369.20
BT178	Cardiac	Biotronik	Orsiro	$2,484.00	£330.00 $623.70	$1,050.00 $987.00	€760.00 $1,238.80

Service cost model comparison between markets

A number of nominal costs are frequently cited by the device industry to justify observed premiums for medical device prices in Australia. The problem with assessing the veracity of these claims is that there is both resistance to proper indexation and no willingness to – even for a few examples – provide comparative cost of goods (COG) data between markets. While the reticence of device companies operating in multiple markets to share cost data is understandable for commercial reasons, it undermines the claims of specific Australian cost increments.

A number of these are discussed below. While marginal differences in delivery costs may exist between Australia and other markets, a lack of consistency in price premiums and the sheer scale of price differences call into question the impact of such factors.

While **unique to Australia** *service costs* have been referenced as a cause for price differences between Australia's private health model via PL reimbursement and comparable international and domestic supply channels. This review found little evidence to support this claim, with a number of devices being at parity or below while others were up to 5 times the price. It seems axiomatic that, if service costs were a dominant factor, their impact should be visible across the full schedule of medical devices or at least all those imported into Australia. While Australian port costs are unquestionably inefficient, the suggestion that these are excessively borne by devices in specific DRGs or particular item categories seems unsupportable.

This claim also supposes that freight price from supplier warehouses imparts unique costs in Australia. However, for the last decade or longer, global manufacturers have based their international logistics centres in tax-effective markets including Singapore. There should be little or no difference to supporting the Australian market against European countries or New Zealand where significant discounts to the Australian price were observed. Once landed in Australia, geography would not appear a substantial impediment with a highly urbanised population and over 60% of it serviced with low cost overnight road freight. The model is at least equally challenging in NZ given that there are two islands and a more regionalised population to be serviced. At worst, these imposts should resemble costs associated with pharmaceutical distribution in Australia, which is transparently priced via a publicly-funded community service obligation (CSO).

The price of device registration with the Therapeutic Goods Administration (TGA) does not appear onerous, in the order of $920-$1,340 per device. Given the majority of suppliers are based in Europe and USA, they also benefit from harmonised global registration processes required for Europe. Current listing costs on the Prostheses List are $200 for initial listing and an annual fee of $200 for sustaining that listing. While the annual fee per listing is not trivial at $200 it was observed that 4,829 (44.9%) of the 10,748 billing codes listed on the 2017/18 PL had no sales in the prior 12 months, indicating over $2 million in billing codes potentially retained for no benefit. This suggests that an inefficient cross-subsidy is taking place within portfolios of medical devices, funded by both public and private dollars.

Another cost raised in the Australian private hospital environment is device company staff attendance during cases. While the motivations for this practice are beyond the scope of this review, it can be considered in light of clinical outcomes and payment mechanisms. It is unlikely that Australian surgeons require significantly greater support in private cases in Australia than in publicly performed ones, or when compared to other global markets. Either representative attendance is clinically unnecessary or should be replicated across all mature markets.

From the highlighted NJRR review and paper, there would not appear to be any benefit to patients from device company staff attendance and, in fact, based on private revision rates, possibly the opposite is true. Nor subjectively would there appear a difference in skills and training of Australian clinical teams compared with peers in other markets.

While there may be evidence that having skilled representatives familiar with instrumentation present in an operating theatre aids surgical speed, this is primarily a benefit to the hospital and should not be included as a cost to the surgical funder. Private hospitals are funded under agreements with health insurers to supply appropriately competent staff. Should this gap be better served by device company employees than hospital staff, then an agreement between hospitals and suppliers to that effect would be appropriate and should be included in either service costs or under the MBS (although it should be noted that device company staff may not carry sufficient insurances to contribute to surgery).

Device companies claim surgeons' preferences are to have company representatives attend surgery, which may aid the speed of the surgery or substitute for potential gaps in surgical nursing experience. Again, whatever the reason, it is clearly not appropriate that this cost is covered by private insurers via elevated

device prices while they are also being required to fund the service through DRGs, case payments or other agreements.

