

Executive Summary

Clinical Guideline

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

This is an executive summary of the main guideline intended for use in managing continuous glucose monitoring (CGM) or real-time flash glucose scanning (FGS) for children and young people under 18 years with Type 1 diabetes mellitus.

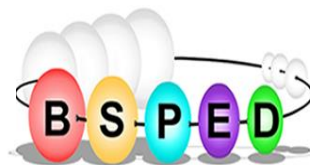
Introduction

Real-time continuous glucose monitoring (CGM) and flash glucose scanning (FGS) are new and evolving technologies in the management of type I diabetes. In addition CGM can be linked to insulin pump therapy providing sensor augmented pump technology (SAPT). In order to ensure that healthcare professionals, families and children are appropriately informed and educated on these technologies, the Association of Children's Diabetes Clinicians (ACDC) has developed a comprehensive guideline following extensive reviews of the literature and consultation to help identify which patients may be most likely to benefit and how these technologies may be practically implemented.

The National Institute of Clinical Excellence (NICE) has produced two guidelines relevant to the use of CGM. Guideline NG18 on management of children and young people with type I and type II diabetes and diagnostics guidance DG21 regarding the use of SAPT. A Medtech Innovation Briefing (MIB) 51 regarding the Minimed™ 640G has also been published.

The main guideline has 2 key sections:

- Section 1** A review of the evidence to support the use of CGM and FGS and recommendations regarding patient selection, criteria for regular use, criteria for diagnostic use and circumstances where technology should be withdrawn.
- Section 2** A Practical Guide for Healthcare Professionals - Implementation of the Technology and a Toolkit of Resources to Support Professionals Facilitating Patient Self-Management. All material is freely available on the ACDC website www.a-c-d-c.org



NICE guidance

The NICE recommendations in its guideline NG 18 for the management of children and young people with diabetes regarding the use of CGM are as follows:

1.2.62	Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have: <ul style="list-style-type: none">• frequent severe hypoglycaemia or• impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) or• inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).
1.2.63	Consider ongoing real-time continuous glucose monitoring for: <ul style="list-style-type: none">• neonates, infants and pre-school children• children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level)• children and young people who have comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult.
1.2.64	Consider intermittent (real-time or retrospective) continuous glucose monitoring to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.

NICE has also issued a diagnostics guidance DG21 relating to sensor augmented pump therapy (SAPT) and when it should be considered. DG21 suggested that:

“NICE recommends the use of sensor augmented pump therapy systems (specifically the integrated Minimed Paradigm Veo insulin pump and CGM system) for children and young people with type 1 diabetes providing:

- they have episodes of disabling hypoglycaemia despite optimal management with continuous subcutaneous insulin infusion
- the system is used under the supervision of a multidisciplinary team who are experienced and appropriately trained in integrated sensor augmented insulin pump therapy”

There must be agreement that the CYP with diabetes and/or their parents(s)/carer(s):

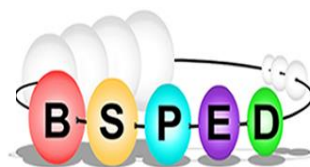
- agrees to use the sensors for at least 70% of the time
- understands how to use it and is physically able to use the system
- agrees to use the system while having a structured education programme on diet and lifestyle, and counselling.

NICE has produced a Medtech Innovation Briefing (MIB) regarding the Medtronic Minimed™ 640G. MIB51 suggests that:

“There is no evidence that the Medtronic Minimed™ 640G system has any further benefit in reducing the risk of hyperglycaemia compared with any other pump systems” (MIB51)

Recommended use of the Medtronic Minimed™ 640G include:

- Children and young people with type 1 diabetes who experience problematic blood glucose levels undertaking capillary self-monitoring and multiple daily injections
- those who have difficulty identifying hypoglycaemia
- those with a history of severe hypoglycaemia
- those susceptible to nocturnal hypoglycaemia
- those with a fear of either daytime or night time hypoglycaemia



