Country Health SA Local Health Network

Protocol (Clinical)

Title: Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM) in the inpatient setting

Protocol developed by: CHSALHN Diabetes Service

Protocol Sponsor: CHSALHN, Executive Director, Medical Services

Approved by: CHSALHN, Clinical Governance Committee on: 31/10/2018

Next review due: 31/10/2021

Summary	This protocol outlines responsibilities and actions required by medical staff, nurses and midwives to ensure the safety and quality of patient care of Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM).
Policy/Procedure reference	This protocol supports the Controlled Substances Act 1984, SA Health Directive: High Risk Medicines Management, SA Health Directive: Patients' Own Medications, CHSALHN Diabetes Service Plan and Diabetes Inpatient Model of Care.
Keywords	Clinical, Protocol, CHSA, Nursing, Midwifery, Safety, Blood Glucose, CGM, FGM, CSII, Communication, Consumer Participation, Standards
Document history	Is this a new CHSA Protocol? **Y** Does this protocol amend or update an existing protocol? **N** Does this protocol replace an existing protocol? **N**
Applies to	This procedure applies to all hospital nursing, midwifery and medical staff and CHSA Diabetes Service staff.

Version control and change history

Version	Date	Amendment	Amended by:
1.0	31/10/2018	Original version	Jane Giles

Table of Contents

Protocol | Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM) in the inpatient setting

1. Purpose

This protocol supports clinical decision making by describing the best practice evidence based process for managing continuous glucose monitoring (CGM) and flash glucose monitoring (FGM) in the inpatient care settings.

The protocol will assist nursing, midwifery and medical staff to determine appropriate health care for the management of patients self-managing CGM or FGM systems at the time of hospital admission, to continue to do so during their hospitalisation. The protocol also provides credentialled diabetes educators and dietitians with information for the ongoing clinical and educational services provided by the CHSA Diabetes Service.

The admitting medical practitioner will be responsible for:

- explaining inpatient management
- supporting the maintenance of CGM or FGM and
- outlining the use of hospital based blood glucose (BG) monitors to inform clinical decisions in the inpatient setting.

Nurses have an important role in providing the applicable education to support safe CGM or FGM self-management. It is recommended that the advice of a credentialled diabetes educator (CDE) be sought wherever possible to ensure a high standard of care for patients and the best opportunity for enhancing nursing knowledge and expertise.

This guide is not a complete or definitive resource but is designed to be used in conjunction with SA Health and SA Government regulatory documents regarding scope of practice, competencies and professional development frameworks.

2. Glucose Monitoring

Glucose measurements are critical to effective diabetes management. Although measurement of glycated haemoglobin (HbA1c) has been the traditional method for assessing glycaemic control, it does not reflect the blood glucose excursions that may lead to hypoglycaemia or postprandial hyperglycaemia, which have been linked to both microvascular and macrovascular complications.

Self-monitoring of blood glucose has been demonstrated to improve glycaemic control and quality of life, however, it cannot predict impending hypoglycaemia.

Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM) address many of the limitations in HbA1c testing and self-monitoring of blood glucose.

In Australia, many people with type 1 and type 2 diabetes and/or their families are keen to have the opportunity to benefit from these technologies.

CGM and FGM systems should be used in conjunction to HbA1c and self-monitoring of blood glucose.

3. Background Evidence

Several systematic reviews and meta-analyses have been undertaken examining the impact of CGM on HbA1c and hypoglycaemia in particular. However, on reviewing the literature, the following key limitations were noted:

- the studies are only of a short duration
- study numbers are small and not adequately powered to detect statistical differences
- studies concentrated on older children and younger children are especially poorly studied
- the assumption is that improving HbA1c and reducing glucose variability with CGM will reduce complications but no studies have been of a sufficient duration to test this hypothesis
- some CGM systems studied are no longer commercially available
- the use of CGM may decline over time
- the patient selection process was poorly reported in many studies.

The National Institute of Clinical Excellence (NICE) has produced two guidelines relevant to the use of CGM. The 2015 Guideline on management of children and young people with type I and type II diabetes (NG18) and the 2016 Diagnostics Guideline regarding the use of Sensor Augmented Pump Therapy (SAPT) (DG21). A Medtech Innovation Briefing regarding the MinimedTM 640G has since also been published (MIB 51).

In 2017, the Advanced Technologies & Treatments for Diabetes Congress convened an international panel of physicians, researchers, and individuals with diabetes with the purpose of providing guidance for clinicians, patients, and researchers in utilizing, interpreting, and reporting CGM data in clinical care and research. Following this congress, the Association of Children's Diabetes Clinicians (ACDC) developed a comprehensive guideline to help identify which patients may be most likely to benefit and how these technologies may be practically implemented. Most recently, Diabetes UK has produced a consensus guideline for FGM.

This protocol has been developed from the evidence available and expert consensus recommendations. The information provided represents the current state of knowledge on CGM results affecting outcomes.

4. Benefits of CGM and FGM

CGM and FGM can be used continuously and/or intermittently as a management tool and diagnostic instrument for people with diabetes and/or their healthcare providers. CGM and FGM can identify glucose trends during various forms of dietary intake, physical activity, stress, illnesses, steroid medications or menstrual cycles.

There is evidence to support the benefit of continuous and intermittent use of CGM and FGM as an educational motivational tool in those challenged by diabetes management and those who have poor glycaemia control as a consequence.

Real-time CGM

Real-time CGM tracks the glucose concentrations in the body's interstitial fluid, providing near real-time glucose data.

Some CGM systems can be linked to blood glucose meters, smart phones and/or insulin pumps which can display the glucose result, recent history and alert the patient and/or carer of the glucose excursion (trend) moving above or below the glucose target.

Some CGM systems can be linked to insulin pump therapy providing sensor augmented pump technology (SAPT). SAPT can be programmed to automatically suspend insulin delivery if the glucose falls below target.

