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Diabetes technology in Australia: scoping report

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Contents

Summary

Diabetes is a chronic condition in which the body cannot properly use its main energy source—the sugar glucose—resulting in high levels of glucose in the blood. It is caused either by the inability of the body to produce insulin (a hormone made by the pancreas to manage blood glucose levels) or by the body not being able to use insulin effectively, or both.

Management for people with diabetes includes healthy eating, regular physical activity and ongoing monitoring of glucose levels to minimise the risk of diabetes-related complications. All people with type 1 diabetes, and some people with type 2 diabetes, gestational diabetes and other forms of diabetes will also require insulin to manage their condition. Some people with diabetes may require other medications to maintain glucose levels within their target range.

Technology is transforming care for people with diabetes. It is increasingly being used for management of the condition. The technology available can be categorised in 3 broad groups: technology for monitoring glucose; technology for insulin delivery; and information technology for managing diabetes.

This report will assess and describe the current data gaps and currently available data sources for monitoring the use of technology (devices) in managing diabetes. The report will also briefly outline the approval, access and distribution pathways for diabetes technology in Australia.

Data gaps and future opportunities

The data landscape has changed in recent years, with information about the uptake and characteristics of the users being captured in a range of administrative data sets and outcomes in clinical registries. Information about the number and characteristics of diabetes technology users, and adverse events associated with the use of technology, is being captured in some administrative data sets and clinical outcomes in clinical registries. However, there are gaps in information about the use of diabetes technology among the diabetes population and the impact of the technology on diabetes-related complications. Data gaps identified include the lack of nationally representative data sources, and the inability to comprehensively report across key monitoring areas including the trends in the uptake of devices for the management of diabetes; characteristics and experiences of diabetes technology users; and the impact on short-term and long-term diabetes-related complications.

Undertaking data improvement activities such as reporting using available data sources, modifying or developing data sources and linkage of data sources will require considerable resources. Future work will need to consider carefully the availability of data for reporting across key areas from existing data sources, balanced against the costs and benefits of undertaking data activities to improve the monitoring of the use of technology in managing diabetes.

Approval, access and distribution pathways

The availability of and access to effective technology for Australians with diabetes has expanded in recent years. The approval, access and distribution pathways of new diabetes technology involve multiple stakeholders and processes. While there is a rigorous approval process for most diabetes management technology before it is available on the market in Australia, public information regarding the approval, access and distribution pathways for diabetes technology is limited.

1 Background

Diabetes that does not meet management goals can lead to the onset of diabetes-related complications including heart disease, stroke, kidney disease, retinopathy (loss of vision), neuropathy (nerve damage) and lower limb amputation. Maintaining glucose levels in range can prevent and reduce these complications.

Recently, the uptake of technology for managing diabetes to improve self-management as an adjunct to conventional therapy has increased. The availability of and access to these technologies has changed in recent times and a range of technology for monitoring glucose levels, such as continuous glucose monitoring (CGM), flash glucose monitoring (flash GM), and self-management tools such as mobile phone apps, is used. Other devices, such as insulin pumps, have been available for the last few decades in Australia as an alternative to the traditional method of injecting insulin with a pen or syringe.

The Australian Institute of Health and Welfare (AIHW) previously reported on the use of insulin pumps for people with type 1 diabetes in Australia (AIHW 2012). That report provided information regarding the number and characteristics of people using insulin pumps, and insights into their experiences. Since the *Insulin pump use in Australia* (2012) report, there has been an accelerated uptake of other technology for monitoring glucose levels and self-management tools, and changes in the access to these technologies.

There is a lack of comprehensive national data regarding the use of technology to manage diabetes and the impact of the technology on short-term and long-term diabetes-related complications, and the approval, access and distribution pathways for these technologies. The data landscape has changed in recent years, with some technology for delivering insulin and monitoring glucose being subsidised by the Australian Government, and information about usage and characteristics of users being captured in administrative data sets. With the increasing uptake of technology, clinical registries capturing information about diabetes care now also collect information on technology use.

Comprehensive information is needed to continue to build the evidence base about technology use in diabetes care, and its impact on the health of people with diabetes at the national level, and the formulation of policies and guidelines for diabetes care and access to technology.

This report describes the data sources currently available for monitoring the use of technology in the management and treatment of diabetes; identifies gaps; and provides recommendations for future work. The report also provides a brief outline of the approval, access and distribution pathways for diabetes technology.

Structure of this report

This report has 6 chapters:

- Chapter 1 outlines the purpose and structure of the report.
- Chapter 2 describes diabetes and provides an introduction to its management and treatment.
- Chapter 3 outlines the technology available for diabetes management.
- Chapter 4 describes the approval, access and distribution pathways for diabetes technology.
- Chapter 5 discusses the importance of monitoring the use of technology for diabetes care, and describes the data sources currently available to monitor the use of technology.
- Chapter 6 discusses data gaps and provides recommendations for improving the monitoring of technology use in managing diabetes.

2 What is diabetes?

Diabetes is a chronic condition marked by high levels of glucose in the blood. It is caused either by the inability of the body to produce insulin (a hormone made by the pancreas to control blood glucose levels) or by the body not being able to use insulin effectively, or both.

The main types of diabetes are:

- type 1 diabetes—a lifelong auto-immune disease that can occur at any age
- type 2 diabetes—most common form of diabetes, often associated with lifestyle factors and generally of later onset. Risk is also associated with genetic and family-related risk factors
- gestational diabetes—glucose intolerance of varying severity, which develops or is first recognised during pregnancy
- other types of diabetes—typically related to certain conditions or syndromes which result in defects in insulin secretion, insulin action, or both.

Treatment and management of diabetes

Management for people with diabetes includes healthy eating, regular physical activity and ongoing monitoring of glucose levels to minimise the risk of short-term and long-term diabetes-related complications. Some people with diabetes may require medications to maintain in-range glucose levels. Keeping blood glucose levels within an individual's target range requires a careful balance between glucose monitoring, diet, physical activity and medication.

All people with type 1 diabetes, and some people with type 2 diabetes, gestational diabetes and other forms of diabetes will also require insulin therapy to manage their condition.

Treatment of diabetes by type

Type 1 diabetes

A person with type 1 diabetes requires daily insulin replacement to survive, except in cases where a pancreatic transplant occurs.

Type 2 diabetes

Managed with changes to diet and exercise, oral hypoglycaemic (glucose-lowering) drugs such as sulfonylureas, non-insulin injectable glucose-lowering medications, insulin injections, or a combination of these methods.

Gestational diabetes

Often managed with changes to diet and exercise, while some cases require treatment with insulin and/or oral hypoglycaemic medications.

Other types of diabetes

For some people with other types of diabetes, adequate glycaemic management can be achieved through diet and exercise or the use of other medications. Some, however, may also require insulin to manage their glucose levels.

Glucose monitoring

Monitoring glucose levels, also known as self-monitoring, is an important part of diabetes management. It provides information about how food, physical activity, stress, hormones and medications are affecting glucose levels and helps people with diabetes to change their management if their glucose levels are not within their target range.

Blood glucose monitoring

Self-monitoring of blood glucose involves checking blood glucose levels. Recommendations for glucose management plans for people with diabetes vary according to the type of diabetes and the medications and/or insulin being used (RACGP 2020).

Monitoring of blood glucose by type of diabetes

Type 1 diabetes

Monitoring of blood glucose levels regularly (up to 6 times every day or as directed by a doctor) is recommended (Diabetes Australia 2020c).

Type 2 diabetes

Monitoring of blood glucose is recommended:

- for people on insulin and sulfonylureas
- for people not on insulin but having difficulty achieving glucose levels in their target range
- when monitoring hypoglycaemia or hyperglycaemia arising from another illness
- during pre-pregnancy and pregnancy
- when there is a clinical need for monitoring (for example, during changes in management or lifestyle)
- when glycosylated haemoglobin (HbA1c) estimates are unreliable.

It is not recommended that people with type 2 diabetes who are considered low risk and using oral glucose-lowering drugs (with the exception of sulfonylureas which carry a risk of inducing hypoglycaemia) undertake routine self-monitoring of blood glucose. The method and frequency of monitoring for type 2 diabetes depends on individual circumstances and therapeutic aims (RACGP 2020).

Checking blood glucose levels usually involves pricking the tip of the finger and placing a drop of blood onto a blood glucose strip which is inserted into a blood glucose monitor, which then displays the blood glucose level.

Continuous and flash glucose monitoring

In the last 10 years, monitors measuring interstitial glucose (fluid in the tissue) have been available in Australia. The 2 options are continuous glucose monitoring (CGM) and flash glucose monitoring (flash GM) devices which both use a sensor inserted just under the skin. These devices are increasingly used by people with (predominantly type 1) diabetes. (RACGP 2020).

Insulin therapy

Conventional insulin therapy involves multiple daily injections. Insulin is injected through the skin into the fatty tissue known as the subcutaneous layer, throughout the day.

Insulin can be injected in different ways: by insulin syringe, an insulin pen with a fine needle, or an insulin pump (Shah et al. 2016).

Diabetes-related complications

The objective of diabetes management and treatment is to keep glucose levels within an individual's target range. When levels fluctuate beyond a recommended range, there is increased risk of short-term and long-term diabetes-related complications.

Short-term complications include diabetes ketoacidosis (a life-threatening condition due to lack of insulin, leading to a profound disturbance of the metabolism and a build-up of acids in the blood); hypoglycaemia (low blood sugar); hyperglycaemia (high blood sugar); increased susceptibility to infections; and reduced ability to heal.

Long-term diabetes-related complications may include heart disease, stroke, kidney disease, retinopathy, neuropathy and lower limb amputation.

3 Diabetes technology

Technology is transforming care for people with diabetes. It is increasingly being used for management of the disease. The technology can be broadly categorised into 3 main groups:

1. Technology for monitoring glucose—such as blood glucose monitoring, CGM and flash GM, which provide information about glucose patterns.
2. Technology for insulin delivery—such as insulin pens, syringes, continuous subcutaneous infusion of insulin (insulin pumps).
3. Information technology for management of diabetes—such as mobile phone apps, text messaging, wearable technology (for example, fitness trackers), web-based programs and clinic-based chronic condition care programs (RACGP 2020).

Some technologies have different components which have different functions (such as monitoring blood glucose levels, or medication delivery), and can fit more than 1 category.

