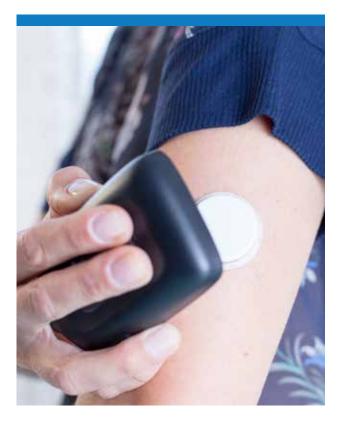diabetes
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Position Statement

Glucose self-monitoring in adults with type 1 diabetes or type 2 diabetes

Key Points

Health Policy Context

1. Managing glucose levels is very important for preventing or delaying the complications of both type 1 diabetes and type 2 diabetes.

2. Glucose self-monitoring is a rapidly changing and confusing area, with new technologies becoming available, many devices to choose from, and changes to government subsidies.

3. Making new glucose self-monitoring technologies affordable and accessible is critical to improving the health and quality of life for the 1.2 million Australian adults currently living with type 1 diabetes and type 2 diabetes.

4. Government should subsidise the cost of glucose self-monitoring technologies where there is evidence it can improve outcomes and quality of life.

5. Age should not be the deciding factor in Government subsidies. Too often subsidies are limited to those aged under 21 despite the evidence of health benefit being equally strong for adults.

6. Government should regularly review its policies concerning subsidised access to glucose self-monitoring technologies and supplies to incorporate the latest evidence and to allow greater affordability and accessibility.

Adults with Diabetes and Healthcare Professionals

7. People with diabetes should have access to an informed and supportive health care team who understand the use and benefits of glucose self-monitoring to inform adjustments to the person's diabetes self-care (including food/drink, physical activity, and medications).

8. People with diabetes should be supported by their health care team and the National Diabetes Services Scheme (NDSS) to develop their knowledge and skills in glucose self-monitoring. Initial training should be undertaken soon after diabetes is diagnosed. Skills, devices, and use of monitoring should be reviewed by the health care team at least once every year to ensure the person is continuing to benefit from glucose self-monitoring.

9. People with diabetes should feel comfortable that any change to their glucose self-monitoring - whether it is changing from one type of glucose monitoring to another, if subsidised access is discontinued, or if glucose self-monitoring is stopped altogether – has been managed appropriately, with discussion, shared decision making, and support from their health care team.

Subsidised access to glucose self-monitoring devices and support through the NDSS

10. Subsidised access to blood glucose monitoring strips is essential for people with type 1 diabetes and type 2 diabetes:

    a. all people with type 1 diabetes or type 2 diabetes using insulin or other medication with risk of low blood glucose (hypos) currently have unrestricted access to subsidised blood glucose monitoring strips and this should continue

    b. structured glucose monitoring should be encouraged and supported through the NDSS for all people with type 2 diabetes

    c. all people with diabetes should have their individual glucose monitoring needs assessed by an informed and supportive heath care team, taking into account their overall health and quality of life

11. Subsidised access to flash glucose monitoring (sensors) should be made available through the NDSS to adults with type 1 diabetes and type 2 diabetes using insulin.

12. Subsidised access to continuous glucose monitoring (CGM; devices and sensors) is currently available to people under 21 years of age, and should also be made available to the following groups:

    a. adults with type 1 diabetes experiencing recurrent severe hypos or impaired awareness of hypos, or significant fear of hypos

    b. women with type 1 diabetes using insulin while planning for a pregnancy and during pregnancy, due to the adverse effect that high and low glucose levels can have on the unborn child

13. All adults newly diagnosed with type 1 diabetes or type 2 diabetes should receive structured education about glucose self-monitoring as soon as possible after diagnosis. All adults with type 1 diabetes or type 2 diabetes should be able to access diabetes self-management education and support programs through the NDSS.

ABOUT THIS POSITION STATEMENT

Diabetes Australia believes we need to make it easier for Australians living with diabetes to self-monitor their glucose levels and better self manage their condition.

Diabetes Australia believes that every person with diabetes should be able to access and use technologies that help them manage their diabetes to the best of their ability, to protect their health and quality of life.

This position statement is written for adults with type 1 and type 2 diabetes to help them to decide the type of glucose monitoring that is right for them. It may also be useful for carers, family members, as well as the general community and policy makers. It explains the various technologies available, their pros and cons, and the evidence for each. The recommendations in this statement are informed, but not limited, by evidence.

This statement provides general information. People with diabetes should always consult their healthcare professional to discuss their own diabetes care. The statement is not intended as a clinical guidance document for health professionals. It is not intended for women with gestational diabetes or for children/young people with diabetes.

1. Introduction

Glucose self-monitoring is an important aspect of day-to-day self-care for people with diabetes. It can help inform the choices people make about food/drink, physical activity and medications, as well as monitoring the effects of those choices. It can also identify and inform the management of low blood glucose (hypos) or high blood glucose.

Maintaining glucose levels in a target range is important for people with diabetes to prevent or delay long-term complications such as blindness, kidney damage, amputation, heart attack and stroke.

