POSITION STATEMENT

EQUITABLE ACCESS TO DIABETES TECHNOLOGY

UNITE IN THE FIGHT FOR CHANGE.

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Contents

Diabetes Australia acknowledges the Traditional Owners of the lands on which we live and work. We recognise their connection to land, waters and culture. We pay the utmost respect to them, their cultures and to their Elders past and present. We recognise that Australia is made up of hundreds of different Aboriginal and Torres Strait Islander peoples, each with their own culture, language and belief systems. Their relationship with country remains of utmost importance as it is the foundation for culture, family and kinships, song lines and languages.

Group Chief Executive Officer introduction

Australians living with all types of diabetes should have equitable access to the technology they need to live well.

Right now they don't, and this needs to change.

Over the past 100 years, advances in technology and medicines have delivered significant improvements in quality of life and health outcomes for people living with all types of diabetes. Advances in diabetes technology have been particularly revolutionary, including the introduction of continuous glucose monitors and insulin pumps.

The technology, is both life changing and life saving.

In 2022, the Federal Government implemented subsidised access to continuous glucose monitoring (CGM) devices for all people living with type 1 diabetes. This was a significant win for the type 1 diabetes community and has improved the lives of tens of thousands of Australians. There is, however, more to be done.

While CGM devices are now subsidised for all people with type 1 diabetes, they are not funded for people who live with type 2 diabetes, including people who use insulin. This is not equitable.

Moreover, while some Australians can afford to access insulin pumps through private health insurance, many cannot as they do not have the financial means to pay for health insurance. Hence insulin pumps are not currently an option for many people living with type 1 who would benefit significantly from this technology. The costs are simply unaffordable.

Australia urgently needs a comprehensive approach to diabetes technology subsidies that would expand access, accelerate approvals, and ultimately improve health outcomes.

Investing in diabetes technologies is proven to improve health outcomes and economic outcomes. Research shows that these devices are game-changing in terms of managing blood glucose levels and improving time-in-range, which ultimately improves quality of life, reduces diabetes related complications and hospitalisations.

In developing this position statement, Diabetes Australia has led a national conversation bringing together people living with all types of diabetes, industry, health professionals, researchers, and private health insurers and we have a common and cohesive position.

Our collective goal is clear: to ensure every Australian with diabetes receives the care and tools they need to live healthier, fuller lives. The time for change is now. Join us in this critical fight for equitable access to diabetes technology.

Justine Cain

Group CEO, Diabetes Australia

Equitable access to diabetes technology

Over the past 100 years, advances in technology and medicines have delivered significant improvements in quality of life and health outcomes for people living with all forms of diabetes.

There are now more than 1.5 million people living with diabetes in Australia. Diabetes Australia's State of the Nation 2024 report revealed that there is an unrelenting diabetes epidemic unfolding across Australia.

Australia has one of the highest rates of type 1 diabetes in the world. In the past year alone, over 3,000 new cases of type 1 diabetes were diagnosed, bringing the current total number of Australians living with type 1 diabetes to 137,700 people.

Type 2 diabetes is one of the fastest growing health conditions in Australia. In 2000 approximately 400,000 Australians were living with type 2 diabetes.[1] More than two decades later, there are now 1.3 million Australians living with type 2 diabetes and registered with the National Diabetes Services Scheme.[2] This does not include the estimated 500,000 Australians living with silent, undiagnosed type 2 diabetes.

If the growth rates of the past decade continue, there will be more than 3.1 million Australians, around 8.3% of the projected population, living with diabetes by 2050.

Diabetes is a complex medical condition that requires daily monitoring, and it can have a physical, mental, social and financial impact on a person. It is a condition that can cause debilitating and costly complications. It is often the underlying cause of serious complications such as heart attack, stroke, eye damage leading to blindness, vascular damage leading to limb amputation, and kidney damage leading to dialysis. A staggering 65 per cent of all cardiovascular-related deaths in Australia are among people with diabetes or pre-diabetes where blood glucose is elevated but not to the same degree as overt diabetes.[3,4]

Supporting people to live well with diabetes and reduce the risk of diabetes related complications must be a major priority.

There have been significant, revolutionary advancements in diabetes management technology in recent years. This technology brings substantial improvements in quality of life and health outcomes for people living with all types of diabetes.

Insulin pump therapy, when linked to glucose sensors, can reduce the frequency of severe hypoglycaemia (low blood sugar), enable better blood glucose management to reduce the risk of complications, and reduce costs associated with ambulance use, emergency department presentations and hospital admissions. It can also reduce fear of hypoglycaemia, diabetes-related distress and depressive symptoms and can improve health status and quality of life for people with type 1 diabetes.

Continuous glucose monitors (CGM) alone provide users with more accurate and frequent data about glucose levels without regular finger prick checks and supports more informed decisions about diabetes management. CGM technologies have been demonstrated to improve quality of life, reduce diabetes related mental health conditions and lower a person's long-term risk of diabetes-related complications.

Inequitable access

Despite the benefits of this technology, **many Australians living with diabetes are missing out**.

The technology is too expensive and out of reach for hundreds of thousands of people.

All Australians living with type 1 diabetes are eligible for subsidised CGM technology. While this has had a significant impact, **there are still many others who would benefit– including people with type 2 diabetes who are using multiple daily insulin injections, children and young adults living with type 2 diabetes and people with a range of other types of diabetes**.

Similarly, while many Australians living with type 1 diabetes have affordable access to CGM, they cannot afford insulin pumps. Only around 24% of people living with type 1 diabetes are currently able to access this technology. This is significantly lower than in comparable countries including the United States where an estimated 63% of adults and 58% of children and young people use an insulin pump to manage type 1 diabetes.

The benefits of insulin pumps, when linked to CGM, are significant. Automated insulin delivery (AID) systems, also referred to as hybrid closed loop systems, are considered standard care for people with type 1 diabetes. AID systems combine an insulin pump and CGM to automatically adjust insulin delivery based on real-time glucose readings, reducing the burden of constant manual adjustments and helping to maintain more stable blood glucose levels. Given it is estimated more than 90,000 people with type 1 diabetes currently access subsidised CGM, there is a compelling case to make insulin pump therapy, and therefore AID, more accessible for people with type 1 diabetes.

The inequity in access to diabetes technology is compounded by the lack of transparent pathways to assess, approve and fund new diabetes technology. Australia needs a comprehensive approach to diabetes technology to expand access, accelerate approvals, and ultimately improve health outcomes.

Diabetes Australia, together with the Australian Diabetes Society and the Australian Diabetes Educators Association, are advocating to improve:

- subsidised access to insulin pumps and automated insulin delivery for people living with type 1 diabetes;
- subsidised access to CGM for people with type 2 diabetes and other forms of the condition;
- a transparent and streamlined health technology assessment process that facilitates the timely and effective review of new technologies.

