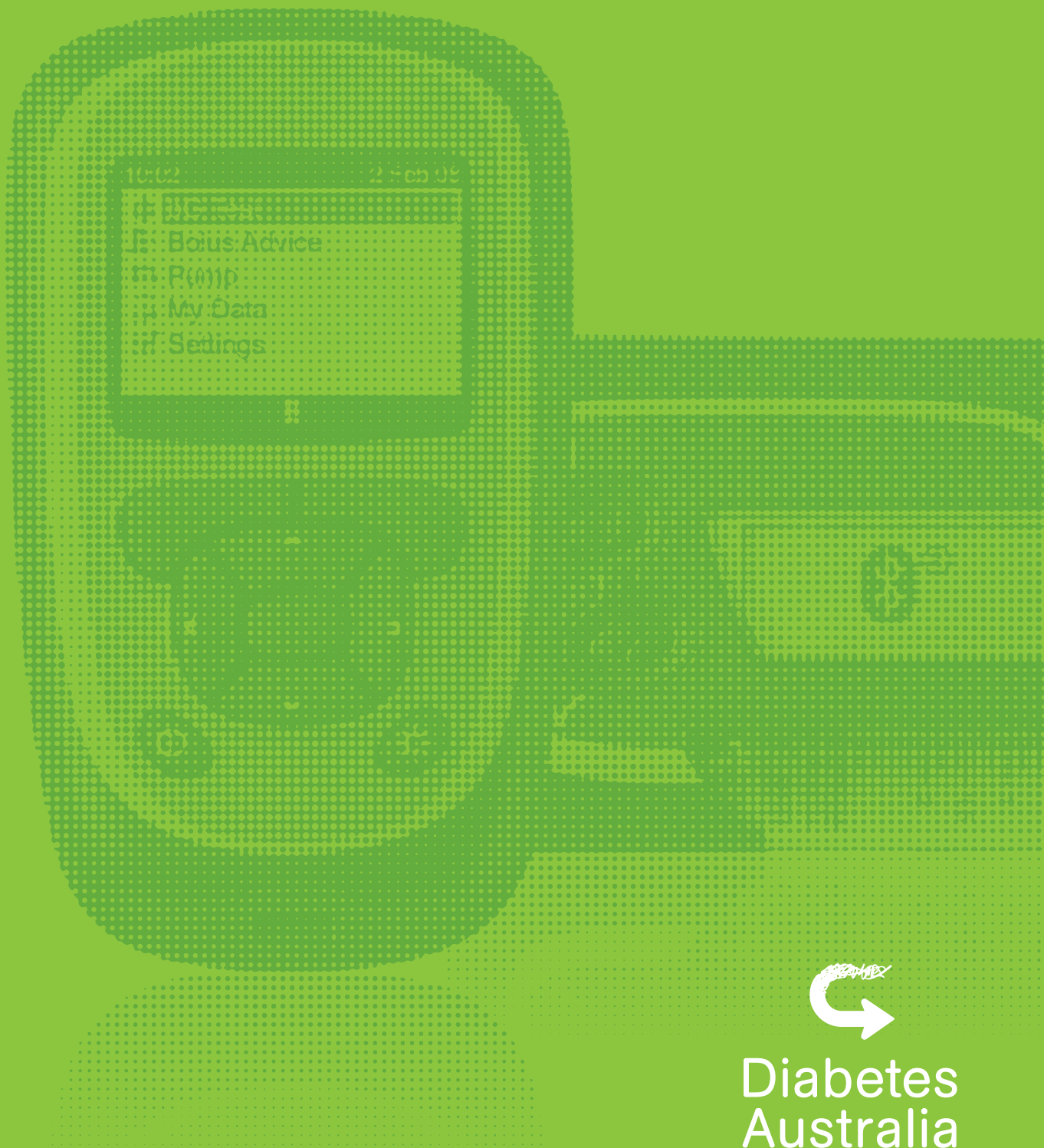


Insulin Pump Therapy in Australia

The Case for Action



Diabetes
Australia

This report has been prepared by Diabetes Australia.

Diabetes Australia is the national body for all people affected by all types of diabetes and those at risk. We are committed to reducing the impact of diabetes.

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THE CASE FOR ACTION

Insulin pump therapy can be life-changing and together with new technologies such as continuous glucose monitors, potentially life-saving for people with type 1 diabetes.

