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ORIGINAL ARTICLE

Is semaglutide cost-effective at closing the gap for Aboriginal and Torres Strait Islander Australians with cardiovascular disease and obesity without type 2 diabetes?

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Key words
cardiovascular disease, obesity, Aboriginal and Torres Strait Islander, prevention, economic analysis, semaglutide.

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Abstract

Background: Aboriginal and Torres Strait Islander Australians experience worse healthcare outcomes due to increased prevalence of cardiovascular disease (CVD). A large proportion of this is preventable if CVD risk factors, such as obesity, are effectively treated. In the SELECT (Semaglutide Effects on Cardiovascular Outcomes in People With Overweight or Obesity) trial, the use of semaglutide for patients with CVD and obesity without type 2 diabetes (T2D) significantly reduced the prevalence of CVD.
Aim: To determine the cost–benefit to the Australian healthcare system of funding early-access semaglutide for treating Aboriginal and Torres Strait Islander Australians with CVD and obesity without T2D.
Methods: A Markov cohort state-transition model was annually cycled for 25 years. The population was Aboriginal and Torres Strait Islander Australians with CVD and obesity without T2D. They received either semaglutide or standard care. Transition probabilities, utilities, costs and discounting were literature-derived. The incremental cost-effectiveness ratio (ICER) was our primary outcome. Disability-adjusted life-years (DALYs) and fatal and non-fatal CVD events prevented were secondary outcomes. Sensitivity analysis for various scenarios was performed.
Results: In the estimated 13 650 Aboriginal and Torres Strait Islander Australians with CVD and obesity without T2D, semaglutide was modelled to prevent an additional 929 fatal CVD events, 13 480 non-fatal CVD events and 8628 DALYs over 25 years at an additional cost to the Australian government of $25 956 522/year (<0.2% of annual CVD expenditure). The ICER was $75 206/DALYs.
Conclusion: A strategy of early-access funding and use of semaglutide for Aboriginal and Torres Strait Islander Australians with CVD and obesity without T2D may be cost-effective to the Australian healthcare system while closing the gap in healthcare disparities.

Introduction

Aboriginal and Torres Strait Islander Australians unfortunately experience worse healthcare outcomes compared to non-Indigenous Australians.[1] Cardiovascular disease (CVD) significantly impacts the health outcomes of Aboriginal and Torres Strait Islander Australians, contributing to 21% of the life expectancy gap, which remains at 10 years despite efforts to close it.[1] Addressing CVD through the modification of risk factors is crucial to improving healthcare outcomes and equity for this high-risk, disproportionately affected population.[2]

Obesity as a cause of CVD and all-cause mortality is well-known.[3] Among Aboriginal and Torres Strait Islander Australians, obesity is the second most prevalent modifiable

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CVD risk factor, after smoking, in its contribution to the health gap. In this population, 71% of adults are overweight or obese, accounting for 530 preventable deaths and 13 954 years of life prematurely lost in 2018 alone.[4]

Global cardiovascular guidelines unanimously call for weight reduction to reduce CVD risk.[5] While patient education, behavioural modification and lifestyle interventions focussed on improving diet and exercise are crucial, these alone have not been able to adequately reduce the disease burden. Furthermore, medications such as orlistat or duromine have significant side effect profiles causing intolerance. Moreover, while bariatric surgery is becoming safer and more accessible, it still fundamentally remains invasive, costly and confers risk. A novel approach is required for the Australian government to achieve their goal of closing the life expectancy gap by 2031.[6]

Semaglutide, a glucagon-like peptide-1 receptor agonist, stimulates increased insulin secretion, glucagon release inhibition, hepatic gluconeogenesis suppression, gastric emptying delay and appetite reduction with subsequent reduced caloric intake.[7] In meta-analyses, they significantly reduce not only obesity but also type 2 diabetes (T2D), hypertension and hypercholesterolaemia; all modifiable CVD risk factors.[8] The recent SELECT (Semaglutide Effects on Cardiovascular Outcomes in People With Overweight or Obesity) trial confirmed these findings, with over 8000 patients with CVD and obesity but without T2D receiving semaglutide demonstrating a 20% reduction in major adverse cardiovascular events (MACE) irrespective of diabetic status.[7]

Semaglutide may offer a novel approach to reducing the CVD burden faced by Aboriginal and Torres Strait Islander Australians with CVD and obesity without T2D. However, while approved by the Australian Therapeutic Goods Association (TGA), its subsidisation by the Australian government based on the recommendation of the Pharmaceutical Benefits Advisory Committee (PBAC), is limited to patients with T2D only (Table 1).