Real-time CGM (also known as Personal CGM) is most commonly used by the person with diabetes and/or their family.

Retrospective CGM

Retrospective CGM uses similar methodology, however, the glucose concentrations are 'masked' until the device is removed, the data uploaded and a report is generated.

Retrospective CGM systems are owned by healthcare professionals and loaned to patients with diabetes intermittently and can be worn for up to 6 days.

Retrospective CGM *(also known as Professional CGM*) is most commonly used by credentialled diabetes educators (CDE) and diabetes educators (DE) in CHSA.

Flash Glucose Monitoring

FGM also tracks the glucose concentrations in the body's interstitial fluid. FGM can provide a current glucose reading, the last 8 hours of glucose history, and a trend arrow showing if glucose is going up, down, or changing slowly. Information is not automatically displayed but only after physically scanning the sensor with the reader.

FGM is most commonly used by the person with diabetes and/or their family.

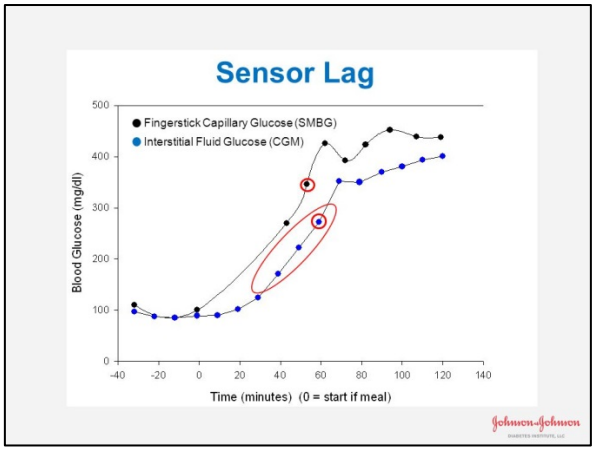
Both CGM and FGM can offer the potential to:

- improve time in target glucose range
- reduce hypoglycaemia
- reduce hyperglycaemia
- and improve HbA1c.

5. Limitations of CGM and FGM

CGM and FGM systems are accurate but the level of glucose in interstitial fluid reacts slower than the level of glucose in the blood. This is because interstitial glucose result lags approximately 10 minutes behind the blood glucose result. Figure 1 identifies the variance between blood glucose and interstitial glucose.

Figure 1: Interstitial Glucose Sensor Lag Time



Although CGM and FGM can reduce frequency, ***capillary blood glucose monitoring*** is recommended:

- for calibration of the CGM. Two - four blood glucose results (depending on type of CGM system used) are required for calibration for each day. The FGM requires no calibration.
- when glucose levels are rapidly changing (eg hypoglycaemia and hyperglycaemia)
- when results do not correspond to symptoms

- to use the bolus calculation function (FGM only).
- where the reader indicates a low glucose result (FGM only)
- to meet driving a vehicle licensing authority requirements
- when unwell
- on presentation to an emergency department
- during hospital admission.

Patients with diabetes who wear CGM or FGM systems in the outpatient setting, when admitted to hospital can continue to wear their personal system. However, hospital blood glucose meter results will be used to make changes to their inpatient diabetes management.

Apart from minor discomfort at the time of the insertion of the sensor, there is no expected discomfort when wearing the CGM or FGM. When applied, the CGM and FGM systems are to be worn 24 hours a day and if the sensor is removed, it cannot be reinserted and data collection will cease.

There is a small risk of infection but this risk is reduced by using a sterile technique when inserting the electrode and protecting the skin site with the dressing.

Mechanical faults can occur.

6. Criteria for CGM and FGM Selection

CGM and FGM is indicated in people with diabetes who have:

- hypoglycaemia seizures
- frequent severe hypoglycaemia
- impaired awareness of hypoglycaemia
- inability to recognise hypoglycaemia due to age, cognitive or neurological disabilities
- anxiety regarding to hypoglycaemia
- high levels of physical activity were risk of hypoglycaemia is significant
- hyperglycaemia - to reduce HbA1c, improve glycaemic control or reduce glycaemic variation.

In CHSA, the diabetes services accept referrals and facilitate acquisition and training of CGM and FGM products for people who meet the above criteria.

7. Types of CGM and FGM systems available in Australia

The CGM and FGM devices currently available for both personal and professional use and their specifications are identified on Table 1.

In Australia, children and young adults with type 1 diabetes under the age of 21 years can access CGM products for personal use. These products are fully subsidised and are available through the National Diabetes Services Scheme (NDSS). For further information, visit the NDSS website https://www.ndss.com.au/CGM.

In CHSA, the diabetes services provide loan CGM systems and products for short-term use to people with diabetes who are unable to access the NDSS subsidy and who meet the above selection criteria.

8. Inpatient management

Current CGM and FGM systems are designed for the ambulatory setting only. However, in time there will be CGM and FGM systems approved for use in the acute care setting.

Health care professionals are increasingly faced with the issue of how to manage such inpatients in the interim.

The continued use of current CGM and FGM by the person with diabetes and/or their carer in the inpatient setting can be supported. However, the patient and/or carer must be informed that hospital blood glucose monitoring is required.

The Blood Glucose Monitoring Chart (MR59H) is to be completed. The BG results obtained from these capillary BG meters must be used to assess inpatient diabetes management and subsequent actions are to be initiated according to the colour zone.

Who to consult

The following health professionals should be consulted:

- the patient's diabetes specialist (eg endocrinologist, specialist physician or paediatrician) or medical practitioner
- CDE or DE trained in CGM and FGM.

9. Discontinuation of CGM and FGM

CGM and FGM systems are costly for both the person with diabetes, their family and the health care service. Whilst they can be very valuable, if they are used infrequently, with insufficient engagement in the structured education process, they should be withdrawn.

