THE HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON HEALTH, AGED CARE AND SPORT – PARLIAMENTARY INQUIRY INTO DIABETES

Improving access to diabetes-related technology and medicines

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IMPROVING ACCESS TO DIABETES-RELATED TECHNOLOGY AND MEDICINES

Introduction

Diabetes Australia, the Australian Diabetes Society and the Australian Diabetes Educators Association represent 1.5 million Australians living with known, diagnosed diabetes; 500,000 Australians living with silent, undiagnosed type 2 diabetes; around 2 million Australians living with prediabetes; as well as the families and carers of people living with diabetes, diabetes healthcare professionals and researchers.

We are dedicated to reducing the incidence and impact of diabetes on people, health systems and society. We work with people living with, or at risk of, diabetes, their families and carers, health professionals, researchers, funders, other diabetes organisations and the community to positively change people's lives.

Given the scale and complexity of the diabetes epidemic, we will be making several submissions to the Inquiry including this submission on expanding access to diabetes technology and medicines. This will be augmented by submissions focusing on significant topic areas:

- General overview of diabetes
- Type 2 diabetes detection, prevention and remission
- Aboriginal and Torres Strait Islander diabetes.

For in-depth information about these topics please see the relevant submission.

The Parliamentary Inquiry into Diabetes is an opportunity to act decisively to reduce the impact of the diabetes epidemic, save lives and safeguard the sustainability of Australia's health system. We strongly encourage the Committee to recommend that the Australian Government adopt the recommendations contained herein.

Background

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

While some Australians living with diabetes enjoy good to very good access to diabetes technology, products and medicines, there are significant gaps in access to certain products or among certain cohorts of people that mean many Australians are missing out on essential technology or medicines.

One of the key reasons for this is the high cost of diabetes-related technology which makes it unaffordable for hundreds of thousands of people. This has real consequences for their health and our health system. Australia needs a comprehensive approach to diabetes technology subsidies that would expand access, accelerate approvals, and ultimately improve health outcomes.

Current access

Many diabetes products, medicines and technologies are available free or heavily subsidised by the world-leading diabetes products, services and support scheme, the National Diabetes Services Scheme (NDSS), or via the Pharmaceutical Benefits Scheme (PBS).

Every Australian living with type 1 diabetes has access to subsidised CGM or Flash GM technology. An estimated 70% of Australians living with type 1 diabetes are currently using the technology to manage their diabetes. [1] Access to subsidised insulin pumps in Australia is currently obtained via the Federal Government-funded Insulin Pump Program, which is administered by JDRF Australia, or via private health insurance or out of pocket.

Insulin pumps

Insulin pumps are battery-operated electronic devices about the size of a small mobile phone that can deliver background (basal) and meal-based (bolus) insulin to help a person manage their type 1 diabetes. Insulin pumps have been shown to help people keep blood glucose levels within a target range and reduce their risk of long-term and short-term diabetes-related complications.

However, despite their clear health benefit they are expensive and unaffordable for many. 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.[2]

The Federal Government's Insulin Pump Program, administered by JDRF Australia, provides fully subsidised access to a limited cohort of children and young people aged ≥21 years (up to 255 pumps per year) if they meet financial and medical criteria. There are around 16,000 Australians living with type 1 diabetes in this age group, which means only around 1.4% of children and young people can access insulin pumps via this pathway.

The second pathway is private health insurance (PHI); however, pumps are only required to be offered under "Gold" or Premium plans. Diabetes Australia, the Australian Diabetes Society and the Australian Diabetes Educators Association believe insulin pumps have been categorised incorrectly. Insulin pumps are essential therapy for many people living with type 1 diabetes who rely on them to maintain optimal blood glucose levels and prevent serious complications. They should be available on Basic health insurance plans.

Insulin pumps are already funded in New Zealand and via the National Institute for Health and Care Excellence (NICE) in the UK, with both countries having robust mechanisms for relating cost impact to patient-reported measures, particularly quality of life. Given the substantial quality of life and health benefits associated with insulin pump usage there are clear cost-effective reasons to significantly expand access.[3]

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[1] Based on an analysis of National Diabetes Services Scheme data.

[2] Walsh J, Roberts R, Weber D, Faber-Heinemann G, Heinemann L. Insulin pump and CGM usage in the United States and Germany: results of a real-world survey with 985 subjects. *J Diabetes Sci Technol*. 2015;9(5):1103–1110. doi: 10.1177/1932296815588945.