Daily diabetes self-care can involve adjustments to food and drink, carbohydrate counting, exercise and physical activity, medications, adjusting medication doses (e.g. insulin), and monitoring of glucose levels (see Section 2).

These daily self-care activities can differ from person to person depending on many factors. Key factors can include the type of diabetes, how long a person has had diabetes, their treatment plan, their age and life stage, and their overall health.

Glucose self-monitoring is an essential part of self-care for people with type 1 diabetes. It is also important for people with type 2 diabetes who:

- are using insulin or other medications that carry a risk of hypos (e.g. sulfonylureas)
- are using other medications that affect glucose levels (e.g. corticosteroids)
- have another short or long term illness that may affect glucose levels
- have had a change to their diabetes treatment.

However, for other people with type 2 diabetes (not covered above), the role of glucose self-monitoring is more about individual choice.

Currently, the most common form of glucose monitoring involves a finger-prick blood sample using a blood glucose meter.

Over the past decade there have been significant developments in glucose monitoring technologies (see Section 3).

There is now considerable research providing evidence of the advantages and disadvantages of glucose self-monitoring technologies, and who benefits most (see Section 4).

The Australian Government helps subsidise the cost of some types of glucose self-monitoring through the NDSS (see Section 5).

In 2016, the Government changed the rules for subsidised access to blood glucose strips for people with type 2 diabetes. Now, anyone can have an initial six months subsidised supply. After this, ongoing access is restricted for people with type 2 diabetes not using insulin or medications that carry a risk of hypos, and not having some other clinical need.

In 2017, the Australian Government added subsidised access to CGM transmitters and sensors for children and young adults (under 21 years of age) with type 1 diabetes (subject to certain eligibility criteria).

Diabetes Australia supports government subsidisation of glucose monitoring technologies where there are health and quality of life benefits, to make them affordable and accessible to all Australians (see Section 6).

2. About Glucose Self-Monitoring

Types of glucose monitoring

There are two types of glucose monitoring. Both are important for managing diabetes, preventing complications, and improving overall health outcomes.

HbA1c

HbA1c (glycated haemoglobin) gives an indication of the average blood glucose over the past 8-12 weeks. It is an important indicator of the risk for developing long-term diabetes complications and can provide useful information to inform treatment changes.

HbA1c involves measurement of a blood sample. It is usually done at a pathology centre but, increasingly, a "point of care" HbA1c check can be done on the spot. It is recommended that most people with diabetes have their HbA1c checked every 3-6 months and discuss the findings with their diabetes specialist, credentialled diabetes educator and/or GP.

HbA1c is an important diabetes check. However, it is unable to show the day-to-day ups and downs of glucose levels. So, it is of limited help to the person with diabetes in their daily self-care.

Glucose self-monitoring

Glucose self-monitoring can be done in various ways. Currently, the most common method is a 'finger-prick' check using a home blood glucose meter. Other types of glucose self-monitoring are available (see Section 3).

A 'finger-prick' check provides a 'snapshot' of the glucose level at that moment in time. When and how often people check their glucose levels will vary for each person, depending on their type of diabetes, and their individual self-care plan (including the tablets and/or insulin they use).

Why is self-monitoring useful?

Glucose self-monitoring can help people with diabetes to:

- identify how their glucose levels are affected by food/drink, physical activity, alcohol, medications, illness, stress and other factors
- inform and adjust insulin doses, food/drink or physical activity to enhance their diabetes self-care
- identify and manage low glucose levels (hypos) or high glucose levels
- check whether it is safe to drive or to operate machinery.

When is glucose self-monitoring not useful?

Glucose self-monitoring can be unhelpful if the person with diabetes:

- is only checking at random times of the day (with no context of risk, change in health or treatment, food/drink or activity level)
- does not know what the glucose level means
- does not know how to adjust their self-care to bring a high or low glucose level into target range
- does not intend to do anything with the information
- is *only* monitoring because they think it keeps their doctor or diabetes educator happy.

Glucose self-monitoring needs active engagement in self-care

For glucose self-monitoring to be effective, the person with diabetes needs to:

- agree with their diabetes specialist, CDE or GP why glucose self-monitoring will be useful to them

- set personal glucose targets to aim for (a diabetes specialist, CDE or GP can help with this)

- know when to check their glucose levels; checking at random times of the day can be important for people at risk of hypos

- know how to properly use the device and interpret the glucose levels

- know what to do to bring high or low glucose levels into target range

- be willing and able to check their glucose levels at the best times

- be willing and able to make necessary changes to food/drink, physical activity, and medications

- feel supported by their health professional

- be motivated to monitor their glucose levels.

If any of these factors are missing, glucose monitoring can produce meaningless data and become a frustrating and demoralising experience for the person with diabetes.

Box A shows how the words used when thinking or talking about glucose monitoring can affect motivation and self-care.