For the personal use of CGM and FGM in the outpatient setting, literature evidence shows that increased sensor wear of more than 60% of the time is associated with improvement HbA1c. Common barriers to use included insertion pain, system alarms and body image issues; while common benefits included glucose trend data, opportunities to self-correct out-of-range glucose levels and to detect hypoglycaemia.

Contraindications for use of CGM and FGM in the inpatient setting

The use of the CGM and FGM is contra-indicated in situations where the patient's safety may be compromised by their physical illness or mental state.

Absolute contra-indications for supporting continued CGM and FGM use are;

- impaired level of consciousness
- critical illness requiring intensive care
- major psychiatric disturbance
- diabetic ketoacidosis (DKA)
- refusal or unwilling to participate in self-care

- inability to demonstrate a basic level of competency in the operation of their CGM, FGM and insulin pump (if applicable)
- lack of sensors other equipment required to maintain patient on CGM or FGM
- extensive skin infections or inflammation
- concerns regarding technical malfunction of the CGM or FGM
- numerous radiological procedures
- lengthy or complicated surgery, or serious medical illness likely to be accompanied by significant metabolic disturbance
- any other medical circumstance deemed unsuitable by the supervising medical officer.

If the patient presents with any contraindication, the CGM or FGM must be discontinued and the device managed according to the hospital's policy for storage of patient valuables.

Assessing patient competency to self-manage CGM or FGM

On admission to hospital, either to a ward or emergency department, the patient must demonstrate to the satisfaction of the assessing health care professional that they have the ability to use their CGM or FGM.

It is acknowledged that the assessing health care professional may have limited exposure to the practical management of the specific CGM or FGM used. The role of the health care professional is to assess the competency of the patient to use CGM or FGM.

Competency assessment will involve asking the patient to demonstrate that they;

- identify the CGM and FGM used
- are able to identify the CGM glucose result on their connected blood glucose meter, insulin pump and/or smart phone
- are able to identify the FGM glucose result by scanning the sensor with the reader
- can re-site their CGM or FGM sensor (eg this could involve discussing how it is done, rather than actually undertaking the activity at this initial assessment)
- can demonstrate technical competency regarding sensor sites / how they would trouble shoot
- can undertake appropriate problem solving actions if blood glucose (BG) is higher or lower than target
- have adequate supplies of sensors for the anticipated duration of the admission
- have been performing regular BG tests (eg four tests per day).

A CDE should be notified upon admission of a patient with CGM or FGM. An urgent consultation should be obtained if there is a concern about competency of the patient to continue.

The CDE can advise or rectify any issues or concerns, allowing the patient to continue using their CGM or FGM and reiterate the important of hospital blood glucose monitoring and the use of the hospital meter to guide diabetes management decisions during the admission.

Children and adolescents

The continuation of CGM and FGM in a child or adolescent needs to be considered carefully in consultation between the patient, their parent or carer and their specialist diabetes team.

In the circumstances that the parent or carer is responsible for the management of the CGM

or FGM system, the medical practitioner must be satisfied that the responsible person can satisfy all essential requirements and that this decision may be made in consultation the patient's medical practitioner and CDE. Additionally, the parent or carer must be able to stay with the patient at all times during the admission so that the CGM of FGM daily requirements can be supported.

If the above conditions cannot be met, the CGM or FGM should be discontinued until the parent or carer can resume their responsibilities.

Obstetric and gynaecological patients

Labour and birth is not an absolute contradiction to the use of CGM and FGM, and may be used as determined by the endocrinologist, obstetrician and CDE.

Surgical procedures

The use of the CGM and FGM in operating theatres, procedure rooms, etc. is not contra-indicated. However, CGM and FGM must be considered carefully in consultation between the anaesthetist, surgeon, physician, medical practitioner, CDE, patient, parent or carer as it will be left insitu and untouched until the patient or carer can resume their self-care responsibilities.

10. Device management

CGM Sensors and transmitters are worn 24 hours a day for up to 6 days. The sensor cannot be re-sited once removed.

Some real-time CGM systems can be linked wirelessly to blood glucose meters, smart phones and/or insulin pumps. When linked to a specific smart phone, the patient and/or a family member can be alerted before the glucose is above or below the glucose target. When linked to an insulin pump, the insulin delivery via the pump can be suspended to avoid hypoglycaemia.

FGM sensors are worn 24 hours a day for up to 14 days. FGM sensors cannot be re-sited once removed.

When the FGM sensor is scanned by the reader, a current glucose reading and the last 8-hours of glucose history is displayed. A trend arrow showing if glucose is going up, down, or changing slowly, is also offered.

To apply a CGM or FGM, the person with diabetes and/or their carer inserts a small sterile subcutaneous needle just under the skin using an applicator. The needle will be removed leaving an even smaller plastic (teflon) electrode (tube) in place. At the end of the electrode is a 'glucose sensor'.

In CGM, the sensor is then attached to the transmitter, covered by an adhesive see-through dressing (Figure 2) if required. In FGM, the sensor has a self-adhesive backing which holds it in place (Figure 3).