Through healthcare economic modelling driven by best available data, we sought to determine whether a novel strategy of prescribing semaglutide for Aboriginal and Torres Strait Islander Australians with CVD and obesity but without T2D was cost-effective to the Australian healthcare system. And, if so, how much of the CVD burden could be reduced and therefore how much of the healthcare gap could be closed.

Table 1 Criteria for semaglutide – both current and proposed

Current PBS indications for semaglutide	Our proposed strategy for semaglutide
Type 2 diabetes AND In combination with one of, or having inadequately responded to; metformin, sulfonylurea or insulin AND No clinically meaningful glycaemic response to an SGLT2 inhibitor OR contraindication/intolerance to same AND Cannot be using an SGLT2 inhibitor, a DPP4 inhibitor or another GLP-1RA	Aboriginal and Torres Strait Islander Australian AND diagnosed with atherosclerotic CVD AND body mass index >27 kg/m^2

CVD, cardiovascular disease; DPP4, Dipeptidyl Peptidase-4; GLP-1RA, Glucagon-like peptide-1 receptor agonist; PBS, Pharmaceutical Benefits Scheme; SGLT2, Sodium-glucose cotransporter-2.

Methods

Setting and design

Team members, including Indigenous liaison officers, from the better cardiac care and Aboriginal and Torres Strait Islander Australians Cardiology outreach teams from Cairns Hospital were consulted on, and collaborated in, the study design. One of our co-authors is a proud Iamalaig and Kaantju woman working in the National Centre for Aboriginal and Torres Strait Islander Wellbeing Research at the Australian National University. Ethics approval was provided by the James Cook University Higher Research Ethics Committee, with further approval from the Aboriginal and Torres Strait Islander Ethics subcommittee (24H-9669).

A cohort of Aboriginal and Torres Strait Islander Australians with CVD and obesity without T2D, taken from Australian government secondary epidemiological data sources, were included. A continuous-time Markov cohort state-transition model was built using Microsoft Excel (Microsoft Corporation, USA) (Appendix S1). The intervention was semaglutide. The comparator was standard guideline-directed care consisting, predominantly, of diet and lifestyle recommendations. The outcomes were no event, fatal CVD event, non-fatal CVD event or fatal-other event. The time-cycle occurred annually for 25 years (the difference between average Aboriginal and Torres Strait Islander Australian life expectancy and first CVD event). The population, defined in Table 2, was Aboriginal and Torres Strait Islander Australians with CVD and obesity. The primary outcome was the ICER. The ICER estimates the cost-effectiveness of an intervention by taking the difference in effect of an intervention and the difference in cost of an intervention and dividing the two to provide the average incremental cost associated with benefit. Our ICER reflected cost per

Table 2 Estimated annual burden of CVD attributed to obesity in Aboriginal and Torres Strait Islander Australians with CVD

Cohort	Number of at-risk	CVD-related hospitalisations	CVD-related deaths	CVD-related DALYs	Annual CVD healthcare costs (AU$)
Aboriginal and Torres Strait Islander Australians with CVD	42 000	17 275	1150	24 612	$424 800 000
Aboriginal and Torres Strait Islander Australians with CVD attributable to Obesity	13 650	5614	374	7999	$138 060 000

CVD, cardiovascular disease; DALY, disability-adjusted life-year.

disability-adjusted life-year (DALY) prevented. The secondary outcomes were death, disability and healthcare cost prevented. Proposed health states and transitions (Fig. 1) are defined in the following section. The perspective taken was that of the Australian Healthcare system.

Transition probabilities – intervention arm

Transition probabilities for the group modelled to receive semaglutide were taken from the SELECT trial (Appendix S1). This multicentre, double-blind, randomised, placebo-controlled, event-driven superiority trial enrolled 17 604 patients who had CVD and were obese (defined as having a body mass index >27 kg/m^2). Compared to placebo, the interventional arm receiving semaglutide for obesity had significantly fewer MACE (hazard ratio, 0.80; 95% confidence interval, 0.72–0.90; $P < 0.001$) during the 3 years of trial time.[7]