The recent Federal Parliamentary Inquiry into Diabetes, chaired by Dr Mike Freelander, supports this call. The Committee's report, tabled on 3 July 2024, states that "*ensuring better access to this technology for all Australians must be a priority. The Committee recognises that all patients with insulin*

dependent diabetes have similar clinical needs, and should thus be supported regardless of diabetes type".[5] The Committee made a number of recommendations related to access to technology, these include the following recommendations:

Recommendation 15

The Committee recommends that subsidised access to Continuous Glucose Monitors (CGMs) be further expanded. In the first instance, all access limitations in relation to patients with Type 1 diabetes should be removed. Furthermore, individuals with insulin-dependent Type 3c diabetes and patients with gestational diabetes should be made eligible for subsidised CGMs and for those with Type 2 diabetes requiring regular insulin. The Committee recommends prioritising the removal of age limitations on access to subsidised access for Type 1 diabetes patients.

Recommendation 16

The Australian Government should explore expanding subsidised access to insulin pumps for all Australians with type 1 diabetes. A gradual increase, such as expanding access to those aged 40 and under, would be useful as an initial step.

What do people living with diabetes want?

To develop this policy position, Diabetes Australia consulted broadly across Australia engaging with industry, health professionals, researchers, policymakers, health insurers and, most importantly, people living with all types of diabetes.

We acknowledge the insights and expertise of these groups, which helped define the problem, consider the evidence, share stories, and develop recommendations to improve equitable access to diabetes management technologies for Australians living with diabetes.

Throughout the consultation, people living with diabetes expressed their concerns about the cost of living. The affordability of CGM was a particular concern among those living with type 2 diabetes (for whom CGM remains unsubsidised) particularly when the financial burden of diabetes is already high.

Individuals also identified the opportunities for technology to ease the burden of diabetes on them as individuals, reduce the stigma associated with living with diabetes, and improve their quality of life.

People living with type 1 diabetes reported the significant improvement in managing blood glucose levels through linking CGM with an insulin pump. For many people, these technologies improve the length of time their blood glucose is in the target range and also reduce the mental load of daily diabetes management.

People living with type 1 diabetes identified that they vary with their needs, preferences and priorities when it comes to technology, and that embedding choice with access is important.

Diabetes Australia recently joined with leading health organisations and members of the diabetes community to endorse a consensus statement on the need for more affordable access to AID for Australians living with type 1 diabetes.

It is abundantly clear that technology has been life changing and likely life saving for many people living with diabetes.

Recommendations

Diabetes Australia has developed these recommendations in consultation with the Australian Diabetes Society, the Australian Diabetes Educators Association, JDRF Australia, people living with diabetes and some of Australia's leading diabetes health professionals.

Recommendations to improve equitable access to CGM for people living with diabetes

1. Recognising the demonstrable benefits of subsidised continuous glucose monitoring for people living with diabetes, the Australian Government should expand access to subsidised CGM devices to people living with all types of diabetes who need it to manage their condition.
2. This expansion of subsidised CGM should be conducted in a staged approach over the next four years, prioritising the following groups of people:
    a. people who are pregnant and have type 2 diabetes;
    b. people under the age of 21 who have type 2 diabetes;
    c. people who identify as an Aboriginal or Torres Strait Islander person, who have type 2 diabetes, with a prioritisation for those people using insulin;
    d. people living with other types of diabetes who require intensive insulin therapy (who do not already have access to subsidised CGM); and
    e. people who are over the age of 21 years who have type 2 diabetes and are using insulin, requiring multiple daily injections (with a full subsidy for people who hold a Health Care Card and partial subsidy for people who do not hold a Health Care Card).
3. Based on the modelling set out in this position paper, the Commonwealth budget should include $70M over the next four years to expand access to subsidised CGM.
4. Undertake an extensive evaluation of expanded access to CGM, with favourable results being used to support expanding access to more groups over the medium term.
5. Review the current health professional diabetes technology training and education provided and consider the impact of a further expansion of subsidised CGM, with a view to providing further training and education to the healthcare workforce, especially those working in primary care, including when to refer to a CDE.

6. Provide Medicare Benefits Schedule support to fund diabetes technology initiation and support by health professionals including CDEs outside of clinic hours for people accessing CGM. Also ensure that the public hospital system is provided with funding to support out of clinic hours support for diabetes technology initiation and usage.

Recommendations to improve equitable access to insulin pumps and automated insulin delivery systems

1. Recognising the demonstrable benefits of subsidised insulin pumps for people living with diabetes, the Australian Government should expand access to insulin pumps, and therefore automated insulin delivery systems, for all people living with type 1 diabetes.
2. This expansion to subsidies for insulin pumps should be delivered in a staged approach over time, with the initial prioritisation and implementation over the forward estimates being for the following groups:
    a. people who are under 21 and have type 1 diabetes (full subsidy);
    b. people who are aged over 21 years and have type 1 diabetes and hold a Health Care Card (full subsidy); and
    c. all Aboriginal and Torres Strait Islander people who have type 1 diabetes (full subsidy).
3. Based on the modelling set out in this position paper, the Commonwealth budget should include $130M over the next four years to expand access to subsidised insulin pumps.
4. Any expanded program should be delivered through the National Diabetes Services Scheme.
5. Any expanded subsidy program must also include all consumables that are currently subsidised through the NDSS.
6. Recognising the significant role that private health insurers play in the provision of pumps, there is no intention to reduce the scope of private health insurers in funding insulin pumps. However, it is recommended that ongoing consultation is held with private health insurers to continue to fund access to pumps. A review of current pricing for pumps on the prosthesis list is recommended as well as other strategies to ensure private health insurers are incentivised to offer pumps as part of silver or bronze categories.

Recommendations to improve health technology assessment pathways

1. Implement a comprehensive strategy for diabetes technology to broaden access, expedite approvals, and ultimately enhance health outcomes.
2. Amend Health Technology Assessment policies and methods to allow for the consideration of hybrid systems that incorporate technology that is currently assessed in different categories.

3. Amend HTA processes to allow for greater weighting of international approvals by respected and comparable international agencies. This would streamline the process for introduction of new technologies that are already approved for use in other countries, into Australia.

4. Allow for HTA assessment to consider the holistic needs of people living with diabetes, including the mental health benefits of a particular technology.

Diabetes workforce

With any expansion to subsidies for diabetes related technology, Diabetes Australia, the Australian Diabetes Society, and the Australian Diabetes Educators Association strongly support the further provision of funding to, and collaboration with, the diabetes health workforce. It is imperative that people living with diabetes are given appropriate support when initiating any diabetes technology, as well as on an ongoing basis, that they know how to best use the technology, understand the information it provides, and get the best results.

An effective way to support the diabetes workforce would be the expansion of Medicare item numbers to cover health professionals, including Credentialled Diabetes Educators to provide initiation and support for those living with diabetes and accessing CGM. Furthermore, there needs to be an increase in the number of visits that a person with diabetes can access credentialed diabetes educators.