"Australia is just a high cost market." This has been raised with everything from prices of cars to Apple iTunes serviced from outside Australia but billed locally. This statement would have more validity if there were greater consistency in price discrepancies across the 283 reviewed items. What is actually observed is that many items are priced comparably between Australia, Europe and NZ while others were significantly more expensive on the PL. This would suggest a failure in the PL model, where global comparators and market forces are not observed and, as a result, the PL fails to be an efficient market price mechanism.

In any case, this argument is more typically based on exposure to high labour costs – particularly in manufacturing – and Australian company tax rates. The principal employment of device companies within Australia is in marketing, distribution and regulatory affairs, rather than manufacturing, and there is ample evidence that international healthcare firms are adept at optimising their global tax exposure.

Global parity in some codes, inflated prices in others suggest model failure not $A being the issue

Billing code	CAG	Supplier	Item	$A PL	NHS £	NZ$	France € /US$
CO069	ENT	Cochlear	Cochlear™ Nucleus ® CP910 Sound Processor	$10,925.00	£5,139.60 $9,354.07	N/A	€6,000.00 $9,480.00
MI259	Cardiac	Medtronic	Medtronic CoreValve™ Evolut™ R transcatheter aortic valve	$22,932.00	£16,272.00 $29,615.04	N/A	€16,230.75 $25,644.59
SJ374	Neuro	Abbott Medical	Prodigy IPG	$24,700.00	£13,500.00 $24,750.00	N/A	€16,510.21 $26,086.13
AS246	Gen/Misc	Medtronic	Absorbatack	$509.00	£300.00 $546.00	N/A	US$279.00 $390.60
MC755	Urogenital	Medtronic	Interstim II	$9,072.00	£7,344.00 $13,366.08	N/A	€5,385.00 $8,508.30
BT193	Cardiac	Biotronik	Edora 8 DR-T	$8,482.00	N/A	N/A	€2,947.63 $4,657.26
MC933	Cardiac	Medtronic	Advisa DR MRI Surescan	$8,482.00	£2,676.00 $4,870.32	N/A	N/A
SN857	Knee	Smith & Nephew	Genesis II Tibial base plate	$1,923.00	£500.94 $911.71	$1,665.00 $1,565.10	€728.96 $1,151.76
DY464	Hip	Johnson & Johnson	Depuy Delta Ceramic head	$2,022.00	£916.80 $1,688.58	$1,350.00 $1,269.00	€334.84 $529.03
BX258	Gen/Misc	Baxter	Floseal	$665.00	£211.20 $384.38	N/A	US$275.00 $385.00

Principles for 21st century protheses pricing

The following could be considered best practice principles either at the conclusion of the current MTAA agreement or prior for the future of the Australian private prostheses reimbursement and access systems:

1. Surgeons' ability to choose devices should be retained;

2. Pricing of devices should be directed by an HTA process, where devices offering proven superior outcomes are reimbursed at a higher level. Conversely, items with higher revision rates or lower effectiveness should receive lower reimbursement. This should also encourage suppliers to only offer or retain proven designs;

3. HTA should be retrospectively applied to existing high price groupings that have access to CQRs. With 80% of PL sales covered by just 6.4% of Billing Codes, and largely in Orthopaedics and Cardiac groups, this should not be overly onerous for the MSAC and Department of Health to undertake;

4. Related to the above, a simplification of sub-groups would also benefit stakeholders and gatekeepers within the PL framework. Current groupings with independent benefits offer limited equivalence to the clinical outcomes generated. Currently there are eight different subgroups and pricing for cementless hips, despite well- and poorer-performing devices being dispersed amongst the eight groups;

5. Improved transparency over MPCs that sit within billing codes. This would be necessary should Unique Device Identifiers (UDI) be introduced into Australia to support recalls. For payers, including the Government and private health insurers, this would facilitate easier market comparisons and awareness of what is being funded;

6. Restoration of a clear definition of a prosthesis should be considered and ideally should reflect a device's functional performance within the body for a period greater than 24 months. The Department of Health has recently commissioned a review of the General and Miscellaneous clinical group. This group has a significant number of items that are consumable in nature, many of which are likely funded under existing hospital and insurer payment models, and a clearer definition of a prosthesis would help manage this; and,

7. The introduction of a list of innovative technologies validated by HTA should be considered, i.e., of technologies where MSAC- or Department-approved third party assessors have determined that the technology offers comparable or superior outcomes to existing prostheses and procedures. This should remove the current incentive to select device "*hardware*" over potentially more effective treatment. Significantly, the determination of where the "*value*" is realised becomes critical in determining the appropriate payment stream for this innovation. In most cases, this should be factored into the DRG or casemix model.