The Australian Evidence-Based Clinical Guidelines for Diabetes provide recommendations for the use of medical technology to manage type 1 diabetes by health professionals and people living with diabetes, and guide shared decision making for treatment (Living Evidence for Diabetes Consortium 2020). In addition, the Australian Diabetes Society, the Australian Diabetes Educators Association, the Australasian Paediatric Endocrine Group and the Australasian Diabetes in Pregnancy Society Working Group have developed an Australian consensus statement for the implementation of technologies for people with type 1 diabetes. The Working Group recommended a shift from a focus on strict glycaemia criteria towards engagement and individualised management goals for commencing or continuing diabetes management technologies (Pease et al. 2021).

A comprehensive assessment of the evidence regarding the benefits and harms, the outcomes and key issues (such as equitable access, acceptability and feasibility) are presented in the Australian Evidence-Based Clinical Guidelines for Diabetes for the use of medical technology in managing type 1 diabetes (Living Evidence for Diabetes Consortium 2020). A range of studies investigate the impacts of the use of technology in managing diabetes on short- and long-term outcomes. A detailed analysis of the evidence regarding these impacts was not undertaken for this report, and information has been summarised from the published studies in Table 3.1.

The evidence regarding the impact of the use of technology on outcomes summarised in the sections below is drawn mainly from randomised controlled trials, cohort studies and meta-analysis or review of these studies. Randomised controlled trials are the gold standard for assessing the impact of an intervention, due to the lack of bias. However, randomised controlled trials are often relatively short in duration and might not mimic the treatment and management of diabetes in everyday life. Other sources such as administrative data sets and clinical registers present an opportunity to examine the effects of the technology on long-term diabetes-related complications and the impact of technology on experiences and outcomes.

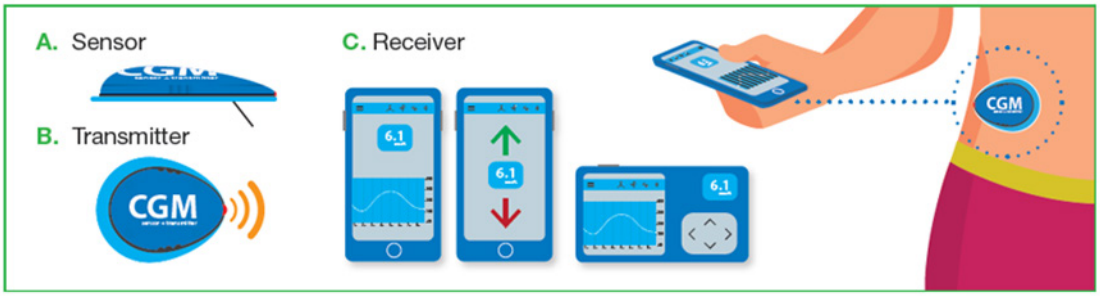
Due to limited evidence regarding the use of technology in the management of gestational diabetes and other types of diabetes, this chapter focuses on type 1 and type 2 diabetes.

Continuous glucose monitoring

CGM devices continuously monitor blood glucose levels, taking glucose measurements at regular intervals 24 hours a day. They collect information and provide real-time and summary glucose data. This real-time information allows people with diabetes to make timely decisions regarding management, whether by adjusting their insulin therapy or changing behaviour to achieve in-range glucose levels (Reddy et al. 2020).

The CGM system sensor is inserted under the skin to measure glucose in the fluid in the tissue. A transmitter is attached to the sensor and sends glucose readings through Bluetooth to a receiver (such as a standalone reader device, compatible insulin pump or smart phone apps) that allows people to view their glucose data (Figure 3.1). CGM devices have alarms that alert the user to out-of-range blood glucose levels, and can also be integrated with compatible insulin pumps. Data collected can be shared with health care professionals through secure Cloud-based platforms. CGM reduces the need to check blood glucose levels by pricking the tip of the finger and using a blood glucose monitor. However, finger prick checks are required at least twice daily for calibration (Diabetes Australia 2017).

Figure 3.1: Diagram of continuous glucose monitoring



Source: National Diabetes Services Scheme Continuous Glucose Monitoring fact sheet (Diabetes Australia 2020a).

The Australian Evidence-Based Clinical Guidelines for Diabetes recommends CGM instead of self-monitoring of blood glucose for adults with type 1 diabetes who are using multiple daily injections (Living Evidence for Diabetes Consortium 2020). CGM devices may also be used in the management of other diabetes such as type 2, especially for those at high risk of hypoglycaemia, with impaired awareness of hypoglycaemia and with high glucose variability (RACGP 2020).

Outcomes for people with type 1 diabetes

Randomised controlled trials in the United States and Germany have shown that adults with type 1 diabetes using multiple daily insulin injections and CGM with alerts see a decrease in HbA1c, increase in the time in target glucose range and decrease in severe hypoglycaemia when compared with self-monitoring blood glucose (Beck et al. 2017; Jendle & Heinemann 2018; Riddlesworth et al. 2017).

Since 2017, the Australian Government has provided access to fully subsidised CGM for eligible people. For more information see ‘Chapter 4 Approval, access and distribution pathways for diabetes devices’. A recent study in Australia examined the impact of CGM at a large tertiary paediatric diabetes centre between May 2017 and December 2019 following the subsidisation of CGM devices for people under 21 years of age with type 1 diabetes.

The study found that people ceasing CGM use was high, with 28% and 33% of people ceasing use at 12 and 24 months after CGM commencement. People cited a dislike for wearing the device; technical and alarm issues; and site issues as reasons for ceasing use. There was no change in HbA1c levels before or after the use of CGM over the 24-month period. There was a reduction in the rate of severe hypoglycaemia over the 24 months but this was not statistically significant (Swaney et al. 2020).

The impact of CGM on long-term diabetes-related complications was not investigated by randomised controlled trials or cohort studies examining the impact of CGM in people with type 1 diabetes.

Outcomes for people with type 2 diabetes

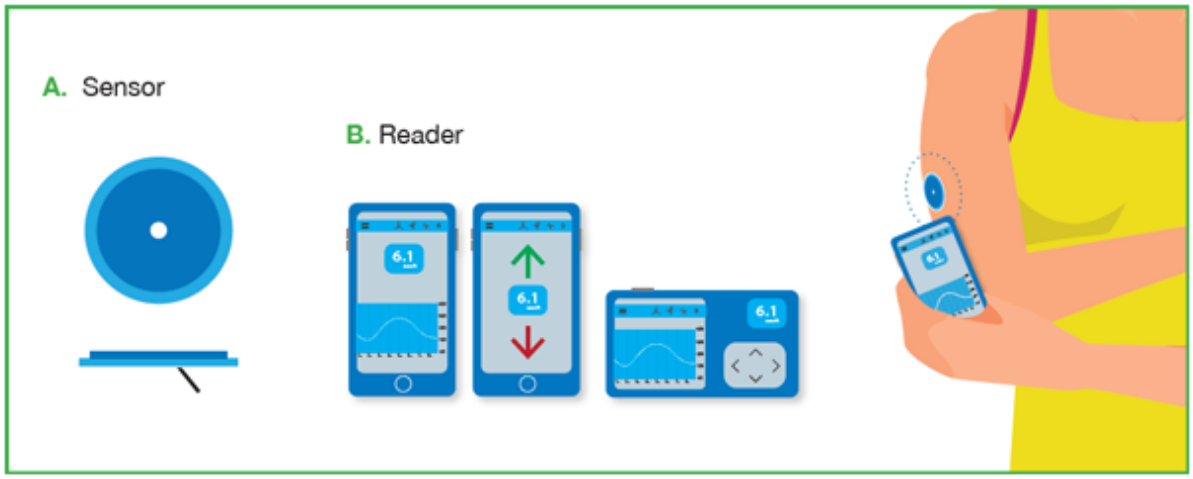
The evidence from a narrative review of randomised controlled trials and observational trials also showed that CGM reduced HbA1c, bodyweight and caloric intake; promoted increased maintenance of personal eating plans; and increased physical activity compared with self-monitoring of blood glucose in adults with type 2 diabetes (Taylor et al. 2018). However, results should be interpreted with caution as the studies included in the review had small sample sizes and confounding from adjunctive counselling, education techniques and clinical involvement.

Relatively few studies have investigated the effects of CGM on outcomes in people with type 2 diabetes, and most are short in duration. Hence the use of CGM and associated impacts on short-term and long-term diabetes-related complications for adults with type 2 diabetes have not been investigated to a significant extent and are not supported by robust clinical evidence.

Flash glucose monitoring

Flash GM is a sensor technology that measures glucose in the fluid in the tissue and collects information about the patterns in glucose levels. A small disc is positioned on the back of the upper arm, holding a sensor that is inserted under the skin into the subcutaneous tissue. The generation of flash GM in Australia at present requires the user to scan over the sensor (with either a mobile phone open to the compatible app), or a standalone reader device to give a glucose reading (Figure 3.2). Data are gathered in a smart phone app and can be shared with health professionals through a secure Cloud-based platform. Currently, these devices do not alert the user to either hypoglycaemia or hyperglycaemia without scanning (Diabetes Australia 2017).

Figure 3.2: Diagram of flash glucose monitoring



Source: National Diabetes Services Scheme Flash Glucose Monitoring fact sheet (Diabetes Australia 2020a).

Outcomes for people with type 1 diabetes

A randomised controlled trial in Australia showed that flash GM did not result in greater improvements in glucose management than self-monitoring of blood glucose in youths with type 1 diabetes and high-risk glucose management. However, the use of flash GM resulted in higher glucose checking frequency and diabetes treatment satisfaction in youths with type 1 diabetes and high-risk glucose management (Boucher et al. 2020).

The use of flash GM devices in people with type 1 diabetes treated with multiple daily injections was associated with reductions in the time and frequency of hypoglycaemia compared with self-monitoring of blood glucose in another multi-centre randomised controlled trial that included 23 European diabetes centres (Oskarsson et al. 2018).

In Australia, the use of flash GM in people with type 1 diabetes with a recently confirmed episode of clinically significant hypoglycaemia did not reduce the incidence of severe hypoglycaemia when compared with people with type 1 diabetes who were self-monitoring their blood glucose levels (Davis et al. 2020).

International randomised controlled trials examining the impact of flash GM on outcomes were short in duration and have not investigated the effects of the technology on long term diabetes-related complications.

