ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

Senate Community Affairs References Committee
Inquiry into Price regulation associated with the Prostheses List Framework

RACS Submission

January 2017

The Royal Australasian College of Surgeons (RACS) is the leading advocate for surgical education, training and standards of practice in Australia and New Zealand. Our Fellows and staff work closely with other health organisations to promote the best health outcomes for patients and the community.

RACS supports the principle of universal and sustainable healthcare provision across all communities in Australia, recognising the important contribution of the private sector in the financing and delivery of health services under the Medicare framework. The increasing costs associated with providing health services in Australia, including surgery, is a significant challenge for the government and the health sector. In 2014-2015 Australia's health expenditure was $161.6 billion, with the share of the economy (GDP) represented by health reaching 10% for the first time.[1] In relation to prosthetic devices, there is currently a significant discrepancy between public versus private sector pricing, with higher prices in the private sector usually resulting in significant cost distortions which is ultimately passed onto the patient (when treated in the private sector).

At the same time an increasing number of Australians are cancelling or reducing their private health insurance cover, citing value for money as a key factor influencing their decision making. In 2013-2014 public hospitals provided approximately 29 elective admissions involving surgery per 1,000 population and private hospitals provided approximately 57 per 1,000[2]. If the trend away from private health insurance continues, pressure will increase on government to step in to provide those services that are currently delivered by private hospitals. The long term viability of the private health model in Australia will also decline if health insurance premiums continue to rise above CPI and wages growth. When considered in conjunction with an ageing Australian population, improving life expectancy and increasing prevalence of chronic disease, the principle of universal healthcare in Australia is under threat unless these challenges are addressed.

The regulation of prostheses costs in Australia is complex and RACS welcomes the Community Affairs References Committee's inquiry into price regulation associated with the prostheses list framework. In making a submission to this inquiry, RACS considers the following principles as being central to improving existing processes and structures - patient safety and quality assurance; clinician driven reviews and; greater transparency and improved coordination.

Recommendations

In reviewing price regulation associated with the prostheses list framework, RACS recommends the following:

1. Each prosthetic device should be subjected to a period of independent review, overseen by relevant specialty representatives, before it is introduced into the Australian market (including a review of previously approved devices that have been subject to minor changes)
2. That the superior clinical performance suffix be maintained
3. Explore opportunities for improved coordination and collaboration between Clinical Advisory Groups (CAGS) and Therapeutic Goods Administration (TGA) that maximises the value of clinical expertise
4. Continue to progress the development and introduction of global standards for superior clinical performance
5. Reduce complexity and improve transparency around how prices are determined. Utilise the knowledge and experience of clinicians to understand how prostheses are evaluated in comparable markets

[1] Australian Institute of Health and Welfare, Health Expenditure Australia, October 2016.
[2] Australian Institute of Health and Welfare, Surgery in Australia's Hospitals, March 2015.

Patient Safety and Quality Assurance

Patient safety must always be central to the provision of any health product or service. While instant access to new prosthetic devices may satisfy patient demand or give the appearance of maintaining pace with technological advances, it is important to balance innovation with evidence. RACS does not support the introduction of prosthetic devices without an appropriate period of review and research. Before a Class 3 device is introduced into the Australian market, RACS supports a clinical trial being commissioned and that a minimum of two years of independent data is provided in support of the application to the Prostheses List Advisory Committee (PLAC)[3]. We also recognise that in some circumstances (e.g. in vascular surgery), a two year comparative clinical outcome assessment may not be possible for some devices, including those in Class 3.[4] Ensuring that relevant specialty representatives are involved throughout the assessment of a device will support best practice decision making.

Australia's response to concerns about DePuy ASR hip replacements, the first country in the world to recognise the prosthesis had greater than the anticipated rate of revision surgery which, after some time, initiated regulatory action that ensured its removal from the Australian market, highlights the importance of on-going and transparent review of prosthetic devices. In the past there have been a number of issues that have highlighted how a minor change to a prosthesis design can have a significant impact on the performance of that device when implanted and subsequently influence patient outcomes. RACS would support a review of the requirements associated with approved devices which are subject to minor changes, with clinicians who have an expertise in using that device or in the relevant sub-specialty being best placed to provide guidance and advice to the PLAC and TGA.