These principles inform the following recommendations.

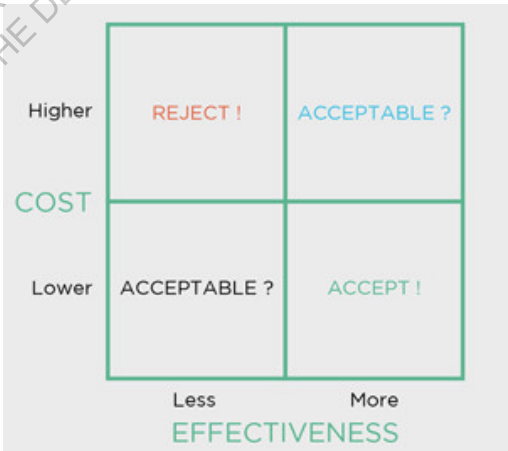
Recommendations to reform the reimbursement model

The first question that should be determined is whether the PL remains a critical and effective mechanism for device funding. With recent data including the APRA FY2018/19 report indicating device growth of 8.6% compared to just 0.3% growth in hospital admissions, it looks likely that commercial incentives and promotion are trumping clinical need.

In addition, the environment that generated the PL and its precursor (Schedule 5) in 1985 are no longer applicable today. Specifically, waiting lists and access in the private sector are not a factor as they were in 1985. The PL mechanism is also not the appropriate mechanism for capturing the value of non-devices that may offer greater clinical efficacy at lower procedural cost, yet are underutilised due to the constraints of the PL mechanism and, in some cases, its interrelationship with MBS funding.

In the thirty-five years since the PL was introduced, case-based DRG-style payment regimes have become the most common model for both the Australian public system and many international markets both public and private. This model has recently been advocated for adoption with the Australian private system by the Grattan Institute.[23]

The use of these models support surgeons, private hospitals and payers to rank technologies under both clinical and cost effectiveness grounds. Based on comparative international data as outlined in this review, it would also facilitate price-based competition and remove perverse incentives for greater utilisation of devices, particularly for increased use of more expensive devices. Under a case-based model, accurate determination of technology value – be it implanted prostheses or consumable devices or techniques – becomes the critical factor in decision making. This is represented in this simple graphic from Value Based Access.[24]



If the view is taken by the Department of Health and the Minister that a complete replacement of the PL would impose excessive transaction costs, then the following recommendations should strongly be considered.

Alignment of PL Billing Codes to indicated MBS items and TGA listing

A review of billing codes delivering greatest growth from FY2017/18 to FY2018/19 highlights strong weighting to consumable items within the General Miscellaneous group. With this group reported by HCP1 data to have grown 19.2% in units compared to 0.3% growth in hospital admissions for FY2018/19, it is clear that the current billing approach is sub-optimal from a cost management perspective. Again it should be noted that this is not solely a private sector concern.

The expanded *Prosthesis Definition* that facilitated the inclusion of non-prostheses, such as haemostats, glues, tissue separators and other consumables, effectively decoupled the natural alignment of demand between devices used and surgical volumes. While many of these items may be removed under the pending General Miscellaneous review, it highlights the importance of matching devices to approved usage indications.

This has been successfully achieved by the Department of Health with both TAVI and atrial fibrillation (AF) electrodes. Where device utilisation is matched to both the MBS item recorded by the surgeons and the TGA-indicated use for the device, spend on utilisation data has matched expectations, i.e., around 1,050-1,100 TAVI procedures per annum since PL listing.