Box A: Language Matters

Language can be very powerful, and the way we talk about diabetes management matters.[1]

People with diabetes may be discouraged by the idea of doing blood 'tests'. The words 'tests' and 'testing' may remind people of doing exams and being at school; it may make them feel like they are being judged for 'passing' or 'failing' the test.

Talking about 'checking' glucose is less judgemental and more empowering. 'Checking' glucose simply means that a person is looking for information to guide what they will do next or to provide feedback on what they have had to eat or drink, or following exercise.

People tend to look at glucose readings and think of them as being 'good' or 'bad'. Thinking or talking about glucose levels using emotive language has a tendency to lead to emotional reactions, such as getting upset, frustrated, or thinking it's all 'too hard'. Instead, using words such as 'high', 'low' or 'in range' removes the emotion, as they are more factual and less judgmental.

Remember, the glucose level is just a number that reflects the amount of glucose in the blood – it does not suggest a person is 'good' or 'bad' at managing their diabetes.

Box B provides a summary of how to do 'structured' glucose self-monitoring, to ensure it is meaningful and useful for improving diabetes self-care. People with type 2 diabetes who are not using insulin may think that everyday glucose self-monitoring is not helpful, but they may find it useful to do 'structured' monitoring from time to time.

Box B: What is 'Structured' Glucose Monitoring?

Knowing how to improve your diabetes self-care can be difficult. 'Structured' monitoring helps you to see how food/drink, activity and medications affect your glucose levels. There are two types of structured monitoring:

Looking for patterns

1. Decide on a 3-day period when you will be able to check your glucose levels at set times

2. Every day for 3 days, check and write down your glucose level before and 2 hours after breakfast, lunch and dinner, and then again before bedtime

3. Also write down any other relevant information, e.g. what you ate, any physical activity

4. Check your glucose levels against your personal targets, to see if they are within, above or below target

5. What did you discover? Was your glucose level ever low (hypo) before meals or after activity? Was it ever high (hyper) after meals? By how much? What had you eaten?

6. What does this mean for your ongoing diabetes self-care? e.g. you might want to reduce your portion sizes, or take a daily walk after breakfast or lunch

Before-and-after checks

1. Start with one simple question, e.g. how does my breakfast affect my glucose levels? Or, how does physical activity affect my levels?

2. Every day (e.g. for the next 3 days), check your glucose level before and after the activity (e.g. 2 hours later). Write down the glucose levels and what the activity was. For a meal, write down what and how much you ate. For physical activity, write down what it was and for how long you did it

3. How did your glucose levels change following each activity? The more times you do this, the clearer the patterns will be

4. What did you discover? Did your glucose level stay the same after the activity? Did it rise or fall? If so, by how much? You are likely to discover that what and how much you eat or exercise really matters to your glucose levels

5. What does this mean for your ongoing diabetes self-care? e.g. you might want to reduce your portion sizes, or take a daily walk after breakfast or lunch

6. Go back to step 1 (above) and consider a different question

You may not need to monitor every day to benefit from changes to your self-care. It may be useful to use structured monitoring for just three days in the week before a visit to a diabetes specialist or GP, so you can share your findings and discuss the best way of managing your diabetes moving forward.

3. Glucose Self-Monitoring Technologies

Box C shows the various types of glucose self-monitoring technologies currently available. This is followed by a detailed description of each technology. At the end of this section, Box D shows the pros and cons of each technology.

Box C: Types of Glucose Self-Monitoring Technologies

BLOOD GLUCOSE MONITORING	FLASH GLUCOSE MONITORING	CONTINUOUS GLUCOSE MONITORING	CONTINUOUS GLUCOSE MONITORING WITH AN INSULIN PUMP
• Glucose strips • Snapshot of glucose level at a single point in time • Available since the 1980s • Most common form of glucose monitoring	• 14-day sensor • Shows glucose trends • Available since June 2016	• 6 to 7-day sensor • Real-time glucose reading • Shows glucose trends • Alarms when glucose levels are out of target range • Available since 2000s	• 6 to 7-day sensor • Real-time glucose readings • Shows glucose trends • Alarms when glucose levels are out of target range • Integrated with insulin pump • Available since 2000s

Blood glucose meters

A blood glucose meter is a small, handheld electronic device. A lancet is used to prick the tip or side of the finger and obtain a relatively small drop of blood. This is placed on a disposable strip, and the level of glucose in the blood is measured by the meter. Within several seconds, the level of blood glucose will be shown on a digital display. There are many types of blood glucose meters offering different features.

When choosing a meter, key questions to consider include:

- How much does the meter cost?

- Ease of use? Are both the meter and glucose strips easy to hold? Are the numbers on the screen clear and easy to read? Is it easy to get the blood sample onto the strip? How much blood is needed for each check?

- Does it have a memory? Some meters can record as few as 10 samples, others can record up to 500. So, if a person wants to look back at levels over the past week or month, they might want a meter with a bit more memory.

- Does it have (and does the person want) high tech features? Most modern meters come with software so that readings can be uploaded to a computer, smartphone or tablet device. Some connect directly to the device, while others work wirelessly with an insulin pump or upload via Bluetooth connection. The data can then be used to identify patterns / trends in glucose levels and to assist people to make changes to diabetes management.