Outcomes for people with type 2 diabetes

Systematic review and meta-analysis of 2 randomised controlled trials have shown that flash GM use was associated with a non-significant reduction in HbA1c compared with self-monitoring of blood glucose in people with type 2 diabetes (Castellana et al. 2020).

In Australia, a randomised controlled trial (GP-OSMOTIC study) found that people with type 2 diabetes using flash GM had lower HbA1c levels than those with usual clinical care at 6 months after commencement of flash GM. There were no differences in HbA1c level in those using flash GM compared with those on usual care at 12 months, suggesting any effect in HbA1c reduction is short-term. However, glucose data were not available to participants in the study until their general practice visit, where the results were discussed

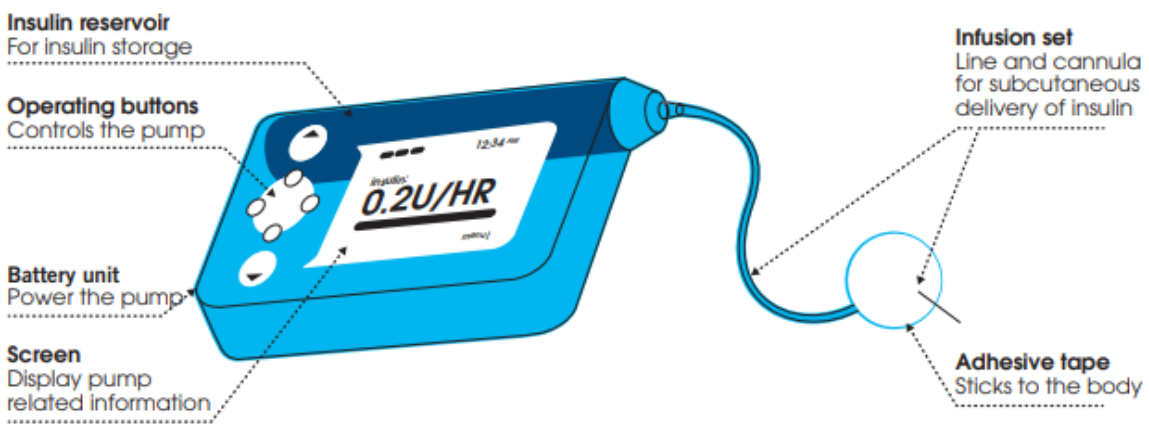
with a health professional (Furler et al. 2020). The same study also found that GP consultations increased in those using flash GM in the 6 months following its use (McMorrow et al. 2021). Another study in Australia found that there were no differences in the incidence of severe hypoglycaemia in people with insulin-treated type 2 diabetes with a recently confirmed episode of clinically significant hypoglycaemia and using flash GM compared with those self-monitoring their blood glucose levels (Davis et al. 2020).

Relatively few studies have investigated the effects of flash GM on outcomes in people with type 2 diabetes and none of these studies investigated its effect on long-term diabetes-related complications.

Continuous subcutaneous insulin infusions

Continuous subcutaneous insulin infusions pump devices, more commonly known as insulin pumps, are computerised devices that deliver insulin subcutaneously through a plastic tube attached to the body. An insulin pump is a small battery-operated electronic device that holds a reservoir of insulin. It is programmed to deliver insulin into the body through thin tubing known as an infusion set, and is worn 24 hours a day outside the body. The infusion set has a fine needle or flexible Teflon cannula that is inserted just below the skin where it stays in place for 2 to 3 days (Figure 3.3). Whenever food is eaten the pump is programmed to deliver a surge of insulin into the body similar to the way the pancreas does in people without diabetes. Between meals a small and steady rate of insulin is delivered (Diabetes Australia 2020d).

Figure 3.3: Diagram of insulin pump (without CGM)



Source: Understanding insulin pumps: information for people with type 1 diabetes (Diabetes Victoria 2013).

In recent years, insulin pumps have been integrated with CGM. There are 2 broad categories of insulin pumps:

- non-automated insulin pumps with or without CGM (including low glucose suspend or predictive low glucose suspend functions that suspend insulin delivery)
- automated insulin delivery systems, also known as ‘hybrid closed loop insulin pumps’.

Insulin pumps are being used increasingly to manage type 1 diabetes. However, factors such as high acquisition costs, ongoing costs for insulin pump consumables, and not wanting to be attached to a device influence the use of pumps in people with type 1 diabetes (Pyrlis et al. 2019).

The Australian Evidence-Based Clinical Guidelines for Diabetes recommends the use of an insulin pump or multiple daily injections for children and adolescents based on the preference of the person with type 1 diabetes and the carer. In adults with type 1 diabetes, it is suggested that insulin pump therapy is used rather than multiple daily injections (Living Evidence for Diabetes Consortium 2020).

Non-automated insulin pumps

Non-automated insulin pumps are worn 24 hours a day and the delivery of insulin through the pumps is controlled by the user. The basal dose is a continuous dose of insulin designed to keep blood glucose levels within the normal range between meals without inducing hypoglycaemia and the bolus dose is administered at meal times or when blood glucose levels are high, to prevent hyperglycaemia. Current pumps require the user to periodically review and modify settings for insulin basal rates based on their blood glucose levels and insulin requirements. Insulin boluses are adjusted manually by the user according to carbohydrates consumed at meal times or when blood glucose levels are high.

These devices are available with or without CGM. Various options include insulin pumps with low glucose suspend setting (the insulin pump suspends the delivery of insulin if low blood glucose is detected via the CGM) and predictive low glucose suspend setting (the insulin pump suspends the delivery of insulin if low blood glucose is detected or glucose trajectory predicts low blood glucose levels via the CGM).

Outcomes for people with type 1 diabetes

Meta-analysis and randomised controlled trials have shown that people with type 1 diabetes using non-automated insulin pumps have lower HbA1c levels, lower insulin requirements and improvements in glucose management compared with people using multiple daily injections (Benkhadra et al. 2017; Pickup et al. 2002). One cohort study showed that the non-automated insulin pump compared with multiple daily insulin injections, and was associated with lower risks of severe hypoglycaemia and diabetes ketoacidosis among young people with type 1 diabetes in Germany (Karges et al. 2017).

There is limited evidence on the effects of non-automated insulin pumps on long-term diabetes-related complications. Cohort studies have shown that non-automated insulin pump therapy was associated with lower cardiovascular mortality and lower rates of retinopathy and peripheral nerve abnormality in people with type 1 diabetes in Europe (Marchand et al. 2017; Steineck et al. 2015; Zabeen et al. 2016).

Outcomes for people with type 2 diabetes

The evidence surrounding the use of insulin pumps for people with type 2 diabetes is mixed. A meta-analysis of randomised controlled trials has shown that non-automated insulin pumps did not significantly improve HbA1c levels and the rate of hypoglycaemic episodes in comparison with multiple daily injections (Monami et al. 2009). Smaller multi-centre randomised controlled trials have shown that people with type 2 diabetes using non-automated insulin pumps had lower HbA1c and lower insulin requirements than people treated with multiple daily injections in Canada, Europe, Israel, South Africa, and the United States (Bode 2010; Reznik et al. 2014).

Automated insulin delivery systems

In recent years, insulin pumps have been integrated with CGM. These combined technologies are known as automated insulin delivery systems, or hybrid-closed loop systems. An automated insulin pump works like an artificial pancreas: glucose levels are monitored by CGM and a computerised algorithm automatically adjusts insulin delivery based on glucose readings. In most cases, automated insulin pumps deliver basal doses of insulin automatically based on glucose measurements from the CGM. Insulin boluses are adjusted manually by the user. Current studies are assessing the ability of new algorithms to deliver insulin boluses automatically. Fully automated insulin delivery systems are not available outside clinical trials.

The hybrid closed loop system, which automates all background or basal insulin but requires the user to adjust manually for bolus insulin when they consume carbohydrates, is the only device currently available for the management of diabetes.

Several do-it-yourself (DIY) diabetes technologies are also used by people to manage their condition. Due to the limited availability of automated insulin delivery systems, DIY technology such as open-source closed loop systems are being developed by people with diabetes, or parents of children with diabetes. These DIY technologies are not approved for use through the regulatory bodies such as the Therapeutic Goods Administration (TGA) in Australia (Diabetes Australia 2018).

Outcomes for people with type 1 diabetes

Randomised controlled trials have found that hybrid closed loop systems increased the time spent in target glucose range and reduced HbA1c levels and the risk of hypoglycaemia in people with type 1 diabetes, compared with non-automated insulin delivery systems, in France, the United Kingdom and the United States (Benhamou et al. 2019; Tauschmann et al. 2018). The impact of hybrid closed loop systems on long-term complications was not investigated in these short-duration trials.

Information technology

Information technology such as mobile phone apps, text messaging, wearable technology (for example, smartwatches), web-based programs and clinical-based programs are increasingly being used in the management of diabetes.

These technologies include simple applications providing general information, reminders, documentation of clinical statistics, and data sharing with health care professionals and others (such as carers), to more complex analysis of blood glucose level patterns to derive insulin delivery recommendations and glucose predictions.

Outcomes for people with type 1 diabetes

A systematic review and meta-analysis of cohort studies has shown that mobile phone apps had variable effects on HbA1c, following glucose monitoring goals and hypoglycaemia in people with type 1 diabetes (Sun et al. 2019; Wu et al. 2019).

Outcomes for people with type 2 diabetes

A systematic review of cohort studies showed that mobile phone apps and web-based applications combined with standard diabetes care resulted in reductions in HbA1c in people with type 2 diabetes (Yoshida et al. 2018). Based on findings from a randomised controlled trial, a meta-analysis of randomised controlled trials and a narrative review, there is emerging evidence that information technology interventions are associated with reduced sedentary time through mobile and wearable technologies, increased physical activity (online self-tracking program) and improvements in diet in people with type 2 diabetes (Kooiman et al. 2018; Rollo et al. 2016; Stephenson et al. 2017). A systematic review and meta-analysis of cohort studies also found that mobile health interventions such as text messaging and applications reduced body weight and waist circumference, and improved glucose management in people with type 2 diabetes (Bacigalupo et al. 2013; Cai et al. 2020).

