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Poor policy and inadequate regulation of medical technology is driving low-value care in Australia's private health system

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ABSTRACT

Millions of Australians use the private health system every year. They should receive safe, high-quality, value-based care. However, poor policy and inadequate regulation of medical technology is driving low-value care at great expense to consumers and the broader health system. Key drivers include the Prescribed List of Medical Devices and Human Tissue, gaps in quality and safety controls for devices being used, and marketing and conflicts of interest. All of these should be addressed to reduce low-value care in Australia's private health system, so consumers are protected from harm and limited health budgets are used effectively.

Keywords: low-value care, medical technology industry, Prescribed List of Medical Devices and Human Tissue, private hospitals, private health system, spinal cord stimulation, spinal cord stimulators, value-based care.

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Introduction

Millions of people use Australia's private health system each year.[1] In 2023, more than 12 million Australians had health insurance with hospital cover, accounting for 45% of the population. Approximately 61% of all surgical procedures occur in private hospitals, along with 23% of child births and 62% of inpatient mental health care.[2]

Australians using the private health system should receive safe, high-quality, value-based care. This means services should be evidence-based and delivered in an appropriate place by a qualified team at a competitive price. While there are many examples of exemplary care in the private system, poor policy and inadequate regulation of medical technology is allowing low-value care to occur at great expense to consumers and the broader health system.

Low-value care comes in many forms that consumers may not be aware of, including paying too much for equipment and technology used in their treatment, receiving devices that lack high-quality evidence showing they are safe and effective, or receiving devices shown to be ineffective or inferior to others. Some of this is likely occurring due to conflicts of interest between medical device companies, doctors, hospitals and patient advocacy groups that warrants more transparency and regulation.

Problem 1: exorbitant costs due to the Prescribed List of Medical Devices and Human Tissue

Paying too much for common medical supplies wastes limited funding that could be better spent delivering timely, effective services. In Australia, consumers are paying some of the highest prices in the world for medical devices in the private system due to the Australian Government's Prescribed List of Medical Devices and Human Tissue (PL) for private healthcare.[3]

Special Issue: Value-based Healthcare

The PL includes more than 10,000 generic items, including everything from basic surgical equipment through to pacemakers and insulin pumps. It is one of the few remaining systems in the world that regulates prices for surgical implants and supplies on a fee-per-item basis. It is inflationary because prices for many items have been fixed at 30–100% more than global benchmarks and there are no regulated controls on volume. These inflated benefits have led to a 'shadow economy' of financial rebates and other benefits paid to doctors and hospitals by big multinational suppliers to secure continuing sales.

Prices are higher than international benchmarks because they are negotiated between the Australian Government and medical device manufacturers without input from payers such as private health insurers. This means Australians pay 70% more than New Zealanders for a hip replacement stem, for example, and 30% more for a drug eluting stent.[3]

The Australian Government is working on reforms to reduce prices, but it is moving slowly with few savings achieved by the end of 2023. There is an opportunity to further reform this system to lower prices and boost patient outcomes by embracing a more open and competitive market. Our aging population will continue to drive demand for medical devices, so ensuring prices are sustainable for high-quality technology is a critical challenge facing Australian healthcare.

Problem 2: gaps in safety and quality controls for medical devices being used

Consumers should be able to trust that medical technology being used in private healthcare has been rigorously tested to show it is safe and effective, and that there are processes to address safety and quality problems to protect people from preventable harm. However, there are gaps in the system which put consumers at risk.

In Australia, the main way to assess the value of a medical test, treatment, device or prosthesis is to perform a Health Technology Assessment (HTA). HTAs examine a combination of scientific evidence and data to assess quality, safety, efficacy and cost-effectiveness, and are meant to ensure taxpayers' money supports safe, effective healthcare improvements. HTAs are key tools for the Medical Services Advisory Committee (MSAC), the Pharmaceutical Benefits Advisory Committee (PBAC), and the Medical Device and Human Tissue List Advisory Committee (MDHTAC).

However, the process has limitations. Not all medical interventions, including surgical implants, devices and procedures, have been subject to a HTA. Most HTAs are done on new entrants to the health system, not interventions or items that have been in use for many years. This is a particular problem for procedural medicine where the great majority of items used are generic and have been in the market for long periods. Furthermore, inadequately regulated access pathways such as the PL mean items can be used for any purpose, not just the one a HTA has deemed it safe and effective for.

Other tools to determine the safety and cost-effectiveness of an intervention, such as the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), have saved hundreds of millions of dollars by identifying procedures and devices that lead to poor outcomes. However, poor devices can remain in use because the AOANJRR is only an advisory and research tool, not a pathway for removal of Medicare Benefits Schedule (MBS) funding and devices.

The Department of Health and Aged Care has advocated for investment in similar registries, but progress has been slow. These registries can identify non-clinical reasons driving low-value care including financial incentives to use a particular procedure or device. In 2018, research by the directors of the AOANJRR showed that patients receiving surgery in the private health system were more likely to require a revision procedure than those in the public system because they were receiving different devices.[4] A Private Healthcare Australia analysis found that the devices used in the private system were routinely A$3000–5000 more expensive and failed at a higher rate in matched public to private patient cohorts.

Another limitation of HTAs is they can be superseded by changes in clinical practice, technology and research. A technology found to be safe and cost-effective in 1995 may not represent value-based care in 2023. The ability for the MBS payment system to adapt quickly to changing clinical evidence is also limited.