People with diabetes can get advice on choosing a meter that suits their individual needs from a credentialled diabetes educator, diabetes specialist, pharmacist or GP.

Flash glucose monitors

Flash glucose monitoring is a relatively new form of glucose monitoring first approved for use in Australia in 2016. A small sensor (the size of a 20c coin) is worn on the upper arm.

These devices do not measure glucose from blood samples. The sensor measures glucose levels in the interstitial fluid (the tissue between the cells beneath the skin). There is a lag time between blood glucose and flash sensor readings of 6-12 minutes.

There is no need for finger prick glucose checks for calibration of the device. The person scans a handheld reader (the size of a smartphone) over the sensor to get the reading. The sensor is disposable and needs to be changed every 14 days.

Unlike CGM systems (see below), the glucose data is only displayed if the sensor is scanned by the reader. The sensor samples glucose automatically every 15 minutes and stores glucose data for the past 8 hours.

Similar to CGM, a flash glucose monitor displays arrows to show when glucose levels are rising, falling or remaining steady. Each scan provides glucose data from the past 8 hours.

A flash glucose monitor has no alarms – depending on the person's individual needs this may be an advantage or a disadvantage.

For those people using flash glucose monitoring, finger-prick monitoring is still recommended:

- during times of rapidly changing glucose levels

- to confirm hypoglycaemia

- when symptoms do not match the flash glucose monitor readings

- before giving insulin to correct a high glucose level.

Continuous glucose monitors (CGM)

Continuous glucose monitors are small, wearable devices that measure glucose levels continuously and provide patterns and trends throughout the day and night. They can be programmed to sound alarms and send warnings if glucose levels are getting too low or too high. CGM systems display arrows to show whether glucose is rising, falling or remaining steady, and can identify trends in glucose levels. The data are displayed on either a receiver or an app on a smartphone or tablet.

CGM systems include a sensor inserted under the skin (usually on the stomach), a transmitter and a reader. The reader can be either a standalone device, or a smart phone/device (via an app), or an insulin pump (see CGM combined with pump).

These devices do not measure glucose from blood samples. The sensor measures glucose levels in the interstitial fluid (in the tissue between cells beneath the skin) and estimates the glucose level from this. There is a lag time between blood glucose and CGM sensor readings of 6-12 minutes. The sensor transmits glucose readings every five minutes.

The sensor is disposable and needs to be changed according to manufacturers' recommendations, typically every 6-7 days.

CGM reduces the need for finger prick checks, although calibration using a blood glucose strip/meter reading is required at least twice daily.

For people using CGM, finger-prick monitoring is recommended and necessary:

- to calibrate the system (twice daily)
- during times of rapidly changing glucose levels, when sensor glucose levels may not accurately reflect blood glucose levels
- to confirm hypoglycaemia
- when symptoms do not match CGM readings

- before dosing to correct a high glucose level
- to ensure it is safe to drive.

CGM devices can be used by anyone with type 1 or type 2 diabetes, though most studies have been conducted in people who use insulin (see Section 4).

CGM with an insulin pump

Some CGM devices can be combined with an insulin pump – a small, wearable device that delivers doses of insulin through a cannula inserted under the skin (usually on the stomach or hips).

Some insulin pumps can act as the receiver of data from a CGM device. The data are sent wirelessly to the pump by the CGM transmitter.

Some pumps can stop insulin delivery if glucose levels are predicted to go low, or reach a set low level. However, the CGM system does not necessarily automatically trigger the pump to stop delivery of insulin and the person needs to make insulin adjustments manually.

Technologies in the pipeline

Glucose monitoring technologies continue to evolve. The focus is on developing devices that are smaller, cheaper, more accurate, less invasive, and longer lasting. There are new integrated and automated glucose monitoring and insulin delivery systems (also known as 'closed loop' or 'artificial pancreas') being developed and tested in research studies across the world. The aim is to develop a fully-automated system which is able to increase or decrease insulin depending on sensor glucose readings, with minimal input from and reduced burden on, the person with diabetes.