Table 3.1: Summary of evidence on short-term complications related to diabetes technology used in the management of diabetes

Technology for monitoring blood glucose			
Type of technology	**Description**	**Impact on short-term complications in people with type 1 diabetes**	**Impact on short-term complications in people with type 2 diabetes**
Continuous Glucose Monitoring (CGM)	Involves a small sensor being inserted under the skin to monitor glucose in the fluid in the tissue. 'Real-time' CGM continuously records and reports glucose levels, with devices using alarms to alert users to out of range glucose levels.	Decreases in HbA1c, improvements in glucose management and reductions in severe hypoglycaemia compared with self-monitoring blood glucose.	Reduced bodyweight and caloric intake; increases in following of a personal eating plan and increases in physical activity compared with self-monitoring of blood glucose.
Flash Glucose Monitoring (flash GM)	Involves a small disc with a sensor inserted under the skin and worn on the arm. The sensor is scanned with a reader or mobile phone app to read interstitial glucose results.	Reduction or no effect on glucose management compared with self-monitoring of blood glucose in people with type 1 diabetes.	Reduction or no effect on HbA1c compared with self-monitoring of blood glucose.
Technology for delivering insulin			
Non-automated insulin delivery systems (insulin pumps)	Non-automated insulin delivery systems are worn 24 hours a day. Basal insulin is programmed into the pump and delivered throughout the day, and bolus insulin is given by the user at meal times or to address high glucose levels.	Lower HbA1c, lower insulin requirements and improvements in glucose management compared with multiple daily insulin injections. Some evidence of lower cardiovascular mortality and lower rates of retinopathy and peripheral nerve abnormality.	Evidence surrounding the use of insulin pumps for type 2 diabetes is mixed. Some studies showed lower Hba1c levels and insulin requirements in comparison with multiple daily injections. Other studies did not show a reduction in HbA1c and hypoglycaemia.
Automated insulin delivery systems	Some insulin pumps have interoperable CGM. The system works like an artificial pancreas, and glucose levels are monitored by the CGM and a computerised algorithm automatically adjusts basal insulin delivery based on glucose readings. Bolus insulin is given by the user at meal times. However, automated insulin delivery systems are not available for use outside of clinical trials. Hybrid closed loop systems, where the user manually adjusts for bolus insulin when they consume carbohydrates, is the only device currently available for the management of diabetes.	The hybrid closed loop system was associated with increased time spent in target glucose range, reduced HbA1c levels and the risk of hypoglycaemia compared with non-automated insulin delivery system.	No studies reporting on the use of Automated insulin delivery systems in people with type 2 diabetes.

continued

Table 3.1 (continued): Summary of evidence on short-term complications related to diabetes technology used in the management of diabetes

Information technology			
Mobile apps, web based applications and wearable technology	The function of the technology ranges from simple such as providing information and reminders to the more complex—analysis of glucose patterns to derive insulin dose recommendations and glucose predictions.	Mobile phone apps had varying effects on HbA1c, following glucose monitoring goals and hypoglycaemia.	Mobile phone apps and web-based applications combined with standard diabetes care resulted in reductions in HbA1c. Reduced sedentary time, increased physical activity and improved diet through mobile and wearable technologies.

4 Approval, access and distribution pathways for diabetes devices

Diabetes technology is an emerging and growing area and access to effective technology for Australians with diabetes has expanded in recent years. While a rigorous process precedes the approval of most diabetes management technology before it is available on the market in Australia, there is limited public information regarding access pathways.

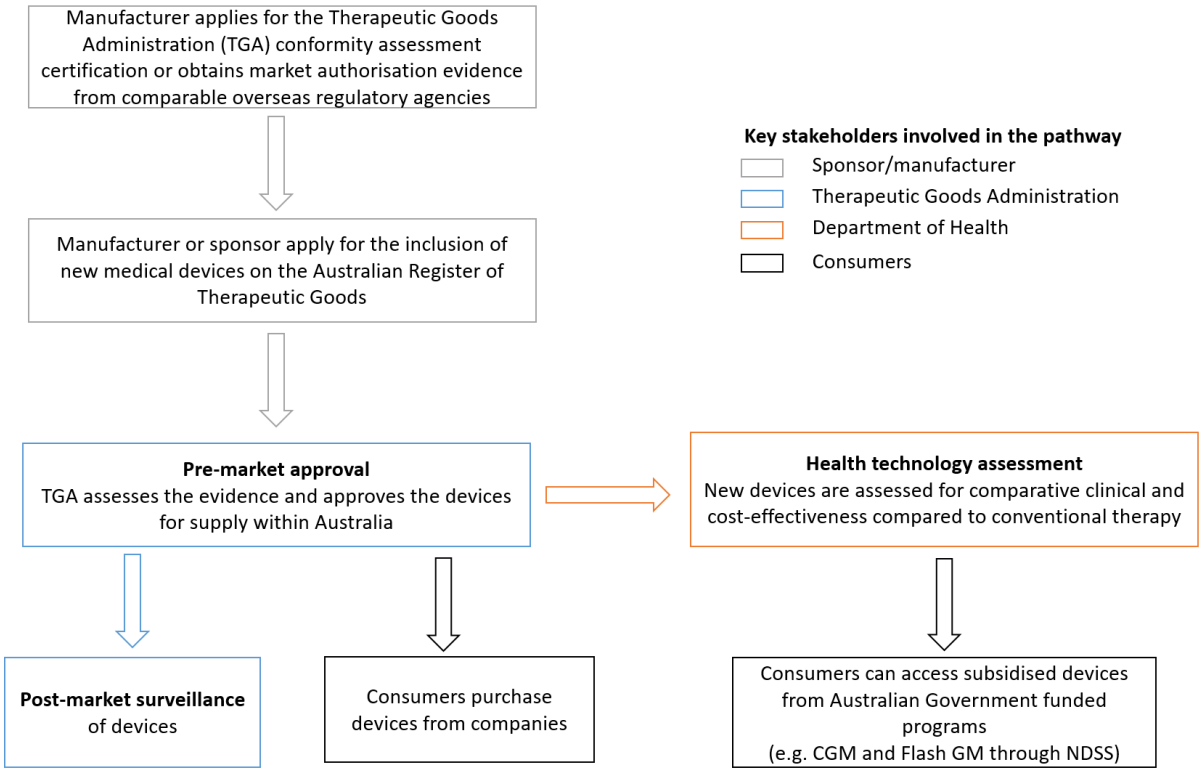
Key stakeholders including the Department of Health, the TGA, Diabetes Australia and the AIHW Diabetes Expert Advisory Group consulted to discuss approval and access pathways and to collate information regarding these processes.

Broadly, the approval, access and distribution of new technology involves the following processes:

- Where required, the manufacturer obtains a TGA conformity assessment certificate or provides market authorisation evidence from comparable overseas regulatory agencies to demonstrate appropriate conformity procedures have been applied to the device.
- The sponsor applies for the inclusion of new technology in the Australian Register of Therapeutic Goods (ARTG) and submits evidence to the TGA for pre-market approval and assessment (depending on the purpose and risk of the device). The sponsor may also be the manufacturer of the technology.
- The TGA approves new technology for inclusion in the ARTG if evidence shows that the technology is safe and performs as intended.
- Manufacturer or sponsor may also submit an application to undergo health technology assessment to seek a public or private subsidy under Australian Government Funding programs.
- The TGA conducts post-market surveillance of technology to ensure that the devices continue to meet safety standards and regulatory requirements.
- All sponsors of devices listed on the ARTG have a legal obligation to report adverse events to the TGA.
- Consumers access devices through Australian Government funding programs such as the National Diabetes Services Scheme (NDSS) or purchase devices directly from companies or through private health insurance.

A summary of the pathway is presented in Figure 4.1 and information regarding each process is provided in the sections below.

Figure 4.1: Summary of the approval, access and distribution pathways for new technology used in the management of diabetes



Approval of diabetes devices

All medical devices, including insulin pumps, CGM and flash GM devices, must be approved by the TGA to be included in the ARTG before they can be supplied within, imported to, or exported from Australia.

This approval process consists of 2 components: a conformity assessment and an application to include the device in the ARTG. The person or company (sponsor) responsible for the importation, exportation and supply of the device in Australia is responsible for submitting an application to include the device in the ARTG. The sponsor may also be the manufacturer of the device. Before an application is submitted to include a medical device in the ARTG, a conformity assessment is required. Where a TGA conformity assessment is required, the manufacturer is responsible for submitting an application for conformity assessment certification (TGA 2020b).

What is a medical device?

A medical device is defined as an instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended to be used for human beings for the purpose of 1 or more of the following:

- diagnosis, prevention, monitoring, prediction, prognosis**,** treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- investigation, replacement or modification of the anatomy or of a physiological process or pathological process or state
- control or support of conception
- in vitro examination of a specimen derived from the human body for a specific medical purpose (TGA 2020c).

Pre-market assessment and approval

Pre-market approval consists of 2 components:

1. A conformity assessment—an independent assessment that a manufacturer has applied appropriate procedures to manufacture the device and these procedures comply with the regulatory requirements for safety, quality and performance.
2. An application to include the medical device in the ARTG.

The pre-market assessment and approval process for new medical devices differs according to the risk classification of the device. A classification system for devices based on the device's intended purpose, materials used in the device, degree of invasiveness in the human body and the duration of use has been adopted by the TGA. The manufacturer of the device is responsible for determining the risk classification by applying the TGA's risk classification rules (TGA 2020b). Table 4.1 presents examples of devices with different risk classifications.

Table 4.1: TGA medication device classification system [a]

Risk level	Classification(s)	Example
Low	Class I	Surgical retractors Continuous Glucose Monitoring transmitters[b]
Low to Medium	Class I – supplied sterile Class I – with a measuring function Class IIa	Hypodermic needles Medicine cup with specific units of measurement Digital or infrared thermometers
Medium to High	Class IIb	Insulin pump[b] Continuous Glucose Monitoring receivers
High	Class III	Continuous Glucose Monitoring and Flash Glucose Monitoring sensors
High	Active implantable medical devices	Implantable defibrillator

(a) Information presented in the table was obtained from the TGA website and the ARTG (TGA 2020b).

(b) The device classification may be subject to changes as the TGA implements reforms including introducing new classification rules in the regulations (i.e. active medical devices, software based medical devices).

