

BUDGET IMPACT ASSESSMENT OF KNEE ORTHOSES FUNDING IN PATIENTS WITH OSTEOARTHRITIS OF THE KNEE CONSIDERING TOTAL KNEE RECONSTRUCTIVE SURGERY A PRIVATE AUSTRALIAN PAYER PERSPECTIVE

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BACKGROUND: Osteoarthritis (OA) of the knee is a common degenerative condition which is characterised by pain, stiffness, reduced motion, crepitus, swelling and other symptoms which may lead to reduced ability to carry out activities of daily living (such as walking distance and ability to climb stairs), increased emotional distress (such as anxiety and depression), and reduced quality of relationships (1-4).

Unfortunately, the widespread prevalence of COVID-19 has disrupted the capacity for hospitals to undertake elective surgeries such as total knee replacement (TKR) (5,6). A low-cost pre-operative clinical management approach to help improve patient's mobility and symptoms while reducing the burden on elective surgery wait lists may come in the form of appropriate knee braces (7-13).

OBJECTIVE: The purpose of this study was to determine the budget/financial impact associated with funding of knee orthoses for patients with end-stage OA of the knee (i.e., those awaiting TKR) from an Australian private health insurance (PHI) payer perspective.

METHODS: The ISPOR Principles of Good Practice were used to guide the budget impact analysis (BIA) (14). A literature review of electronic databases and web-based searches were used to inform analysis inputs on delayed TKR and other clinical benefits of knee orthoses. The review identified a UK study by Lee et al. (2017) which prospectively followed 63 consecutive patients with end-stage OA of the knee awaiting TKR for up to 8 years (12). Patients in this study delayed TKR for a mean period of 26 months by wearing a knee orthosis. In our BIA, this was rounded down to a conservative 24-month delayed TKR. In addition, to account for uncertainty, the proportion of patients benefiting from delayed TKR (i.e., responders) was halved to only 50% of the eligible population. Scenario analyses were used to test the break-even response-rate. The utilisation of TKR (sourced from Australian Medical Benefits Schedule statistics) was projected over a 5-year time horizon (2023 to 2027) (22). The clinically eligible (i.e., target) population only included patients who may be suitable for delayed surgery. This was estimated based on the proportion of patients with OA of the knee in a large US cohort study deemed to have had TKR prematurely (26% of N=8,002) (15). In a joint report by the Australian Institute of Health Innovation (AIHI) and National Health and Medical Research Council (NHRMC) Partnership Centre for Health Sustainability, it was noted that this figure may be even higher – closer to 30% – in Australia (6). The cost of TKR (\$18,466.66) was based on Australian hospital separation data (16). All costs are in Australian Dollars (AUD).

FINDINGS: Several studies identified in our search showed unloading knee braces improved symptoms, mobility, and delayed the need for TKR (7-12, 17, 18).

The BIA results are presented in **Figure 1**. The eligible population over 5 years was expected to include over 36,000 patients. In these patients, the base case resulted in over 18,000 delayed TKRs and a cost-saving of \$122 to \$126 million (when applying a \$395 and \$500 device cost, respectively) over the same period.

Given the base-case only captured 50% of expected responders, alternative scenarios were also examined (see **Figure 2**). By increasing response to 90% of eligible patients, cost-savings increased to approximately \$230 million. The program was estimated to break-even if as little as 6.5% of the eligible population achieved a delayed TKR of 24 months.