Insulin pump therapy can reduce the frequency of severe hypoglycaemia¹ (low blood sugar), enable better blood glucose management to reduce risk of complications, and reduce costs associated with ambulance use, emergency department presentations and hospital admissions.

Insulin pump therapy can reduce fear of hypoglycaemia¹, diabetes-related distress and depressive symptoms and can improve health status and quality of life.

Australia has one of the highest rates of type 1 diabetes in the world. In the past year alone over 3021 new cases of type 1 diabetes were registered (8 new cases every day). There are over 25,000 young people with type 1 diabetes under age 30 and there are 118,000 Australians with type 1 diabetes.

Due to cost and poor access only 14,990 (12%) Australians with type 1 diabetes have accessed insulin pump therapy, comparing poorly to the USA which has twice the level of access, estimated at 25%.

Australia has an unfair funding model for insulin pumps with around 80% of all pumps in Australia provided to people with private health insurance. Australians without private insurance do not have affordable access to insulin pumps.

The Insulin Pump Program introduced by the Australian Government in 2008 to improve access has to date only provided 611 pumps and has not been available to high-needs groups including young adults over age 18 years.

High and/or urgent clinical needs, people over 18 years, and women planning for and during pregnancy should be eligible for access to the Insulin Pump Program.

Currently, some people with type 1 diabetes with a clear clinical need are missing out on insulin pump therapy through the Government funded Insulin Pump Program. Funds are currently being allocated to ongoing consumables, reducing the number of pumps being provided.

There is strong consumer demand for access to insulin pumps because of quality of life and wellbeing benefits. These benefits must be considered to ensure people with type 1 diabetes have the freedom to manage their diabetes in the best way possible.

There are currently many divisions between the funding sources for insulin pump therapy, the provision of the pumps, the multidisciplinary clinical services required to commence pump therapy and ongoing review. This leads to many problems due to lack of integration and coordination and insulin pump therapy is often not optimised.

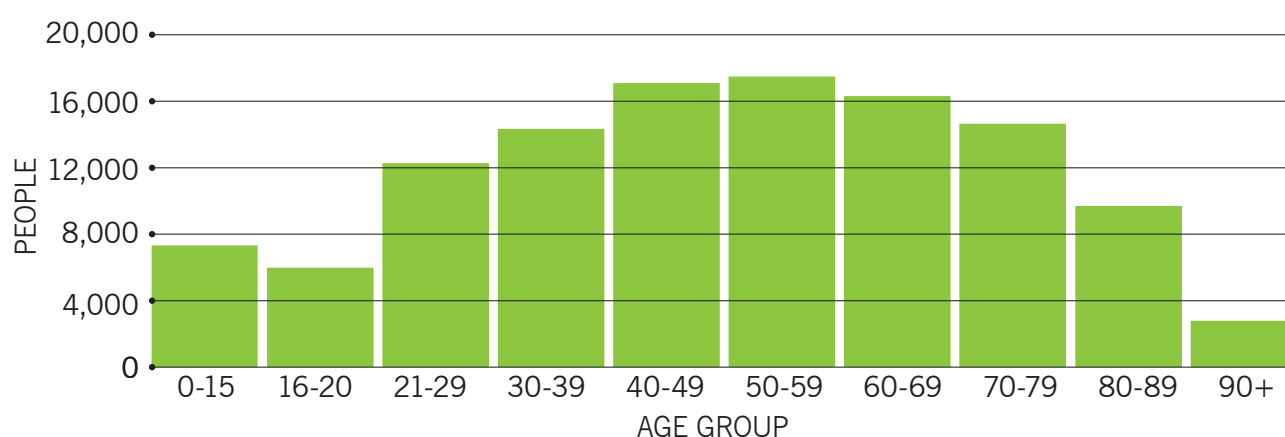
There is disadvantage and inequity caused by a lack of regional access to insulin pump commencement and management support.

Currently related new technologies such as continuous glucose monitoring are not accessible as they are not included in any funding or subsidies. These important new technologies need to be made more accessible to improve the lives of many families with type 1 diabetes and maximise the health outcomes possible.