Part 1 – Type 2 diabetes: Continuous Glucose Monitoring

Continuous glucose monitoring (**CGM**) devices are small wearable monitors that measure and show glucose levels. A CGM device provides information about whether glucose levels are rising or falling, or whether they are staying steady.

Access to CGM means that a person with diabetes can reduce the frequency of finger pricks to check blood glucose levels, relying instead on the CGM to provide that information. This has a flow on effect of optimising glycaemic management for a person with diabetes. **This is critical to reducing the risk of expensive and debilitating diabetes-related complications including amputations, vision loss and heart and kidney failure.**

Further, the technology can have a positive impact on the mental health of people with diabetes, as it can reduce the fear of hypoglycaemia, diabetes- related burnout and diabetes-related depression.

Over the last decade, the Australian Government has incrementally expanded access to subsidised CGM for groups of people with diabetes. From July 2022, subsidised access to CGM was expanded to all Australians living with type 1 diabetes.

Now, under the NDSS, delivered by Diabetes Australia on behalf of the Australian Government, all individuals with type 1 diabetes, as well as some people with rare conditions similar to type 1 diabetes, are eligible to apply for subsidised CGM. This has transformed clinical care and improved health outcomes for Australians living with type 1 diabetes. The potential exists to do the same for many more Australians living with insulin treated type 2 diabetes.

A 2023 survey of Australians[6] confirmed that **cost is one of the biggest barriers to widespread use of CGM in people with type 2 diabetes.** Subsidised access to CGM for people with type 2 diabetes, particularly those who use insulin, would increase uptake of this technology, and also bring cost savings to both to the individual and the health system.

According to the Australian Institute of Health and Welfare, expenditure on type 2 diabetes is estimated at 68% of the total diabetes expenditure in the health system – some $2.312B.[7] This represents a significant cost which would be reduced by greater availability of CGM for people with insulin treated type 2 diabetes. International studies demonstrate that CGM use in people living with insulin treated type 2 diabetes is cost effective, improves quality of life and reduces the psychological impact of living with diabetes.[8] There is a significant opportunity to reduce the impact of diabetes-related complications on Australia's health system by the targeted expansion of subsidies to people living with insulin treated type 2 diabetes who would benefit the most.

Clinical Need and Evidence

Blood glucose levels change throughout the day and are impacted by factors such as

eating, exercise, illness, alcohol and diabetes medications.[9] The worst health outcomes for people living with diabetes arise when blood glucose levels are not well managed and fall outside their target ranges. If blood glucose levels fall too low then this can lead to hypoglycaemia which, if not treated, can cause loss of consciousness and seizures. Conversely, blood glucose levels can be too high, known as hyperglycaemia and in the short-term, this can lead to dehydration. If blood glucose levels continue to be too high this can lead to a worsening of diabetes, which may require more medications and/or more frequent insulin injections. Over the longer term, high blood glucose levels can damage the body's organs. Possible long-term effects include damage to large (macrovascular) and small (microvascular) blood vessels, which can lead to heart attack, stroke, and problems with the kidneys, eyes, feet and nerves.

The cornerstone of managing blood glucose levels and maintaining levels within a target range is to measure them. Traditionally this has been done through finger-prick tests (known as self-monitored blood glucose (**SMBG**) tests), done several times throughout the course of a day. Once blood glucose levels are known then action can be taken (such as medication, or dietary changes) to manage and keep them within target ranges to avoid serious medical episodes and severe complications. The landmark UK Prospective Diabetes Study (UKPDS) showed that starting management of blood glucose levels at the time of type 2 diabetes diagnosis, is associated with sustained reductions in microvascular disease, and reduced incidence of myocardial infarctions and death from any cause.[10]

Randomised controlled trials (RCTs) and real-world studies have demonstrated that **CGM improves management of blood glucose levels when compared with self-monitored blood glucose checks for people with type 2 diabetes.**[11,12,13,14,15] This can lead to a reduction in severe complications; retrospective analyses of multiple large cohorts of people with type 2 diabetes showed **a reduction in hospitalisations.**[16] CGM has also been shown to **reduce the mental toll of living with type 2 diabetes**[17] and can **improve quality of life and overall wellbeing,**[18,19] help people living with diabetes to **feel empowered**[20] and be **more satisfied with their diabetes treatment.**[21] Real-world studies indicate that CGM can support **healthy behavioural changes to meal planning, physical activity and exercise**, as emphasised in international guidelines for diabetes self-management education and support.[22,23]

People who are pregnant and have type 2 diabetes

Pre-existing diabetes of any type places pregnant women and their children at an increased risk of complications during and even after pregnancy. This includes increased rates of large and small birth weight for gestational age babies, increased likelihood of needing a caesarean section, and increased rates of perinatal death.[24,25]

Studies show reductions in neonatal morbidity, mortality and miscarriage when CGM devices are used in women who are pregnant with pre-existing type 1 diabetes.[26,27,28,29] While there are fewer studies of the use of CGM in women who are pregnant with pre-existing type 2 diabetes[30], real-time monitoring via CGM offers a comprehensive view of blood glucose

fluctuations, helping make timely adjustments to insulin doses, diet, and lifestyle.[31] Data from studies of pregnant women with pre-existing type 1 diabetes have emphasised the benefits of CGM[32,33] and these benefits are likely to be reflected in pregnant women with pre-existing type 2 diabetes. Furthermore, some studies have shown that children of women with type 2 diabetes may be even more susceptible to small changes in maternal blood glucose levels[34] and so the benefit for pregnant women with pre-existing type 2 diabetes may be even higher.

People under the age of 21 who have type 2 diabetes

The number of children and young adults being diagnosed with type 2 diabetes has risen significantly in recent decades. NDSS data shows that, in the last decade, the number of type 2 diabetes diagnoses in people aged 20 and below has increased by 17%. The impact of early onset type 2 diabetes is profound and complications can appear prematurely, and are potentially more severe in this cohort.[35,36] There are potentially underlying biological and behavioural reasons for this, however being diagnosed at a younger age also means living with, and having to manage blood glucose levels, for longer. The risk of mental burnout and depression, that are closely linked with managing type 2 diabetes, are therefore also exacerbated for younger people.