In this way, device suppliers would identify at the time of submission to the PL what the indicated usage case is for their device. This would allow government and other payers to reference the potential additional cost of the new technology against known MBS utilisation. This approach is described as **Conditional Listing** and would almost certainly have avoided the blow-out in units in FY2018/19 on the PL. This is because current barriers to use once a device is listed on the PL are largely non-existent outside TAVI and AF, which in turn results in consumable devices being used across a broad and often ineffective cost base. The introduction of **matched MBS and PL codes would also allow an automated fraud detection system to be employed** to reduce waste.

Where suppliers were seeking expanded MBS indications outside the TGA approved use, these would require an appropriate level of scrutiny by the MSAC or a Department-endorsed HTA provider.

Transparency of Manufacturer Product Codes within Billing Codes

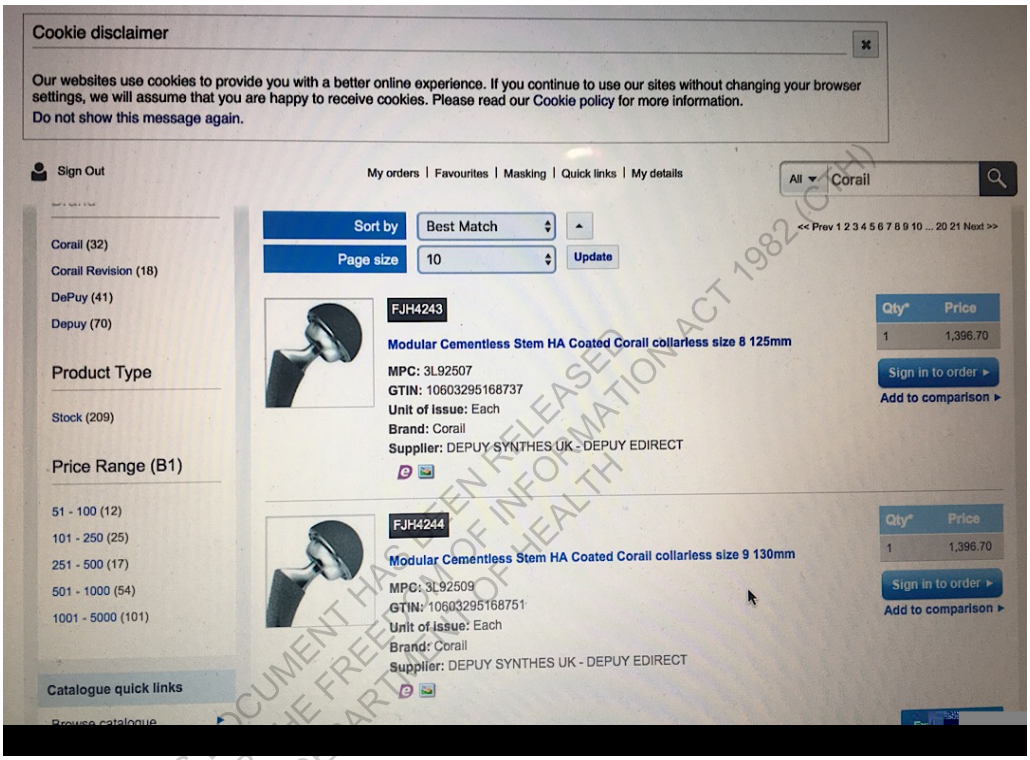
With the likely introduction of UDI legislation, it will be a requirement for MPCs, Billing Codes and UDI details to be included on all invoices to private health insurers. This will improve traceability of patient records.

This transparency will allow better understanding of what devices are in use within the private health system. A secondary outcome will be the ability to undertake a global comparison of device prices that sit within billing codes. This could be achieved by adopting a model similar to the NHS Supply Chain which is available as a buying channel to both public and private hospitals in the UK. This online tool includes core device data including Global Trade Item Number (GTIN), unit of measure, device photo, supplier, related ordering codes from the same device family and the option to buy directly from the site. Currently many state tenders hold this information in isolation and it is inefficiently duplicated across different states.

