Worcestershire Acute Hospitals NHS Trust

Continuous Glucose Monitoring Guideline for Children and Young People with Diabetes

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Key Amendment

Date	Amendment	Approved by
17th July 2019	Updated guideline	Paediatric QI
19TH Nov 2020	Document extended for 1 year	Dr J West/Paediatric QIM
26th March 2021	Document reviewed and approved for 3 years	Paediatric Guideline Review meeting
9th Feb 2024	Document reviewed and approved	Paediatric Guideline Review Meeting

This guideline is intended for use in managing continuous glucose monitoring (CGM) or real-time flash glucose monitoring (FGM) for all children and young people (CYP) under 18 years with Type 1 diabetes mellitus. It is based on the policy agreed with commissioners in April 2019.

The purpose of this policy is to define when CGM and FGM are indicated for use in children and young people under the care of the paediatric diabetes services. The policy will also define initiation, review and continuation/discontinuation criteria.

FOR STAFF

Healthcare professionals involved in care of children and young people with Type 1 Diabetes Mellitus

PATIENTS

CYP with diabetes mellitus

Quick Reference Guide – Patient Eligibility Criteria

Flash Glucose Monitoring (FGM)
- Monitoring > 8 times a day
- Diabetes associated with cystic fibrosis
- During pregnancy (12 months total including post-delivery period)
- Unable to routinely self-monitor blood glucose due to disability requiring carer support for monitoring and insulin management
- Occupational or psychosocial circumstances warranting use
- Recurrent severe hypoglycaemia
- Impaired awareness of hypoglycaemia
- Avoidance of alternative specialist treatment e.g. insulin pump or rtCGM where appropriate

Real-time Continuous Glucose Monitoring (rtCGM)
- Frequent severe hypoglycaemia
- Hypoglycaemia unawareness with adverse consequences
- Inability to recognise or communicate hypoglycaemia symptoms

- Neonates/infants/<4yrs of age where persistent difficulties with blood glucose control

And where FGM has provided insufficient benefit:
- Impaired awareness of hypoglycaemia evidenced by FGM
- High levels of physical activity or recurrent severe hypoglycaemia following activity that cannot be resumed
- Comorbidities/other treatments causing persistent difficulties with blood glucose control
- Hyperglycaemia despite insulin adjustment and additional support

Contents

Introduction

CGM is used in diabetic patients who rely on insulin to control their diabetes. It involves the use of a small device worn just under the skin; this measures interstitial glucose (sugar) levels continuously throughout the day and night, identifying trends in glucose levels. Some devices provide alerts for highs and lows to facilitate disease control. There are different types of CGM available:

a. **Real-time CGM** (rtCGM) uniformly tracks glucose concentrations in the body's interstitial fluid, providing near real-time glucose data. There are different types of rtCGM, those that can be used independently (standalone) and those that are used with an insulin pump (insulin pump compatible).