While clinical studies of the use of CGM in children and young adults with type 2 diabetes are limited, there is evidence that demonstrates CGM for just 3 months resulted in a mean reduction in HbA1c from 11.5% to 8.7% compared with SMBG.[37] Another study showed that the use of CGM was associated with significant improvements in quality of life over 12 weeks.[38] There is additional qualitative, evidence that suggests that real-time glucose readings can prompt self-management behaviour changes in children and young adults with type 2 diabetes.[39] The use of CGM has therefore been recommended internationally for all youth with type 2 diabetes as soon as possible after diagnosis, to promote diabetes self-management, improve blood glucose management and reduce long-term complications.[40]

People who identify as Aboriginal or Torres Strait Islander with type 2 diabetes, with priority given to those using insulin

Diabetes disproportionately affects Aboriginal and Torres Strait Islander communities in Australia and rates of diabetes are likely to be even higher than reported. Based on the available data, Aboriginal and Torres Strait Island people are three times more likely to develop type 2 diabetes than non-Indigenous Australians.[41] A study in central Australia found that 40% of Aboriginal adults were living with diabetes.[42] The risks associated with type 2 diabetes are also much more pronounced for Aboriginal and Torres Strait Islander people, with rates of hospitalisations due to type 2 diabetes complications more than 5 times higher than for non-Indigenous Australians. In particular, rates of kidney and cardiovascular disease and amputations[43] are higher and inadequate access to culturally appropriate healthcare services, particularly in rural and remote settings exacerbate these disparities further.[44] Type 2 diabetes has emerged as the leading cause of death among Aboriginal and Torres Strait Islander women nationally and the leading cause of death for all Aboriginal people in the Northern Territory.[45]

Expanding CGM access for Aboriginal and Torres Strait Islander people, particularly in remote areas could improve diabetes management and health outcomes, while reducing healthcare costs. Pilot studies have demonstrated that CGM use is feasible among remote and diverse populations across Australia, including in Aboriginal and Torres Strait Islander communities and remote parts of Northern Australia.[46] Adequate funding for health professionals to support CGM use is essential for effective implementation.

People who have other types of diabetes which require multiple daily injections of insulin and who do not have access to subsidised CGM

In addition to type 1 diabetes and type 2 diabetes, there are other recognised forms of diabetes including:

- pancreatic diabetes
- cystic fibrosis related diabetes
- medication requiring maturity onset diabetes of the young
- latent autoimmune diabetes in adults
- people who have had a pancreatectomy

According to the NDSS Australian Diabetes Map, there are 11,860 people living with these other forms of diabetes.[47]

Each of these conditions presents unique challenges that can be better managed with real-time glucose monitoring. By offering continuous, real-time glucose data, CGM helps in tailoring treatment plans, enhancing glycaemic control, and ultimately improving the quality of life and health outcomes.

People who require multiple daily injections of insulin

It is estimated that approximately 1.3 million Australians live with type 2 diabetes, and a quarter of these people require insulin injections. Of these people, around 10% (approximately 30,000 people) need multiple daily injections of insulin (MDI).

People who have type 2 diabetes and require MDI have a demonstrated clinical need which would benefit from CGM; this is in accordance with recommendations from the American Diabetes Association (ADA) and other International medical societies. This is supported by a substantial body of research that highlights people with type 2 diabetes needing MDI experience significant benefits with CGM (mirroring those observed in people with T1D). The benefits include a reduction in HbA1c levels,[48,49] a decrease in hypoglycaemia[50,51] and a lower frequency of acute diabetes-related events that lead to hospital admissions.[52,53]

In addition to the health benefits for people with type 2 diabetes that need MDI, the use of CGM in this population could also lead to a greater understanding of the heterogeneous nature of type 2 diabetes. This could increase the ability to personalise treatments and actions based on the data received through the CGM devices. As in other priority groups, the use of CGM can also support behaviour change and optimal choices around food, exercise and other modifiable risk factors, ultimately reducing the risk of acute and chronic diabetes complications and improving quality of life.

Economic evidence and modelling

Given the clinical benefits associated with CGM, there are also significant economic benefits that result from using CGM instead of SMBG. These include reduced healthcare costs due to fewer and less severe complications and slowing progression of type 2 diabetes; people living with type 2 diabetes are able to work more consistently and for longer, and requiring less care from family members; and there is an improved quality of life for people living with type 2 diabetes using CGM.[54]

A detailed cost-effectiveness analysis from the UK, using costs and clinical outcomes estimated from the CORE Diabetes Model, showed that CGM was associated with an extra 0.731 quality-adjusted life years (QALY) at a cost of 2694 Great British Pounds (GBP) compared with SMBG for people living with type 2 diabetes. This resulted in an incremental cost effectiveness ratio (ICER) of GBP 3684 per QALY gained; this suggests that CGM is very cost-effective compared to SMBG. **Key drivers of the cost-effectiveness were due to improvements in HbA1c and quality of life with CGM use.**[55] A second cost-effectiveness analysis focusing on people living with type 2 diabetes requiring intensive insulin therapy also demonstrated that CGM was cost effective when compared to SMBG tests with an ICER of GBP12,309 per QALY gained.[56] Similar studies conducted in other countries (such as Japan[57], Canada[58] and France[59]) also demonstrated that **CGM is a cost-effective form of monitoring blood glucose levels for people living with type 2 diabetes**. Early results from data modelling suggest the same benefits in Australia.[60]

Reduced healthcare needs and costs

Access to CGM can lead to reduced healthcare needs and costs, particularly because of the reduction in acute diabetes-related events. Hypoglycaemia and hyperglycaemia are common and costly complications of diabetes, often resulting in emergency room visits and hospitalisations. In Australia, it is estimated that people living with type 2 diabetes who require insulin and who do not have well managed blood glucose levels experience complications that cost on average $9,645 per year to treat.61 CGM provides an early alert system to warn when blood glucose levels are about to fall outside of target ranges avoiding costs and complications.

A US study found that people using CGM had significantly fewer hospital admissions and emergency room visits related to diabetes compared to those using SMBG. The study estimated that the annual healthcare cost savings associated with CGM use ranged from US$3,376 to US$7,640 per patient.[62]

UK research found use of CGM devices was associated with a reduction in paramedic callouts of 86% and a 62% reduction in hospital admissions due to hypoglycaemia.[63]

Productivity gains and quality of life improvements

CGM also leads to additional benefits that go beyond the improvements in direct healthcare usage and cost; **CGM can result in significant productivity gains and quality of life improvements for people living with type 2 diabetes**. The impact of diabetes on work productivity is well recognised, both in terms of presenteeism (reduced productivity while at work) and absenteeism (absence from work due to illness). A study found that people living with type 1 or type 2 diabetes

incurred between 5.4-18.1 days off work per year; comparatively, people without diabetes had between 3.4-8.7 days off work per year.[64] This presenteeism and absenteeism impacts productivity costs with several studies demonstrating that any level of hypoglycaemia confers substantial indirect costs on employers as well as people living with diabetes because of lost work days.[65]

Better glycaemic management can reduce the frequency of diabetes-related symptoms such as fatigue and cognitive impairment, enabling individuals to be more productive at work and in their daily lives. A study highlighted that CGM use was associated with a reduction in work absenteeism and improved work productivity among individuals with type 1 diabetes. The study estimated that the annual productivity gains per patient ranged from $1,500 to $4,000, depending on the severity of their diabetes.[66] Additionally, improved quality of life and reduced caregiver burden can further contribute to the economic benefits of CGM. An Australian analysis found **CGM for people with type 1 diabetes is cost effective when compared with a completely user-funded model**.[67]

Long term economic benefits

The long-term economic benefits of subsidising CGM are substantial, particularly when considering the rising prevalence of type 2 diabetes and the associated costs. As the global population ages and the incidence of diabetes increases, the economic burden of diabetes is expected to grow. Investing in technologies like CGM can mitigate these costs by reducing the incidence, progression and severity of diabetes-related complications.

