

REGIONAL LOCAL HEALTH NETWORKS

Protocol (clinical)

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

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Summary This protocol outlines responsibilities and actions required by medical staff, nurses and

midwives to ensure the safety and quality of inpatient care of Continuous Glucose Monitoring

(CGM).

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.

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Consumer Participation, Standards.

Document history Is this a new LHN protocol? N

Does this protocol amend or update an existing protocol? Y

Does this protocol replace an existing document? N

Applies to This protocol applies to all regional LHN hospital nursing, midwifery and medical staff and

RSS Diabetes Service staff.

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| 1.0 | 31/10/2018 | Original version | Jane Giles, Advanced Nurse Consultant |
| 2.0 | 07/11/2022 | Reference to Flash Glucose Monitoring deleted, device and sensor information updated. | Collette Hooper, Nurse Practitioner |
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Continuous Glucose Monitoring (CGM) in People with Diabetes in the Inpatient Setting - Flowchart

Person with diabetes with continuous glucose monitoring (CGM) presents for hospital admission

Nurse or midwife to:

- > discuss with the person (and/or their carer) their preference in continuing CGM) in the inpatient setting.
- > assess the person's individual competency to self-manage CGM in the inpatient setting.
- > identify any absolute contraindications for use of CGM in the inpatient setting.
- > consult with admitting medical practitioner and discuss the persons' (and/or carer) preferences, competency assessment outcome and proposed diabetes management plan in the inpatient setting.
- > initiate referral to diabetes specialist nurse and/or dietitian (if required).

\blacksquare

If no contraindications are identified

Medical practitioner to:

- > explain inpatient management which supports the maintenance of CGM
- identify limitations of CGM and requirement of capillary blood glucose monitoring with the hospital blood glucose meter.

Nurse or midwife to:

- reinforce inpatient management which supports the maintenance of CGM.
- reiterate limitations of CGM and requirement of capillary blood glucose monitoring with the hospital blood glucose meter.
- monitor blood glucose (BG) and blood ketone as per the regional LHN:
 - > IV Insulin Infusion Chart Type 1 Diabetes (MR-INF-A)
 OR
 - Hyperglycaemia Protocol and Basal Bolus Chart (MR62A) OR
 - > Blood Glucose and Blood Ketone Monitoring Chart (MR59H)
- take action in accordance with the Rapid Detection and Response Instructions.

Person with diabetes and/or carer to:

inform staff immediately of hypoglycaemia or hyperglycaemic events, alerts, alarms or CGM failure.

If the above conditions cannot be met, CGM should be discontinued, until the person and/or carer can resume their responsibilities.

If contraindications are identified

Medical practitioner to:

explain contraindication/s, limitations of CGM and requirement of capillary blood glucose monitoring with the hospital blood glucose meter.

Nurse or midwife to:

- > reiterate limitations of CGM and requirement of capillary blood glucose monitoring with the hospital blood glucose meter.
- monitor blood glucose (BG) and blood ketone as per the regional LHN:
 - > IV Insulin Infusion Chart Type 1 Diabetes (MR-INF-A)
 OR
 - Hyperglycaemia Protocol and Basal Bolus Chart (MR62A) OR
 - Blood Glucose and Blood Ketone Monitoring Chart (MR59H).
- take action in accordance with the Rapid Detection and Response Instructions.
- > store CGM in a secure location.

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Recommencement of CGM

Medical practitioner to:

- > review previous identified contraindications and determine return to CGM
- consider consultation with diabetes specialist and/or diabetes specialist nurse.

Nurse or midwife to:

- confirm the person and/or carer is ready to resume their CGM responsibilities.
- confirm the person and/or carer is confident that they can continue their CGM responsibilities on discharge and if not, discuss concerns with medical practitioner and/or diabetes specialist nurse.

Discharge

Medical practitioner to:

discuss discharge planning including referrals (e.g. diabetes specialist, diabetes specialist nurse and/or dietitian) and recommendations with CGM.

Nurse or midwife to:

> confirm discharge plan including referrals (e.g. diabetes specialist, diabetes specialise nurse and/or dietitian) and recommendations for diabetes management with CGM.

1. Purpose

This protocol supports clinical decision making for managing continuous glucose monitoring (CGM) in the inpatient care settings.

The protocol assists regional LHN nursing, midwifery and medical staff to appropriately manage people with diabetes self-managing CGM systems at the time of hospital admission who wish to continue CGM during their hospital stay. The protocol also provides diabetes specialist nurses and dietitians with information for the ongoing clinical and educational services provided by the regional LHN and RSS Diabetes Services.

The admitting medical practitioner will be responsible for:

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

Nurses and midwives have a role in providing education to support safe CGM self-management. It is recommended that the advice of a diabetes specialist nurse be sought.

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.