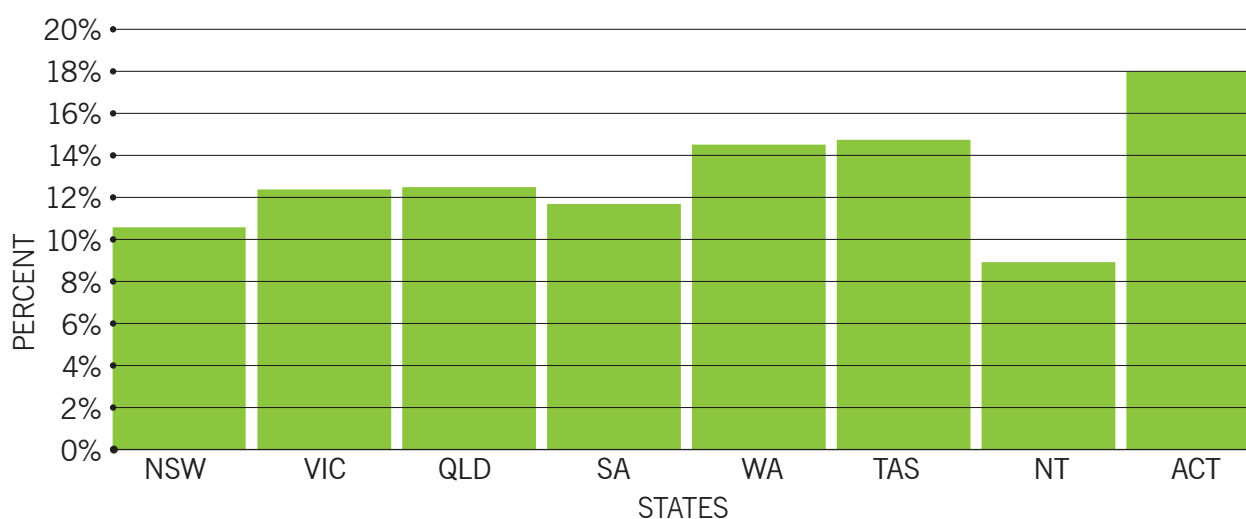
There were 117,939 people with type 1 diabetes registered on the NDSS at 30 June 2014

AGE GROUP	NUMBER	%
0–20	13,320	11
21–39	26,605	23
40–59	34,581	29
60+	43,433	37
Total	117,939	100

People With Type 1 Diabetes by Age Group



Per Cent of Type 1 NDSS Registrants Using Insulin Pumps by State at June 2013



The facts

Type 1 diabetes (formerly known as insulin dependent diabetes or juvenile diabetes) is a chronic, autoimmune condition. Approximately 118,000 Australians have type 1 diabetes and prevalence is increasing.

Australia has one of the highest rates of type 1 diabetes in the world.

Type 1 diabetes affects people of all ages, although it is most commonly diagnosed in childhood or adolescence. Last year, there were 3021 people newly registered with type 1 diabetes.

In the past decade the incidence of type 1 diabetes has increased by 30%³, at an average rate of 2.8% per year⁴.

Insulin pumps are an excellent tool for consistent delivery of insulin and maintain optimal blood glucose levels for people who choose to use them, and for whom it is clinically recommended.

High average blood glucose levels (HbA1c) are a strong predictor of the risk of developing long-term diabetes-related complications. Some people with type 1 diabetes cannot achieve optimal blood glucose control without the use of an insulin pump.

The long-term complications of type 1 diabetes can be devastating and include renal failure, neuropathy, cardiovascular disease, stroke and retinopathy.

The annual cost to the Australian health system of type 1 diabetes is at least \$570M. The average annual cost per person with type 1 diabetes is \$4669 (ranging from \$3468 with no complications to \$16,698 for both microvascular and macrovascular complications⁴).

Despite type 1 diabetes affecting less than 1% of the general population, complications alone are responsible for 4% of all ambulatory care or hospital admissions and 5% of all hospital bed days - more than angina or asthma⁵.

There are more than 14,990 insulin pump users in Australia, around 12% of people with type 1 diabetes. While access to insulin pumps is growing, Australia lags behind the USA where it is estimated that up to 25% of people with type 1 diabetes use insulin pump therapy.

To date, the Insulin Pump Program established in 2008 to improve access has provided access for only 611 young people under 18 years. There are currently 10,897 young Australians with type 1 diabetes under 18 years.

Currently, commencement of insulin pump therapy involves a hospital admission (usually as a day in-patient) and consultation with a multidisciplinary team that involves an endocrinologist (diabetes specialist), diabetes educator and dietitian, all trained in pump therapy. Only a small proportion of endocrinologists, diabetes educators and dietitians are trained and competent to initiate and monitor insulin pump therapy.

Ongoing use of an insulin pump costs approximately \$29 per month³ which covers the cost of consumables (reservoirs/cartridges to hold insulin in the pump and infusion sets to deliver insulin into the body). Consumables have been listed and subsidised on the National Diabetes Services Scheme (NDSS) since November 2004.