Transition probabilities – comparator arm

Out of the total Aboriginal and Torres Strait Islander Australian population of 812 728,[9] approximately 42 000 individuals have CVD. This contributes to 17 275 hospitalisations, 1150 deaths, 24 612 DALYs lost and 3.6% of the total $11.8 billion Australian CVD healthcare expenditure ($424 800 000). The Australian Institute of Health and Welfare (AIHW) has calculated that 32.5% of CVD cases in this population are attributable to obesity (Table 2).[4] The baseline population entering the model was the 13 650 at risk. The baseline MACE consisted of the 374 fatal events annually and the 5614 CVD-related hospitalisations, as a proxy for non-fatal CVD events, as no data exist on this. The fatal other event rate reflected Aboriginal and Torres Strait Islander Australian mortality rates.[9]

Costs and discounting

Semaglutide costs AU$4175 per person per year.[10] CVD event costs were taken from Australian government disease-related diagnosis groups (DRGs) and mimic similar studies.[11] The Pharmaceutical Benefits Advisory Committee (PBAC) has no defined willingness-to-pay threshold (WTPT) as it assesses cost-effectiveness relative to other factors including clinical need and equity, although <AU$50 000/QALY WTPT is preferred, not prescriptive.[12] Discounting was standard 5% per annum.

Utilities

No data exist on health state utility for Aboriginal and Torres Strait Islander Australians with CVD. Hence, utilities were taken from VALIANT (Valsartan in Acute Myocardial Infarction Trial), a cohort with pre-existing CVD.[13] The baseline utility for those with CVD and no event was 0.80, and 0.70 for a recurrent non-fatal CVD event as used by similar Australian CVD cost-effectiveness studies. The utilities for fatal CVD event and fatal other event were 0.

Sensitivity analysis

Variations to semaglutide costs and duration of use, discount rate, utility values, calculations for the comparator arm and the intervention arm all underwent deterministic sensitivity analysis.

Model validation

The systematic reporting on validation efforts for our Markov model is presented via the Assessment of the Validation Status of Health-Economic decision models (AdViSHE) tool (Appendix S2).[14]

Results

25-Year Markov model

The addition of semaglutide to standard therapy in the target population saved an additional 929 lives, 13 480 CVD events and 8628 DALYs during the 25-year time horizon at an additional cost of $648 913 056 (or $25 956 522/year) to the Australian healthcare