Box D: Pros and Cons of Glucose Self-Monitoring Technologies

	Blood glucose monitoring	Flash glucose monitoring	Continuous glucose monitoring	CGM with an insulin pump
Cost to the person with diabetes	Devices cost from $30 - $150 Some devices may be available free from health professionals. Private health insurance extras cover may cover the cost of glucose meters. Through the NDSS, 100 strips cost $16.70 ($2.60 for people with a health care card). Over a year, the cost of checking glucose levels 4 - 6 times per day is approximately $300.	Scanning device costs $95. Sensors cost $92.50 each (they need to be changed every 14 days). Continuous use for one year is estimated to cost approximately $2,500.	Transmitters cost from $500 - $600. Sensors cost about $90 (they need to be changed every 6 - 7 days). Continuous use for one year is estimated to cost approximately $4,000 - 5,000 (some device companies offer discount deals). CGM is unlikely to be covered by health insurance (check individual's policy).	Information on CGM costs applies (see left), plus: Insulin pump consumables cost an additional $30 per month. Insulin pumps cost about $9,000 - $10,000. Costs may be covered by private health insurance (check individual's policy).
Subsidies	Blood glucose strips are subsidised by the NDSS. Cost $16.70 for 100 strips ($2.60 if on healthcare card).	Currently no subsidies.	CGM devices and sensors are subsidised by the NDSS for children and young adults under 21 who meet eligibility criteria. No subsidy for adults 21 years and over.	Information on CGM subsidies applies (see left). Insulin pump consumables are also subsidised by the NDSS. Cost $30 per month.
Frequency of glucose readings	Dependent upon how often the person pricks their finger.	Dependent on how often the sensor is scanned. Device automatically samples interstitial glucose every 15 minutes and stores in memory for 8 hours.	CGM automatically samples interstitial glucose every 5 minutes and shows readings on a graph.	CGM automatically samples interstitial glucose every 5 minutes and shows readings on a graph on the insulin pump.
Glucose trends shown	No. Some meters can show patterns if glucose checks are done at the same time over several days.	Yes. When sensor is scanned, transmitter displays past 8 hours of glucose levels.	Yes.	Yes.
Memory	Varies depending on meter chosen.	Device stores readings from the past 8 hours.	Device displays and stores up to 24 hours of glucose readings.	Device displays and stores up to 24 hours of glucose readings.
Time taken for glucose check	1-2 minutes. Varies depending on meter.	Scan takes 1 second. Inserting sensor takes a few minutes.	Data viewed on demand on smart device, receiver or insulin pump.	Data viewed on demand on insulin pump.
Alarms	No. Alerts (not alarms) can be shown on smart devices for low and high blood glucose levels.	No. Alerts (not alarms) are shown on device but only if scan is done at a time when glucose is low or high.	Yes. Devices can be programmed to alarm for low and high glucose levels.	Yes. Devices can be programmed to alarm for low and high glucose levels.
Body part used for sampling	Tips or sides of fingers.	Approved for use on upper arm.	Approved for use on stomach.	Approved for use on stomach.
Calibration	Some meters need intermittent calibration using a solution.	Not needed.	Finger prick calibration needed at least twice daily.	Finger prick calibration needed at least twice daily.

4. What does the evidence say about different types of monitoring technologies?

Box E: Summary of evidence for glucose self-monitoring technologies

	Blood glucose monitoring	Flash glucose monitoring	Continuous glucose monitoring	CGM with an insulin pump
Type 1 diabetes	Frequent daily blood glucose checks with finger pricks can help people lower their HbA1c. This was recently confirmed by a large study involving more than 20,000 people with diabetes, which found that regular glucose monitoring resulted in lower HbA1c levels in people using multiple daily injections or insulin pump therapy.	Research is only just emerging as the technology is new. One recent trial has found flash glucose monitoring reduces the amount of time a person spends per day with glucose levels in the hypo range.	Most trials have used CGM in people already using pumps. These often show improvements in HbA1c, satisfaction and quality of life. A recent study has shown benefits for people using CGM with multiple daily insulin injections. The alarm feature means CGM offers a 'safety net' to protect against hypos. Because of this, CGM is often recommended for people who lack awareness of their hypo symptoms, or who experience frequent severe hypos (i.e. needing assistance for recovery). However, very few studies include people with problematic hypos. There is not enough evidence to show that CGM, on its own, is effective in reducing the frequency of hypoglycaemia. Diabetes education and support from health professionals are important for preventing hypos.	Consistent with continuous glucose monitoring evidence (in adjacent column). Most studies showing CGM improves HbA1c involves people using CGM in combination with insulin pump therapy.
Type 2 diabetes (using insulin)	The evidence about how effective blood glucose monitoring is for people with type 2 diabetes on insulin is similar to those for adults with type 1 diabetes.	There is little research into this new technology. One trial found there was no difference in HbA1c and reduced hypoglycaemia in people with type 2 diabetes using insulin and using flash monitoring. This means flash monitoring could be a safe, effective replacement for finger-prick monitoring.	Very few trials of CGM in people with type 2 diabetes using insulin, however one recent trial found it improved HbA1c. A recent trial using CGM found people with type 2 diabetes using insulin were having more hypos than has previously been thought. This suggests that many people with type 2 diabetes using insulin do not recognise or report hypos.	
Type 2 diabetes (not using insulin)	Reviews suggest that glucose self-monitoring is of limited value. This is often because it is low frequency, random and the person doesn't know what to do with the results. However, some trials (using a 'structured' approach, see Box A) have found that glucose monitoring can improve HbA1c. If health professionals support glucose monitoring, they are more likely to recommend changes to self-care plans, which can prevent or delay complications.	No research to date	Limited research suggests that CGM may be beneficial for people with type 2 diabetes not using insulin.	

Box E summarises the evidence. For more details, see Appendix 1.

5. Funding for Glucose Self-Monitoring in Australia

Currently, there are 1.2 million Australian adults living with diabetes (including both type 1 diabetes and type 2 diabetes).