Problem 3: marketing and conflicts of interest

Like the pharmaceutical industry, the medical device industry is a multi-billion-dollar sector in Australia. The highly competitive business means sales representatives typically work off commissions with incentives to increase the volume of products used and the use of more expensive devices.[5] Medical technology companies engage in many activities to build relationships with health professionals and promote sales of their products, including:

- company-sponsored educational events;
- engaging key opinion leaders as speakers or consultants;
- paying for travel, meals or professional development; and
- sponsoring post-market trials.[6]

Research suggests that company representatives also spend time in clinical areas, attend surgical procedures, and offer technical support 24 h a day.[6] Patient consent may not be given for sales representatives to be in clinical settings and company representatives may be involved in hospital purchasing processes as a source of product information and

free samples, as well as driving in-house evaluation and training on the product.[6]

This results in a dual role for device company representatives with potentially conflicting interests: working as a commissioned sales representative while also providing advice on medical treatment. As a team of Australian academics argued in 2018, 'This duality raises the concern that clinical decision-making may be unduly influenced by commercial imperatives', and it creates ethical concerns about the impacts on healthcare costs, the outsourcing of expertise, and issues of accountability and informed consent.[6]

A class action brought against Johnson & Johnson in Australia over its vaginal mesh implants demonstrated how some of these activities can jeopardise clinical care. Internal documents dating from 2009 show Johnson & Johnson representatives used Lamborghinis and skiing trips among other incentives to influence doctors as they rushed a class of implants to market and encouraged inexperienced surgeons trained by company representatives to use them.[7] This outsourcing of clinical expertise meant some women later found it hard to find surgeons qualified to remove the defective implants that caused widespread pain and suffering in Australia.[7]

The potential impact on healthcare costs has been documented. In 2013, a 1-year retrospective review of medical records of patients who had percutaneous coronary intervention at a Canadian teaching hospital showed that the presence of device representatives was associated with significantly higher costs of balloons and stents per case, driven by the higher costs of the stents selected.[8]

Case study: spinal cord stimulators

Spinal cord stimulators are devices implanted into the back during surgery to send low levels of electricity directly into the spine to attempt pain relief. The devices were introduced to the Australian market decades ago without any high-quality clinical trials proving their effectiveness. Since then, a Cochrane Review, which analysed the results of 13 clinical trials, found that spinal cord stimulation does not provide long-term relief.[9] There is also evidence of considerable harm. A 2022 study of 529 adverse events reported in Australia between 2012 and 2019 found four in 10 spinal cord stimulators were later removed, and most adverse events were classified as severe (79%) or life-threatening (13%).[10]

Health insurance data collated by Private Healthcare Australia shows there were 1351 spinal cord stimulator insertion procedures in 2022–2023, with the average cost per patient A$58,377. The same dataset shows that 27% of people require surgical reintervention within a year and 41% within 3 years. For comparison, there is a 2% revision surgery rate for joint replacements.

Despite this, the Neuromodulation Society of Australia and New Zealand, which represents providers, continues to spruik the benefits of spinal cord stimulation with the help of patient advocacy groups taking their money. In 2023, the 'Pain Australia Spinal Cord Stimulator Implants Consumer Experience Report' detailed the mostly positive experiences of 73 people who received spinal cord stimulators.[11] Sixty-three of these people were selected by doctors who make a living from implanting the devices. The other 10 people responded to a social media call for participants.[11] The Neuromodulation Society of Australia and New Zealand lists four medical device companies as 'corporate supporters' on its website. All four manufacture spinal cord stimulators.[12]

The Pain Australia report, disseminated to the media, coincided with allegations the medical device industry is now employing similar tactics to the tobacco lobby to undermine independent research challenging spinal cord stimulation in Australia.[13] It is a pattern of behaviour that concerns health funds being forced to pay for spinal cord stimulation and it should concern the Australian Government, regulators, and consumers, too.

The way forward

Reducing low-value care in the private health system will require many measures but should start with more Government regulation of the medical technology industry. Australia needs a code of conduct authorised by the Australian Competition and Consumer Commission for the medical technology industry that aligns with the code of conduct for pharmaceutical companies, and company representatives should be banned from clinical areas (Table 1).

Australia also needs to invest in registries and studies of variation, with a commitment for these to be used to adjust payment paths, including the MBS, Pharmaceutical Benefits Scheme, PL and private health insurance funding, so taxpayers are not paying for low-value care. Critical independent adjudicators such as the MBS Review Advisory Committee and the Australian Commission for Quality and Safety in Healthcare should be given more funding to urgently address emerging problems. The cost would be quickly recovered by savings derived from deterring and disinvesting in low-value care.

Overall, the fee-per-item system will continue to be difficult for regulators to monitor without major reform. The Australian Government should consider a move to bundling benefits for medical implants and surgical supplies into the MBS item, which is the preferred benefit-setting method in most comparable economies.

With health expenditure rising unsustainably in Australia, we must step up efforts to address low-value care. In addition to harming consumers physically and psychologically, low-value care is harming our health system. It is wasting scarce resources that should be used for more timely and effective healthcare, it is driving higher out-of-pocket costs for consumers, and it is deflecting investments in public health and

Table 1. The inconsistent approach to regulating pharmaceuticals and medical devices in Australia.

	Pharmaceuticals	Medical devices
The Therapeutic Goods Administration makes sure products are safe for their indicated use	✓	✓
Products are only funded if they are used for the purpose for which they have been assessed	✓	✗
There is a code of conduct enforced by the Australian Competition and Consumer Commission to regulate behaviour of market participants	✓	✗
Prices are compared with international markets to ensure consumers do not pay too much	✓	✗
If competitors enter the market, consumers get a lower price	✓	✗
Sales representatives are prohibited from being in the room when the product is used or prescribed (consulting room, hospital or operating theatre)	✓	✗
Once a product is approved, it can only be used for the clinical indication it was approved for	✓	✗

social spending, both of which are known to contribute to better health and wellbeing.[14]

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