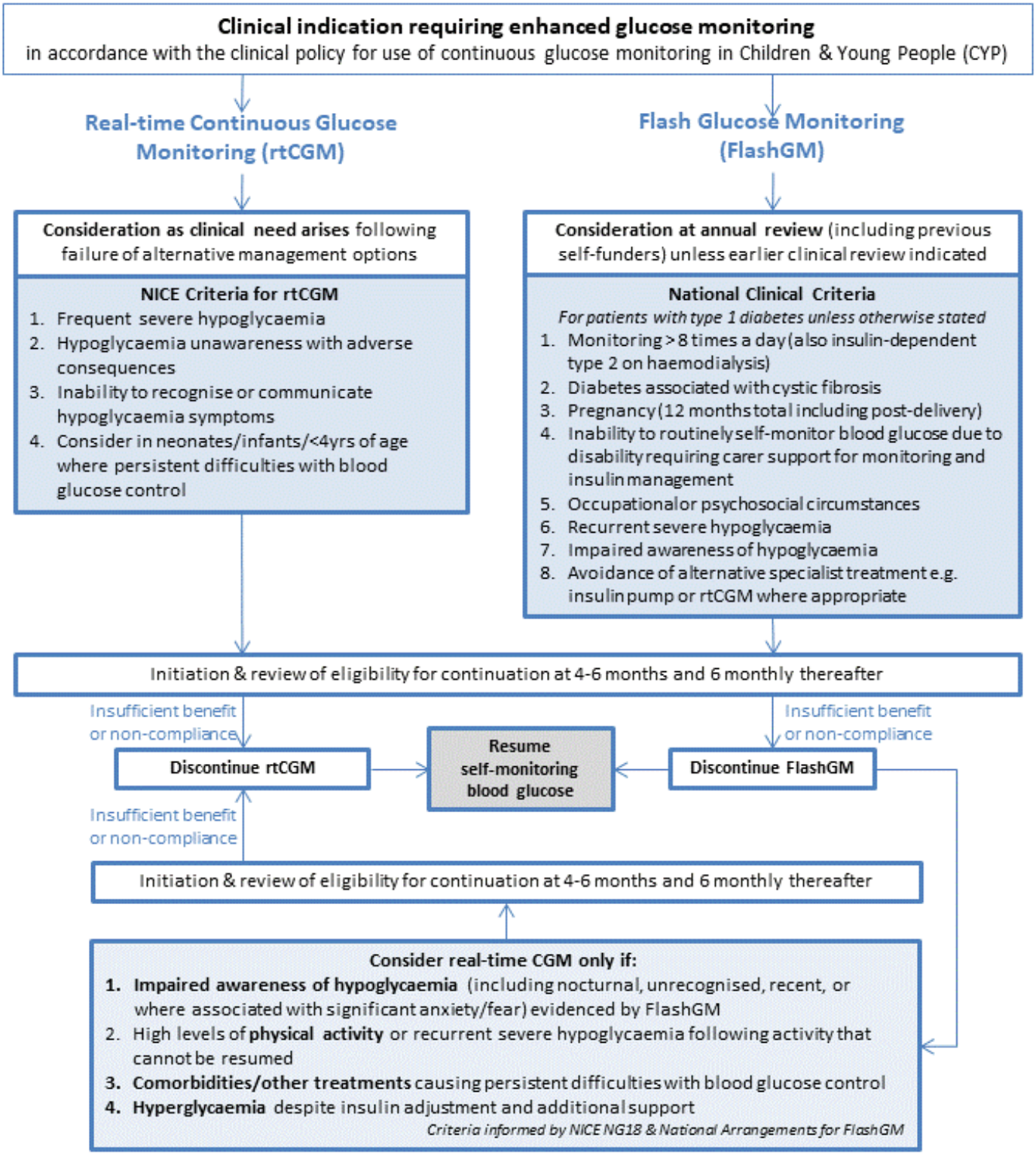
b. **Intermittent CGM** (iCGM) uses similar methodology to show continuous glucose measurements retrospectively at the time of checking. This is also known as **Flash Glucose Monitoring** (FGM).

The NICE guideline 'Diabetes (type 1 & type 2) in children and young people: diagnosis and management' published in 2015 detailed the clinical indications for commencing CGM. However, this was written before FGM became available and therefore doesn't provide any recommendations for FGM. In November 2018, NHS England announced that FGM would be available for patients with insulin-dependent diabetes who meet agreed national clinical criteria.

The Association of Children's Diabetes Clinician's (ACDC) produced a series of patient information leaflets that support structured education for families and children for each system and an education resource toolkit for diabetes healthcare professionals to facilitate the structured education program. All these materials are available on the ACDC website www.a-c-d-c.org

Patient Eligibility

The summary below demonstrates the clinical indications for use of CGM (including FGM).



Notes:

i. rtCGM should not be used to reduce HbA1c or hypoglycaemia in CYP with a HbA1c >10%
ii. CYP services are responsible for provision of readers and sensors for FlashGM until patients meet continuation criteria; at this time general practitioners will be asked to continue ongoing supply with other repeat medication requirements
iii. CYP services are responsible for supply of device and consumables associated with rtCGM throughout the period of use
iv. Patients who have self-funded FlashGM are required to follow this pathway to assess NHS funding eligibility
v. The clinical policy for use of continuous glucose monitoring in CYP provides definitions as appropriate

April 2019

All CYP with insulin dependent diabetes being considered for any type of CGM will need to demonstrate that they (or their carer as appropriate) has:

1. established insulin-dependent diabetes
2. had their insulin regime optimised
3. attended an educational session for diabetes management
4. committed to self-management with attendance at clinical review 3 times a year or more
5. committed, via a patient/carer contract, to the requirements for use of CGM including:
    i. engagement with recommended education (prior to commencement and ongoing)
    ii. baseline assessment
    iii. understanding of the continuation criteria
    iv. regular review

Flash Glucose Monitoring

Consideration of eligibility for a 4-6 month trial of FGM will be undertaken at the next scheduled clinical review with the Paediatric Diabetes Team unless clinical circumstances indicate an earlier review.