A long-term cost-effectiveness analysis projected that widespread adoption of CGM could lead to substantial cost savings for healthcare systems. The study estimated that over a 10-year period, the use of CGM could save the U.S. healthcare system approximately $4.6 billion due to reduced complications and improved health outcomes.[68]

International comparisons

Australia is lagging behind other countries when it comes to access to CGM for people living with type 2 diabetes.

In the **United Kingdom**, a person living with type 2 diabetes who uses insulin two or more times a day, should be offered a flash glucose monitor if one of the following applies:

- the person has recurrent or severe hypoglycaemia
- the person has impaired hypoglycaemia awareness
- the person cannot monitor their own blood sugar levels but could use a scanning device
- the person would be advised to do a finger prick at least eight times a day.[69]

Further, children and young people in England, Wales or Northern Ireland have access to CGM in particular circumstances[70] and people who are pregnant with type 2 diabetes and have severe hypos may also be offered a CGM.

In **Canada**, public funding for CGM is available to people who have access to the Ontario Disability Support Program, or the Non-Insured Health Benefits Program for First Nations and Inuit.

In March 2022, **Japan** expanded reimbursement coverage for CGM (FreeStyle Libre) to all people with diabetes who use insulin at least once a day.[71]

In June 2023, the **French** government expanded reimbursement to FreeStyle Libre 2 for all individuals who use basal insulin.[72] Prior to this, France provided reimbursement to all people living with type 1 diabetes and type 2 diabetes who required intensive insulin therapy. In September 2023, Dexcom announced that Dexcom One would be available by reimbursement in France, for all people with Type 1 or type 2 diabetes who are undergoing intensive insulin therapy (by external pump, or more than three injections per day).[73]

Germany has provided free access to CGM systems for all people requiring insulin therapy since 2016.[74] Studies have shown that the subsidy of CGM in Germany has led to better glycaemic control, reduced rates of hypoglycaemia, and improved quality of life for people with diabetes,[75,76] and minimizing the risk of diabetes-related complications.[77]

Part 2 – Insulin pumps and automated insulin delivery

As of 31 March 2024, there are more than 137,700 people in Australia living with type 1 diabetes.[78] All people living with type 1 diabetes should have equitable access to the technology that best assists with the management of their diabetes.

Subsidies for access to CGM have been expanded in recent years to cover all people with type 1 diabetes. This has been of great benefit. In 2017, people under the age of 21 gained access to subsidised CGM, which was expanded in 2019 to people over the age of 21 who had access to a concession card, and to women with type 1 diabetes

While access to subsidised CGM devices has been of great benefit insulin pump access is much more limited.

Only 24% of adults with type 1 diabetes are using an insulin pump. Australia's outdated funding model remains a major barrier to access. Current insulin pathways include:

- Private health insurance (PHI) – the primary pathway to access an insulin pump (>80%). This requires top tier hospital cover (approximately $2,500 per annum). Recent data shows fewer than half of all Australians have a policy with hospital cover
- Out-of-pocket – purchasing an insulin pump costs $7,000–$10,000 every four years, and this payment may be required upfront, which is out of the reach of many.
- The Insulin Pump Program (IPP) – an Australian Government-funded, means-tested program of limited scale, which has provided fewer than 300 pumps on average per year in its 15-year history. Notably, the IPP does not offer a choice of device. Funding also does not go beyond the age of 21 years.
- Fundraising or philanthropy (e.g., GoFundMe) – for a small number of people.[79]

Improved access to affordable insulin pump therapy is critical to ensure the most effective treatment and management of type 1 diabetes. Insulin pump therapy can be life-changing and, when linked to continuous glucose monitors ("glucose sensors") as an automated insulin delivery (AID) system, are potentially life-saving for people with type 1 diabetes.

AID is now the standard of care for people with type 1 diabetes. AID systems work by connecting an insulin pump to a CGM via an algorithm to automate insulin delivery to suit the person's glucose levels, minute by minute, maintaining them within target range. This is beyond what anyone living with type 1 diabetes can achieve manually with currently funded technologies.

Evidence shows AID brings numerous benefits, such as reduced risk of hypoglycaemia, improved glycaemic control, and enhanced overall quality of life.[80,81]

Right now, the Australian Government funds half of an AID system with subsidisation of CGM. There is a significant opportunity to leverage this existing investment in CGM, to provide addition funding to support pump access, and ensure equitable access to AID.

"Currently, less than 50% of Australians have private health insurance, and only a third of them hold policies – gold tier – that provide the necessary coverage for privately insured patients to receive access to insulin pumps. This means that even for the majority of Australians who have private insurance coverage, there is no option but to self-fund the purchase of insulin pumps." Medical Technology Association of Australia[82]

Clinical need and evidence

The most recent Australian research shows that insulin pump systems (integrated with real time CGM) are **best for HbA1c reduction and improving time in the target glycaemic range** (TIR), both associated with reduced complications, in people with type 1 diabetes.[83,84] The review demonstrated that AID Systems are superior to all other technologies in achieving Time in Range. Additionally, CGM outperformed self-monitoring of blood glucose (SMBG) when used with daily insulin injections (MDI). These observed benefits of CGM over SMBG, and of AID systems overall compared to other technologies, suggest that **adults with** type 1 diabetes **may experience fewer symptomatic glycaemic extremes and benefit from better long-term outcomes**.