Figure 2: CGM Sensor and Transmitter

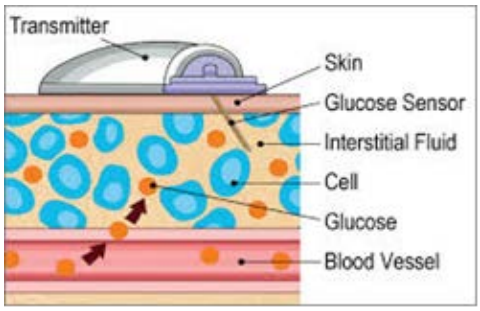
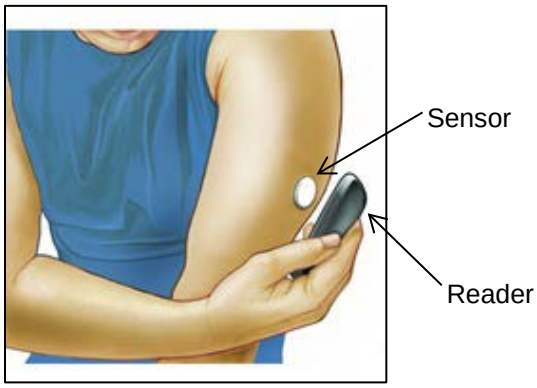


Figure 3: FGM Sensor and Reader

Reader



Consumables

Patients will be required to provide the CGM or FGM consumables if they choose to self-manage their CGM or FGM system in hospital. CGM consumables are subsidised by the NDSS for children and young people up to 21years of age with type 1 diabetes.

The **CGM Sensor** (Figure 4) **and FGM Sensor** (Figure 5) are both thin, flexible cannula made of the synthetic substance teflon that is inserted into the subcutaneous tissue via a steel introducer needle. The introducer needle is then removed and only the soft cannula is left in place.

The CGM sensor is comfortable to wear and can remain inserted for up to 6 days. The FGM sensor is also painless but can remain inserted for up to 14 days.

Figure 4: CGM Sensors

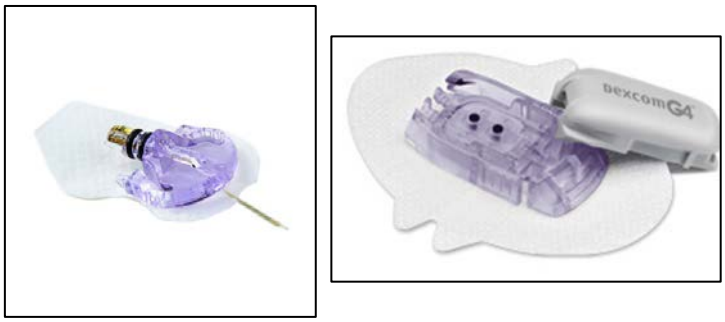


Figure 5: FGM Sensor

Insertion method

There are two options for inserting a cannula, either the manual insertion (eg the patient simply pushes the needle into the subcutaneous tissue as if giving themselves an injection) or the automatic insertion (eg the patient uses a spring-loaded insertion device that automatically inserts the needle into the tissue). The sensor is inserted at 45° or at 90°depending on the system used.

Most people prefer using an insertion device (Figure 6) which also allows the person to insert a cannula more easily into harder-to-reach infusion sites, such as the buttocks for CGM or the back of the arm for FGM. The disadvantages of using an insertion device include the added expense, additional education needed to learn to use it correctly and that the user cannot control the depth or the exact angle of insertion.

Figure 6: Example of automatic insertion aids

Choosing an insertion site

For CGM, the abdomen is the recommended site and for FGM, the upper arm is the recommended site. However, both systems can be applied to the abdomen, upper arm or buttocks. It is important to avoid any wounds, injuries or scars.

Like insulin injections, using the same spot for CGM or FGM insertion will cause lumps (lipohypertrophy).

Patients are encouraged to rotate the cannula insertion sites, check for lumps on a regular basis and look for signs of infection at the insertion site.

At the first sign of an infection, the cannula must be re-sited away from the site of the infection. The infection may require treatment with oral antibiotics. Repeated infections can result in scaring which will reduce the areas available to use for siting the cannula.

Changing the insertion site

The patient should assemble the new sensor, skin cleanser and tape independently;

- remove the old sensor and check the site for redness, bleeding or leakage
- prepare the new sensor according to the manufacturer's instructions
- choose and clean the site for the new senor allowing the skin to dry
- insert the sensor according to the manufacturer's instructions
- remove the insertion needle from the teflon cannula
- connect the new sensor to the transmitter *(for CGM only)*
- apply tape to secure the sensor and transmitter *(for CGM only)*

- 'start or connect' the sensor to the receiver, smart phone or insulin pump
- retain the transmitter *(for CGM only)* for uploading data.

Disposing of sharps

Used sensors must be disposed of in an Australian Safety Standards approved sharps container which is puncture proof and has a secure lid.

Procedures for disposing of sharps containers may vary and patients with diabetes are encouraged to contact their local council for information. Sharps must never be disposed of in household or industrial waste.

CGM and FGM failure

Every CGM and FGM supplier has a 24 hour emergency help line to assist patients / carers who experience difficulty. In most cases, these are free call numbers. It is recommended that the patient / carer have the emergency help line number in their phone in case of an emergency.

All CGM and FGM systems in Australia have a warranty. If the fault occurs during the warranty period, the CGM or FGM is replaced free of charge. If the fault occurs when the CGM or FGM system is out of warranty, the company will often lend the patient a replacement device for a period of time. A replacement or loan CGM or FGM will be sent via express post to the patients address or admitting hospital on request.

11. Medical record documentation

Inpatient Documentation

The continued use of current CGM and FGM by the person with diabetes and/or their carer in the inpatient setting can be supported.

Documentation that the patient has a CGM or FGM insitu and that the patient will self-care for this device during the hospital admission must be included in the medical record.

The Blood Glucose Monitoring Chart (MR59H) is to be completed by nurses or midwives who are trained and competent in the use of BG meters. The blood glucose results obtained from these capillary blood glucose meters must be used to assess inpatient diabetes management and subsequent actions are to be initiated according to the colour zone.

CGM and FGM Software

CGM and FGM reports can be generated by both the patient and/or health care professional.

Reports to assist the glycaemic control of a patient with diabetes admitted to a CHSA Hospital and/or Health Service will require a referral to the Credentialled Diabetes Educator and be dependent on the availability of applicable software.