The use of a single tool, that offered volume price breaks would create greater market efficiency and potential for price-based device competition within a single national market.

Screen shot from the NHS Supply Chain (prices in UK £ Sterling)

NB: Prices have decreased a further 3% across NHS Supply chain from time of this photo.



Introduction of an Independent Purchasing Authority

Price-based competition is a core element of procurement across most industries. The protected price mechanism of the current PL is not aligned with global and state-based tenders. The introduction of a function, such as Australia's Independent Hospital Pricing Authority or PHARMAC in NZ, that delivers optimal pricing at a centralised level is recommended.

To be fully effective, the introduction of such an authority would need to be paired with a DRG approach encompassing all items required for surgery, so clinicians and hospitals could determine the optimal mix of technologies deployed in surgery. Re-instatement of Superior Clinical Performance (SCP), funded by private insurers and potentially the public system, for devices with proven results could be considered. Over the medium to longer term, this would encourage retention of well performed devices by suppliers and encourage surgeons to utilise these technologies.

International Weighted Basket of Devices Index

Maintaining a fixed and constant price structure fails to capture the benefits available from indexation to global competitive markets. Establishing a clear basket of MPC/billing codes that were statistically representative of market utilisation could help address this issue.

The 283 codes identified in this review cover 62.3% of the PL value, noting that the review has been careful not to rely too heavily on extrapolation, as some will be outliers. With some detailed analysis and the availability of data, a basket of 100-200 MPC/billing codes could be established as a general index for prices. Variance in some DRGs may limit the impact of such an approach, but suppliers should be required to justify individual or product group departures from the general index.

Construction of such an index would require regular support from suppliers and/or purchasers in an agreed number of markets including the three discussed in this review and an additional two to three others. It would not require full international disclosure for all items. A variation on this approach is employed in Japan.

Procedural DRGs/bundled payments covering Devices & Surgery

The ability to combine devices within total procedural cost necessitates surgeons and hospitals to make efficient decisions on what products are used within a case. As per the discussion above, distinctions would be required between true implantable devices and items that have a cost whose benefit is captured by the hospital in reduced operating time and increased throughput.

Variations of this model are deployed across many markets. They reward suppliers who implement efficient supply-channel models and benefits payers in realising price reductions created from global competition. This has also been advocated recently by the Grattan Institute.[25]

Introduction of HTA-informed device pricing

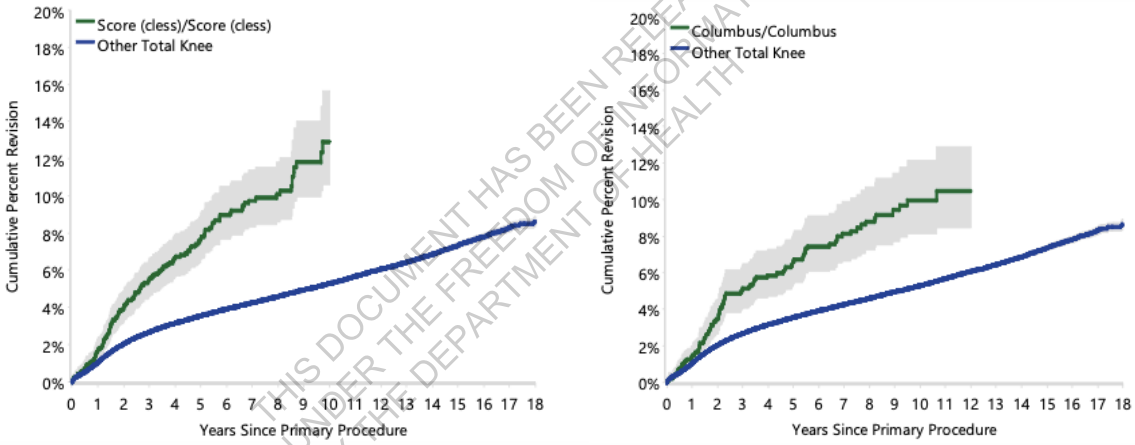
With expanded government support for CQRs imminent, the inclusion of device pricing informed by HTA processes becomes viable. The failure to leverage compelling evidence – now at 20 years from the NJRR – into the pricing structure of the PL is a substantive oversight. While its use in advising the TGA of potential device actions and its directional information to Australian Orthopaedic Association (AOA) members has delivered a substantial positive Return on Investment (ROI), the Minister and Department of Health have failed to embrace its unchallenged evidence to set appropriate prices for device whether that be per device or at a group level as the PL currently reports.