Some glucose self-monitoring options are subsidised by the Australian Government through the NDSS.

The direct healthcare costs of diabetes total $1.7 billion per year.[2] The indirect costs of diabetes may be as high as $14.6 billion per year.[3] These include absence from work, early retirement, premature death. Most of the diabetes budget is spent on treating and managing avoidable complications.[3] The annual direct cost for people with complications is more than twice the cost for those without complications: $9600 compared with $3500.[3]

Given these costs, it makes economic sense to make glucose self-monitoring technologies affordable and accessible to all Australians with diabetes who would benefit. It is important to avoid a two-tiered health system in which glucose self-monitoring is only used by those who can afford to pay.

NDSS access: blood glucose strips

Adults with type 1 diabetes

The NDSS provides subsidised glucose strips for all people with type 1 diabetes.

Adults with type 2 diabetes

The NDSS provides subsidised glucose strips for all people with type 2 diabetes using insulin.

There are some restrictions on subsidised access for people with type 2 diabetes who are not using insulin which were introduced by the Australian Government from 1 July 2016. **Box F** summarises the eligibility criteria for subsidised access to blood glucose strips.

NDSS access: flash glucose monitoring

There is currently no subsidised access through the NDSS for flash glucose monitoring for people with diabetes.

Box F: Eligibility criteria for ongoing subsidised access to blood glucose strips from 1 July 2016

People with type 1 diabetes and all people with type 2 diabetes using insulin can access subsidised blood glucose strips.

All people with type 2 diabetes not using insulin can receive an initial six-month supply of subsidised blood glucose strips.

People with type 2 diabetes not using insulin may be approved for a further six months access, if they meet one of the following criteria (as defined by the Department of Health):

- *the patient has an inter-current illness that may adversely affect blood glucose control;*
- *the patient is undergoing treatment with a medicine that may adversely affect blood glucose control;*
- *the patient's diabetes is inadequately controlled;*
- *there is a clinical need for the patient to self-monitor their blood glucose control; or there has been a change to the patient's existing diabetes management within the previous three (3) months.*

There is no limit to the number of extensions that a person can request. Medical practitioners (e.g. a GP or an endocrinologist) and credentialled diabetes educators (CDEs) are authorised to sign the form to enable a person to have continued access to glucose strips.

CDEs have expertise in using structured monitoring (see **Box B**) and educational techniques to support people with type 2 diabetes in active self-care of their condition.

NDSS access: CGM

From 1 April 2017, CGM transmitters and sensors are free for children and young people with type 1 diabetes under the age of 21 years who meet certain eligibility criteria.

All children aged 10 or under are eligible. Young people with type 1 diabetes (aged over 10 and under 21 years) are eligible for CGM subsidy if they meet one of the following criteria:

- frequent significant hypos, i.e. more than one episode a year of severe hypoglycaemia needing assistance from someone else for recovery; and/or
- impaired awareness of hypos; and/or
- inability to recognise, or communicate about, symptoms of hypos; and/or
- significant fear of hypos for the child/ young person or a family member/ carer, which is seriously affecting the health and wellbeing of the child or young person or contributing to high glucose levels (hyperglycaemia) as a reaction to this fear.

They should also be:

- expected to benefit clinically from the use of CGM; and
- willing and capable to use CGM; and
- committed to actively participate in a diabetes management plan that incorporates CGM.

More information about the NDSS subsidy can be found here: www.ndss.com.au/cgm

Adults over 21 years of age

There is currently no subsidised access to CGM devices for adults aged 21 years or older.
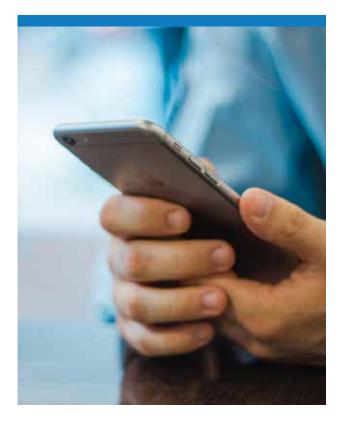
6. Recommendations

General

Glucose self-monitoring is an important tool for managing diabetes and preventing complications.

Diabetes Australia welcomes technologies that provide people with more convenient, less painful and less disruptive ways of monitoring glucose levels. We support new technology that makes it easier for people to better self-manage their condition, to reduce their risk of diabetes-related complications and ultimately improve their health and quality of life.

There are currently more than 360,000 Australians with diabetes using insulin and registered with the NDSS who could benefit from new and emerging technologies. The cost is currently prohibitive for many people with diabetes.

Extension of current NDSS subsidies would greatly improve affordability and access, providing new glucose monitoring options to help thousands of Australians to self-monitor their glucose levels and better self-manage their condition.

Diabetes Australia recommends people with diabetes discuss the various glucose self-monitoring options with their diabetes healthcare team to work out which option best suits their individual needs and preferences.