The various CGM (Figure 7) and FGM (Figure 8) reports, whilst not standardised, offer the following key metrics to assess glycaemic control:

- mean glucose
- episodes of hypoglycaemia using a standard definition and percentage of time in hypoglycaemic range
- episodes of hyperglycaemia using a standard definition and percentage of time in hyperglycaemic range
- percentage of time in individual target range

- percentage of time in hyperglycaemic range
- glycaemic variability reported as primary and secondary
- estimated HbA1c
- data for glucose metrics (reported in three time blocks (sleep, wake, 24 h) with the default times for the sleep (12:00A.M.-6:00A.M.) and wake (6:00A.M.-12:00A.M.)
- data sufficiency (eg minimum 2 weeks of data, 70-80% of possible CGM readings over a 2-week period)
- area under the curve (eg recommended for research purposes)
- indexed risk of hypoglycaemia and hyperglycaemia.

Glossary

Autoimmune Disease Disorder of the body's immune system in which the immune system mistakenly attacks and destroys body tissue that it believes to be foreign. T1D is an autoimmune disease because the immune system attacks and destroys the insulin producing beta cells of the pancreas.

Basal bolus insulin A basal bolus insulin regimen involves taking a longer acting form of insulin to keep blood glucose levels stable through periods of fasting as well as separate injections of shorter acting insulin to prevent rises in blood glucose levels resulting from meals.

Basal Insulin Background insulin required by the body at rest. Basal insulin is administered via injection or insulin pump at a low, steady rate for 24 hour coverage.

Blood Glucose The main sugar that the body makes from the three elements of food–proteins, fats, and carbohydrates–but mostly from carbohydrates. Glucose is the major source of energy for living cells, and is carried to each cell through the bloodstream. However, the cells cannot use glucose without the help of insulin.

Bolus Insulin Additional insulin required to cover meals or to correct high blood glucose levels. Bolus insulin doses are calculated on carbohydrate: insulin ratio, insulin sensitivity factor, target blood glucose levels and duration of insulin action.

Complications of Diabetes Harmful effects that may happen when a person has diabetes. Some effects, such as hypoglycaemia, can happen any time. Others develop when a person has had diabetes for a long time or poor glycaemic control. These include damage to the retina of the eye (retinopathy), the blood vessels (angiopathy), the nervous system (neuropathy), and the kidneys (nephropathy).

Continuous subcutaneous insulin infusion Also known as an 'insulin pump', refers to the constant, continuous infusion of a short acting insulin driven by mechanical force (a pump) and delivered via a needle or soft cannula under the skin.

Credentialled Diabetes Educator A Registered Nurse or Midwife who has completed a post graduate certificate in diabetes education and care that has been accredited by the Australian Diabetes Educator's Association (ADEA).

Diabetes Mellitus A disease that occurs when the body is not able to use sugar as it should. Diabetes occurs when the body cannot make use of the glucose in the blood for energy because either the pancreas is not able to make enough insulin or the insulin that is available is not effective.

Diabetic Ketoacidosis Severe high blood sugar that needs emergency treatment. DKA may be caused by illness, taking too little insulin, or getting too little exercise. If the person is not given fluids and insulin right away, ketoacidosis can lead to coma and even death.

Glucagon A hormone produced by the alpha cells in the islets of Langerhans in the pancreas. Glucagon stimulates the production of glucose from the liver (the conversion of liver glycogen to glucose). Injecting a manufactured preparation of glucagon (Glucagon hypo kit) is used to treat severe or unconscious hypoglycaemia.

HbA1c (Glycated haemoglobin) An indicator of glycaemic control during the previous six to eight weeks. The lowest risk of long-term diabetic complications is in people whose HbA1c is closest to the normal range (below 42mmol/mol or 6.0%). HbA1c targets will be modified to a high level for those at risk of hypoglycaemia.

Hyperglycaemia Too high a level of glucose (sugar) in the blood and occurs when the body does not have enough insulin or cannot use the insulin it does have to turn glucose into energy. For people with T1D, hyperglycemia may lead to diabetic ketoacidosis.

Hypoglycaemia Too low a level of glucose (sugar) in the blood. This occurs when a person with diabetes has injected too much insulin, eaten too little food, or has exercised without extra food.

Insulin A hormone that helps the body use glucose (sugar) for energy. The beta cells of the pancreas (in areas called the islets of Langerhans) make the insulin.

Insulin analogue A modern insulin preparation genetically engineered so that its action more closely resembles the normal physiological action of insulin in a person without diabetes.

Insulin Pump A device that delivers a continuous supply of insulin into the body. The insulin flows from the pump through a plastic/metal tube that is connected to a needle inserted into the body and taped in place. It is also known as Continuous Subcutaneous Insulin Infusion

Ketosis A state of severe insulin deficiency. Untreated, ketosis can lead to diabetic ketoacidosis, coma and death.

Smart Pump A insulin pump capable of calculating the amount of insulin required to cover the carbohydrate eaten and insulin dose required to correct higher than target blood glucose levels using rates set by the endocrinologist and credentialled diabetes educator. Smart pumps' have a feature that prevents stacking' or giving too much insulin by considering the insulin still active or 'on board' from a previous bolus dose before calculating the dose required.

Type 1 diabetes Is an autoimmune disorder characterised by raised blood glucose levels caused by absolute insulin deficiency. People with type 1 diabetes require multiple dose insulin therapy or insulin pump therapy to survive.

Type 2 diabetes Raised blood glucose due to a combination of impaired insulin secretion and insulin resistance to the action of insulin at the cell level. Type 2 diabetes is a

progressive disease, which frequently requires treatment with insulin to achieve glucose targets.

Gestational diabetes mellitus (sometimes referred to as GDM) is diagnosed when higher than normal blood glucose levels first appear during pregnancy when the amount of insulin needed for both the woman and her unborn child's requirements is increased. Hormones produced by the placenta that support the baby to grow and develop, reduces the effectiveness of insulin at the cellular receptor site.

