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Modernisation of Part B of the Prostheses List - Consultation Paper 2(a)

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About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We collectively represent 97% of people covered by private health insurance. PHA member funds today provide healthcare benefits for over 14 million Australians.

Introduction

There has been a large and rapid shift in practice in Australia over the last five years, where more patients are receiving higher volume of human tissue in surgery. The evidence base for this rapid change is lacking, and there are no quality assurance mechanisms to determine if this change is in the best interests of patients.

The use of human tissue products in Australia is not subject to the normal rules in Australia requiring demonstration of quality, effectiveness and efficiency for products placed in the bodies of patients. While the Prostheses List processes have significant flaws, there is at least an attempt to demonstrate that products listed have a consumer benefit.

There is no sound rationale for human tissue products to be treated differently. Human tissue products demonstrate safety through the Therapeutic Goods Administration processes, but they are currently exempt from demonstrating efficacy or efficiency through the Prostheses List.

This is particularly concerning given the massive increases in the use of some of these products over the past five years.

Table 1: Part B Prostheses list data[1]

	2020-21 cost (est)	Five year growth in volume (est)	Five year growth in cost (est)
01 - Cardio-thoracic (Part B Human Tissue)	$440,000	-5.4%	29.2%
02 - Ophthalmic (Part B Human Tissue)	$3,850,000	13.9%	36.9%
03 - Orthopaedic (Part B Human Tissue)	$64,300,000	158.8%	245.1%
04 - Dermatologic (Part B Human Tissue)	$9,430,000	8.2%	61.5%

The dearth of quality research into the use and effectiveness of human tissue products does not accord with the increase in utilisation. The research generally supports autogenous bone graft is the gold standard bone graft material[2], so the significant growth in utilisation of allogenous bone graft material is concerning as it suggests a deviation from highest quality care.

The amount of human tissue product being used per patient has also increased rapidly. For products with multiple sizes, funds are reporting a very large shift towards larger sizes being used in surgery over a short period of time. This is reflected in the table above, with the increases in costs outstripping the increases in volume.

Australia lacks a registry or similar mechanisms to track the quality and effectiveness of autogenous and allogenous human tissue products, or indeed animal-derived or synthetic bone graft materials.

[1] From HCP1 data. Figures are extrapolated from 88.3% complete data set, December 2021, with dollar figures rounded down

[2] Sohn, HS., Oh, JK. Review of bone graft and bone substitutes with an emphasis on fracture surgeries. *Biomater Res* **23,** 9 (2019). https://doi.org/10.1186/s40824-019-0157-y

Such quality assurance mechanisms would help improve patient care by being able to compare methodologies, costs and benefits.

The value of human tissue on the Prostheses List has not been considered by a health technology assessment (HTA) process. The massive growth in utilisation and cost demands that Australian consumers are protected by an HTA framework to determine value. The price of human tissue products on the Prostheses List has traditionally been set with an eye to tissue bank viability. The significant growth of suppliers relying on overseas product, with the cost of supply into Australia set at the Prostheses List price, suggests that economies of scale are not being realised by Australian consumers.

There is consideration benefit in aligning the assessment of human tissue products on the Prostheses List with other products. The focus should be on consumer safety, efficacy, efficiency and quality. The best possible evidence should be used, and where data are lacking, the Australian Government should consider establishing a registry to consider patient outcomes.

Response to the discussion paper proposals

Proposal: That the PL Guide should clarify whether autologous products are eligible for listing and, if ineligible, that skull flaps and an autologous femoral head are removed from the list.

Agreed.

Proposal: That further work is undertaken to develop guidance on an ethical framework for human tissue and human tissue products used for medical treatment, possibly in consultation with the NHMRC.

Agreed. The massive increase in the use of human tissue products in Australia, much of which is being sourced overseas, demands a more robust approach to ethics on harvesting, pricing, and who profits from the trade in human tissue both domestically and internationally. It seems clear that some sponsors are sourcing most of their product overseas, and the landed price matches the listed PL price. This may mean profits are being 'off-shored' by other companies.

Financial incentives that promote the use of allogenous bone graft products over the gold standard autogenous materials are seriously problematic.

Proposal: That the number and nature of ARTG listings for human tissue products is discussed with the TGA to explore the feasibility of greater specificity of ARTG listings for these products.

Agreed. The current nature of ARTG listings means there is no guidance for clinicians on safety and efficacy. Private health insurers have observed significant changes in the use of human tissue products in recent years, with a very sketchy evidence base.

Proposal: That the application and assessment pathways for human tissue products mirror the three proposed application and assessment pathways (i.e., Abbreviated, Focused HTA, and Full HTA) for medical devices.

Agreed. There is no reasonable argument that human tissue products should have lesser standards for quality, efficacy, efficiency and safety.

Proposal: That advice is sought from the TGA regarding whether a Class 3 biological has an equivalent risk level to a Class 3 medical device.

Agreed.

Proposal: That Part B products undergoing HTA assessment have an agreed list of appropriate MBS items assigned to them to enable their use to be restricted to specific clinical indications.

Agreed. This may require the orthopaedic category to be split into differing areas, such as spine, knee, hip and other. There would be value in being able to track where in the body these products are being used.

Proposal: That there is a clear understanding of the nature of the assessments undertaken by the TGA for different groupings of tissue products, before the Abbreviated Pathway is used to determine Benefits for tissue products

Agreed. Advice from the TGA on the risk levels of Class III biologicals compared to Class III medical devices (which will not be eligible for the proposed abbreviated pathway) will help inform this decision.

Conclusion

There has been a large shift in the use of human tissue products in Australia over the last five years. This change is clinical practice should trigger a discussion among clinicians, providers, policy makers and funders as to the best way to ensure patient benefit.

The use of human tissue products or other bone graft substitutes instead of allograft has ethical, practical and quality issues that need to be considered when reforming Part B of the Prostheses List. The minimum is to ensure that human tissue products are assessed on the same basis as mechanical devices implanted in the body. However, this area of practice would benefit from a more structured approach to determine the costs and benefits to Australian patients, and to provide guidance on the best use of human tissue to ensure quality, efficacy, efficiency and safety.

Attachment: changes in the human tissue market in Australia