Increasing time in range can **reduce both hypoglycaemia-related hospital admissions and hyperglycaemia**, which leads to hospital admissions for diabetic ketoacidosis and is associated with serious long-term complications.[85,86,87] A recent article comparing insulin pump alone to MDI modelled a **HbA1c reduction** of 0.24% (2.6 mmol/mol), citing the 'Relative effectiveness of insulin pump treatment over multiple daily injections and structured education during flexible intensive insulin treatment for type 1 diabetes: cluster randomised trial (REPOSE)' study.[88]

The AID system was modelled to **reduce HbA1c** by 0.5% (5.5 mmol/mol)[89] and was assumed to prevent all episodes of severe hypoglycaemia over a lifetime[90]. The recent NHS Closed Loop pilot demonstrated that in adults with type 1 diabetes with a high HbA1c and already on CGM and pump therapy, AID use was associated with a substantial **reduction in HbA1c** (-1.7%, p<0.0001), **reduced diabetes-related distress, and improved quality of life**.[91]

Real-world evidence validates the results from clinical studies across all outcome measures in diverse populations and demonstrates that real-time glucose monitoring systems drive positive outcomes. These findings showed a **reduction in HbA1c**, particularly for those with higher baseline HbA1c, **improvements in hypoglycaemic unawareness, and decreased diabetes-related distress**. They were associated with **significant reductions in paramedic callouts, hospital admissions**

due to hypoglycaemia, and hyperglycaemia/diabetic ketoacidosis, leading to **substantial healthcare savings** in **multiple jurisdictions** in UK, France, Cananda, Belgium, The Netherlands, Sweden, Germany, Denmark, and USA.[92,93,94,95,96,97,98]

Economic evidence and modelling

A review of literature on the health-economic value of AID systems showed that the majority of economic evaluations of AID systems focused on individuals with type 1 diabetes and found **AID systems to be cost-effective** when compared to a range of non-AID comparators across numerous health care settings.[99] The AID systems resulted in substantial increases in quality-adjusted life expectancy versus standalone insulin delivery systems, blood glucose monitoring devices, or combined monitoring and insulin delivery systems only. Despite their higher incremental costs, the AID systems conferred sufficiently **large QALY gains** to balance the incremental costs and fall below the willingness to pay thresholds of health care payers in **11 different countries**. The QALY benefits have been driven mainly by reductions in the incidence of diabetes complications and in some cases reduced fear of hypoglycaemia.

A systematic review of available diabetes management technologies showed that insulin pumps (56% of included studies) were **cost-effective in populations with higher HbA1c levels and rates of hypoglycaemia**.[100] When compared to CSII and SMBG, integrated CSII and CGM systems with a suspend function for low glucose were reported as cost-effective in 80% of included studies. The ICERs for studies reporting that integrated systems were cost-effective ranged from $19,695 AUD per QALY gained (in Denmark) for participants at risk of hypoglycaemia[101] through to $72,025 AUD per QALY (in Italy) for participants with high HbA1c levels > 8%.[102]

Integrated CSII and CGM systems provide **$1,000,792 AUD cost savings** in comparison to MDI with self-monitoring of capillary blood glucose (SMBG) over a lifetime.[103] Use of a hybrid closed loop system was considered cost-effective when compared to CSII and SMBG in the Swedish context with an adjusted ICER of $25,327 AUD per QALY gained.[104] The base case ICER of 156,082 Denmark krone (DKK) reduced to 116,755 DKK per QALY gained when the baseline HbA1c was increased from 8.1% (65 mmol/mol) to 9% (75 mmol/mol) in sensitivity analysis.[105]

A recently conducted cost-effectiveness analysis comparing an AID to MDI and SMBG among adults with type 1 diabetes over a lifetime horizon, from the perspective of the Australian health care system, demonstrated that the **cost of funding these devices would be offset by the projected long-term reductions in complications**.[106] The analysis resulted in an incremental cost-effectiveness ratio of $37,767 per QALY gained, well below the traditionally cited willingness to pay a threshold of $50,000 per QALY gained in the Australian setting. Notably, AID systems remained cost-effective even with a baseline HbA1c of 7.0% and no treatment effect on HbA1c. The NHS Closed Loop pilot reported a significant improvement in HbA1c of 1.7% ($p<0.0001$).[107]

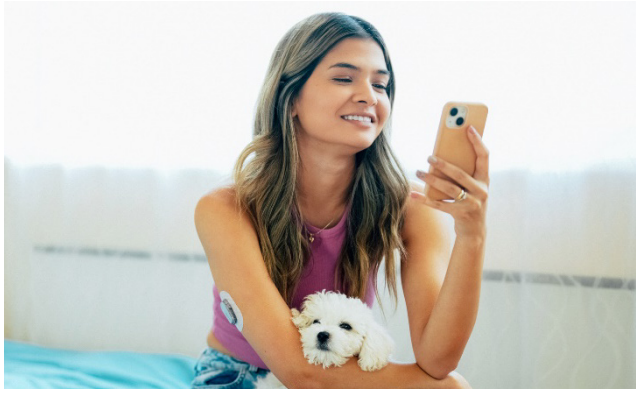
A cost-effectiveness analysis undertaken using the NHS Closed Loop pilot data demonstrated a large decrease in ICER of £12,398 per QALY gained (NICE threshold to pay typically under £20,000-30,000 per QALY gained).[108] Discussions with the industry to establish a cost-effective price for national

access to HCL are ongoing, but the NHS is clearly **dedicated to providing effective, safe, and equitable diabetes care**. Besides the UK, an ICER below the willingness-to-pay threshold has been shown in Austria, Denmark, Greece, France, Italy, Poland, Spain, Sweden, the Netherlands, and Turkey.[109,110,111,112,113,114]

Access to diabetes management technologies can **reduce average lifetime costs by 14%** by minimising the risk of complications and emergencies.[115]

An Australian study investigating the use of diabetes technology across different socioeconomic groups in youth with type 1 diabetes in the setting of two contrasting funding models of CGM and insulin pump therapy found that for nationally subsidised CGM, usage was similar across socioeconomic groups, except for the most disadvantaged quintile.[116] User-funded pump therapy leads to **lower usage among socioeconomically disadvantaged groups**, **highlighting the inequities in this funding approach**. This is despite evidence that improvements in diabetes outcomes are just as significant in children from low socioeconomic status (**SES)** backgrounds as those from high SES.

A recent finding on Australian youth with type 1 diabetes showed that the glycaemic benefits of diabetes technologies were consistent across all socioeconomic quintiles, with the greatest benefits seen with the combined use of a pump and CGM.[117] With rapidly growing evidence from both trials and real-world settings showing that technology, including AID, enhances glycaemic control for youth with type 1 diabetes, it is crucial to **prioritise equitable access to diabetes technology for youth with type 1 diabetes from all backgrounds.**



International comparisons

Australia is lagging behind other countries when it comes to access to insulin pumps, as a pathway to AID, for people living with diabetes.