The inclusion of devices with SCP recognition and excellent results was a positive and justified step from a clinical and health outcomes perspectives, but was not matched by the necessary re-pricing of devices that were "*below the line*" in regards to their outcomes. In many cases, these devices were amongst the most expensive devices offered on the PL and were often in the class of devices with higher than anticipated revision rates (HTARR).

Devices of this type with expensive and below-average results would be less likely to be considered for inclusion in a public tender yet continue to be available at inflated prices to private patients without restrictions. This has directly contributed to the NJRR's comments that the variation observed in hospital outcomes correlates with the differences in prostheses selected. This is reflected in the chart below.[26]

When compared with data presented by the Independent Hospital Pricing Authority to the Senate Inquiry,[27] selected devices consumed in the private system are routinely around $3,500 for hips and $900 for knees more expensive than in the public sector, yet many result in higher revision rates.

With the assumption that surgeons are not seeking to use inferior devices, the conclusion must be that the devices being promoted in the private system is potentially more influenced by reimbursement and does not reflect clinical outcomes informed by the NJRR. Again, this is commercially understandable, but does not reflect optimal healthcare. Where possible, reduction in apparent rents for key devices should reduce the incentive to any such behaviour.



The Score knee has for many years been named as a device with HTARR and, in recent times, the Columbus Knee was also included in the HTARR list. While the average cemented knee, which represents gold standard results at or below the blue line, are reimbursed at between $6,000 and $6,500, the Score knee construct is listed on the PL at over $9,000 and the Columbus at $7,700. Concerningly, despite advice from the NJRR to avoid use of these prostheses on the grounds of HTARR, in the last recorded year on the registry the utilisation of these two HTARR devices grew at over 70% against 1% for all other knees.[28]

Table IP21 Yearly Usage of Total Knee Prostheses Identified as having a Higher than Anticipated Rate of Revision

Year of Implant	≤2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Newly Identified	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Score (cless)/Score (ctd)	.	.	3	.	.	3	3	3	.	5	15	90	181	324	300	267	121
Re-Identified and Still Used	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ACS (cless)/ACS Fixed	.	.	.	.	.	.	.	.	.	41	119	283	337	332	238	266	258
Active Knee (cless)/Active Knee	221	613	790	693	466	510	483	412	479	601	500	427	319	336	176	91	35
Advance/Advance	53	.	8	12	16	2	5	43	115	138	74	7	92	92	100	90	69
Apex Knee CR (cless)/Apex Knee (cless)	.	.	.	.	.	.	.	.	.	.	69	83	118	78	11	3	29
Columbus/Columbus	.	.	.	49	91	90	148	156	134	136	108	69	36	60	119	357	669
E.Motion/E.Motion	.	.	.	.	.	.	.	12	87	114	129	236	106	113	125	140	96
Nexgen LPS Flex (cless)/Nexgen	.	.	.	.	.	.	.	.	73	78	149	312	238	280	225	251	218
Optetrak-PS/Optetrak	126	130	155	252	253	216	168	202	198	202	200	151	115	30	3	5	2
Optetrak-PS/Optetrak RBK	.	.	.	1	81	173	166	119	82	40	37	50	100	56	46	88	75
Score (cless)/Score (cless)	.	.	.	1	.	11	135	212	187	204	196	238	273	263	170	159	214

This data would indicate that a rebasing of device pricing on the PL geared to outcomes is long overdue. With this in place, an SCP premium for devices with proven superior results should be restored as this would offer a positive HTA outcome.

Greater effort should also be made to ensure patients are made aware of the results related to the devices selected for them in their specific age group, as the NJRR has shown some device have variations in outcomes based on age,[29] notably that cementless stems have poorer outcomes in patients over 75 than cemented ones.