Recommendations for action

- **Establish a comprehensive and coordinated national approach to the provision of insulin pump therapy and related support to increase access to this life-changing technology for all Australians with type 1 diabetes integrating federal and state government and private health insurance funding.**
- **Establish equitable access for all Australians with type 1 diabetes of all ages to insulin pump therapy and broaden eligibility to the Insulin Pump Program based on clinical need. This should include:**
 - **People with recurrent severe hypoglycaemia**
 - **Women planning for and during pregnancy**
 - **People with sub-optimal HbA1c**
 - **People with fear of hypoglycaemia, diabetes related distress or ability for insulin pump therapy to improve their quality of life.**
- The choice of pump and related technology should take account of the needs of the individual in consultation with their healthcare team.
- Maximise the clinical benefits of insulin pump therapy after the initiation phase by ensuring ongoing support and monitoring for all people using a pump, a suitably trained, multidisciplinary team, adequate funding and resources for effective ongoing education, support and review to optimise the benefits and outcomes of this therapy.
- Change the current Insulin Pump Program policy to ensure that allocated funds are used to subsidise the cost of the pump only. Ongoing consumable costs should be borne by the National Diabetes Services Scheme (NDSS) which provides access to consumables for all Australians with type 1 diabetes.
- Integrate the Insulin Pump Program with the National Diabetes Services Scheme to enable better integration of provision of pumps and the necessary consumables, and coordinate better ongoing review using the NDSS database as the national register of insulin pump users.
- Develop nationally consistent guidelines to address health insurance funding of insulin pumps and related support.
- Require private health insurance funds to cover the cost of insulin pumps when therapy is initiated as an out-patient service, not only as the currently required in-patient services. This should be possible in accredited diabetes centres with suitable resources (endocrinologists, diabetes educators and dietitians)
- Require private health insurers to cover replacement pumps each four years in line with pump warranty periods.

The evidence for action

In 2011, the National Health and Medical Research Council (NHMRC) published *Evidence-Based Clinical Care Guidelines for Type 1 Diabetes in Children, Adolescents and Adults*, which emphasised that achieving excellent glycaemic control is by far the most critical factor in reducing diabetes complications.

The risk of these complications increases by about 30% for every 1% increase in HbA1c above 7%. Intensive insulin therapy reduces the risk of long-term complications but is associated with a threefold increase in severe hypoglycaemia⁶. Thus, intensive blood glucose management is necessary for long-term health but can be difficult to achieve in routine practice.

The evidence is clear that there are significant clinical benefits to using an insulin pump.

Compared to multiple daily injections evidence indicates that insulin pump therapy;

- is a reliable, safe and valuable management tool for people with diabetes;
- can assist in reducing HbA1c⁶, particularly for those with higher HbA1c⁷ using multiple daily injections, thus reducing the likelihood of developing long-term diabetes-related complications;
- is associated with a four-fold reduction in frequency of severe hypoglycaemia⁸, thus enabling lower HbA1c to be targeted, and reducing costs associated with ambulance use, emergency department presentations and hospital admissions;
- can reduce fear of hypoglycaemia⁸, diabetes-related distress and depressive symptoms; can increase satisfaction with treatment, and improve health status and quality of life;
- is best supported by a multidisciplinary team consisting of an endocrinologist (diabetes specialist), pump-trained diabetes educator and dietitian;
- requires education and regular follow-up care to ensure the person with diabetes is gaining the most benefit from insulin pump therapy;
- benefits can be enhanced when insulin pump therapy is used in combination with continuous glucose monitoring⁹;
- is beneficial to both adults⁷ and children with type 1 diabetes, and is of particular benefit to women with type 1 diabetes when planning for and during pregnancy¹⁰.

The current situation

There are considerable problems with the current system for providing access to insulin pump therapy. Despite significant investment and support by the Commonwealth Government, private health insurers, and hospitals and health services - the provision, use and support of insulin pump therapy in Australia lacks integration and there are many disconnects and problems for people with type 1 diabetes.

Many people, including those with the greatest need and those over 18 years, are not able to access insulin pump therapy. Some funding is not being used efficiently, the suitably trained and skilled workforce and support is not available in sufficient locations around Australia to provide equitable access, and the red tape makes it very difficult for all people with type 1 diabetes to access this potentially life-changing technology.