1.1 Absolute contraindications

The use of the CGM is contra-indicated in situations where the person with diabetes' safety may be compromised by their physical illness or mental state.

- > impaired level of consciousness
- > critical illness requiring intensive care
- > major psychiatric disturbance
- > diabetic ketoacidosis (DKA)
- > refusal or unwillingness to participate in self-care
- > inability to demonstrate a basic level of competency in the operation of their CGM and insulin pump (if applicable)
- > lack of sensors other equipment required to maintain the specific CGM system
- > extensive skin infections or inflammation
- > concerns regarding technical malfunction of the CGM system
- > 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 person with diabetes presents with any contraindication, the CGM must be discontinued, and the device managed according to the hospital's policy for storage of valuables.

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1.2 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 glucose excursions that may lead to hypoglycaemia or hyperglycaemia.

Self-monitoring of blood glucose (BG) has been demonstrated to improve glycaemic control and quality of life, however, requires multiple finger prick checks at discrete time-points before and after meals and activity and cannot predict impending hypoglycaemia.

Continuous Glucose Monitoring (CGM) addresses many of the limitations in HbA1c testing and self-monitoring of BG.

The CGM systems currently available for both personal and professional use are identified on Appendix 1.

1.3 Benefits and limitations of CGM

Benefits

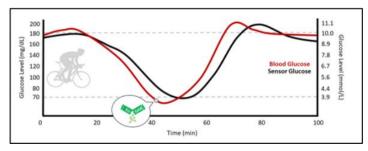
> measures interstitial glucose approximately every 5 minutes.

- may offer a predicted glucose trend to the user in real-time to identify glucose trends during various forms of dietary intake, physical activity, stress, illnesses, steroid medications or menstrual cycles
- > some systems can be linked to BG meters, compatible smart phones and/or insulin pumps which can display the interstitial glucose result, recent history and alert the person with diabetes and/or carer of the glucose excursion (trend) moving above or below the glucose target.
- when linked to insulin pump therapy, systems can provide sensor augmented pump technology (SAPT). SAPT can be programmed to automatically suspend insulin delivery if the interstitial glucose falls below target or administer micro bolus insulin doses if the interstitial glucose rises above target.
- some CGM systems and interstitial glucose sensors have been approved to direct insulin doses without confirmatory finger prick checking or calibration.

Limitations

- accuracy: based on the Mean Absolute Relative Difference (MARD)
- > lag time: current CGM technologies currently provide a 'lag time' of approximately 4-5 minutes behind the BG result. Figure 1 illustrates a potential lag time for between BG and sensor glucose (SG). There is greater different when the blood glucose level is changing more rapidly see Figure 1.
- discomfort: apart from minor discomfort at the time of the insertion of the CGM sensor, there is no expected discomfort when wearing the CGM.
- worn 24 hours a day: If the CGM sensor is removed, it cannot be reinserted and data collection will cease.
- risk of infection: this small risk is reduced by using a sterile technique when inserting the CGM sensor and protecting the skin site with the dressing.
- acetaminophen (paracetamol): interferes with some CGM systems, resulting in falsely elevated interstitial glucose results.
- > mechanical faults: can occur.

Figure 1: Interstitial Glucose Sensor Lag Time



https://www.easd.org/sites/default/files/Exercise%20CGM%20EASD%20position%20statement_final.pdf

1.4 Background evidence

In Australia, people with diabetes can access and benefit from CGM technologies. All people with type 1 diabetes are eligible to access subsidised CGM products via the National Diabetes Services Scheme (NDSS). For further information, visit the NDSS website. People with type 2 diabetes and women with gestational diabetes are ineligible for the subsidised CGM products via the NDSS, however, can access these products independently.

Current CGM systems measure interstitial glucose approximately every 5 minutes and relay this information with an indicator of the predicted glucose trend to the user and/or carer in real-time as well as being recorded to generate periodic reports.

Current CGM systems offer alarms when interstitial glucose levels are predicted to or reach predetermined high or low thresholds. Remote monitoring and alarms particularly beneficial among those persons with diabetes with impaired awareness or reduced ability to recognise and communicate symptoms of hypoglycaemia.

Current evidence suggests that the proportion of time using interstitial glucose monitoring correlates with the degree of glycaemic benefit. Furthermore, the interpretation of periodic reports from interstitial glucose monitoring requires detailed discussions between people with type 1 diabetes and their health care team to correlate multiple potential contributing factors to observed interstitial glucose levels and subsequently, make recommendations and/or changes to their individualized diabetes management.

1.5 Inpatient management

Current CGM are designed for the ambulatory setting only. However, the continued use of current CGM by the person with diabetes and/or their carer in the inpatient setting can be supported.

Assessing competency to self-manage CGM

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

It is acknowledged that the assessing health care professional may have limited exposure to the practical management of the specific CGM system used.

