

Response

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Yes, I consent to my identified submission being published

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What is your name?
Taryn Black

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Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice
Patient or consumer (or representative organisation),Clinician (or representative organisation),University or research sector,Industry association / Peak body

8.1
What is the name of your organisation? - My organisation is called: - Text
The Australian Diabetes Alliance, which includes Diabetes Australia, the Australian Diabetes Educators Association, the Australian Diabetes Society, JDRF Australia, the Australasian Diabetes in Pregnancy Society, and the Australian and New Zealand Society for Paediatric Endocrinology and Diabetes.

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Are you making feedback on behalf of your organisation?
Your organisation

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Please select which chapter/s you would like to provide feedback on. You may provide feedback on as many or few chapters as you wish.
1. Transparency, communication, and stakeholder involvement in HTA,2. Health technology funding and assessment pathways,3. Methods for HTA for Australian government subsidy (technical methods),4. Health technology funding and purchasing approaches and managing uncertainty,5. Futureproofing Australia's systems and processes

14
Please select the topics within the chapter(s) you would like to provide feedback on. 1. Transparency, communication and stakeholder involvement in HTA
1.1. Transparency and communication of HTA pathways, processes and decisions,1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA,1.3. First Nations people involvement and consideration in HTA

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Please select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment pathways
2.1. Streamlining and aligning HTA pathways and advisory committees

16
Please select the topics within the chapter(s) you would like to provide feedback on. 3. Methods for HTA for Australian government subsidy (technical methods)
3.2. Clinical Evaluation Methods

17
Please select the topics within the chapter(s) you would like to provide feedback on. 4. Health Technology funding and purchasing mechanisms and decisions
4.1. Approaches to funding or purchasing new health technologies,4.3. Understanding the performance of health technologies in practice

18
Please select the topics within the chapter(s) you would like to provide feedback on. 5. Futureproofing our systems and processes
5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system,5.3. Consideration of environmental impacts in the HTA,5.6. Strengthen international partnerships and work-sharing

21
Taking all Options within this section: 1.1. Transparency, communication and stakeholder involvement in HTA into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
Address some but not most of the issue(s)

23.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries
Positive

23.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improvements to the HTA webpage including development of a dashboard
Neutral

27
Taking all Options within this section: 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
Mostly address the issue(s)

28
If you would like to expand on your answer above you can do so below:
A key concern is the opaque understanding of the value of stakeholders' evidence, including evidence from consumers and their representative groups. In many cases, the questions in HTA require a scientific and/or medical assessment based on scientific and medical evidence, and potentially health economic evidence. To what extent can (and should) the views of other organisations contribute to this decision-making? Until this question is clarified and communicated, it is difficult to understand the value of our participation in these processes, and what tools should be used to make the pathways, processes and decisions more transparent. We would encourage greater stakeholder engagement (with health providers such as CDEs and endocrinologists as well as people living with diabetes and consumer groups) to ensure the feedback into the decision making process is robust and comprehensive.

29.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework
Positive

29.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence
Very positive

33
Taking all Options within this section: 1.3. First Nations people involvement and consideration in HTA into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
Don't know

34
If you would like to expand on your answer above you can do so below:
Consistent with the Australian Diabetes Alliance's commitment to reconciliation and closing the gap, we believe this question is best addressed by First Nations peoples and organisations.

35.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - First Nations peoples partnership in decision making
Don't know

35.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Dedicated resource for HTA submissions and education
Don't know

46
Taking all Options within this section: 2.1. Streamlining and aligning HTA pathways and advisory committees into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
Don't know

47
If you would like to expand on your answer above you can do so below:
It is not clear that any of these options will address issues that affect access to diabetes technology. We recognises the need to address issues including timeliness, streamlining, and approvals that recognize the rapid evolution of these technologies and their impact on diabetes care and management. There should be clear, transparent pathways for the approval and reimbursement of diabetes technologies, and for access and coverage to CDEs - professional support for helping people initiate onto and adjust to using diabetes technologies. It is essential for these processes to be agile enough to keep pace with technological advancements. We welcome a "technology agnostic" approach, given the barriers between "medicines" and "devices" are more permeable as novel technologies emerge. The Diabetes Alliance is supportive of every person with diabetes having access to the diabetes technologies most suited to them, to manage their diabetes well. However, a "super committee" (potentially with a medicines subcommittee and/or a pharmacy subcommittee) will not necessarily streamline and align pathways " again, this is a question of the effective implementation of any reforms, and the new committee(s) improving their practices (and being properly resourced to realise these improvements). Technological advancements are moving at a rapid pace. Any new committee would need to be nimble enough to address unforeseen future developments.

48.4
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Unified HTA pathway for all health technologies with Commonwealth funding
Very positive

62
If you would like to expand on your answer above you can do so below -Unified HTA pathway for all health technologies with Commonwealth funding
Globally, new therapies, medicines and technologies are being developed at a faster pace than every before. This is particularly true in diabetes. The pace of change is placing a higher burden on Australia's regulatory systems . Our approvals and reimbursement framework must keep pace with these changes.

There are a range of novel diabetes technologies currently available internationally that do not fit into the existing HTA policy and methods. These include interoperative or combined insulin pump and CGM systems, smart insulin pens, new forms of insulin and bionic pancreases.
A key area of advancement is interoperability between insulin pumps and CGM systems. This is often referred to as close loop technology. This is the gold standard of care for people living with type 1 diabetes. The current HTA policy and methods are not suitable for considering hybrid systems that incorporate technology currently assessed in different categories. Any changes to the HTA policy and methods should ensure it can accommodate technologies that fall outside rigid categories.