FIGURE:
THUASNE™
ACTION
RELIEVER KNEE
ORTHOSIS

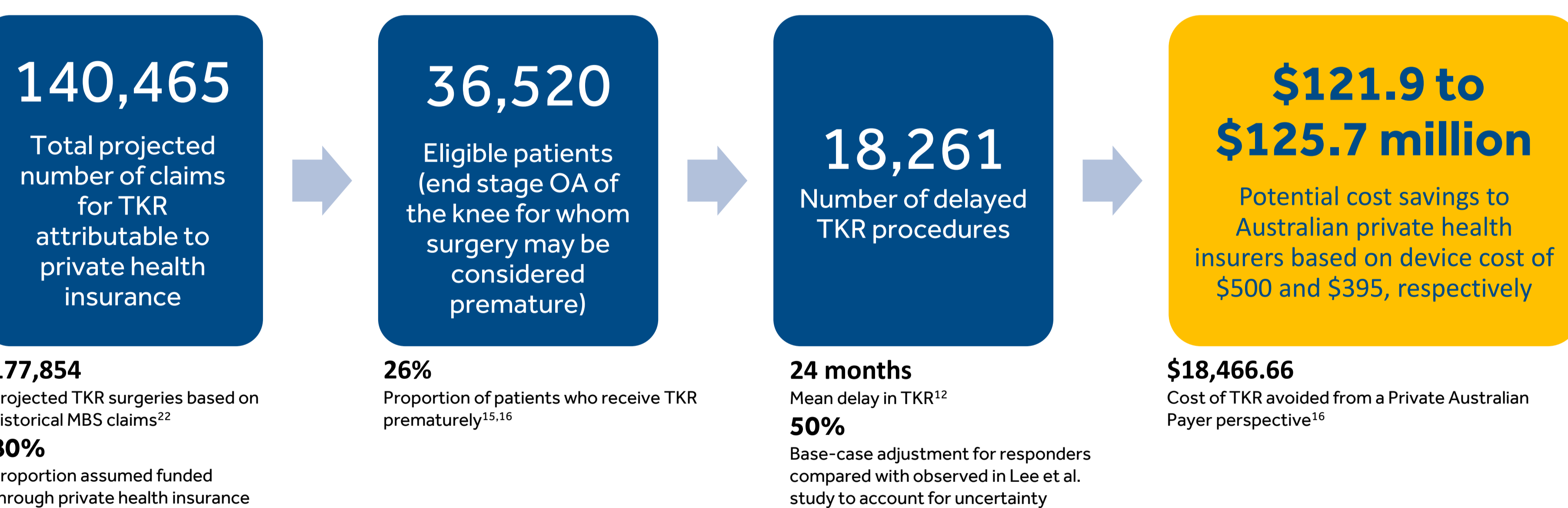


FIGURE 1: KNEE ORTHOSES BUDGET IMPACT ANALYSIS RESULTS OVER 5-YEAR PERIOD (2023 - 2027)