Competency assessment will involve asking the person with diabetes and/or their carer to demonstrate that they;

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

A diabetes specialist nurse should be notified upon admission of a person with diabetes with CGM system insitu. An urgent consultation should be obtained if there is a concern about competency of the person with diabetes or their carer.

The diabetes specialist nurse can advise or rectify any issues or concerns, support the person with diabetes or carer to continue using the CGM system and reiterate the importance of hospital blood glucose monitoring and the use of the hospital meter to guide diabetes management decisions during the admission.

Children and young adults

The continuation of a CGM system in a child or young adult needs to be considered carefully in consultation between the child with diabetes, carer and their specialist diabetes team.

In the circumstances that the carer is responsible for the management of the CGM 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 person's medical practitioner and diabetes specialist nurse. Additionally, the carer must be able to stay with the child with diabetes at all times during the admission so that the CGM system's daily requirements can be supported.

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

Obstetric and gynaecological patients

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

Surgical procedures

The use of the CGM systems in operating theatres, procedure rooms, etc. is not contra-indicated. The decision to maintain a CGM system must be considered carefully in consultation between the anaesthetist, surgeon, physician, medical practitioner, diabetes specialist nurse, person with diabetes, carer as it will be untouched until the person with diabetes or carer can resume their self-care responsibilities post operatively.

1.6 Discontinuation of CGM

CGM should be discontinued in the event of the following situations where the person with diabetes' safety may be compromised by their physical illness or mental state.

Discontinue use of CGM if any of the following occurs during the admission;

- > impaired level of consciousness
- > critical illness requiring intensive care
- > major psychiatric disturbance
- > diabetic ketoacidosis (DKA)
- > refusal or unwillingness to participate in self-care
- > inability to demonstrate a basic level of competency in the operation of their CGM and insulin pump (if applicable)
- > lack of sensors other equipment required to maintain the specific CGM system
- > extensive skin infections or inflammation
- > concerns regarding technical malfunction of the CGM system
- > 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 person with diabetes develops any contraindication, the CGM must be discontinued, and the device managed according to the hospital's policy for storage of valuables.

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1.7 Continuation of CGM

The person with diabetes carer is responsible for the management of the CGM system if they choose to continue their CGM whilst in hospital.

The person with diabetes, and/or their carer must insert their CGM sensor, maintain the CGM system and linkage to their blood glucose meters, compatible smart phones and/or insulin pumps and provide CGM consumables (including automatic insertion device) in the event the sensor requires replacement.

The person with diabetes and/or carer must inform staff immediately of hypoglycaemia or hyperglycaemic events, alerts, alarms or CGM failure.

The person with diabetes and/or their carer must be informed that despite access to the sensor glucose (SG) results via the CGM, hospital blood glucose monitoring is required.

Used CGM sensor introducer needle must be disposed of in an Australian Safety Standards approved sharps container.

Every CGM system supplier has a free call 24 hour emergency help line to assist people with diabetes or their carer who experience difficulty or CGM system failure. If the fault occurs during the warranty period, the CGM system is replaced free of charge. If the fault occurs when the CGM system is out of warranty, the company will often loan a replacement device for a limited period of time. A replacement or loan CGM system will be sent via express post to the person with diabetes' nominated address.

1.8 Medical record documentation

Inpatient documentation

Documentation that the person with diabetes or carer has a CGM system insitu and that he/she will self-care for this device during the hospital admission must be included in the medical record.

The regional LHN *Blood Glucose and Ketone Monitoring* Chart (MR59H) is to be completed by nurses or midwives who are trained and competent in the use of hospital BG meters. For regional LHN hospitals using electronic medical records (EMR) order sets, further information is available at the <u>BGL and Insulin Chart Window</u>.

The blood glucose results obtained from these capillary blood glucose meters must be used to assess inpatient diabetes management. In the event of out of target range BG and/or blood ketone (BK) results, nursing/midwifery staff are to consult the *Rapid Detection and Response Instructions* and action recommendations.

CGM reporting software

CGM system reports can be generated by both the person with diabetes, their carer and/or health care professional.

Reports to assist the glycaemic control of a person with diabetes admitted to a regional LHN hospital will require a referral to the diabetes specialist nurse and be dependent on the availability of applicable software. The various CGM system reports, whilst not standardised, offer the following key metrics to assess glycaemic control:

- > sensor capture data completeness
- > low glucose events
- > estimated HbA1c
- > time below target glucose range
- > time in target glucose range
- > time above target glucose range
- > % coefficient of variation (CV), standard deviation (SD) and individual day data graph.