In **Canada**, the availability and subsidy of insulin pumps vary by province. Ontario's Assistive Devices Program (**ADP**), initiated in 2008, covers 100% of the cost of insulin pumps and supplies for residents with type 1 diabetes.[118] Similar programs exist in British Columbia, Alberta,[119] and other provinces. These programs typically require patients to meet certain medical criteria and have a physician's recommendation. The provincial programs ensure equitable access to insulin pumps, improving diabetes management and quality of life for patients across Canada.[120]

The NHS in the **United Kingdom** has provided insulin pumps since the early 2000s. According to the National Institute for Health and Care Excellence (NICE) guidelines updated in 2008, insulin pumps are available for people with type 1 diabetes who have difficulty achieving stable blood glucose levels with multiple daily injections.[121] Patients are assessed at specialist diabetes centres to determine eligibility based on clinical need. The program aims to improve diabetes management and reduce the risk of complications, enhancing patient outcomes.[122]

Germany's health insurance system covers the cost of insulin pumps for type 1 diabetes patients who meet specific medical requirements, such as frequent severe hypoglycaemia or poorly controlled blood glucose levels despite optimized insulin therapy. This coverage has been in place since the early 2000s. Patients must undergo an assessment by their healthcare provider to determine eligibility. The system ensures that patients have access to advanced diabetes management tools, promoting better long-term health outcomes.[123]

Sweden has provided state-funded insulin pumps to individuals with type 1 diabetes since the early 2000s. The Swedish healthcare system evaluates patients based on their medical needs, including challenges in maintaining blood glucose control with traditional insulin therapy.[124] The program aims to enhance the quality of life for diabetes patients by offering advanced treatment options at no additional cost to the patient, ensuring equitable access across the country.[125]

Israel's healthcare system includes insulin pumps as part of the standard care for type 1 diabetes patients. This inclusion has been in effect since the mid-2000s. Health insurance covers the cost of the pumps, making them accessible to patients who meet clinical criteria.[126] The program emphasizes the importance of advanced diabetes management technologies in improving patient health and reducing complications.[127]

Norway's public health system provides insulin pumps to people with type 1 diabetes who meet clinical guidelines. This program, established in the mid-2000s, ensures that the cost of insulin pumps is covered by the state. Patients are assessed by their healthcare providers to determine eligibility based on their medical condition and treatment needs.[128] The program aims to enhance diabetes management and patient outcomes through access to advanced technology.[129]

Finland's healthcare system has covered the cost of insulin pumps for type 1 diabetes patients since the early 2000s. Patients are evaluated based on their clinical needs, including issues with blood glucose control using multiple daily injections.[130] The program ensures that patients have access to the latest diabetes management tools, improving their overall health and quality of life. However, research has found (but not explained) insulin pump uptake is lower in Finland than in other Nordic countries.[131]

The **French** healthcare system reimburses the cost of insulin pumps for people with diabetes since the early 2000s.[132] Eligibility is based on clinical criteria, including difficulty controlling blood glucose levels with conventional insulin therapy. The program aims to provide equitable access to advanced diabetes treatment, helping to reduce complications and improve patient outcomes.[133,134]

New Zealand's public healthcare system has recently announced a proposal to provide full funded access to CGM, insulin pumps and insulin pump consumables for people living with type 1 diabetes.

Denmark's public healthcare system has provided insulin pumps to people with diabetes who meet clinical guidelines since the early 2000s.[135] The cost of the pumps is covered by the state, ensuring that patients who need them can access them without financial barriers.[136] The program focuses on improving diabetes management and patient quality of life through advanced treatment options.[137]

Key considerations

In developing recommendations to expand access to CGM, Diabetes Australia has considered appropriate funding model options, clinical prioritisation and the implementation of a subsidy arrangement for CGM for people with type 2 diabetes.

The implementation of existing technology subsidy arrangements for people living with type 1 diabetes has been considered. Subsidies to people living with type 2 diabetes, should align with existing CGM subsidy arrangements for people with type 1 diabetes.

It is recognised that not all people who are eligible for a subsidy, will choose to access the technology, and that uptake will scale up over time. Experience with the rollout of CGM for type 1 diabetes has shown that the subsidy introduced in 2017 for people under 21 years of age increased uptake from around 5% to around 79% after two years.

In developing recommendations to expand subsidy arrangements for insulin pumps, Diabetes Australia has considered a number of factors including, the estimated uptake rates of insulin pumps for people under the age of 21 years; uptake of insulin pumps more broadly across the type 1 community; the international experiences of insulin pump access; and prioritisation for people who would most benefit from access to a subsidy for a pump.

Consideration has also been given to the extent to which people have access and utilise private health insurance to access an insulin pump. **Costs, including the costs of private health insurance, the cost of an insulin pump, the limited availability of insulin pumps in Australia, the cost of insulin pump consumables has all been considered**.

Further, a key consideration of the proposed approach was the impact on private health insurance. The **intention is not to shift the cost burden for insulin pumps from private health insurance, to the Government**.

Diabetes Australia recommended approach

All people living with diabetes should have access to the technology that best assists them to manage their diabetes.

We recognise that funding for subsidies to improve access to diabetes technology should be delivered in a staged approach over time.

Diabetes Australia recommends a $200M investment over four years from the Australian Government to increase subsidies to diabetes technology for key priority groups in the first instance.

This initially includes insulin pumps subsidies for people living with type 1 diabetes who are:

- under 21 years of age;
- over 21 years of age with a health care card; or
- Aboriginal and Torres Strait Islander people.

We also recommend, expansion of subsidies for CGM devices for people living with type 2 and other types of diabetes who are:

- pregnant;
- Aboriginal and Torres Strait Islander people;
- under the age of 21; or
- requiring multiple daily injections of insulin.

Using the recommendations outlined above, it is estimated that the net 4 year cost to government for extending subsidies to CGM devices to the type 2 community would be approximately $70M over four years.

The net 4 year cost to government for expanding subsidies for insulin pumps would amount to approximately $130M over four years.

Diabetes Australia acknowledges that there are other key considerations regarding product supply, and health workforce supports that would need to be considered in the roll out of any program. The expansion program should be evaluated to consider the benefits and impact of the increased access.

It is estimated that expanding subsidy for subsidised CGM will create access to CGM for a further 22,000 people living with type 2 diabetes and expanding subsidies for insulin pumps will increase access to a further 16,000 living with type 1 diabetes. A $200 million investment is estimated to have the benefit of:

- Up to 15,800 quality-adjusted life years for people living with type 2 diabetes, which can have the value of between $590M to $1.3BN
- Up to 59,500 quality-adjusted life years for people living with type 1 diabetes, which can have the value of between $1.9BN to $4.7BN.

Part 3 – Approving and funding diabetes technology

Australia's regulatory and funding systems must be more adaptable and efficient in evaluating new technology quickly. With technological breakthroughs certain to continue, Australian regulators must establish processes that allow for timely and robust evaluation.

The Health Technology Assessments process refers to all bodies the Federal Government uses to fund and subsidise health technologies and medicines. This includes the Therapeutic Goods Administration, the Pharmaceutical Benefits Scheme, the Medicare Benefits Scheme, the National Immunisation Program, and the Life Saving Drugs Program.

Significant improvement is needed with regard to both the time it takes for people to be able to access new technologies, and how equitable that access is.

These challenges are being amplified by the technology-driven healthcare revolution currently underway. **Research breakthroughs are leading to technologies faster than at any time in human history**. The pace of change is placing a heavier burden on Australia's regulatory systems than previously seen. **It is critical that the approvals and reimbursement framework is flexible enough to keep pace with these changes**.