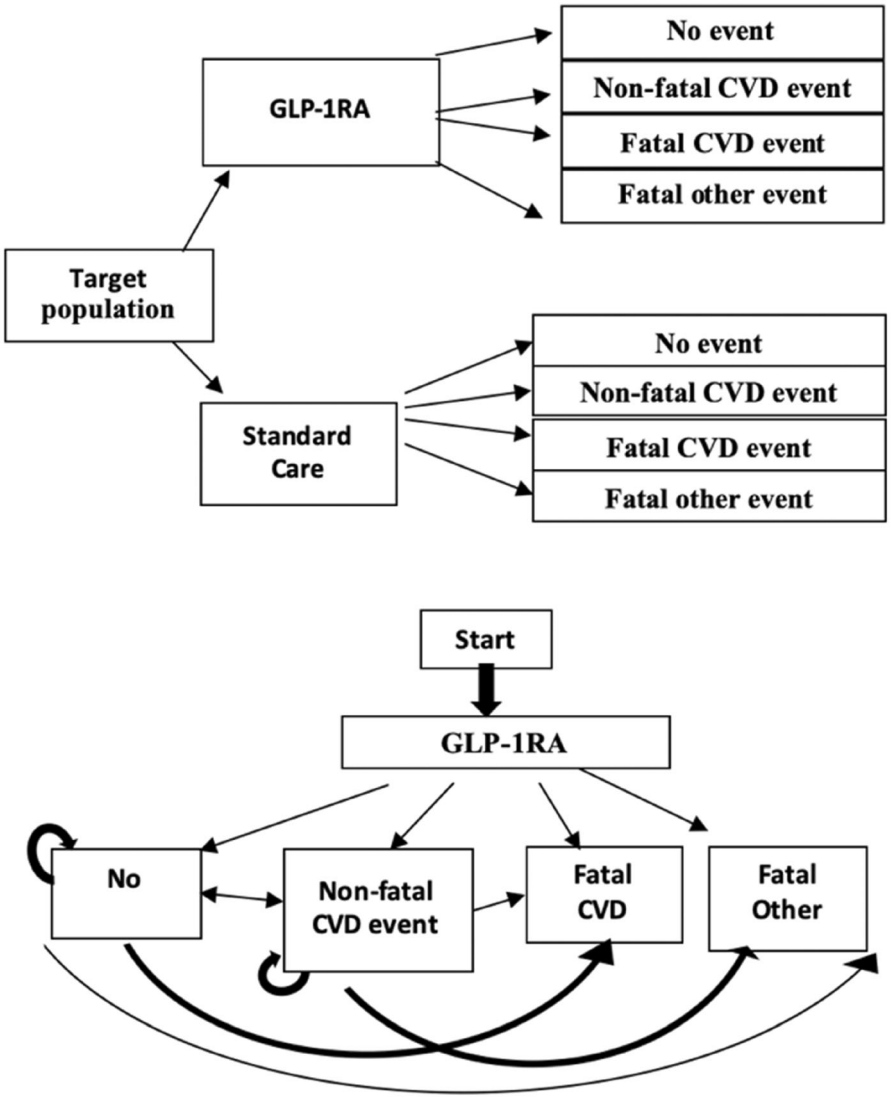

Figure 1 Proposed health states and transitions for Markov model. CVD, cardiovascular disease; GLP-1RA = semaglutide.

system. This represents approximately 0.2% of the total Australian government CVD expenditure for 2024.[4] The ICER was $75 206/DALY (Table 3).

Sensitivity analysis

Key assumptions were adjusted to determine their effects on the ICER (Appendix S3). The effect of semaglutide cost on the ICER was linear. Reducing cost linearly improved cost-effectiveness (Fig. 2). A cost reduction of 25% to approximately AU$3131 annually would be needed to cross a hypothetical WTPT of $50 000. Over the 25-year horizon, semaglutide was more cost-effective year on year with the 25th year delivering incrementally more benefit than the first. Funding this strategy would deliver an ICER under the $50 000 WTPT from the 24th year onwards (Fig. 3). Deriving more utility from the no event baseline population through use of semaglutide would improve the ICER twofold for every increment in utility gained. Deriving 5% more clinical efficacy would yield a 13.3% reduction in ICER. Event cost and discounting insignificantly affected the ICER.

Discussion

Implementing a novel strategy of funding early access and use of semaglutide for Aboriginal and Torres Strait

Table 3 End-of-Markov model results for semaglutide use in the target population (25 years)

Outcomes	Semaglutide and standard care	Standard care alone	Difference
Total non-fatal CVD events	67 937	81 417	(13 480)
Total fatal CVD events	4882	5811	(929)
Total DALYs	155 672	147 043	(8628)
Total cost (25 years)	$3 572 920 994	$2 924 007 939	$648 913 056 ($25 956 522/year)
Incremental cost-effectiveness ratio	—	—	$75 206
Cost to reach willingness-to-pay threshold	—	—	$3131 annually (25% cost reduction)

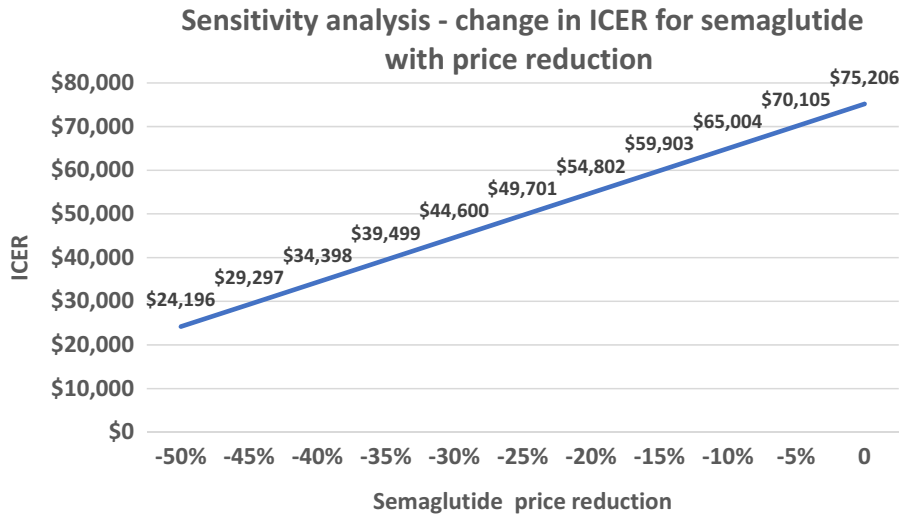

Figure 2 Sensitivity analysis – change in incremental cost-effectiveness ratio for semaglutide with price reduction. ICER, incremental cost-effectiveness ratio.