2. Linked/Attached documents

National Safety and Quality Health Service Standards 4 - Recognising and Responding to Clinical Deterioration in Acute Health Care

Regional LHN Blood Glucose Monitoring Chart (MR59H) (order via the SA Distribution Centre)

Appendix 1 – Available CGM devices

3. References

Pease A, Andrikopoulos S, Abraham MB, Craig ME, Fenton B, Overland J, Price S, Simmons D, and Ross GP on behalf of the ADS, ADEA, APEG, and ADIPS Working Group 2021. *Utilisation, access and recommendation regarding technologies for people living with type 1 diabetes: A consensus statement of the Australian Diabetes Society (ADS), the Australian Diabetes Educators Society (ADEA), the Australasian Paediatric Endocrine Group (APEG), and the Australasian Diabetes in Pregnancy Society (ADIPS) Working Group. Australia. Available from: https://diabetessociety.com.au/position-statements.asp*

Australian Diabetes Society (2022) <u>Consensus Position Statement on: Utilising the Ambulatory Glucose Profile</u> (AGP) combined with the Glucose Pattern Summary to Support Clinical Decision Making in Diabetes Care.

The National Institute of Clinical Excellence (2015) Guideline on management of children and young people with type I and type II diabetes (NG18).

Maahs DM, DeSalvo D, Pyle L, Ly T, Messer L, Clinton P, Westfall E, Wadwa RP, Buckingham B. <u>Effect of acetaminophen on CGM glucose in an outpatient setting</u>. *Diabetes Care*. 2015 Oct;38(10):e158-9. doi: 10.2337/dc15-1096. Epub 2015 Aug 12. PMID: 26269199; PMCID: PMC4876736.

Petrie JR, Peters AL, Bergenstal RM, Holl RW, Fleming GA, Heinemann L. <u>Improving the Clinical Value and Utility of CGM Systems: Issues and Recommendations: A Joint Statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group. *Diabetes Care*. 2017;40(12):1614-1621.</u>

<u>International Consensus on Use of Continuous Glucose Monitoring.</u> *Diabetes Care* 2017;40:1631–1640 | https://doi.org/10.2337/dc17-1600

The National Institute of Clinical Excellence (2016) Diagnostics Guideline regarding the use of SAPT (DG21).

Association of Children's Diabetes Clinicians (2017) <u>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.</u>

4. Accreditation standards

National Safety and Quality Health Service Standards (NSQHSS)

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|--|---------------------------------|---|----------------------|---|----------------------|---------------------------|---|---|--|
| \boxtimes | | | \boxtimes | | \boxtimes | | | \boxtimes | |
| 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 | | Recognising & Responding to Clinical Deterioration | Preventing Falls & Harm from Falls |

Evaluation and Quality Improvement Program (EQuIP)

| 11 | 12 | 13 | 14 | 15 |
|---------------------|----------------------|---|---------------------------|------------------------------------|
| | \boxtimes | | \boxtimes | \boxtimes |
| Service Delivery | Provision of Care | Workforce Planning and Management | Information Management | Corporate Systems and Safety |

5. 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. |
| 2.0 | SA Health Metropolitan LHN Diabetes Services, Regional LHN Diabetes Specialist Nurse Network. |

Appendix 1: Available CGM systems

In Australia, people with diabetes can access and benefit from CGM technologies. All people with type 1 diabetes are eligible to access subsidised CGM products via the National Diabetes Services Scheme (NDSS). For further information, visit the NDSS website. People with type 2 diabetes and women with gestational diabetes are ineligible for the subsidised CGM products via the NDSS, however, can access these products independently.

| System | Works with | NDSS subsidy | Product lifespan | Other features |
|---------------------------------------|--|--|--|---|
| Abbott Freestyle Libre 2.0 | FreeStyle Libre 2 reader or compatible smartphone or device | FreeStyle Libre 2 sensor | Sensor – 14 days | FreeStyle Libre 2 has optional real-time alarms for high or low glucose levels and signal loss. |
| AMSL Dexcom G6 | Compatible iOS (Apple) or Android smartphone or smart device OR Tandem t:slim X2 Insulin Pump OR mylife YpsoPump | Dexcom G6 Sensor | Sensor : 10 days Transmitter: 3 months | No calibration required. |
| Medtronic Guardian Connect (3) | Compatible iOS or Android smartphone or smart device | Guardian Sensor (3) Guardian Connect (3) Transmitter | Sensors: 7 days Transmitter: 12 months | |
| Medtronic Guardian Link (3) | Medtronic MiniMed 670G or MiniMed 640G insulin pumps | Guardian Sensor (3) Guardian Link (3) Transmitter | Sensors: 7 days Transmitter: 12 months | |
| Medtronic Bluetooth Guardian Link (3) | Medtronic MiniMed 770G or MiniMed 780G insulin pump | Guardian Sensor (3) Medtronic Bluetooth Guardian Link (3) Transmitter | Sensors: 7 days Transmitter: 12 months | |