[3] Pease AJ, Zoungas S, Callander E, Jones TW, Johnson SR, Holmes-Walker DJ, Bloom DE, Davis EA, Zomer E. Nationally Subsidized Continuous Glucose Monitoring: A Cost-effectiveness Analysis. Diabetes Care. 2022 Nov 1;45(11):2611-2619. doi: 10.2337/dc22-0951. PMID: 36162008

Recommendation: Increase funding for the Insulin Pump Program to ensure more people, including people from low socio-economic backgrounds, are able to access this technology

Recommendation: Change private health insurance rules to enable people to access insulin pumps on Basic plans

Glucose monitoring technology

All Australians living with type 1 diabetes are eligible for subsidised CGM and Flash GM technology. This technology provides users with more accurate and more frequent data about glucose levels without regular finger prick checks and supports more informed decisions about diabetes management. It has 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. Studies have also shown subsidised access to CGM is a cost-effective health intervention.[4]

While the expansion of subsidies to all people living with type 1 diabetes has been warmly welcomed, Australians living with diabetes still have less access to this technology than people in other OECD countries. For instance, many countries now base eligibility for subsidised access on several clinical factors including insulin usage and hypo unawareness rather than the type of diabetes a person has.

Eligibility for subsidies in Japan, the USA, Germany and France are based on whether or not a person requires multiple daily insulin injections. The UK criteria combine insulin usage with hypo unawareness. In Sweden, eligibility is based on a combination of insulin usage and hypoglycaemic events, irrespective of diabetes type.

These examples all represent established, cost-effective international models of access and provide a framework to expand access to CGM and Flash GM for all people using multiple daily injections of insulin to manage their diabetes. This should include a small percentage of other people living with type 2 diabetes, estimated at around 8%, as well as people living with conditions that are very similar to type 1 diabetes, including cystic fibrosis-related diabetes, maturity-onset diabetes of the young (MODY), latent auto-immune diabetes in adults and Type 3c diabetes.

Studies show access to CGM for people living with type 2 diabetes using CGM is associated with better diabetes management and a lower long-term risk of diabetes-related complications.[5,6]

[4] Ibid.
[5] Beck RW, Riddlesworth TD, Ruedy K, Ahmann A, Haller S, Kruger D, McGill JB, Polonsky W, Price D, Aronoff S, Aronson R, Toschi E, Kollman C, Bergenstal R, DIAMOND Study Group. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. Ann Intern Med. 2017;167(6):365–74.
[6] Martens T, Beck RW, Bailey R, Ruedy KJ, Calhoun P, Peters AL, Pop-Busui R, Philis-Tsimikas A, Bao S, Diabetes Ther (2022) 13:1875–1890 1887 Umpierrez G, Davis G, Kruger D, Bhargava A, Young

Recommendation: Expand access to Continuous Glucose Monitoring to people living with other types of diabetes and to people living with type 2 diabetes using multiple daily injections of insulin

Recommendation: Future subsidies should be considered on clinical need, not the 'type' of diabetes a person lives with

The future of glucose monitoring

Self-monitoring of blood glucose levels is a fundamental aspect of all types of diabetes; however, people living with type 2 diabetes may only be required to do this for identified periods during a year. This is generally referred to as structured self-monitoring and is designed to give people a greater insight into how different foods and physical activities impact their blood glucose levels. These insights can then inform their ongoing diabetes management.

Structured self-monitoring has become more widespread and more effective as blood glucose monitors and testing strips have become cheaper and more widely available. Providing access to subsidised flash glucose monitoring for limited periods to allow people to do structured self-monitoring in this way will become best-practice type 2 diabetes care in the near future.

The benefits are already being demonstrated in a number of trials. For instance, Western Sydney Diabetes data shows CGM can contribute to significant improvements in diabetes management with outcomes including reductions in average HbA1c (from 10.1% to 8.5%) and increasing Time in Range (from 39.4% to 74.7%). Participants' daily insulin requirements have also been reduced. Clinicians have also reported positive behaviour change resulting from the increased information a person receives from Flash GM. Multiple international studies have also shown these significant benefits in people living with type 2 diabetes using some insulin and even people living with type 2 diabetes not using insulin.[7,8,9]

Finally, a recent analysis of the expansion of CGM to people living with diabetes in the United Kingdom compared to traditional self-managed blood glucose monitoring found it to be a cost-effective diabetes management option.[10] This finding is supported by a Health Technology Wales Evidence Appraisal Report on the cost-effectiveness of subsidised Flash GM that found expanding access to people living with type 2 diabetes was a cost-effective intervention when

L, McGill JB, Aleppo G, Nguyen QT, Orozco I, Biggs W, Lucas KJ, Polonsky WH, Buse JB, Price D, Bergenstal RM, MOBILE Study Group. Effect of Continuous Glucose Monitoring on Glycemic Control
in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. JAMA. 2021;325(22):2262–72.

[7] Ibid.