Evidence Review

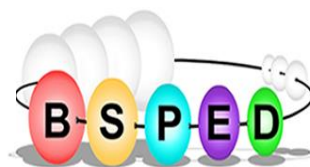
The guideline group reached the following conclusions:

- The evidence base for CGM is weak with many studies underpowered and not definitively conclusive. Evidence was most prevalent for impact on HbA1c and on incidence of hypoglycaemia (Level 1-). Few if any studies addressed the impact on quality of life, economic impact or on aspects of CGM use such as exercise.
- CGM has been shown to lead to modest reduction in HbA1c both with insulin pump therapy (CSII) and in those on multiple daily injections (MDI). However this was not demonstrated universally in all studies. Improvement was approximately 0.3-0.5% HbA1c in the majority of studies (Level 1-). Individual RCT's demonstrated stronger evidence of benefit than systematic reviews and meta-analyses.
- CGM reduces the incidence of hypoglycaemia, particularly nocturnal hypoglycaemia, both with CSII and MDI (Level 1+). But again this effect was not demonstrated in all studies. CGM seems to have the most positive effect on reducing (but not eliminating) hypoglycaemia in motivated patients with good metabolic control who are compliant with sensor wear.
- The efficacy of CGM improves with greater frequency of use. The highest efficacy is seen with usage >60% of the time (Level 1++)
- Fear of hypoglycaemia is reduced with sensor augmented pump therapy (SAPT). Some studies suggested improvement in QOL but there has been no rigorous assessment of QOL.
- Sensor augmented low glucose suspend pump therapy reduced the incidence of hypoglycaemic events particularly nocturnal hypoglycaemia (Level 1+)
- Successful use of CGM and SAPT is likely to require intensive support and education. The degree to which support and the more advanced functions of CGM may optimise therapy is not well documented in the published studies

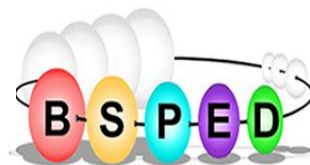
Recommendations for Patient Selection

The guideline development group made the following recommendations regarding which patients may/may not be suitable and may benefit from CGM or FGS. For details and the evidence supporting the recommendations please see the main guideline:

- Recommendation 1:** **Continuous CGM can be considered for any patient irrespective of age, sex socioeconomic status, ethnic or educational background who meet the NICE criteria. (Grade B)**
- Recommendation 2:** **Continuous CGM can be considered in children on CSII or MDI therapy (Grade A)**
- Recommendation 3:** **Continuous CGM with alarms should be considered in any child of any age who has had a hypoglycaemic seizure (Grade B)**



- Recommendation 4:** Continuous CGM with alarms should be considered in all young children (neonates, infants and preschool children) (Grade A)
- Recommendation 5:** Continuous CGM with alarms should be considered in all children of any age with cognitive or neurodevelopmental problems that impair their ability either to recognise or to respond to hypoglycaemia (Grade D)
- Recommendation 6:** CGM with alarms should be considered in frequent hypoglycaemia and in nocturnal hypoglycaemia (Grade B)
- Recommendation 7:** CGM with alarms should be considered in situations where individuals have unawareness of hypoglycaemia (Grade B)
Evidence of this may come from any of the following sources
- Evidence from diagnostic CGM to suggest that individuals have period of significant hypoglycaemia of which they are unaware. Periods with glucose <2.6 mmol for >20 minutes during waking day (Grade C)
 - A score >4 on the Clarke hypoglycaemia unawareness questionnaire (Grade C)
 - A score ≥ 4 on the Gold hypoglycaemia unawareness Likert scale (Grade C)
- Recommendation 8:** CGM with alarms should be considered in individuals where anxiety or fear of hypoglycaemia is high (Grade D)
Anxiety/fear of hypoglycaemia should be documented using a recognised assessment tool. A score on CHFS and HSF-P worry subscale of >3 (or mean score greater than 2) or a score of >4 on the HFS-PYC worry subscale (or mean score greater than 3) would support trial of CGM (Grade D)
- Recommendation 9:** CGM can be considered for improving diabetes control in children & young people by reducing HbA1c and/or reducing the time spent in hypoglycaemia, with any HbA1c $< 10\%$ (Grade B)
- Recommendation 10:** There is little evidence to support CGM use to reduce HbA1c or hypoglycaemia in those children with a very high HbA1c $>10\%$, it is therefore not recommended (Grade D)