The bionic pancreas is technology similar to interoperable insulin pump and CGM systems. There is currently no pathway for approval or reimbursement of this advanced technology.

New smart insulin pens connected to glucose monitoring devices that can calculate insulin dosage are currently available in some countries. This is another example of a technology whose components span different categories.

84
Taking all Options within this section: 3.2. Clinical Evaluation Methods into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
Address some but not most of the issue(s)

86.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Overarching principles for adopting methods in Australian HTA
Positive

86.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Methods for the assessment of nonrandomised and observational evidence

Positive

86.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Methods for the assessment of surrogate endpoints

Positive

86.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Generate a curated list of methodologies that are preferred by decision-makers, in collaboration with evaluation groups and sponsors.

Positive

86.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Therapies that target biomarkers (e.g. tumour agnostic cancer therapies, therapies that target particular gene alterations)

Positive

86.7

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Pharmacogenomic technologies

Don't know

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If you would like to expand on your answer above you can do so below -Generate a curated list of methodologies that are preferred by decision-makers, in collaboration with evaluation groups and sponsors

Another area that will require future consideration is the clinical criteria used to assess technology. An HbA1c check, which measures an individual's average blood glucose levels has long been the gold standard. However, Time in Range (TIR), a measurement facilitated by CGM, is fast emerging as a key indicator of improved long-term outcomes. It refers to the percentage of time a person's blood glucose levels are in a target range over the course of a day. The more time spent in range, the lower the risk of diabetes-related complications. It also highlights the length of time a person spends in hypoglycaemia and hyperglycaemia or if there is considerable glycaemic variability (the degree to which a person's blood glucose levels fluctuate). It can also be a better measure of glucose levels over time than HbA1c where haemoglobin turnover is higher than expected. This may be particularly important in assessing fitness to drive or during pregnancy among ethnic groups with an increased risk of haemoglobinopathies. Additionally, a high-level of glycaemic variability is associated with an increased risk of diabetes-related complications.

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If you would like to expand on your answer above you can do so below -Investigate further options to address budget impact implications of high-cost/high impact health technologies

The pathways for approval and equitable access to new diabetes technology are unclear or non-existent. For instance, there was no pathway to access subsidised CGM. Instead, access was achieved through successful political advocacy by the diabetes sector.

Consequently, subsidised access to this technology is currently restricted to people living with type 1 diabetes despite an emerging body of evidence showing improved physical and mental health outcomes among people living with type 2 diabetes using multiple daily injections of insulin to manage the condition. In addition, patients with type 2 diabetes during pregnancy are also ineligible for subsidised access to insulin pumps or CGM despite often needing high insulin doses administered via a pen.

Insulin pumps are another clinically proven, long-established technology lacking clear equitable mechanisms for reimbursement. There are two current pathways to accessing subsidised insulin pumps. The first is the Federal Government's Insulin Pump Program, which provides fully subsidised access to a limited cohort of children and young people aged 0 to 21 years (up to 230 people) if they meet financial and medical criteria. Only 1.4% of young people can access insulin pumps via this pathway.

The second is private health insurance (PHI), however pumps are only required to be offered under premium plans. The Diabetes Alliance does not believe insulin pumps have been correctly categorised.

123.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Oversight " reforms to optimise access to and use of RWD in HTA

Don't know

123.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop a strategic approach to increase confidence, awareness, and acceptance of cross-jurisdictional and cross-sectoral RWD access and use in HTA

Positive

123.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Data infrastructure

Positive

123.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Methods development

Positive

123.5

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop Guidance framework

Positive

123.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Collection of utilisation and outcome data for provisionally listed health technologies

Positive

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If you would like to expand on your answer above you can do so below -Methods development

It is critical that tools to measure the performance of health technologies in practice are fit for purpose.

By way of example, a recent Canadian study found that existing standardised questionnaires do not adequately capture patient-reported outcomes of greatest importance for those living with T1D in pregnancy. (Gu J, Chaput KH, Dunlop A, Booth J, Feig DS, Donovan LE. Existing standardised questionnaires do not adequately capture quality-of-life outcomes of greatest importance for those living with type 1 diabetes in pregnancy. Diabet Med. 2023 Apr;40(4):e15044. doi: 10.1111/dme.15044. Epub 2023 Feb 3. PMID: 36683387). That study recommended future research assessing the impact of therapies on quality-of-life measures in T1D pregnancies should quantify their influence on day-to-day activities, adjust measures of sleep quality and capture fear of hyperglycaemia in pregnancy and hypoglycaemia postpartum. Fear of hyperglycaemia can increase the risk of managing glycaemia at levels increasing the risk of hypoglycaemia (and in pregnancy fetal undernutrition)and conversely, fear of hypoglycaemia can increase the risk of managing glycaemia at levels increasing the risk of long term complications and in pregnancy harm the offspring through macrosomia, stillbirth and long-term risks of obesity.

It is critical that the right methods and tools are used to understand the performance of healthcare technologies in practice.

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Taking all Options within this section: 5.6. Strengthen international partnerships and work-sharing into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Mostly address the issue(s)

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If you would like to expand on your answer above you can do so below:

The Australian diabetes community expresses frustration that technologies available in other jurisdictions lags in Australia. While this is often a consequence of commercial decisions by industry, any effort that harmonises approvals with international best practice would be welcomed.