[8]Karter AJ, Parker MM, Moffet HH, Gilliam LK, Dlott R. Association of real-time continuous glucose monitoring with glycemic control and acute metabolic
events among patients with insulin-treated diabetes. JAMA. 2021;325(22):2273–84.

[9] Jackson MA, Ahmann A, Shah VN. Type 2 diabetes and the use of real-time continuous glucose monitoring. Diabetes Technol Ther. 2021;23(S1):S27–34.

[10] Marschner, S. et al. (2023) 'Cardiovascular risk management following gestational diabetes and hypertensive disorders of pregnancy: A narrative review', Medical Journal of Australia, 218(10), pp. 484–491. doi:10.5694/mja2.51932.

compared to self-managed blood glucose monitoring. Studies on the impact of this technology in Canada[11] and France[12] have reported similar quality-of-life and cost-effectiveness measures.

Recommendation: Consider the introduction of subsidies to support self-managed blood glucose monitoring via Flash GM or CGM for short periods

Technology and medicines assessment

New diabetes technology does not always fit within approval categories. It will be essential that any future assessment process is adaptable enough to respond to novel and unique technologies.

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 closed loop technology. This is the gold standard of care for people living with type 1 diabetes, both in terms of physical and mental health outcomes. Most major pumps and CGM devices will have at least some degree of interoperability in the future.

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

Here are examples of emerging technology without approval pathways:

Bionic pancreas: Similar to interoperable insulin pumps and CGM systems, the bionic pancreas combines an insulin pump, dosing decision software and a CGM to provide insulin doses automatically.

Smart pens: Connected to glucose monitoring devices, smart pens can calculate insulin dosage based on inputted carb ratios and other data.

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.

Ensuring assessment criteria remains person focussed

Diabetes technology is generally considered for approval and reimbursement based on clinical criteria; however, this should be expanded to consider emerging clinical markers and psychosocial benefits.

[11] Elliott, T et al. 2021. The impact of flash glucose monitoring on glycated hemoglobin in type 2 diabetes managed with basal insulin in Canada: A retrospective real-world chart review study. Diabetes and Vascular Disease Research 18(4): 14791641211021374.

[12] Roussel et al. Important Drop in Rate of Acute Diabetes Complications in People With Type 1 or Type 2 Diabetes After Initiation of Flash Glucose Monitoring in France: The RELIEF Study. Diabetes Care. 2021 Jun;44(6):1368-1376.

For people living with diabetes, the best care is care that reflects an individual's personal diabetes management preferences. Every person living with diabetes is different and people who manage a lifelong chronic condition have individual preferences about their diabetes management that should be respected.

This includes being able to choose the technology and medicines that best suit their preferences and biological needs, including at different stages of life such as during pregnancy and childhood.

The mental and emotional health impacts of diabetes can be serious. Up to 50 per cent of people living with diabetes experience mental health challenges in a given year.[13] This can include general mental health conditions as well as diabetes-specific challenges including diabetes-related anxiety, fear of hypoglycaemia and depression.

Diabetes technology can play a substantial role in alleviating many of these mental health challenges including by reducing the fear and anxiety related to unpredictable blood glucose levels, giving people greater freedom and reducing worry about long-term diabetes-related complications. This is why assessment of diabetes technology and medicines should consider the quality-of-life improvements and mental and emotional health benefits of new therapies, including Patient Reported Outcome Measures, experiential reviews, and quality-of-life measures, to ensure assessment processes are person-centred.

Additionally, it must be noted that the clinical criteria used to assess technology and medicines is evolving. An HbA1c check, which measures an individual's average blood glucose levels, has long been the gold standard. It is still an important measure; however, in some cases a healthy HbA1c result can obscure broad fluctuations in a person's blood glucose levels including dangerous highs and lows because they are tallied into an average number. Time in Range (TIR) is fast emerging as a more accurate indicator of improved long-term outcomes.[14,15] 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, the lower the risk of developing diabetes-related complications. It is essential assessment criteria evolve to keep pace with improving clinical measurements.

Recommendation: Broaden assessment criteria to ensure it remains person-centred and accounts for quality-of-life improvements

Recommendation: Ensure assessment criteria keep pace with research into the most effective clinical metrics

Health professional support

When commencing using diabetes technology a person requires dedicated diabetes education to ensure they can operate the technology and understand and appropriately respond to the data it provides. The introduction of CGM subsidies saw a large increase in the number of people

[13] Diabetes Australia (2020) Survey on the Mental and Emotional Impact of living with diabetes, Surveyed by: Orima Research. 6 July 2020.
[14] Gabbay, M.A. et al. (2020) 'Time in range: A new parameter to evaluate blood glucose control in patients with diabetes', Diabetology & Metabolic Syndrome, 12(1). doi:10.1186/s13098-020-00529-z.
[15] Battelino, T. et al. (2019) 'Clinical targets for continuous glucose monitoring data interpretation: Recommendations from the international consensus on time in range', Diabetes Care, 42(8), pp. 1593–1603. doi:10.2337/dci19-0028.

living with diabetes requiring education and support to commence using this technology; however, there were no education reimbursement arrangements in place. Without specific reimbursement mechanisms, such as an MBS item number, the people who can access this support, which is essential to maximising the health benefits of the technology and reducing risks associated with misinterpretation of the data, is limited.