For all medical devices (other than Class I devices that do not have a measuring function and are not intended to be supplied sterile), manufacturers have to obtain a TGA conformity assessment certification or market authorisation evidence from comparable overseas regulatory agencies for their medical device before an application for the inclusion of the device in the ARTG can be submitted. The TGA conformity assessment process involves the manufacturer:

- determining the risk classification of the device
- applying the appropriate conformity assessment procedures to obtain conformity assessment evidence to demonstrate compliance with the Essential Principles of Safety and Performance (the manufacturer applies different conformity assessment procedures based on the risk classification of the device)
- providing this manufacturer's evidence to the TGA for the device to be included in ARTG (TGA 2020b).

Following this process, the sponsor submits an application for the inclusion of the medical device in the ARTG.

The approval process for diabetes management devices is complex and highly dependent on the risk classification of the device and the materials incorporated in the device. For example, CGM devices consist of a sensor kit, transmitter and receiver and each component has a different risk classification with different assessment and approval processes. CGM and flash GM sensors contain glucose oxidase from microbial origin, hence are Class III devices that require a conformity assessment before an application for their inclusion on the ARTG can be submitted.

The level of assessment required for a medical device before it is approved for inclusion in the ARTG by the TGA depends on the risk the device poses. Some lower-risk Class I medical devices can be included in the ARTG via the manufacturer's self-declaration without assessment, while high-risk medical devices must be assessed for quality, safety and performance by the TGA regardless of whether or not manufacturers have manufacturer's evidence from overseas comparable regulatory agencies. Once the medical device is approved for inclusion in the ARTG, it can be marketed for use in Australia (TGA 2020b).

Approvals of medical apps

In recent years, mobile apps to monitor blood glucose have become available for the management of diabetes. Depending on the function and intended purposes, some devices are regulated by the TGA. Mobile apps are considered medical devices when used for the diagnosis, prevention, monitoring, treatment or alleviation of disease.

The TGA has implemented reforms to the regulation of software-based medical devices, including software that functions as a medical device in its own right. The TGA has consulted with the technology sector to increase awareness of this requirement for medical apps (TGA 2020a). Changes to the regulation of software-based medical devices (including software as a medical device) took effect on 25 February 2021.

The TGA has published guidance documents that summarise the regulatory requirements for medical device software. The documents outline transition arrangements available for devices that may need to be reclassified or that qualify for an exemption or exclusion from the *Therapeutic Goods (Medical Devices) Regulations 2002*. The documents are available on the TGA website: https://www.tga.gov.au/regulation-software-based-medical-devices (TGA 2020a).

However, manufacturers may not be aware of changes and are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia.

Post-market surveillance

After approval and inclusion in the ARTG, medical devices are monitored closely post-market to ensure that the devices continue to meet safety standards and regulatory requirements. Activities conducted for post-market surveillance of devices include:

- requiring sponsors (the person or company supplying the device in Australia) to report adverse events and other information within specific timeframes
- assessing and investigating reports of problems with medical devices submitted by consumers, health care professionals, the medical device industry and overseas signals
- checking evidence that medical devices are compliant (TGA 2020b).

The sponsor supplying the medical device is responsible for submitting annual reports from the manufacturer containing information such as the number of devices supplied, complaints received, and adverse event data to the TGA following the inclusion of a high-risk medical device (active implantable medical devices, implantable Class IIb medical devices, Class III medical devices, and Class 4 in vitro diagnostic medical devices) in the ARTG. Annual reports are submitted to the TGA in the first 3 years of the device being available on the market (TGA 2020b). Sponsors supplying diabetes devices such as Class III sensors for use with CGM and flash GM are required to provide annual reports to the TGA for post-market surveillance following the approval of these devices.

The TGA also monitors adverse events related to medical devices. In addition to reports from sponsors and manufacturers, adverse events reported by members of the public or health professionals are recorded in the Incident Reporting and Investigation Scheme database (IRIS). Information is transferred from the IRIS to the publicly available Database of Adverse Event Notifications (DAEN) after the TGA has verified the information reported in the IRIS. The DAEN provides general information on the medical device about the adverse event report. Information provided about the adverse event includes:

- an event description (a description of the adverse event)
- the reported event outcome (a description of the outcome reported to have been caused by the adverse event, for example injury)
- event type (general categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011–Medical devices–Hierarchical coding structure for adverse events–Part 1: Event-type codes) (TGA 2018).

The TGA may also undertake a post-market review of a medical device at any time during inclusion in the ARTG. A post-market review can be initiated as a result of safety signals or a quality or performance issue from registry data; international regulatory notifications; publications in journals; or media articles. As part of a post-market review the sponsor will be required to provide evidence from the manufacturer to support the inclusion of the device in the ARTG. The evidence must demonstrate the continued compliance with the legislated requirements on the quality, safety, and performance of medical devices (TGA 2020d).

Health technology assessment

The manufacturer or sponsor of a diabetes technology may also submit an application for their technology to undergo a health technology assessment (HTA) to seek public or private subsidy under the Australian Government Funding programs. Applications for health technology assessment may be considered on a case-by-case basis for government funding by the HTA expert advisory committees. This process assesses the technology for comparative clinical and cost effectiveness compared with existing conventional interventions (Department of Health 2019).

The Australian Government has 3 HTA expert committees providing advice on whether health technologies should receive government funding:

- the Pharmaceutical Benefits Advisory Committee for pharmaceuticals to be funded under the Pharmaceutical Benefits Scheme and vaccines to be funded under the National Immunisation Program
- the Medical Services Advisory Committee (MSAC) for medical services involving new procedures or health technologies to be funded under the Medicare Benefits Schedule (MBS) or other programs
- the Prostheses List Advisory Committee for prostheses to be funded through private health insurance arrangements under the Prostheses List.

In recent years, technologies such as CGM and flash GM have been subsidised by the Australian Government for people with diabetes who meet the eligibility criteria. Diabetes technologies have been assessed by both the PBAC and MSAC for subsidisation in previous years. From November 2020, the MSAC is the designated health technology assessment body to consider diabetes-related products for subsidisation under the NDSS and the CGM Initiative (Department of Health 2020).

Access and funding of diabetes devices

There are a number of pathways for accessing and funding diabetes management technology. This section focuses on technologies used for monitoring blood glucose levels and insulin delivery, which are currently subsidised by the Australian Government for a sub-population of people with diabetes.

Insulin pumps

The current cost of an insulin pump is about $10,000 (Paldus 2018). Eligible insulin pump users (including those with type 1 diabetes and gestational diabetes) can access subsidised insulin pump consumables under the NDSS. Subsidised insulin pump consumables cost an additional $30 a month (Diabetes Australia 2017). The ways people with diabetes can access and fund insulin pumps are shown in Figure 4.2.

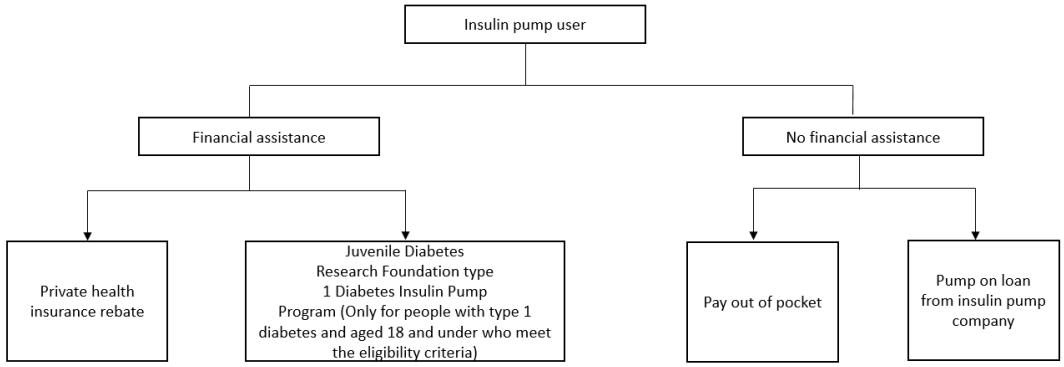
In Australia, people with diabetes can access insulin pump therapy through private health insurance. Currently, the Australian Government provides some funding for insulin pumps and children and adolescents with type 1 diabetes can access subsidised pumps through the Insulin Pump Program administered by the Juvenile Diabetes Research Foundation Australia (JDRF Australia). The program provides fully subsidised insulin pumps to low income families who have children aged under 18 with type 1 diabetes, and who do not have access to other forms of reimbursements such as private health insurance. In the 2018–19 Budget, the Australian Government provided additional funding to the Insulin Pump Program, which allowed for the number of pumps subsidised to increase from 68 to around 220 each year (JDRF 2020).

Adults with type 1 diabetes and people with type 2 diabetes and gestational diabetes who require insulin therapy do not have access to any subsidised programs for insulin pumps. However, insulin pump consumables (such as infusion sets and reservoirs) are subsidised under the NDSS for all people with type 1 diabetes. Insulin pump users who do not receive financial assistance pay the entire cost of the pump themselves or use a pump lent to them from the pump company. The cost of an insulin pump may be covered by private health insurance.

Most respondents to the 2011 Insulin Pump User Survey indicated that they received some kind of financial assistance to purchase insulin pumps, with 88% indicating this to be the case. Another 7% received no funding and paid for the cost of the insulin pump themselves or used a pump that had been lent to them (AIHW 2012). Of insulin pump users who received financial assistance, the majority (97%) received a rebate through private health insurance, 3% indicated they received an Australian Government subsidy and 2% a JDRF grant (AIHW 2012).

There is limited up-to-date information about the way people with diabetes access and fund the purchase of insulin pumps.

Figure 4.2: Summary of the pathways for accessing and funding insulin pumps



Continuous and flash glucose monitoring devices

The cost of CGM devices including the consumables is around $4,000–5,000 per year (Diabetes Australia 2020a). The cost of flash GM products is around $2,500 per year (Diabetes Australia 2020b). CGM and flash GM devices are unlikely to be covered by private health insurance. The cost of blood glucose meters may be covered by private health insurance in some cases (Diabetes Australia 2017).

Since 2017, the Australian Government has provided access to fully subsidised CGM devices and sensors for eligible people through the NDSS under the CGM Initiative. Flash GM devices were included under the CGM Initiative in 2020. The following groups are eligible for subsidised CGM and flash GM devices:

- children and young people with type 1 diabetes aged under 21
- people with type 1 diabetes aged 21 and over who have valid concessional status
- women with type 1 diabetes who are actively planning pregnancy, pregnant or immediately post-pregnancy
- children and young people aged under 21 with conditions very similar to type 1 diabetes who require insulin.