Diabetes Australia recommends that healthcare professionals supporting people with diabetes should:

- encourage people who use insulin (or any other medication with risk of hypoglycaemia) to self-monitor their glucose for safety reasons

- encourage and support glucose self-monitoring among all people with diabetes who will benefit from its use

- advise on the appropriate use and frequency of glucose self-monitoring, tailoring this to the individual's needs and preferences

- consider the beneficial impact glucose self-monitoring can have for people managing their diabetes with lifestyle alone

- be trained to use 'structured' glucose monitoring to support and encourage people with type 2 diabetes not using insulin to adopt an effective approach to monitoring with minimal burden

- ensure that subsidised access to glucose self-monitoring for a person with type 2 diabetes who is not using insulin (or another medication that carries a risk of hypoglycaemia) is not withdrawn without appropriate discussion and support for the person with diabetes.

Access to blood glucose strips

Diabetes Australia recommends:

- access to glucose strips should not be denied to any person who can demonstrate they benefit from glucose monitoring
- access should never be restricted for adults with type 1 diabetes or type 2 diabetes using insulin or other medication with risk of hypoglycaemia
- access for adults with type 2 diabetes not using insulin (or other medication with risk of hypoglycaemia) should be based on individual assessment of need.

Access to flash glucose monitoring

Diabetes Australia supports the subsidy of this technology to make it more accessible for people with diabetes.

Diabetes Australia recommends that subsidised access to flash glucose monitoring (sensors) should be made available to adults with type 1 diabetes or type 2 diabetes using insulin.

Access to CGM

Diabetes Australia strongly supports the subsidised access to CGM, for children and young people (under 21) with type 1 diabetes, which commenced from 1 April 2016.

Diabetes Australia recommends that subsidised access to CGM (through the NDSS) should be extended to adults aged 21 and over in the following groups:

- people with recurrent severe hypos (i.e. needing assistance for recovery)
- people with impaired awareness of hypos, as they are at high risk of severe hypos
- people with significant fear of hypos, where this is significantly affecting their diabetes management (leading them to maintain high glucose levels (hyperglycaemia) and/or their quality of life)
- women with type 1 diabetes while planning for a pregnancy and during pregnancy, due to the adverse effect that high and low glucose levels can have on the unborn child.

Diabetes Australia recognises that CGM is neither necessary nor appropriate for all people with type 1 diabetes and those with type 2 diabetes using insulin. Many people will prefer to use other glucose self-monitoring devices.

More studies are needed in adults with type 2 diabetes not using insulin to determine the benefit of CGM in this group.

Further information

Diabetes Australia produces a range of resources with additional information that may be useful:

- www.diabetesaustralia.com.au
- www.ndss.com.au
- Diabetes Australia and NDSS Fact sheet- Blood Glucose Monitoring
- Accessing CGM through the NDSS Brochure

You can find out more about blood glucose monitoring by contacting your:

- State or Territory Diabetes Organisation on 1300 136 588
- Local hospital or your nearest diabetes clinic

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Acknowledgements

Appendix 1: Summary of the research evidence

The highest forms of evidence are systematic reviews. These include all relevant studies and summarise the overall findings. Randomised controlled trials (RCTs) include people randomised to the intervention or to a 'control' condition (often usual care). The groups are then compared after a given period of time (e.g. 6 months) to see if there is any significant difference between them. A 'significant' finding is one that we would not expect to see by chance.

Type 1 diabetes

Blood glucose monitoring

Successful lowering of HbA1c to target is strongly associated with a higher number of blood glucose checks per day. This has been confirmed most recently in a large study of 20,555 people with type 1 diabetes from the US T1D Exchange Clinic Registry – in all age groups, and regardless of whether the person uses multiple daily injections or insulin pump therapy.[4]

Flash glucose monitoring

Flash monitoring is a new technology, so there are few published RCTs. An RCT was conducted among adults with type 1 diabetes, whose HbA1c was in target range (≤58mmol/mol; 7.5%). It found that flash monitoring reduced the time they spent in hypoglycaemia range by 38% (i.e. from 3.4 hours per day down to 2.0 hours per day).[5]

CGM

Systematic reviews show that CGM reduces HbA1c, particularly in those with highest HbA1c at baseline, and among those who used sensors more of the time.[6,7] Most CGM studies have been conducted in adults using insulin pump therapy. A recent RCT in adults using multiple daily insulin injections has shown HbA1c improves after 6 months of CGM.[8]

Most studies include adults aged 18 to 70 years. Few focus on older adults. One RCT which only included older adults (average age 67 years) with type 1 diabetes using multiple daily insulin injections found HbA1c improved at 6 months.[9]

Most RCTs of CGM are short-term (e.g. 6 months) and long-term data are needed.