This is essential to ensure both the Australian health system and people living with diabetes can experience the considerable benefits from access to technologies, including reduced incidence of diabetes-related complications.

New technologies

A range of novel diabetes technologies currently available internationally do not fit neatly 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 pancreas. These technologies will deliver improved physical and health outcomes for the people living with diabetes who choose to use them. HTA policy and methods must be revised to support a more agile approach to assessing novel health technology and medicines.

Interoperability

A key area of advancement is interoperability between insulin pumps and CGM systems. This means pumps can respond to CGM data and adjust insulin dosages based on algorithms that determine the correct amount of insulin required to regulate a person's blood glucose levels.

This is often referred to as a hybrid closed loop system or close loop technology or automated insulin delivery. This is the standard of care for people living with type 1 diabetes, both in terms of physical and mental health outcomes.

The current HTA policy and methods are not unsuitable for considering hybrid systems incorporating technology currently assessed in different categories. Any changes to the HTA policy and methods should ensure they are nimble enough to accommodate technologies outside rigid categories. This is particularly important given the rapid speed of technological developments.

Bionic pancreas

The bionic pancreas is a technology similar to interoperable insulin pumps and CGM systems. The FDA has recently approved the iLet ACE insulin pump and the iLet dosing decision software for people living with type 1 diabetes. The dosing system uses an adaptive closed-loop algorithm to calculate insulin needs, replacing the need for accurate carbohydrate counting with a simple entry for a meal. The two devices, along with an FDA-approved CGM, will comprise the iLet bionic pancreas. It will be delivered by an algorithm that determines and commands insulin delivery.

There is currently no pathway for approval or reimbursement of this technology, despite it being one of the most transformative technologies since the discovery of insulin.

Additionally, differences exist in relation to the algorithms various products use. The process for approving and providing reimbursement for this software is not clear.

Smart pens

New smart insulin pens connected to glucose monitoring devices that have the ability to calculate insulin dosage based on inputted carb ratios and other data are currently available in some countries. This is another example of a technology whose components span different assessment categories and therefore may face difficulty securing approval in Australia. Additionally, there are no clearly identified reimbursement pathways for this technology to support people to access it.

Other emerging technologies

Implantable glucose sensors, sensors for additional analytes, more rapid acting insulins, longer-lasting glucose sensors and insulin delivery infusion sets as well as alternative technologies for glucose sensing continue to be investigated. The automated review of uploaded insulin and glucose data is another focus, with machine learning anticipated to provide advice for manual pump settings and to inform control algorithms. Closed loop systems involving insulin and glucagon are also being studied. In addition, control algorithms for closed loop systems continue to develop with the ultimate aim of devising a fully automated system that does not require manual boluses or other input from the user.

What is working well?

People living with all types of diabetes can access a wide range of products to help them manage their condition. Many of these products are available without charge or heavily subsidised by the NDSS. They include insulin pens, needles and syringes, consumable products for insulin pumps and continuous glucose monitoring systems, and blood glucose and ketone urine testing strips.

Other positive examples of the HTA's policies and methods include the addition to the NDSS of the Medtronic 780G insulin pump, the Dexcom G6 CGM system, and the Omnipod DASH patch pump.

The availability of all these technologies increases the choices for people living with diabetes. Best practice diabetes care is individualised, and different technologies can support people's diabetes management in different ways. This is why choice and equitable access in diabetes technology and medicines is so critical.

Areas for improvement

The main areas where improvement in the assessment of new technologies is required are:

- greater flexibility to allow prompt assessments of evolving technologies that don't fit current criteria;
- faster access to technology and medicines that have already been approved in reputable international markets such as the European Union and the United States; and
- considering the needs of the person living with diabetes, including mental health benefits, during the assessment of new technology.

In Australia, there is an emerging theme among new technologies which are available internationally: **they do not fit neatly into existing categories for assessment**. Assessment processes need to be more transparent and capable of assessment new

technologies when they don't fit neatly into existing categories for assessment.

Australia is a relatively small, secondary market for many companies. This means they delay introducing technology here until it has been launched in larger markets such as the US and Europe. Therefore, Australia's assessment and approval process generally trails assessments conducted by the Food and Drug Administration (FDA - US), the European Medicines Agency (EMA – EU), and the Medicines and Healthcare products Regulatory Agency (MHRA – UK).

There is an opportunity to provide greater weighting to international approvals by respected international agencies. This would streamline the process for introduction into Australia, especially if international approvals could be leveraged for faster access in Australia for updated or advanced models of already approved technology.

For people living with diabetes, the best care is one that reflects an individual's personal preferences for managing the condition. **Everyone is different**, and people who are managing a 24/7 lifelong chronic condition have preferences for how they do this that should be respected.

This includes being able to choose the technology and medicines that best suit their preferences and biological needs, including during childhood and pregnancy. Therefore, while there may be three or four options available in a particular technology class, a new alternative may have slightly different features that could be of great benefit to a person living with diabetes.

In some cases, the clinical outcomes may be very similar, but the product may confer a psychosocial or lifestyle benefit that significantly improves a person's quality of life.

Technology can play a substantial role in alleviating some of the mental health challenges associated with living with diabetes. It can help reduce the fear and anxiety related to unpredictable blood glucose levels, give people greater freedom, and reduce worry about diabetes-related complications. For these reasons, assessment of diabetes technology should consider the quality of life and mental and emotional health benefits of new therapies. This could include patient-reported outcome measures (PROMS), international experiential reviews, quality of life measures, and other data to ensure the HTA process remains person-centred.

Additionally, it must be noted that the clinical criteria used to assess diabetes technology is evolving. An HbA1c check, which measures an individual's average blood glucose levels, has long been the gold standard. In some cases, a healthy HbA1c result incorporates large fluctuations in blood glucose levels but because those fluctuations are tallied into an average number, the result can disguise potentially dangerous highs and lows. Time in Range (**TIR**) is fast emerging as a more accurate indicator of improved long-term outcomes. TIR measures 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, and more so, tight time in range, the lower the risk of diabetes-related complications. As improvements in clinical criteria evolve, our assessment and approval systems need to be flexible enough to incorporate them.

Conclusion

The current disparity in affordable access to diabetes technologies means many Australians are unable to benefit from this life changing healthcare. Right now, diabetes technologies remain prohibitively expensive for many people, leading to tangible health repercussions and unnecessary strains on the healthcare system.

This situation will continue for as long as access to diabetes technologies continues to be constrained by the type of diabetes a person has, or their ability to afford private health insurance.

Furthermore, systemic regulatory changes also need to be made, to ensure clearer pathways for evaluating, approving, and funding new diabetes technology quickly. Australia urgently requires a comprehensive strategy for diabetes technology to broaden access, expedite approvals, and ultimately enhance health outcomes.

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