5 Monitoring diabetes technology use in Australia

Why is it important to monitor diabetes technology use?

Diabetes technologies have been developed to improve glucose management and reduce the risk of diabetes-related complications. The use of technology for insulin delivery and glucose monitoring in the management of diabetes is increasing. However, there are gaps in information about the use of the technology among the diabetes population and the impact of the technology on long-term diabetes-related complications. Monitoring the use of technology for the management of diabetes is important for:

- assessing the impact of devices on the management of diabetes and short-term and long-term complications
- developing, implementing and evaluating policies for the subsidisation of new diabetes technology
- improving access to new diabetes technology
- providing recommendations and guidelines for the management of diabetes.

Key areas to monitor

Comprehensive monitoring of the use of diabetes technologies requires specific data on the:

- type of device(s) used
- number of users
- characteristics of the users
- experiences of the users
- impact on short-term and long-term diabetes-related complications
- adverse events associated with the use of the technology.

Devices used in the management of diabetes

Data on the type of diabetes technology used is important for evaluating the characteristics and experiences of the users, the impact on short-term and long-term diabetes-related complications, and adverse events across the different categories of technology available.

Number of users of diabetes technology

Data on the number of users of diabetes technologies such as insulin pumps and CGM and flash GM devices over time is important for evaluating the uptake of new technology and the impact of new guidelines and introduction of subsidies on the use of these devices

The majority of people with diabetes will register with NDSS. Since 2017, the NDSS CGM initiative provides subsidised CGM to eligible cohorts of people with type 1 diabetes and other forms of diabetes that require insulin, or those who require controlled clinical management of their glucose levels. Flash GM products were included in the initiative from

2020 onwards. The NDSS could provide data on the number of people accessing subsidised products for insulin pumps, CGM and flash GM (only people with diabetes eligible for subsidised products) at a national level. Information about the number of people with diabetes currently accessing subsidised devices could be included in future reporting as data become available.

Characteristics of the users of diabetes technology

Demographic characteristics such as the age, sex, socioeconomic status and Indigenous status of users will allow for the identification of disparities in the access to devices for the management of diabetes.

Experiences of the users of diabetes technologies

Information on the factors, such as education and support, that influence decisions for starting, interrupting and ceasing using diabetes devices would provide a more accurate picture of the benefits and difficulties of using new diabetes management technology. It would also provide insights into the barriers to accessing new technology, such as the high costs associated with use and its impact on quality of life.

Short-term and long-term diabetes complications

While studies have shown that the use of technology for monitoring glucose levels and delivering insulin improved glucose management and decreased the frequency of hypoglycaemia and diabetes ketoacidosis, information about the impact of technology on reducing HbA1c levels over a long period, and subsequently long-term diabetes-related complications, is limited. There is also limited information about factors such as device acceptability, useability and adherence that affect the use of technologies, and the impact of technologies on behavioural changes (Taylor et al. 2018). It is important that these data are collected from device users over time to assess the long-term impact of technology on glucose management and subsequently the risk of long-term diabetes-related complications. These data will also help inform the development and evaluation of funding programs providing subsidised access to new technology, and clinical guidelines for the management of diabetes.

Adverse events

The TGA monitors adverse events related to medical devices and records of the adverse events are publicly available in the Database of Adverse Event Notifications (TGA 2018). While it is not mandatory for consumers or health professionals to report adverse events to the TGA, adverse event reporting is mandatory for sponsors or manufacturers of the medical devices.

The National Hospital Morbidity Database (NHMD) captures diagnostic information relevant only to the current episode of care—including conditions or disorders that affect the treatment received by the person during the episode. Diagnostic information relating to diabetes-related complications and mechanical complications due to the use of insulin pumps (for example, a broken insulin pump) are captured for an episode of care, and might provide some information about adverse events resulting from the use of pumps. However, mechanical issues with pumps or failures of monitoring sensors are more likely to occur outside the hospital setting and will not be captured in hospital data.

Despite data being captured for some technology in some data sources, there are still limited national data on specific adverse events experienced by people using technology to manage their condition.

Data sources available to monitor diabetes technology use

Data about technology use in, especially, people with type 1 diabetes are currently available from a number of sources in Australia.

Based on various methods of data collection, these data sources can be categorised into:

- administrative data
- survey-based data
- registry data sources
- other data sources.

Key stakeholders including Diabetes Australia and the AIHW Diabetes Expert Advisory Group consulted to discuss the data sources available for monitoring technology use. Information regarding the data sources presented in this chapter was based on discussions with stakeholders or publicly available information.

Administrative data sources

Administrative data sources contain information about the delivery of services, or a record of events, collected for historical or funding purposes. Data from administrative data sets such as the NDSS and Hospital Casemix Protocol data collection can be used for secondary purposes including monitoring the supply and usage of insulin pumps and CGM and flash GM devices. The NDSS and Hospital Casemix Protocol data collections are examined further in tables 5.1 and 5.2.

Table 5.1: Assessing the National Diabetes Services Scheme for monitoring diabetes technology use

National Diabetes Services Scheme (NDSS)		
Type of data source		Administrative (national)
Brief description		Established in 1987, the NDSS is an initiative of the Australian Government, administered with the assistance of Diabetes Australia. People with a diagnosis of diabetes by a health professional can be registered with the scheme. Once registered, they can access diabetes self-management information, services, and subsidised products—such as pens and needles to administer insulin, blood glucose strips, insulin pump consumables, and, if eligible, CGM and flash GM products.
Geographic coverage		Australia; state and territory
Scope and coverage		Majority of people with diabetes will register with NDSS to access education material or subsidised products. However, registration with the NDSS is voluntary. All people with type 1 diabetes use insulin and are therefore most are likely to obtain subsidised products through the NDSS. Coverage of people with diabetes on the NDSS is thought to be relatively high, especially where diabetes-related products are required for management purposes.
Limitations		Data related to the usage of CGM and flash GM products will only be available for the following groups eligible for subsidised products: children and young people with type 1 diabetes aged under 21 people with type 1 diabetes and aged 21 and over who have valid concessional status women with type 1 diabetes who are actively planning pregnancy, pregnant or immediately post-pregnancy children and young people aged under 21 with conditions very similar to type 1 diabetes who require insulin. NDSS Access Points may be limited in rural Australia and unavailable in remote communities, with other programs being available in these areas to assist with the purchase of diabetes-related products. As a result, the coverage of the NDSS may be lower in remote and very remote areas or across states and territories with large remote communities. Aboriginal and Torres Strait Islander Australians can access diabetes-related products through other programs and this might result in lower registration for the NDSS, among Indigenous Australians.
Data available	Type of diabetes technology	Blood glucose monitoring consumables, insulin pump consumables, CGM and flash GM.
	Number of users of diabetes technology	Trends data available.
	Characteristics of the users	Demographic information such as age, sex, date of birth, postcode and state of current residence, postcode and state of diagnosis, Indigenous status. Diagnosis information such as the type of diabetes and diagnosis date.
	Experiences of the users	No data.
	Short-term and long-term complications	No data.
	Adverse events	No data.

Table 5.2: Assessing the Hospital Casemix Protocol data collection for monitoring diabetes technology use

Hospital Casemix Protocol (HPC) data collection		
Type of data source		Administrative (national).
Brief description		The HCP data collection is a legislated data collection for all private health insurance funded admitted patient separations for which private health insurers have paid benefits. The data is collected by public and private hospitals, including day facilities, and then supplied to private health insurers, who in turn submit the data to the Department of Health.
Geographic coverage		Australia; state and territory
Scope and coverage		The HCP data collection has records of all episodes of admitted patient care for which private health insurers have paid benefits. The collection has episodic, benefit and charge data for privately insured admitted patient episodes nationally from 1996–97.
Limitations		Data are only available for privately insured patients starting a new pump or being fitted with an insulin pump in hospital. The data source also only provides information about the number of hospital separations for patients being fitted with an insulin pump. Patients might not be fitted with an insulin pump in hospital and patients are not admitted to hospital for the procedure.
Data available	Type of diabetes technology	Procedure information on patients being fitted with an insulin pump.
	Number of users of diabetes technology	Trends data available.
	Characteristics of the users	Patient demographic and clinical information.
	Experiences of the users	No data.
	Short-term and long-term complications	No data.
	Adverse events	No data.

Registry data sources

Registry data sources collect detailed information on persons with certain diseases or receiving particular treatment. Data from registries such as the Australasian Diabetes Data Network (ADDN) and Australian National Diabetes Audit (ANDA) can be used to report on the usage of insulin pumps and CGM and flash GM devices, as well as short-term and long-term complications. The ADDN and ANDA are examined further in tables 5.3 and 5.4.

Table 5.3: Assessing the Australasian Diabetes Data Network for monitoring diabetes technology use

Australasian Diabetes Data Network (ADDN)		
Type of data source		Longitudinal register
Brief description		ADDN is a research collaboration among Australia's largest diabetes centres to share clinical diabetes data. The ADDN registry holds longitudinal de-identified data to allow for the national surveillance of clinical outcomes.
Geographic coverage		18 diabetes centres in New South Wales, Queensland, South Australia, Victoria, Western Australia and New Zealand.
Scope and coverage		The ADDN registry holds clinical data for children and adolescents aged under 19 diagnosed with type 1 diabetes, type 2 diabetes, cystic fibrosis related diseases, monogenic diabetes, neonatal diabetes and other rarer forms of diabetes; and adults diagnosed with type 1 diabetes who have attended an ADDN centre for their diabetes clinical management.
Limitations		While the ADDN registry provides data for paediatric and adult patients attending diabetes centres at the participating ADDN tertiary public hospitals, it is not representative of the entire diabetic population in Australia.
Data available	Type of diabetes technology	Information about CGM use such as usage time, start date and type of CGM device. Information about insulin pump use such as pump brand.
	Number of users of diabetes technology	Trends data available.
	Characteristics of the users	Demographic information such as age, gender, date of birth, current postcode, postcode of diagnosis, ethnicity, and Indigenous status. Diagnosis information such as diabetes type and diagnosis date.
	Experiences of the users	No data.
	Short-term and long-term complications	CGM related measures such as mean glucose and time in target range of blood glucose in the last 2 weeks. Diabetes ketoacidosis episodes, HbA1c measure at time of visit, severe hypoglycaemia, moderate hypoglycaemia
	Adverse events	No data.