CGM devices have alarms that sound/vibrate when glucose levels drop below target range. For this reason, CGM is often recommended for those who have frequent severe hypos (i.e. requiring assistance from another person for recovery) or impaired awareness of hypo symptoms. However, most CGM studies have excluded people with prior severe hypos or impaired awareness of hypo symptoms. When CGM is studied in research projects, people often receive a lot of diabetes education and ongoing support from the research team. Those studies that have controlled for education/support have shown little additional benefit from the CGM.[10]

CGM is often recommended for women during pregnancy – again, because of the alarms, which can help to keep women safe from hypos while keeping blood glucose levels in target range to protect the unborn child. However, the current evidence for the effectiveness of CGM in improving outcomes during pregnancy is not convincing.[11] Two RCTs (CONCEPTT[12] and GlucoMOMs[13]) have been completed recently with the aim of clarifying whether CGM improves pregnancy outcomes. The results will be published soon.

Type 2 diabetes (using insulin)

The following section applies to people with type 2 diabetes who use insulin. Most research into glucose self-monitoring has included people using multiple daily insulin injections. The research reported here may not apply to people using basal (once/twice daily) insulin or a class of tablets known as sulphonylureas, which can also cause hypos.

Blood glucose monitoring

For those using multiple daily insulin injections, the evidence is similar to type 1 diabetes . Glucose self-monitoring is needed to identify/ correct high or low blood glucose levels) and to adjust insulin doses.

To our knowledge, there are no specific studies about the effectiveness of SMBG in people using basal insulin (alone or with tablets).

Flash glucose monitoring

Flash monitoring is a relatively new technology, so RCTs are only just emerging. In adults with type 2 diabetes using multiple daily insulin injections, the REPLACE trial showed that flash monitoring did not affect HbA1c at 6 months but it reduced hypos. This suggests flash is a safe, effective replacement for finger-prick monitoring in this group.[14]

CGM

In a recent RCT, 158 adults with type 2 diabetes using multiple daily insulin injections were randomised to use CGM for 24 weeks or to finger-prick monitoring (at least 4 times daily). At 6 months, those using CGM had improved HbA1c and high satisfaction with using CGM.[15]

Most studies include adults aged 18 to 70 years. Few focus on older adults. One RCT which only included older adults (average age 67 years) with type 2 diabetes using multiple daily insulin injections also found HbA1c improved at 6 months.[9]

In another RCT, CGM was used intermittently (for 2 out of every 3 weeks) for a period of 12 weeks by 100 adults with type 2 diabetes (half using basal insulin and the other half using tablets/lifestyle). At 12 weeks, those in the CGM group had improved HbA1c levels, and this was sustained without CGM during the following 40 weeks.[16] This suggests that using CGM (even for limited periods) may improve HbA1c.

The 4-T trial demonstrated recently that CGM detects more hypos than people typically report based on their hypo symptoms or finger-prick self-monitoring. This suggests that hypos may be more common in people with insulin-treated type 2 diabetes than previously thought, or that people do not report hypos to their health care team, or that they may have impaired awareness of their hypo symptoms.[17]

Type 2 diabetes (not using insulin)

The following section applies to people with type 2 diabetes who are not using insulin. They may be managing their diabetes with lifestyle changes and/or tablets or injectable therapy (GLP-1) that do not cause hypos.

Blood glucose monitoring

Self-monitoring of blood glucose (SMBG) is considered essential in those using insulin, but its role for people not using insulin is still debated. While some people find it useful and motivating, others find it frustrating and demoralising. People with type 2 diabetes (not using insulin) report that their GPs rarely look at their SMBG data. They perceive this to mean that SMBG is worthless, and so they stop monitoring.[18]

Two systematic reviews have cast doubt over the benefit of SMBG, and indicate that, overall, it is unlikely to be cost-effective.[19,20] Cost-effective means it is 'value for money', that it will mean savings now or in the long term. However, there was a lot of variation in the studies included in these reviews.[21] The main points of difference are summarised below.

Many of the RCTs involved people doing SMBG at random times of day, and the people had not been trained in how to get the most from their monitoring. This is now known as 'unstructured' monitoring. It is unhelpful because it does not enable people to detect patterns in their glucose levels or to change their self-care to improve their glucose levels. People with type 2 diabetes report this 'unstructured' monitoring as "frustrating", "painful", "inconvenient", "expensive", and "demotivating", and they report "feelings of failure or anxiety in response to high blood glucose readings".[22,23]

However, in RCTs where people were asked to use a 'structured' approach to SMBG (see Box A), the findings are more positive. In such trials, they found improved HbA1c, reduced variability in glucose levels, weight loss, and less time spent with high glucose levels.[24,25]

Trials of 'structured' SMBG have also shown important psychological benefits, e.g. increased satisfaction with treatment, general emotional wellbeing, confidence in, and motivation for, diabetes self-care, as well as reduced diabetes-related distress.[26,27]

Studies also show that health professionals using 'structured' SMBG are more likely to recommend changes to the individual's diabetes self-management plan to improve their diabetes care and outcomes.[27]

Flash glucose monitoring

To our knowledge, there are no published studies of flash monitoring in adults with type 2 diabetes not using insulin.

CGM

In the previously mentioned RCT of 100 adults with type 2 diabetes, half were using tablets or diet/exercise to manage their diabetes. HbA1c improved at 24 weeks. This suggests that using CGM (even for limited periods) may improve HbA1c.[16]

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