The current Insulin Pump Program provided by the Australian Government is inadequate and needs to be enhanced to achieve its policy objective and potential. A significant proportion of Insulin Pump Program funds (intended to provide pumps) are being allocated to the costs of consumables, despite the pre-existing and comprehensive coverage of their costs through the National Diabetes Services Scheme.

There is disconnection and disadvantage caused by a lack of regional access to insulin pump commencement and management support. Currently related new technologies such as continuous glucose monitoring are not accessible as they are not included in any funding or subsidies. These barriers to access must be addressed and the important new technologies need to be made more accessible to improve the lives of many families with type 1 diabetes and maximise the health outcomes possible.

‘If the Insulin Pump Program funds were exclusively used to subsidise the cost of the pump, at least another 160 pumps could have been provided in the 2012–13 period’.

The role of private health insurance

Nationally consistent guidelines around health insurance funding of insulin pumps and related support are required. These need to be easy-to-understand for consumers.

Private health insurers should cover the cost of insulin pumps when therapy is initiated in appropriately accredited diabetes centres with appropriate resources (endocrinologists, diabetes educators and dietitians).

The largest source of funding support to access a pump is private health insurance. Approximately 80% of insulin pump users obtained a private health insurance rebate for the purchase of their insulin pump.

Health insurance companies will normally cover the cost of an insulin pump, but there are many grey areas causing confusion for people with type 1 diabetes, particularly related to pump therapy initiation and replacement of a pump.

Since late 2011, insulin pumps were permanently added to Section C of the Government's prostheses list. This means a health insurance policy which covers hospital treatment must pay a benefit for an insulin pump when treatment is in a hospital setting as an in-patient.

For those requiring a replacement insulin pump, health insurers have different policies on replacement periods. For some, a benefit is provided on a cycle of every four to five years. Some policies do not recognise any wait time. Typically, the manufacturers' warranty for a pump is four years.

A person living with diabetes may find their request for a replacement pump out of warranty and not reliable or faulty is denied by their health insurer because their current pump is still in working order. If a pump is out of warranty and there is a fault, the device company will not provide a replacement pump.

Private health insurance funds should have a nationally consistent policy framework to guide the provision and replacement of pumps. Private health insurers should cover replacement pumps each four years in line with pump warranty periods.

Health insurers are not required to cover the cost of the pump if therapy is initiated (or a pump replaced) in a clinic outside of a hospital stay or as an out-patient service. This creates a drain on acute care medical facilities and could be easily reduced if insulin pump therapy is initiated (or upgraded) by appropriately trained healthcare professionals in appropriately accredited diabetes centres.

The role of private health insurance needs to be expanded beyond just funding the pump. New and related technologies such as continuous glucose monitoring should be covered by private health insurers based on clinical need as determined by clinicians in consultation with people with diabetes.

The current Insulin Pump Program

Diabetes Australia recommends that the Insulin Pump Program be changed to ensure that all allocated funds are used to subsidise the cost of the pump only. No ongoing insulin pump consumable costs should be charged to the Insulin Pump Program and these costs should be part the National Diabetes Services Scheme (NDSS).

The Insulin Pump Program should be integrated within the National Diabetes Services Scheme to enable better integration of provision of pumps and the necessary consumables and to enable ongoing monitoring and support for all Australians on insulin pump therapy linking with diabetes centres and services around Australia.

The Australian Government's Insulin Pump Program provides a means-tested subsidy (of up to 80% of the cost of the pump) to assist with the purchase cost of an insulin pump. The Insulin Pump Program is currently available only to people with type 1 diabetes under the age of 18 years who meet the eligibility criteria.

Unfortunately this program is not reaching maximum impact because pump consumable costs are incorporated into the program, reducing the funds intended for pump hardware.

In 2012-13, the Insulin Pump Program provided only 74 pumps. At a maximum subsidy of \$6400 each, this totals \$473,600, however it is understood that the budget allocation for this period was approximately \$1.5 million. This equates to only a small proportion of funding going to subsidise pump costs.

All recipients of the Insulin Pump Program subsidy are eligible to receive the ongoing consumables through the NDSS. If the Insulin Pump Program funds were exclusively used to subsidise the cost of the pump, at least another 160 pumps could have been provided in the 2012–13 period.

The National Diabetes Services Scheme has operated successfully for over 27 years and insulin pump consumables were already listed on the Scheme prior to the Insulin Pump Program commencing.