Exercise Management

The guideline development group made the following recommendations regarding the use of CGM and FGS in exercise. For details and the evidence supporting the recommendations please see the main guideline:

- Recommendation 11:** **Continuous CGM should be considered for exercise in children and young people in the following circumstances: (Evidence - Grade D)**
- For those competing or exercising regularly. It can be used to optimise glycaemic control (including carbohydrate and insulin adjustment) before, during and after exercise to maximise the effect of exercise on improving diabetes control and ensure that potential sporting performance is optimised.
 - For adolescents trying to lose weight but fearful of the hypoglycaemic effects of exercise
 - For those who have had a severe episode of hypoglycaemia following sporting activity and cannot resume activity
 - For those in whom there is concern regarding overcompensation with additional carbohydrate for activity
 - Those involved in high endurance sporting activities where it is difficult to test blood sugar
 - For those where exercise results in unpredictable hypoglycaemia

Diagnostic Use of Systems

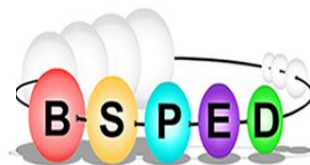
Diagnostic use (whether retrospective and/or real-time) usually involves intermittent use of sensors to help identify patterns of glucose excursion and to guide therapeutic change in the following:

- Suspected nocturnal hypoglycaemia and/or early morning hyperglycaemia
- Suspected unrecognised hypoglycaemia eg exceptionally low HbA1c without reported hypoglycaemia
- HbA1c above individualised target despite intensified insulin therapy apparently optimised with self-monitoring
- Persistent disabling hypoglycaemia

- Recommendation 12:** **Intermittent or diagnostic CGM should be considered for:**
- Suspected nocturnal hypoglycaemia
 - Suspected unrecognised hypoglycaemia
 - HbA1c above individualised target despite apparently optimised with self-monitoring
 - Evidence of benefit is limited in those with HbA1c >10% and should only be undertaken in exceptional circumstances in this group (Evidence - Grade C)

- Recommendation 13:** **Families and young people should be willing to undertaking 4 blood tests each day and to complete diaries. (Evidence - Grade D)**

- Recommendation 14:** **Diabetes clinics should have diagnostic CGM systems available to them (Grade A)**



Criteria to Withdraw Systems

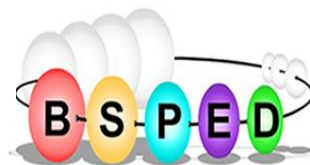
CGM systems are a cost to the NHS. Whilst they can be very valuable, if they are used infrequently, with insufficient engagement in the structured education process required to maximise benefit and the intended benefits are not realised, then they should be withdrawn.

- Recommendation 15:** **Withdraw continuous CGM after 1 month if:**
- **CGM has not been used 60-70% of the time – 5 days a week minimum (Grade A)**
 - **Family have not attended all 4 Education step 1,2,3,4 sessions unless extenuating circumstances (Grade D)**
- Recommendation 16:** **Withdraw CGM at 3 months if:**
- **CYP does not wear it for at least 5 days a week. (Grade A)**
 - **No improvement in glycaemic control – eg HbA1c did not improve by >0.5% if it was >7.5% at start of CGM therapy**
 - **No improvement in scores on fear of hypoglycaemia scales where CGM was introduced for anxiety**
 - **No improvement in hypoglycaemia unawareness if introduced for hypoglycaemia unawareness (Clarke or Gold score)**
 - **No reduction in frequency of hypoglycaemia – particularly nocturnal hypoglycaemia (assessed from CGM download)**
 - **Its use for sport /exercise is not being optimised**
- Recommendation 17:** **Benefit from CGM should be clearly evidenced and documented in the notes (Best Practice Point). CGM does not need to be reviewed for withdrawal if it was introduced following hypoglycaemic seizures and provided it is being used > 5 days per week or in younger children providing it is in regular use**