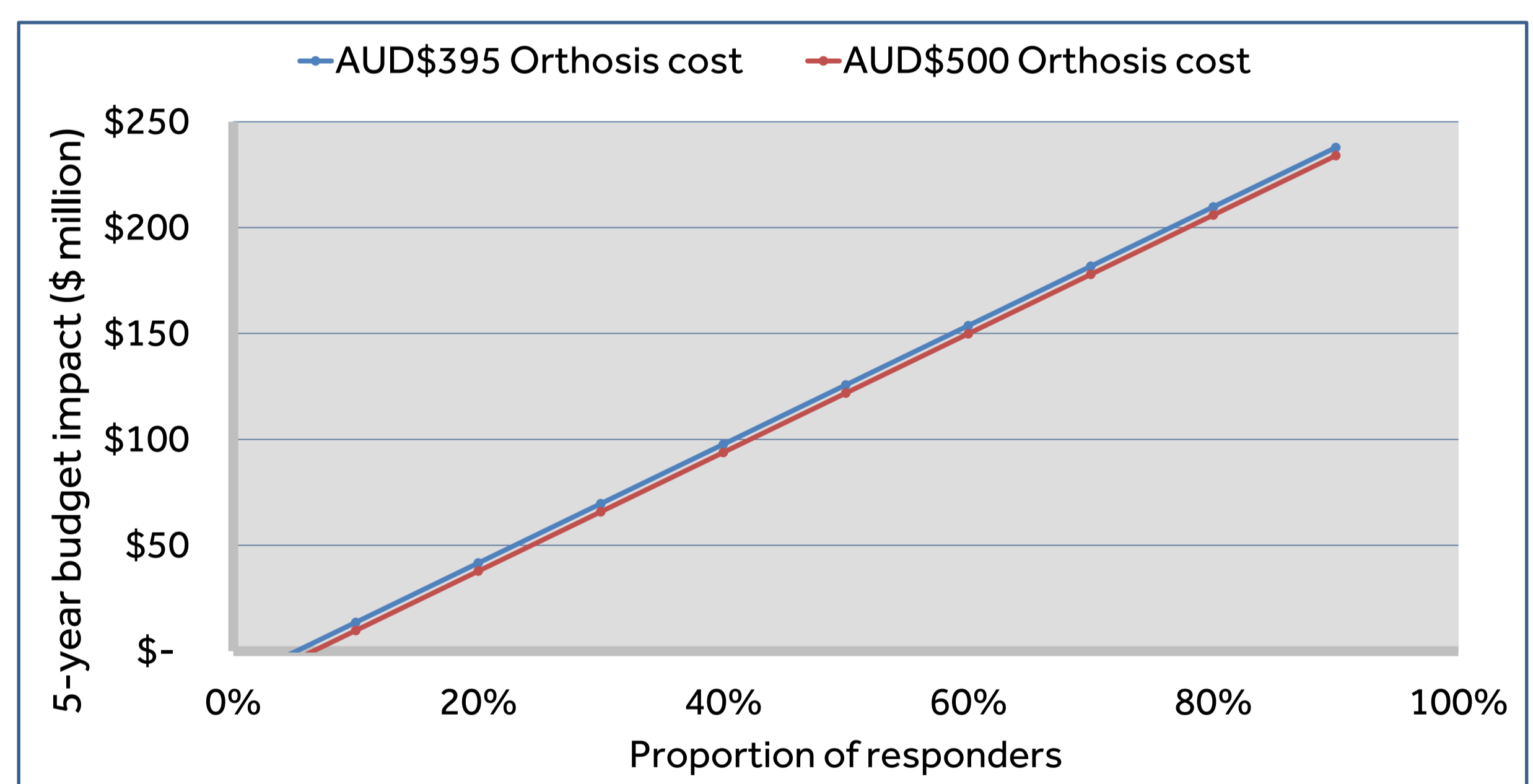


FIGURE 2: SCENARIO AND BREAK-EVEN ANALYSIS

DISCUSSION

CLINICAL AND FINANCIAL BENEFIT The findings of this evidence review and BIA from an Australian PHI payer perspective highlights clear clinical, and financial incentives for Australian PHIs to fund and actively promote the use of knee orthoses in eligible patients with end-stage knee OA. As indicated by the conservative base-case inputs and results from the break-even analysis, the overall cost-saving position is potentially substantial and robust to extreme market assumptions.

WHY IS THIS IMPORTANT Severe OA of the knee can be debilitating for patients and take a substantial emotional toll on patients and their caregivers (1-4). The Australian Orthopaedic Association National Joint Replacement Registry recorded 62,000 knee replacements in 2020. Increasing demand and reduced capacity for elective surgeries due to COVID-19 have increased the average wait-time substantially (21). A national report by the AIHI and NHRMC Partnership Centre for Health Sustainability identified that premature knee replacement surgeries (up to 30% of all TKR procedures) present a low-value and high-cost – burden on the health system and should be delayed to reduce surgical waste and wait-list pressures (6). These patients present an important unmet need for treatments other than surgery.

KNEE ORTHOSES The specifications of appropriate knee orthoses will ultimately be determined by the treating clinician, physiotherapist, orthotist or other qualified health professional and be based on the patient's needs. It would be expected that the chosen brace would provide structural integrity and unload the joint in order to provide functional benefit and delay TKR. Unloader orthosis specifications may include a 3-point leverage system with inelastic straps to provide alignment support and offloading of the affected knee. These devices, such as the Thuasne™ Action Reliever have published evidence on improvements in pain-free walk distance, pain during exercise, and the lequesne index score ($P < 0.005$) (19,20).

CONCLUSION: Improving market access through PHI-funded knee orthoses may offer clinical benefits to patients, reduce demand on surgical wait lists, and substantial cost savings for private health insurers.