Promoting on-going quality assurance and improvement is a key principle of healthcare service provision throughout Australia and internationally. In supporting the delivery of the highest standards of care to patients and as a measure of quality assurance, RACS supports the on-going use of superior clinical performance suffix[5] with the associated on-going requirements regarding a minimum ten year follow-up with an appropriate cohort and an unchanged prosthesis; appropriate peer review non-designer publications showing greater than 95% survivorship at a minimum of ten years and; all data reviewed at the discretion of the CAG clinicians. RACS accepts that this time period is not possible or attainable with some prosthetic devices (e.g. intravascular devices). RACS would also support the development and introduction of global standards for superior clinical performance, which it understands is currently being considered. As a means of on-going quality assurance, further consideration could also be given to conducting appropriate audits, particularly of new technologies, as they are introduced into practice through the Prostheses List Framework.

Clinician Driven Reviews

RACS supports clinician driven reviews of prostheses across all aspects of the assessment process. The CAGs associated with the PLAC act as an effective means of gaining input from specialist clinicians when assessing the value of introducing a new prosthetic device into the Australian market. RACS believes there is further scope to use this expertise more broadly, including by the TGA, which may assist in ensuring greater consistency and coordination when reviewing prosthesis pricing across both public and private sectors.

Surgeons frequently travel overseas to undertake further post Fellowship training or to refine their

[3] Data that is independent of the manufacturer or research funded by the manufacturer
[4] Noting that the definition of Class 3 devices may not include some vascular devices that, if failing, impose serious risks to the patient
[5] Department of Health, Australian Government, Superior Clinical Performance (SCP) Evidence Requirements for HPCAG, KPCAG & SOCAG, October 2011.

skills during a clinical attachment to a specialist peer. The experience and knowledge gained during their time overseas could assist in gaining a better understanding of international benchmarks and how prostheses are evaluated in comparable markets. While the size of the Australian healthcare sector may limit the ability to match the unit price of a device in comparison to larger markets, the knowledge gained by surgeons who have experienced how overseas healthcare systems evaluate devices could support a better analysis of cost from the Australian perspective - beyond that proposed by the device manufacturer when submitting a product for approval.

Greater Transparency and Improved Coordination

Prosthesis prices in the Australian private hospital setting are amongst the highest in the world, with estimates indicating that prosthesis benefits payments comprise 14% of total reimbursements by private health insurers - totalling $1.9 billion in 2014-15.[6] While the introduction of increased regulation has helped to ensure the cost of prosthetics has stabilised after a period of exponential growth, RACS supports further efforts to increase transparency associated with the pricing of prostheses. While there is a need to maintain a balance between government regulation and competition, the existing complexity and lack of transparency around how the ceiling price is determined makes it difficult to assess whether the price is appropriate. Given this lack of clarity and transparency, it is also difficult to make an informed assessment as to whether models used in other areas, such as the Pharmaceutical Benefit Scheme (PBS), offer a better alternative. Assessing pricing against proven international benchmarks offers one way of using existing evidence to support decision making.

In reducing costs associated with healthcare services in Australia, on-going quality improvement which explores ways to reduce unnecessary bureaucracy and administration while maintaining standards should be considered. RACS believes that there is further scope to improve the coordination of reviews. There remains some disconnect between the PLAC examining costs within the private setting only and the TGA operating across public and private settings. This methodology may impede quality improvement to existing processes that would support greater efficiency, coordination and consistency in the approach to pricing prostheses in Australia. RACS would support exploring the use of members from the CAGs across both PLAC and TGA as a way to maximise clinician input and streamline the review of prostheses while maintaining robust standards.

RACS would like to thank the Community Affairs References Committee's invitation to provide a submission to its inquiry into price regulation associated with the prosthetics list framework. We look forward to receiving a report on the outcome of this review and working with Commonwealth and State Governments to improve the sustainability of surgical services utilising prosthetic devices throughout Australia.

[6] Private Healthcare Association Australia, Private patients paying too much for medical implants and surgical supplies, February 2016