Disconnection and disadvantage

The current Insulin Pump Program needs to be integrated with the National Diabetes Services Scheme (NDSS) to ensure seamless integration of provision of pumps and consumables by the Australian Government. Insulin pump therapy initiation should be supported by a trained multidisciplinary team, with sufficient funding, staff and resources for education of the person with diabetes (and family where necessary), and for ongoing support and education to maximise the clinical benefits of insulin pump therapy.

The NDSS database of insulin pump users (currently 14,990 Australians) should be utilised as a register for ongoing contact and information for people with type 1 diabetes using pumps and to facilitate recall to diabetes centres and supports to ensure ongoing care and support is optimised.

All Australians with type 1 diabetes, regardless of age, should have equitable access to insulin pump therapy and eligibility for the Insulin Pump Program needs to be based on clinical need and broadened to include adults over the age of 18 years, as well as children.

The disconnection between the Insulin Pump Program and the NDSS means that there is no data sharing and ability to match the pump supply with the consumable supply for the same person. If the pump program is integrated with the NDSS it will be far simpler for ongoing support to be improved for people with type 1 diabetes using insulin pump therapy.

Glycaemic benefits for people using pumps are likely to be limited by ineffective self-management, and strategies are needed to promote engagement and ongoing motivation. People using an insulin pump receive some education at insulin pump therapy initiation, largely focused on the technical skills needed to use the insulin pump, with some attention to matching carbohydrate intake to insulin doses, and dose adjustment.

‘All Australians with type 1 diabetes, regardless of age, should have equitable access to insulin pump therapy and eligibility for the Insulin Pump Program needs to be based on clinical need and broadened to include adults over the age of 18 years, as well as children’.

Access to support varies depending on where a person lives. Those living in regional areas are disadvantaged. According to the Australian Institute of Health and Welfare, 70% of pump users are located in major cities, a further 21% in inner regional areas, 9% in outer regional and just over 1% in remote and very remote areas.

This lower access in remote and regional areas reflects difficulties in finding qualified health professionals able to initiate and support insulin pump therapy. This service is predominantly available in diabetes clinics in metropolitan teaching hospitals, although private services are also provided by some community-based credentialled diabetes educators and a number of smaller regional hospitals.

The current age-based eligibility criterion means that 107,576 adults over 18 years of age (representing some 91% of all people with type 1 diabetes) are currently excluded from the Insulin Pump Program solely on the basis of their age.

There is evidence of equivalent benefit of insulin pump therapy for adults with type 1 diabetes as for children/adolescents in terms of glycaemic control; for those who experience recurrent severe hypoglycaemia; women with type 1 diabetes planning for and during pregnancy; and for older people, many of whom may have impaired awareness of hypoglycaemic symptoms.

New technologies

The technological advances in diabetes care are progressing at a rapid pace and in the next few years some will become more common management tools in Australia.

Continuous glucose monitoring (CGM) technology has been a big step forward in enhancing diabetes management, bringing us one step closer to a 'closed loop' or artificial pancreas. CGM-augmented insulin pumps will sound an alarm when glucose levels drop too low, helping to identify and prevent hypoglycemia. Historical glucose profiles can be provided, helping the user to predict 'out of target' blood glucose levels and communicate patterns with their healthcare team.

Currently there is no pathway for new diabetes technologies to be considered by government, made accessible to people living with diabetes and subsidised when appropriate.

The major barrier to uptake of this new diabetes monitoring technology is cost. There is no subsidy or support currently available to cover the cost of transmitters or sensors, even for those eligible for a subsidy for an insulin pump. The additional cost, over and above the cost of the pump is around \$5000 per year.

The NDSS is the obvious and most efficient and effective existing national program to help facilitate access to new technologies and pathways.

Coordinated action

Diabetes Australia is calling for a comprehensive and coordinated national approach to the provision of insulin pumps and related support to increase access to this life-changing technology for all Australians with type 1 diabetes.

We need a national insulin pump therapy initiative that coordinates and integrates across the current disconnects and considers:

- eligibility for all people with type 1 diabetes with a focus on clinical need and consumer benefits in terms of quality of life
- initiation of insulin pump therapy in more settings
- linkage of pump technology access with ongoing consumables and other emerging technologies
- capacity for diabetes centres and appropriately trained healthcare professionals to meet demand of ongoing review and support
- integration of public and private access in a shared system.

Diabetes Australia is calling for a comprehensive and coordinated national approach to the provision of insulin pumps and related support to increase access to this life-changing technology for all Australians with type 1 diabetes.

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