Table 5.4: Assessing the Australian National Diabetes Audit – Australian Quality Clinical Audit for monitoring diabetes technology use

Australian National Diabetes Audit— Australian Quality Clinical Audit (ANDA—AQCA)		
Type of data source		Clinical quality registry
Brief description		The ANDA is an annual diabetes audit that collects information from centres providing diabetes services across Australia. The audit provides participating diabetes services with individualised reports of their diabetes practice processes and patient outcome data in comparison with their peers. The following two ANDA audits alternate each year: Australian Quality Self-Management Audit focusing on self-management and diabetes distress and collects data related to diabetes education, self-care practices and quality of life. ANDA—AQCA focusing on clinical indicators known to affect the care of the person with diabetes. The addition of longitudinal linkage to the ANDA—AQCA in 2019 will allow for the analysis of trends in diabetes health outcomes and correlation to different treatment approaches.
Geographic coverage		Participating diabetes centres across Australia. In 2019, the ANDA-AQCA collected data from 80 diabetes centres.
Scope and coverage		The ANDA-AQCA clinical quality registry holds data on clinical indicators for the care of people with diabetes from participating primary to tertiary diabetes centres.
Limitations		The ANDA-AQCA registry collects data from people attending participating diabetes centres and data are not representative of the diabetes population across Australia. Most people referred to tertiary care diabetes services are referred by their general practitioners to receive specialist assessment and treatment. It is likely that people attending tertiary care diabetes services will be those with poorer glycaemic control, and with an increased number of comorbidities and diabetes-related complications.
Data available	Type of diabetes technology	Data for glucose monitoring (including the use of CGM).
	Number of users of diabetes technology	Trends data available.
	Characteristics of the users	Demographic information such as age, gender and Indigenous status. Diabetes type and diagnosis date.
	Experiences of the users	No data.
	Short-term and long-term complications	Diabetic ketoacidosis and hypoglycaemic events. Diabetes-related complications including eye disease, foot problems, kidney disease and vascular diseases.
	Adverse events	No data.

Surveys

Survey-based data sources collect health-related information through a population sample. Currently, information regarding the use of technology for the management of diabetes is not routinely collected in survey-based data sources such as the National Health Survey.

In 2011, the AIHW conducted a national survey of insulin pump users. The survey collected information relating to the experiences of those using pumps, including the benefits and problems with using them. The Insulin Pump User Survey is examined further in Table 5.5.

Table 5.5: Assessing the Insulin Pumps User Survey for monitoring diabetes technology use

Insulin Pumps User Survey		
Type of data source		Survey
Brief description		The Insulin Pump User Survey was conducted by the AIHW in October–November 2011. The survey was developed to provide information about the factors that influenced people's choice to commence insulin pump therapy and the benefits and problems they experienced.
Geographic coverage		Australia
Scope and coverage		Participants were registrants on the NDSS, who were also eligible to purchase insulin pump consumables and had given consent to be contacted for research purposes. Nearly all participants on the scheme and who participated in this study have type 1 diabetes, though people with type 2 and gestational diabetes can be eligible in certain circumstances and may therefore have received and completed a survey. There were 9,618 people eligible to participate. The survey had a response rate of 59%.
Limitations		The Insulin Pump User Survey was a one-off national survey of insulin pump users and there have been substantial changes in the use of technology for managing diabetes.
Data available	Type of diabetes technology	Information about insulin pump use.
	Number of users of diabetes technology	Number of users available. No trends data available.
	Characteristics of the users	Demographic information such as age, sex and postcode of current residence. Age at diagnosis and age at start of insulin pump use.
	Experiences of the users	Funding of insulin pumps, reasons for commencing insulin pump therapy and benefits of using an insulin pump. Problems with using the pump (hospitalisation or attendance at emergency department due to control issues). Breaks from insulin pump use and reasons for discontinuation.
	Short-term and long-term complications	No data.
	Adverse events	No data.

Other data sources

Data from private companies

Data regarding the purchase and sale of technology are available from private companies providing the technology. Demographic information and glucose management data for the use of CGM are also collected by companies supplying CGM devices in Australia. Further consultation with companies is required to determine the governance surrounding the use of the data and assess the quality of data for monitoring the use of technology to manage diabetes.

Juvenile Diabetes Research Foundation Australia

The JDRF Australia Insulin Pump Program provides subsidised insulin pumps to children aged under 18. The number of insulin pumps subsidised and the demographic characteristics of the children receiving them are likely to be captured by the JDRF Australia program (JDRF Australia 2020).

Fremantle Diabetes Study Phase II

The Fremantle Diabetes Study Phase II is a cohort study that recruited people with diabetes from the Fremantle hospital catchment area (postcode-defined population living in and around Fremantle in Western Australia) to examine clinically relevant aspects of diabetes including clinical management, metabolic control, complications and cost. Demographic information, diabetes-related information including the mode of insulin administration and clinical information including glucose management, HbA1c levels and complications were collected from consenting participants (Davis et al. 2013).

Database of Adverse Event Notifications – medical devices

The DAEN – medical devices collects information from reports of adverse events that the TGA receives in relation to medical devices. Information in the database comes from reports made to the TGA by patients, consumers, health professionals and manufacturers of the medical devices since July 2012.

Information about the total number of people using a device, the total number of adverse events, and the number of medical devices supplied in Australia are not captured on this database. Due to the limited information collected, the database cannot be used to determine the incidence of adverse events and the likelihood of a user experiencing that adverse event (TGA 2018).

Data gaps

Data on the use of diabetes devices such as insulin pumps and CGM and flash GM devices are available from various data sources. Compared with CGM and flash GM, there is more detailed information about the use of insulin pumps. However, these data sources have their strengths and weaknesses and do not provide data to comprehensively monitor across key areas including the experiences of users and the impact of technology on short-term and long-term diabetes-related complications.

Information about the type of device used for insulin delivery and monitoring glucose levels is captured in most data sources. However, information about the use of information technology (such as mobile phone apps and wearable fitness trackers) for the management of diabetes is limited and rarely captured in the available data sources.

Data for the key monitoring areas are available from separate data sources and comprehensive national reporting of the use of diabetes technology from 1 data source is not possible. Furthermore, data sources collecting information on the use of diabetes technology do not capture all people with diabetes and it is difficult to monitor the use of diabetes technology across the population.

Experiences of users

Comprehensive data on the experiences of people with diabetes using technology for the management of their condition are not available from current administrative and registry data sources collecting data on the use of insulin pumps and CGM and flash GM devices.

A survey is probably necessary to collect this information. For example, the one-off Insulin Pump User Survey conducted in 2011 provided comprehensive information about the experiences of pump users.

Long-term diabetes-related complications

Clinical registry data sources such as the ADDN and ANDA collect data on glucose management and hypoglycaemia. Analysis of the data from these registries may allow associations to be drawn on the impact of the use of insulin pumps and CGM and flash GM devices on glucose management and subsequently reduction in hypoglycaemia. However, the scope and coverage of these clinical registries is restricted to people attending diabetes centres for treatment, and data on the use of these devices are collected mainly from people with type 1 diabetes.

Cohort studies have examined the association of the use of insulin pumps and long-term complications such as the progression of kidney disease, eye disease and vascular diseases. However, there is no national data source to monitor the impact of insulin pumps on long-term complications. Few studies have examined the effects of new technology such as CGM and flash GM devices on long-term diabetes-related complications.

There is currently no longitudinal national data source to monitor the outcomes of people with diabetes who use technology in their management of diabetes, especially the impact of new blood glucose monitoring technology.

Linkage of administrative data sources containing data on diabetes diagnosis, the use of technology and clinical outcomes to examine the impact of the use of technology on glycaemic control and subsequently long-term diabetes-related complications could be explored in the future. The potential use of data linkage to fill this gap in knowledge is discussed further in ‘Chapter 6 Future opportunities and recommendations’.

Scope and coverage of data sources

No data sources presented in this report capture all people using technology as part of their diabetes management. This limits the ability to assess comprehensively the use of diabetes technology, and the experiences and outcomes of people using technology to manage their condition. A data set that captures all people with diabetes would also allow for the comparison of the experiences and outcomes of people using newer technology to manage their diabetes with those who manage their diabetes through conventional therapy.

The majority of people with diabetes will register with NDSS. The NDSS CGM initiative provides subsidised products to eligible cohorts of people with type 1 diabetes and other forms of diabetes that require insulin, or those who require controlled clinical management of their glucose levels—and will capture eligible people accessing subsidised CGM and Flash GM devices from the NDSS. However, there will be a proportion of people, such as those with type 2 diabetes, who are not eligible for subsidised products or not registered with the NDSS, and subsequently not captured in the administrative data set.

Other registry data sources such as the ADDN and ANDA collect data for a sub-population of people who have attended a diabetes care centre for treatment, but contain extensive data on the usage of insulin pumps and CGM and flash GM devices, as well as some data on short-term complications.

6 Future opportunities and recommendations

Based on the data gaps, data sources and information related to the use of diabetes technologies outlined in this report, the following opportunities for analysis and future work have been identified:

- Baseline reporting could be carried out, involving analysis of the currently available data sources outlined in this report, to look at the use of technology in the management of diabetes at the national level.
- Enhancing the existing data, including experiences of users, adverse events and long-term outcomes associated with the use of technology in the management of diabetes.
- Data linkage to bring together data to report comprehensively on the use of technology and longer-term outcomes of people with diabetes.

Baseline reporting

The next steps in monitoring the use of technology to manage diabetes could be to undertake analysis to report on baseline estimates of the users of diabetes technology.

Analysis of data sources such as the NDSS could provide data on the number accessing subsidised products for insulin pumps, CGM and flash GM (only people eligible for subsidised products) at a national level; and the characteristics of the users of these devices. This would provide a national snapshot of the data available and could be used to facilitate further work in this area.