Future subsidies must be accompanied by clear reimbursement mechanisms (such as an MBS item number) to support initiation of a technology. Ideally, this would be considered in parallel with technology assessments by the Medical Services Advisory Committee to ensure that when people have access to a technology, health professionals have access to appropriate reimbursement to provide essential education and training.

Recommendation: Introduce reimbursement mechanisms to ensure CDEs are appropriately funded to provide diabetes education to people commencing diabetes technology

Future of medicines

New diabetes medicines including Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and twincretins are transforming diabetes management. As outlined in our submission *Reducing the impact of type 2 diabetes: Detection, prevention and remission* these medications are very effective in supporting weight loss. It is essential that the people who would benefit most from these medications are able to access them. It is also important that the PBAC work with the manufacturers to ensure PBS indications keep pace with emerging research demonstrating clear benefits for different groups.

Additionally, all reasonable efforts should be made to encourage pharmaceutical companies to bring their medicines to Australia. For instance, Lyumjev is a fast-acting mealtime insulin produced by Eli Lilly that is comparable to Fiasp (see below). Lyumjev was approved by the FDA in 2020 and is now available in the US, Europe and Japan; however, it is uncertain when or if it will be accessible by Australians living with type 1 diabetes.

Medicines access

An emerging area of concern is the increasing frequency of shortages of diabetes-related medicines and products. In the past 18 months people living with diabetes have been impacted by shortages of Ozempic (semaglutide), Ryzodeg (insulin) and the GlucaGen HypoKit. In the case of both the HypoKit and Ozempic, there are no comparable products available in Australia. Shortages of diabetes medicines and products interrupt diabetes self-management and add to the mental health challenges associated with living with diabetes.

The three products outlined above are all produced by Novo Nordisk. It is not clear whether these are isolated cases or a systemic issue.

It is essential the Therapeutic Goods Administration thoroughly investigate the cause of these shortages and implement measures to ensure Australians can be confident that supply chains are sufficient to meet their needs.

Recommendation: Pharmaceutical Benefits Advisory Committee should consider a sponsor's capacity to meet demand for a medicine

Notifications of delisting

Earlier this year the only ultra-fast, rapid-acting insulin available in Australia, Fiasp, was removed from the PBS by its sponsor Novo Nordisk. Currently, the PBS only requires sponsors to provide one month's advance notice before delisting medicines.

While this may be suitable for generic drugs and those where there are a range of alternatives, it is not an appropriate time period for insulins, and particularly an insulin without available alternatives.

Insulin is a complex molecule and different formulations of insulin are not interchangeable. Switching between formulations can require multiple visits to a range of health professionals to obtain a new prescription, develop a new care plan, review that plan and titrate dosing before assessing the insulin's effectiveness after three-months. The current month's notice required means people may not even be able to secure an appointment with an endocrinologist to get a new prescription.

Recommendation: Pharmaceutical companies should be required to provide three-months' notice of their intention to remove an insulin formulation from the PBS

RECOMMENDATIONS

1. Increase funding for the Insulin Pump Program to ensure more people, including people from low socio-economic backgrounds, are able to access this technology
2. Change Private Health Insurance rules to enable people to access insulin pumps on Basic plans
3. Expand access to Continuous Glucose Monitoring to people living with other types of diabetes and to people living with type 2 diabetes using multiple daily injections of insulin
4. Future subsidies should be considered on clinical need, not the 'type' of diabetes a person lives with
5. Consider the introduction of subsidies to support self-managed blood glucose monitoring via Flash GM/CGM for short periods
6. Broaden assessment criteria to ensure it remains person-centred and accounts for quality-of-life improvements
7. Ensure assessment criteria keep pace with research into the most effective clinical metrics
8. Introduce reimbursement mechanisms to ensure CDEs are appropriately funded to provide diabetes education to people commencing diabetes technology
9. The Pharmaceutical Benefits Advisory Committee should consider a sponsor's capacity to meet demand for a medicine
10. Pharmaceutical companies should be required to provide three-months' notice of their intention to remove an insulin formulation from the Pharmaceutical Benefits Scheme