Links you may find helpful

CHSA Diabetes Service: http://www.chsa-diabetes.org.au/

Australian Diabetes Educators Association: http://www.adea.com.au/

Diabetes Australia: http://www.diabetesaustralia.com.au/

National Prescribing Service: http://www.nps.org.au/

Linked Documents

Document Name
National Safety and Quality Health Service Standards 4 - Recognising and Responding to Clinical Deterioration in Acute Health Care
CHSA Blood Glucose Monitoring Chart (MR59H) CHSA Inpatient blood glucose and ketone monitoring chart (MR59H) Protocol
The National Institute of Clinical Excellence (2015) Guideline on management of children and young people with type I and type II diabetes (NG18).
The National Institute of Clinical Excellence (2016) Diagnostics Guideline regarding the use of SAPT (DG21).
Association of Children's Diabetes Clinicians (2017) A Practical Approach to the Management of Continuous Glucose Monitoring (CGM) / Real-Time Flash Glucose Scanning (FGS) in Type 1 Diabetes Mellitus in Children and Young People Under 18 years
Diabetes UK (2017) Consensus Guideline for Flash Glucose Monitoring
International Consensus on Use of Continuous Glucose Monitoring (2017)

Attachments

Document Name
Available CGM and FGM devices
Example of Medtronic CGM report
Example of AMSL CGM report
Example of Freestyle Libre FGM report

References

Document Name
Australian Diabetes Society (2012). Guidelines for routine glucose control in hospital. Sydney, ADS.
Craig, M., S. Twigg, K. Donaghue, N. Cheung, F. Cameron, J. Conn, A. Jenkins and M. Silink (2011). *National evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults,* Australasian Paediatric Endocrine Group and Australian Diabetes Society. Canberra, Australian Government Department of Health and Ageing.

Accreditation Standards

***National Safety and Quality Health Service Standards* (NSQHSS)**

1 ☒	2 ☐	3 ☐	4 ☒	5 ☐	6 ☒	7 ☐	8 ☐	9 ☒	10 ☐
Governance for Safety and Quality in Healthcare	Partnering with Consumers	Preventing & Controlling Healthcare Associated Infections	Medication Safety	Patient Identification & Procedure Matchng	Clinical Handover	Blood & Blood Products	Preventing & Managing Pressure Injuries	Recognising & Responding to Clinical Deterioration	Preventing Falls & Harm from Falls

***Evaluation and Quality Improvement Program* (EQuIP)**

11 ☒	12 ☒	13 ☐	14 ☒	15 ☒
Service Delivery	Provision of Care	Workforce Planning and Management	Information Management	Corporate Systems and Safety

Consultation

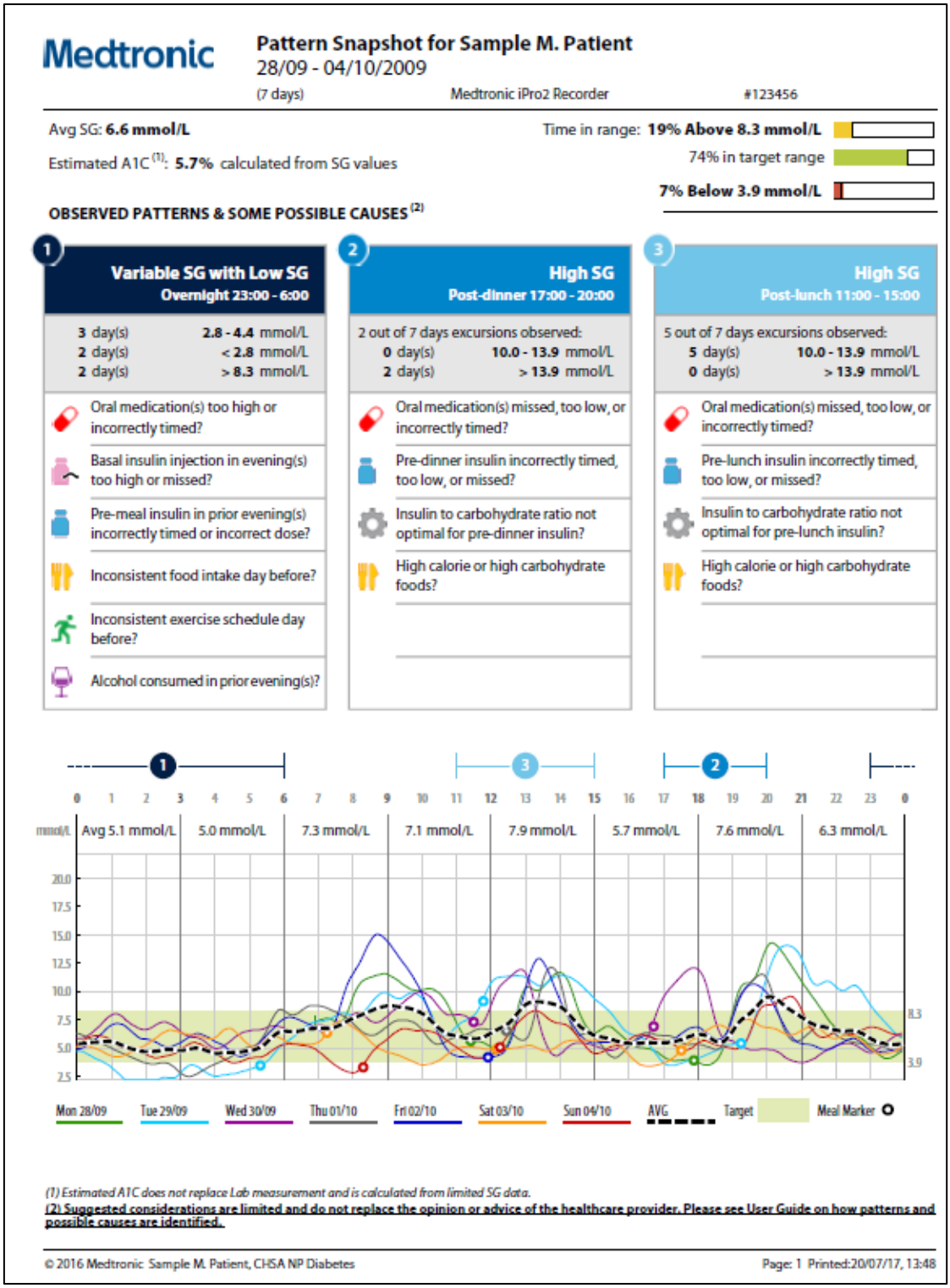
Version	Consultation
1.0	SA Health Metropolitan Diabetes Services, Flinders University SA, NP-Diabetes - Mt Gambier, CHSA Diabetes Specialist Nurse Network, Clinical Pharmacists, CHSA Director of Endocrinology.