Table 1 Use of higher than anticipated rate of revision (HTARR) prostheses in private and public hospitals

	Private	Public	% Difference	*P*-value
THR for osteoarthritis				
HTARR prostheses	25 738 (12.2%)	11 735 (11.6%)	0.58% (0.34%, 0.82%)	<0.0001
Other prostheses	185 090 (87.8%)	89 196 (88.4%)		
THR for fracture				
HTARR prostheses	882 (14.4%)	754 (8.0%)	6.47% (5.43%, 7.50%)	<0.0001
Other prostheses	5236 (85.6%)	8730 (92.1%)		
TKR				
HTARR prostheses	29 854 (8.8%)	5031 (3.1%)	5.69% (5.57%, 5.82%)	<0.0001
Other prostheses	308 405 (91.2%)	155 611 (96.9%)		

THR, total hip replacement; TKR, total knee replacement.

Identification of valid non-device technologies via HTA

While the current use of the PL as a *proxy mechanism* for pricing non-prosthesis technologies is not appropriate, an effective mechanism should be established to quantify the value of innovative technologies. Validation of these should be via an HTA process, which could be performed by MSAC or a Department of Health-approved third party assessor.

The PL has unquestionably generated a perverse maintenance of certain procedures that are device "*hardware*" dependent, as is often cited for certain spinal procedures. These technologies are potentially not clinically- or cost-effective compared with new innovative approaches yet remain in first-line use due to the reimbursement mechanisms supporting them.

This is quite distinct from the miscellaneous items like haemostats that are currently and inappropriately on the list which are routine consumables used in surgery. While AF electrodes and mapping catheters were

added in February 2019, these items had been funded through a variety of mechanisms, i.e., DRGs and *ex gratia* for the 20 years prior. These were funded on request from clinicians in the first instance, however an efficient mechanism to confirm the HTA value of all such technologies would be a positive initiative for stakeholders. Whether these items are then either added to a technology (non implant) list with conditional approval for use in conjunction with certain MBS item numbers; or are merely agreed to be covered under DRGs by funds at an HTA-appropriate level, the potential to reduce waste and potentially excessive surgery would be captured.

Restoring the PL to cover only genuine prostheses

The substantive growth in PL unit sales over the last 4 years – most pronounced in FY2018/19 – resulted largely from devices that were short term in functional use and were not prostheses, particularly those with no specified MBS indication, such as general surgical consumables including haemostats and skin glues.

The traditional definition of a device should be restored, i.e., that it was listed on the ARTG, provided in an episode of hospital care, that a Medicare benefit was payable to the professional service and that it be surgically implanted in the body in order to replace an anatomical body part. This definition not only covered permanent devices, such as joint replacements and stents, but was sufficiently broad to cover long-term absorbable devices, such as shoulder anchors and anterior cruciate ligament devices, that had a functional life in restoring the anatomy for 2-4 years before resorbing.

As per the previous point, a list covering innovative technologies that are not prostheses could be established and funded by a separate method. The extension circa 2010 to include the terms “combat a pathological process” or “modulate a physiological process” along with “integral to the insertion” of a device, while intended for pacemakers, led to non-prosthetic devices being added. These include BioModels that are merely software used for designing 3D plates. The plate itself also achieved a reimbursement premium for being personalised for the patient so this feels like double-charging.

While a number of technologies, including BioModels, may show a positive value to a procedure, the real beneficiary of that saving needs to be identified. If a technology reduces a procedure by thirty minutes, then the DRG for the procedure should be adjusted accordingly or the price of the technology carried by the hospital, reflecting better use of their operating room. Unless the value can be attributed to a clinical outcome for the patient, it is only opportunism that it is charged to a private health Insurer or the patient through a gap payment. As the PL is currently constructed, this cost-shifting is magnified by the inclusion of poorly constrained Australian price premiums. Reform of this model will not only reduce costs to insurers, patients and governments, but will return clinical fitness as the dominant criterion for device and consumable selection.

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