Filling data gaps

Another next step could be engaging with key stakeholders to modify existing data sources or develop new data sources to capture information about the characteristics and experiences of users; complications; and adverse events. Modification or development of data sources should also consider expanding the information captured about the type of technology used in the management of diabetes to include information about the use of technology such as mobile phone apps and wearable technology. This data development work would require an assessment of information available in existing data sources (such as the adverse event data collected in the DAEN by the TGA) and additional information required for comprehensive reporting on the use of technology in the management of diabetes, before undertaking the work to modify or develop data sources.

Clinical registers, such as the ADDN, already capture most data regarding the use of technology to manage diabetes and short-term diabetes-related complications, to monitor the use of technology. These data sources could be modified to enable a more comprehensive capture of information, such as adverse events and experiences of the users.

In 2011, the AIHW conducted an Insulin Pump Use Survey. Diabetes Australia, which maintains the list of registrants in the NDSS, distributed the survey to registrants using insulin pumps on behalf of the AIHW (AIHW 2012). A similar survey examining the use of different technology could be designed and distributed to all registrants with diabetes to examine their experiences with using technology to monitor their glucose and deliver insulin, and conventional therapy. This would allow for comprehensive reporting of the experiences of

users of diabetes technology including the factors that influence choice, and the benefits and difficulties of using technology for the management of their condition. Data from this survey could be extrapolated to the broader diabetes population.

Further investigations into the ability to access data from pharmaceutical and technology companies could be undertaken. Future work could examine the possibility of accessing detailed data regarding the purchase of technology for delivering insulin and glucose monitoring from these companies.

Data linkage

There is no data source that can provide complete information on the use of diabetes technology, and the experiences and outcomes of the users of diabetes technology. Data linkage to bring together information from 2 or more data sources to determine associations between the use of diabetes technology for medicine delivery and monitoring of glucose levels and outcomes could be explored and considered.

The linkage of data sources such as the administrative NDSS data set, which captures most people with diabetes who are using technology to manage it, with emergency and hospital data could allow for the examination of the impact of the use of technology on severe hypoglycaemic or ketoacidosis hospitalisations and progression of diabetes-related complications. However, severe hypoglycaemia can be managed by family members/carers or via ambulance call out without presentation to a hospital, and information might not be comprehensively captured in hospital data sets. Nationally linked longitudinal data would also allow insights into the pathways and individual impacts to be assessed. As new technologies such as CGM and flash GM were subsidised through the NDSS CGM initiative only in 2017 and 2020 respectively, future work will also need to assess the quality and completeness of data on the usage of these diabetes devices for linkage.

Conclusion

Diabetes increases the risk of diabetes-related complications such as heart disease, stroke, kidney disease, retinopathy, heart failure and limb amputation. Maintaining optimal glucose management can prevent and reduce the risk of these complications. In addition to conventional self-monitoring using blood glucose monitors and insulin delivery through injections or insulin pumps, a range of newer technologies is available to manage diabetes. Many information technologies such as mobile phone apps and web-based applications are also available.

In recent years, the availability of and access to technology to manage diabetes has changed and there is emerging evidence that technologies can prevent or reduce progression to diabetes-related complications.

The approval, access and distribution pathway of new technology involves multiple stakeholders and processes. While there are clear pathways for the approval of new technology in Australia through the TGA, this varies based on the intended purpose, materials used in the device, and degree of invasiveness of the device used in the management and treatment of diabetes. Information technology such as mobile apps and web-based applications are a particular challenge as manufacturers and companies might not be aware that these applications may require pre-market approval for distribution and use in Australia.

Access to new technology for monitoring glycaemia has changed in recent years with the subsidisation of CGM and flash GM devices by the Australian Government. New devices may be considered by the health technology assessment bodies on a case by case basis for public or private subsidy. In November 2020, the MSAC was designated the health technology assessment body to consider diabetes-related products for subsidisation under the NDSS and the CGM Initiative.

There are also limited national data about the use of diabetes technology in Australia. The data landscape has changed in recent years, with information about the uptake and characteristics of the users being captured in a range of administrative data sets, and outcomes in clinical registries. However, data on the characteristics, experiences and outcomes of users of diabetes devices are available in separate data sources and comprehensive national reporting from a single combined data source is not possible.

Undertaking reporting using currently available data sources such as the NDSS can provide baseline data on the number of people accessing subsidised products for insulin pumps, CGM and flash GM devices. This would provide a national snapshot of the users of the common technologies in diabetes care and could facilitate further work in this area. Given that currently no data source can provide complete information on the use of technology in Australia, opportunities for data linkage or modifying existing data sources could be explored.

While there are opportunities for improving the data for monitoring the use of technology for the management of diabetes, considerable resources are likely to be required to improve existing data sources or develop new ones. The development and availability of new technology, the uptake of new technology to manage diabetes in the clinical setting and the capture of information across administrative data sets and clinical registries are also changing over time. Comprehensive data for some key areas such as the characteristics of the users of technology, and short-term complications, are already available from existing data sources. Future work will need to consider the factors affecting the use of technology over time and data already available for reporting across the key areas, and explore the costs and benefits of undertaking further data improvement activities to report on the use of technology for managing diabetes.

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Abbreviations

ADDN	Australasian Diabetes Data Network
AIHW	Australian Institute of Health and Welfare
ANDA	Australian National Diabetes Audit
ARTG	Australian Register of Therapeutic Goods
AQCA	Australian Quality Clinical Audit
CGM	Continuous glucose monitoring
DAEN	Database of Adverse Event Notifications
DIY	Do it yourself
Flash GM	Flash glucose monitoring
HbA1c	Glycosylated haemoglobin
HCP	Hospital Casemix Protocol
HTA	Health technology assessment
IRIS	Incident Reporting and Investigation Scheme
JDRF	Juvenile Diabetes Research Foundation
MSAC	Medical Services Advisory Committee
NDSS	National Diabetes Services Scheme
NHMD	National Hospital Morbidity Database
RACGP	Royal Australian College of General Practitioners
TGA	Therapeutic Goods Administration

Glossary

Basal rate (dose): A continuous low level delivery of insulin, required to keep blood glucose levels within the normal range as the liver releases glucose into the blood.

Blood glucose: The main sugar that the body makes from the food in the diet. Glucose is carried through the bloodstream to provide energy to all cells in the body. Cells cannot use glucose without the help of insulin.

Bolus dose: A delivery of insulin that provides the boost of insulin needed to stop the rise in blood glucose levels that occurs after meals**.**

Diabetes: A chronic condition in which the body cannot properly use its main energy source: the sugar glucose. This is due to either the pancreas not producing enough of the hormone insulin, or the body being unable to effectively use the insulin produced. Insulin helps glucose enter the body's cells from the bloodstream and then be processed by them. Diabetes is marked by an abnormal build-up of glucose in the blood, and can have serious short- and long-term effects on many of the body's systems, especially the blood vessels and nerves.

Gestational diabetes: A form of diabetes that is first diagnosed during pregnancy (gestation). It may disappear after pregnancy but signals a high risk of diabetes occurring later on in life.

Incidence: Refers to the number of new cases of an illness, disease, or event occurring during a given period.

Insulin: A hormone produced by the pancreas. Its main action is to enable body cells to absorb glucose from the blood and use it for energy.

Insulin pump: A device worn close to the body that delivers insulin subcutaneously.

HbA1c (glycosylated haemoglobin): Can be used to assess the average blood glucose over the preceding 6–8 weeks and is considered the gold standard for assessing glycaemic control. Targets for HbA1c in people with diabetes should be individualised, but a general target of less than or equal to 7.0% is recommended for people with type 2 diabetes.

Heart attack: Life-threatening emergency that occurs when a vessel supplying blood to the heart muscle is suddenly blocked completely by a blood clot. The medical term commonly used for a heart attack is acute myocardial infarction.

Heart failure: A term that describes when the heart functions less effectively in pumping blood around the body. It can result from a wide variety of diseases and conditions that can impair or overload the heart, such as heart attack, or other conditions that damage the heart muscle directly.

Hypoglycaemia (low blood glucose): A common and dangerous condition for many people with type 1 diabetes. It can be caused by eating less than usual, undertaking more exercise than normal or if too much insulin or sulfonylurea medication is administered.

Hyperglycaemia (high blood glucose): Occurs when the body has too much food or glucose, or too little insulin. It can be caused by a blockage in insulin pump tubing, missing an insulin dose, eating more than usual, stress or less exercise than usual.

Ketoacidosis: when the body cannot turn glucose into energy (due to insufficient insulin) it uses its own fats for energy. When these fats are broken down they release acids known as ketones, which can accumulate in dangerous levels in the blood and urine, causing diabetes ketoacidosis. This condition is potentially life threatening if not treated.

Low suspend glucose: A setting within the insulin pump system to suspend basal insulin delivery in response to detected low glucose levels.

Predictive low glucose suspends: A setting within the insulin pump system to suspend basal insulin delivery in response to predicted low glucose levels.

Other types of diabetes: Other types of diabetes are relatively uncommon, and are most typically related to certain conditions or syndromes that result in defects in insulin secretion, insulin action, or both. For some people with other types of diabetes, adequate glycaemic control can be achieved through diet and exercise or use of diabetes non-insulin medications. Some, however, may also require insulin to manage their blood glucose.

National Diabetes Service Scheme (NDSS): Started in 1987 and is an initiative of the Australian Government, administered by Diabetes Australia. The NDSS delivers diabetes-related products at subsidised prices and provides information and support services to people with diabetes.

Neuropathy: A complication of diabetes that results in damage to the nerves.

Retinopathy: A complication of diabetes that causes damage to the capillaries of the retina in the eye.

Procedure: A clinical intervention that is surgical in nature, carries a procedural risk, carries an anaesthetic risk, requires specialised training and/or requires special facilities or equipment available only in an acute-care setting.

Statistical significance: Variation or difference in observed values or rates may reflect only a random variation or difference. Statistical significance assesses whether differences in values of rates are statistically significant—that is, that they are likely to not be due to chance alone.

Stroke: An event that occurs when an artery supplying blood to the brain suddenly becomes blocked or bleeds. A stroke often causes paralysis of parts of the body normally controlled by that area of the brain, or speech problems and other symptoms.

Type 1 diabetes: Marked by the inability to produce insulin. People with type 1 diabetes need insulin replacement for survival. Most cases are caused by an autoimmune condition that destroys the pancreatic cells which produce insulin.

Type 2 diabetes: The most common form of **diabetes**, occurring mostly in people aged 40 and over, and marked by reduced or less effective insulin.

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