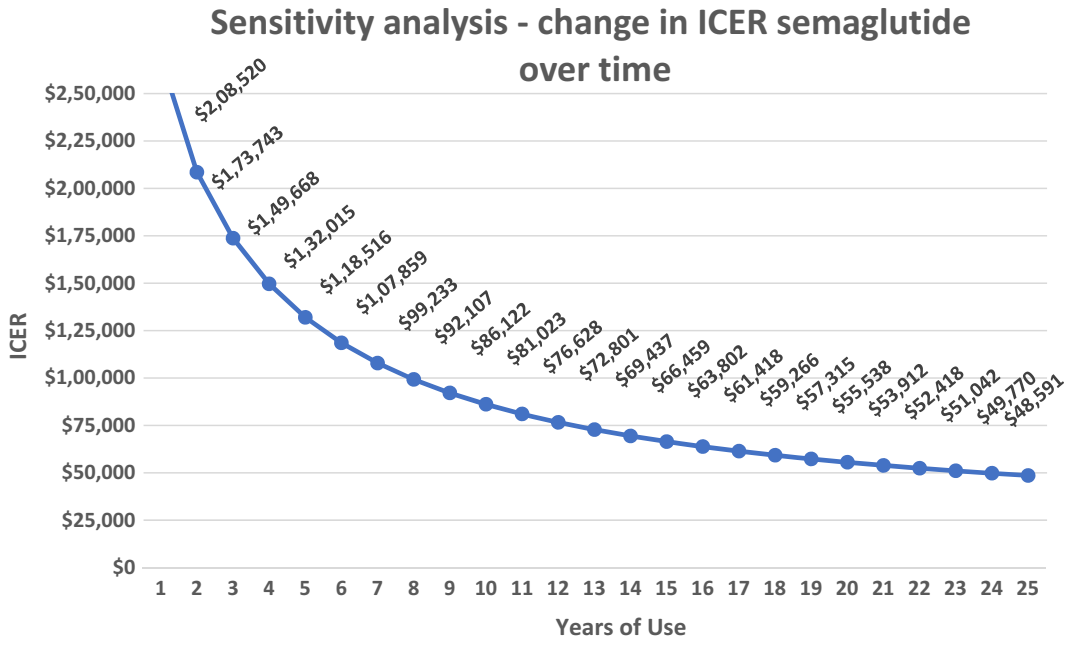

Figure 3 Sensitivity analysis – change in incremental cost-effectiveness ratio for semaglutide over time. ICER, incremental cost-effectiveness ratio.

Islander Australians with CVD and obesity may cost-effectively close the gap in healthcare outcomes while providing value to the Australian healthcare system.

For too long the disproportionate burden of CVD has impacted Aboriginal and Torres Strait Islander Australians. Current strategies to address this are not expected to meet the Australian government's promise to close the life expectancy gap between Aboriginal and Torres Strait Islander Australians and their non-Aboriginal and Torres Strait Islander Australian counterparts by 2031.[15] Something must change if this is to be achieved.

Earlier access to, and increased usage of, evidence-based medicines are a well-known strategy to prevent cardiovascular disease.[16] To provide but one example, a real-world study of an early-access strategy of dulaglutide for Māori and Pacific New Zealanders with T2D demonstrated a clear reduction in their health equity gap.[17] Meta-analyses of over 50 000 patients with obesity have demonstrated the safety, efficacy and potency of semaglutide in CVD prevention such that American College of Cardiology guidelines now recommend its use (class 2a).[18,19] For Australian clinicians to effect change for their patients, and reduce the national CVD burden, the Australian government should consider subsidisation of semaglutide via the Pharmaceuticals Benefit Scheme (PBS).

Australian healthcare resources are finite, however, and semaglutide is not cheap. While there are less expensive glucagon-like protein receptor 1 agonists such as liraglutide, for example, they were found to be less cost-effective, driven by less MACE reduction. Cost-effectiveness studies are thus required to assess whether the benefits of semaglutide use outweigh the costs to the Australian taxpayer. This is particularly important for the Australian context as few global studies have assessed the cost-effectiveness of semaglutide for obesity and CVD, with ICERs calculated as high as $443 000 USD per QALY gained.[20] One other Australian study by Zomer *et al.* estimated the ICER of semaglutide at $96 055.[10] They also used SELECT trial data and Markov modelling methodology, and used similar costs for semaglutide and for no event, fatal, non-fatal and fatal-other events. The key difference was the use of all Australians with CVD and obesity as the target population. Key recommendations to improve cost-effectiveness were either price reduction to <$2000 per person per year, or use in a higher-risk cohort of Australians.