Appendix 1: Available CGM and FGM devices

	Medtronic Guardian 2 Link and MiniLink	Medtronic Guardian Connect and iPro2	AMSL Dexcom G4	AMSL Dexcom G5	Abbott Freestyle Libre
Sensor Augmented with Insulin Pump	MiniMed 640G Pump with Smart Guard  Paradigm VEO with Smart Guard  and the X22.	No	Animas VIBE 	No	No
Stand Alone Systems	No	Medtronic Guardian Connect  iPro2 	Dexcom G4 PLATINUM Receiver 	Dexcom G5 and Smart Phone or Receiver  Compatible Smart Phones (Applae and Android) at https://www.dexcom.com/ous-compatibility-page	Abbott Freestyle Libre 
Description	Personal Use - An integrated system where the insulin pump acts as a receiver of CGM data. The auto suspend feature helps in suspending the pump if glucose level is predicted to hit a threshold in the next 30 minutes (640G). The 640G has superseded the VEO.	Personal Use - The Guardian Connect system sends data wirelessly to a smart device and can predict future glucose values up to 60 minutes in advance. Professional Use -The iPro2 CGM is a diagnostic CGM device that patients can wear for up to 6 days, without seeing the outcomes.	Personal Use. An integrated system with the insulin pump (VIBE) which acts as a receiver of real-time CGM data. Can also be used as a stand alone with G4 Platinum Receiver. Also available for trial use.	Personal Use - Can be used alone and can send data wirelessly to a compatible smart phone. It is FDA and TGA approved to make treatment decisions upon its results. Dexcom G5 Mobile is a newer version compared to Dexcom G4 PLATINUM.	Personal Use - Reader needs to scan the Sensor to capture the current glycaemic data. The Reader can store approximately 90 days of glucose and clinical notes.
Accuracy Mean Absolute Relative Difference	Guardian 2 Link 9.10% MiniLink 14.20%	Guardian Connect 11.40% iPro2 10.6% Paediatrics 10.8% Adults	15% Paediatrics 13% Adults	10% Paediatrics 9% Adults	13.9% Paediatrics 11.4% Adults Verses Blood Glucose Monitors

	Medtronic Guardian 2 Link and MiniLink	Medtronic Guardian Connect and iPro2	AMSL Dexcom G4	AMSL Dexcom G5	Abbott Freestyle Libre
Approved Age	No age restriction	No age restriction	Age 2 years and over	Age 2 years and over	Age 4 years and over
Sensor Glucose Measurement	Every 5 minutes	Every 5 minutes	Every 5 minutes	Every 5 minutes	Every 1 minute, plotted at 15 minute intervals
Duration of Wear	6 days	6 days	7 days	7 days	Up to 14 days
Calibration Required	Yes	yes	Yes – one blood glucose every 12 hours	Yes – one blood glucose every 12hours	No – Factory Calibrated
Alarms	Yes - 640G and X22 No -VEO	Yes - Guardian Connect No - iPro2	Yes	Yes	No
Trend Arrows	Yes - 640G No – VEO and X22	No	Yes	Yes	Yes
Predictive Low Glucose Suspend	Yes	Not Applicable	No	No	No
Power and Recharge	Transmitter should be charged after 6 days of use. Requires 20mins to recharge.	Transmitter should be charged after 6 days of use. Requires 20mins to recharge.	Receiver to be charged every 3 days or as required. Transmitter battery lasts minimum 6months.	Transmitter battery lasts minimum 3months.	Rechargeable - 7 days of typical use.
Transmission	Sensor and transmitter to be worn together with pump. Sensor to be inserted 2.5cm from pump infusion site.	Sensor and transmitter to be worn together on abdomen.	Receiver has to be within 6 metres of the transmitter.	Receiver and/or smart phone device has to be within 6 metres of the transmitter.	When Reader is scanned near the Sensor.
Blood Glucose Compatible	Bayer Meter is compatible with pump and transmitter. Blood glucose result will automatically be entered for calibration.	Bayer Meter is compatible with pump and transmitter. Blood glucose result will automatically be entered for calibration.	Blood glucose must be manually entered.	Blood glucose must be manually entered.	Reader can be used to test blood glucose or blood ketone using Freestyle Optium blood glucose or blood ketone test strips.
Waterproof	Pump waterproof up to 3.6metres for up to 24hours. Transmitter is waterproof up to 2.4metres for up to 30minutes.	Transmitter is waterproof up to 2.4metres for up to 30minutes.	Receiver is not waterproof. Pump, sensor and transmitter is for up to 2.44metres for up to 24hours.	Receiver or smart phone is not waterproof. Sensor and transmitter is for up to 2.44metres for up to 24hours.	Reader is not waterproof. Sensor is water-resistant up to 1metre for up to 30minutes.