CGM / FGS Systems and Schools

Children of all ages need a robust plan for managing their diabetes at school. Teachers and school nurses will need additional guidance and education on how CGM/FGS data should be factored into care decisions.

- Recommendation 18:** **An individualised care plan should be put in place for every child on CGM (Grade – Best Practice)**
- Recommendation 19:** **Structured education should provided for nursery and teaching staff supervising the child (Grade – Best Practice)**
- Recommendation 20:** **Consideration should be given to adjusting alarm thresholds if disruptive at school (Grade – Best Practice)**
- Recommendation 21:** **Expectations between parents and staff at preschool/school need to be clearly agreed to avoid conflict (Grade – Best Practice)**



CGM / FGS and Driving

Current DVLA (Driver and Vehicle Licensing Agency) rules state :

- Group 1 drivers may now use finger prick glucose testing and continuous glucose monitoring systems (FGM and RT-CGM) for the purposes of driving.
- Group 2 (bus and lorry) drivers must continue to use finger prick testing for the purposes of driving.
- RT-CGM and flash glucose monitoring systems are not legally permitted for the purposes of Group 2 driving.
- All glucose monitoring systems used for the purposes of driving must carry the CE mark.
- As there are times when FGM and RT-CGM users are required to check their finger prick glucose, users of these systems must also have finger prick glucose monitors and test strips available when driving.

You must get a confirmatory finger prick glucose level in the following circumstances

- If your glucose level is 4.0mmol/L or below.
- If you have symptoms of hypoglycaemia.
- If your glucose monitoring system gives a reading that is not consistent with your symptoms (that is you have symptoms of hypoglycaemia and your system reading does not indicate this).
- If you are aware that you have become hypoglycaemic or have indication of impending hypoglycaemia.
- At any other times recommended by the manufacturer of your glucose monitoring system.
- Alarms on RT-CGM devices must not be used as a substitute for symptomatic awareness of hypoglycaemia. You must recognise hypoglycaemia through the symptoms you experience for the purposes of Group 1 driving. Should you become reliant on these alarms to advise you that you are hypoglycaemic you must stop driving and notify the DVLA.
- If you are using a glucose monitoring system (RT-CGM or FGM) you must not actively use this whilst driving your vehicle. You must pull over in a safe location before checking your device.

<https://www.gov.uk/government/publications/information-for-drivers-with-diabetes>

Recommendation 22: Patients using CGM and/or flash glucose scanning (FGS) monitoring should be made aware of the requirements in accordance with DVLA rules.

Practical recommendations for Healthcare Professionals introducing CGM/FGS

The second section of the ACDC guideline gives details of the practical recommendations for implementation of CGM/FGS and provides a Step 1,2,3,4 process whereby structured education may be given.

Recommendation 23: All children should have a month's trial with a loan system before being provided with their own personal CGM system

Recommendation 24: It is important to consider the CGM system type for age and whether aiming to link to CSII and potential benefit from predictive low glucose suspend technology (Grade D)

Recommendation 25: If CGM is to be commenced in addition to CSII as a therapeutic tool to improve control the CGM should be commenced prior to CSII (Grade D).



An initial training of a minimum of 4 separate sessions is likely to ensure maximum benefit is derived. Patients and carers need to commit to training in CGM

Recommendation 26: Patients/ carers commencing CGM must commit to formal CGM training and regular skills assessment (Grade D)

Recommendation 27: Patients/ carers commencing CGM must commit to CGM download with diabetes team contact (minimum monthly in the first 6 months) and subsequent regular download (Grade D)