Aboriginal and Torres Strait Islander Australians are a higher-risk cohort. Semaglutide use in this population reduced the ICER found in the Zomer *et al.* paper by 22%, offering a significantly more compelling cost-effectiveness argument. Although a $50 000/DALY WTPT is often quoted by the PBAC to recommend listing a medication on the PBS, unmet clinical need, disease severity, disease prevalence, budget impact and comparative effectiveness also influence decision-making.[21] We propose that Aboriginal and Torres Strait Islander Australians with CVD and obesity treated with semaglutide meet these additional criteria. The WTPT, therefore, should act as a guide, not a guideline, in this instance. Furthermore, the total budget impact is low at $25 956 522/year, representing approximately 0.2% of the total Australian government CVD expenditure for 2024.[22] Additionally, our figures do not encapsulate the estimated 43% reduction in insulin expenditure by the Australian government in people with diabetes due to semaglutide use.[23]

Our sensitivity analysis revealed that if there was only 5% more clinical efficacy to be gained from semaglutide use, the ICER would be reduced by 13.3%. Our ICER does not capture the additional benefits of semaglutide use in this population, namely, the reduction in hypertension, T2D and hypercholesterolaemia that not only contribute to the excess CVD burden but also contribute to the excess chronic renal and liver disease burden documented in Aboriginal and Torres Strait Islander Australians.[8,24] This is particularly important as favourable cost-effectiveness studies have been published for semaglutide use in patients with obesity alone even without considering any CVD prevention.[25] Furthermore, data demonstrate that reducing obesity causes a reduction in all-cause mortality. With all the above in mind, we would argue that our ICER very likely underestimates the true cost–benefit of our strategy to the Australian government, let alone the quality of life gained for our patients.

The robustness of our results was confirmed through various sensitivity analyses that tested our calculations under different assumptions. We showed that earlier initiation of semaglutide was associated with improved clinical outcomes, and the cost-effectiveness improved incrementally year-on-year. We also demonstrate that semaglutide's price reduction linearly improves cost-effectiveness. While the pharmaceutical industry is entitled to profit-making, they must balance this against their ethical responsibility for distributive justice to allow patient access to essential treatments.[26]

It is important to note that our novel strategy to close the gap is just one approach, and it alone may not fully address the healthcare burden and disparate outcomes faced by our Aboriginal and Torres Strait Islander Australian population. It is beyond the scope of our paper to provide a singular comprehensive solution. However, collaborating, consulting and co-designing

solutions with Aboriginal and Torres Strait Islander Australians to address structural inequities and inequalities in Australian healthcare and politics is a crucial step in the right direction (as has been demonstrated here).[27] More specifically for semaglutide use, a coordinated public health approach involving primary healthcare practitioners and allied health practitioners to assist with education and behavioural change, including improvements in diet and exercise, may augment outcomes.

This paper examines the potential of a novel approach to CVD prevention in Aboriginal and Torres Strait Islander Australians by treating obesity, a leading CVD risk factor. It estimates the cost-effectiveness of such a strategy, with various scenario sensitivity analysis performed to strengthen the validity of findings. However, Markov modelling does not account for the complexity of reality, and its memoryless characteristic may not reflect true risks or benefit. Our modelling is hindered by limited data for CVD incidence, utility and semaglutide use for Aboriginal and Torres Strait Islander Australians with CVD and obesity without T2D. Furthermore, the additional value of reducing risk factors that cause excess chronic disease, and reducing all-cause mortality, have not been modelled. Lastly, the SELECT trial conditions and populations may not mimic real-world conditions or be completely generalisable to our population, and there are no outcomes data for 25 years of semaglutide use.

Conclusions

Implementing a novel strategy of early access to semaglutide for Aboriginal and Torres Strait Islander Australians with CVD and obesity without T2D may be cost-effective for the Australian healthcare system, while also helping close the gap in healthcare disparities and improving outcomes.

Acknowledgements

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Supporting Information

Additional supporting information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Data, formulas and methodologies used to construct the Markov model.
Appendix S2. Assessment of the validation status of health-economic decision models.
Appendix S3. Sensitivity analysis data.