Appendix 2: Example of Medtronic CGM report



Medtronic

Pattern Snapshot for Sample M. Patient
28/09 - 04/10/2009
(7 days) Medtronic iPro2 Recorder #123456

Avg SG: **6.6 mmol/L**
Estimated A1C [1]: **5.7%** calculated from SG values

Time in range: **19% Above 8.3 mmol/L**
74% in target range
7% Below 3.9 mmol/L

OBSERVED PATTERNS & SOME POSSIBLE CAUSES [2]

1 Variable SG with Low SG
Overnight 23:00 - 6:00

3 day(s)	2.8 - 4.4 mmol/L
2 day(s)	< 2.8 mmol/L
2 day(s)	> 8.3 mmol/L

- Oral medication(s) too high or incorrectly timed?
- Basal insulin injection in evening(s) too high or missed?
- Pre-meal insulin in prior evening(s) incorrectly timed or incorrect dose?
- Inconsistent food intake day before?
- Inconsistent exercise schedule day before?
- Alcohol consumed in prior evening(s)?

2 High SG
Post-dinner 17:00 - 20:00

2 out of 7 days excursions observed:

0 day(s)	10.0 - 13.9 mmol/L
2 day(s)	> 13.9 mmol/L

- Oral medication(s) missed, too low, or incorrectly timed?
- Pre-dinner insulin incorrectly timed, too low, or missed?
- Insulin to carbohydrate ratio not optimal for pre-dinner insulin?
- High calorie or high carbohydrate foods?

3 High SG
Post-lunch 11:00 - 15:00

5 out of 7 days excursions observed:

5 day(s)	10.0 - 13.9 mmol/L
0 day(s)	> 13.9 mmol/L

- Oral medication(s) missed, too low, or incorrectly timed?
- Pre-lunch insulin incorrectly timed, too low, or missed?
- Insulin to carbohydrate ratio not optimal for pre-lunch insulin?
- High calorie or high carbohydrate foods?

(1) Estimated A1C does not replace Lab measurement and is calculated from limited SG data.
(2) Suggested considerations are limited and do not replace the opinion or advice of the healthcare provider. Please see User Guide on how patterns and possible causes are identified.

© 2016 Medtronic Sample M. Patient, CHSA NP Diabetes

Appendix 3: Example of AMSL CGM report

Patient:	Bugs Bunny	Date interval:	29/05/2018 - 04/06/2018
Patient ID:		Number of days:	7
Print date:	04/06/2018		
Glucose meters:	TDGCLNQK JGMW190-T4093	Insulin pump:	47-69327-16

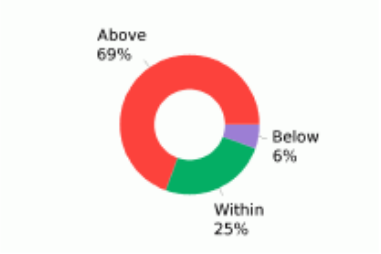
Compilation

Glucose		CGM		Insulin		Carbs		Activity	
Average		Average		Average daily dose		Average carbs / day		Avg steps / day	Avg kcal / day
8.1 mmol/L		7.7 mmol/L		25 U		97 g		0 steps	0 kcal
SD = 2.3	# = 36	SD = 2.1	# = 1875	SD = 7	# days = 7	SD = 37	# = 19	0% of 10000 (target)	0% of 2500 (target)
Avg # / day = 5.1		Avg # / day = 267.9		Avg # bolus doses/day = 6.1		Avg # / day = 2.7			

Glucose (mmol/L)

Glucose values summary	
Average (mmol/L)	8.1
Median (mmol/L)	8.8
Highest value (mmol/L)	11.9
Lowest value (mmol/L)	3.4
Standard deviation (SD)	2.3
Values per day	5.1
Number of values	36
Values above goal (8 mmol/L)	25
Values within goal (3.7-8 mmol/L)	9
Values below goal (3.7 mmol/L)	2

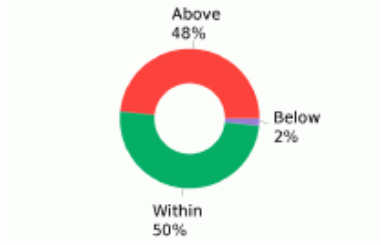
Interval	*Avg BG*	*# BG*	*SD*
00:00-06:00	9	1	0
06:00-08:00	8.9	5	0.4
08:00-10:00	9.1	3	0.3
10:00-12:00	8.6	4	0.3
12:00-14:00	6.1	4	1.9
14:00-16:00	3.4	1	0
16:00-18:00	10	2	0.9
18:00-20:00	6.5	7	2.5
20:00-22:00	9.7	3	1.3
22:00-24:00	9.3	6	2.8



CGM (mmol/L)

CGM readings summary	
Average (mmol/L)	7.7
Median (mmol/L)	7.9
AUC high > 8 mmol/L	0.7
AUC low < 3.7 mmol/L	0
Highest value (mmol/L)	13.0
Lowest value (mmol/L)	3.1
Standard deviation (SD)	2.1
Values per day	267.9
Number of values	1875
Values above goal (8 mmol/L)	902
Values within goal (3.7-8 mmol/L)	945
Values below goal (3.7 mmol/L)	28
Average daily CGM sensor duration	22:20 (93%)
Total CGM sensor duration	6 days 12:15

Interval	*Avg*	*#*	*SD*
00:00-06:00	8	504	2.1
06:00-08:00	7.3	169	1.8
08:00-10:00	7.7	171	1.3
10:00-12:00	7.4	170	1.5
12:00-14:00	6.6	148	1.8
14:00-16:00	7.9	144	2
16:00-18:00	6.9	145	1.8
18:00-20:00	7.3	144	2.5
20:00-22:00	8.7	145	2
22:00-24:00	8.7	148	2.5



Appendix 4: Example of Freestyle Libre FGM report