A trial of FGM may be an option for children aged 4 years and older and young people with insulin dependent diabetes where the patient, in addition to the above, meets one of the following clinical criteria:

1. **Type 1 diabetes requiring intensive monitoring >8 times daily**, as demonstrated on a meter download/review over the past 3 months

2. **Type 1 or 2 diabetes on haemodialysis requiring intensive monitoring >8 times daily**, as demonstrated on a meter download/review over the past 3 months

3. **Diabetes associated with cystic fibrosis**

4. **Type 1 diabetes during pregnancy** (12 months total including post-delivery period)

5. **Type 1 diabetes with disability and carer support** who are unable to routinely self-monitor blood glucose

6. **Type 1 diabetes with occupational or psychosocial* circumstances** (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) that warrant a 6-month trial with appropriate adjunct support.
    * Psychosocial circumstances will be assessed using the Paediatric Quality of Life Inventory (PedsQL) – these can be found on the 'M' drive

7. **Type 1 diabetes experiencing recurrent severe hypoglycaemia****
    ** Recurrent severe hypoglycaemia - defined as more than 1 episode of hypoglycaemia, within a 6 month period, that:
    i. has required third party assistance due to a reduced conscious level needing treatment with oral glucose gel or intra-muscular (IM) glucagon and
    ii. is a diabetic emergency and
    iii. is a very infrequent event

8. **Type 1 diabetes with impaired awareness*** of hypoglycaemia**

   *** Impaired awareness of hypoglycaemia associated with adverse consequences (for example seizures or anxiety) – assessed using:

   i. the Clarke Hypoglycaemic Index and Gold Score (appendix 1) necessitating a score of >4 and ≥ 4 respectively and

   ii. the Hypoglycaemia Fear Questionnaire (appendix 2) necessitating a mean score of 2 or over on the worry subscale of the Children's Hypoglycaemia Fear Survey (CHFS) and Hypoglycaemia Fear Survey – Parent (HFS-P) and/or a mean score of 3 or over on the Parents of Young Children HFS-PYC.

9. **Type 1 diabetes where FGM may enable avoidance of alternative specialist treatment** e.g. insulin pump or rtCGM where appropriate

Following initiation of FGM in eligible people and agreement of the patient contract (appendix 3), baseline parameters will be recorded in relation to the monitoring parameters necessary to determine eligibility for ongoing use. These parameters will be taken from information prior to commencement of FGM and information gathered during use of the first FGM sensor.

Eligibility for ongoing use of FGM will be assessed initially at 4-6 months and 6-monthly thereafter and will require demonstration of compliance with the patient contract and:

a. wearing the sensor for more than 70% of the time and scanning at least 8 times a day

b. clinic attendance at least twice in the first 6 months and then at least 3 times a year thereafter

c. attendance at an annual education event (the initiation session counts for year 1)

d. improved self-management evidenced by one or more of the following parameters and depending on the reason for commencement:

   i. Reduced number of SMBG tests

   ii. Improved HbA1c (>5 mmol/mol if ≥ 58 mmol/mol pre-FGM)

   iii. Improved time in defined patient range

   iv. Reduced number of hypoglycaemic events or time in hypoglycaemia (<4 mmol/l)

   v. Reduced time in hyperglycaemia (>14 mmol/l)

   vi. Improved hypoglycaemic awareness - necessitating an improvement from baseline (pre-FGM) in one or more of the following assessment tools: Clarke Hypoglycaemic Index, Gold Score or Hypoglycaemia Fear Questionnaire

   vii. Improvement in psycho-social well-being – necessitating an improvement from baseline in the PedsQL

The Paediatric Diabetes Team are responsible for determining eligibility for FGM, initiating use of the device (including education) and arranging supply of sensors during the initiation period (4-6 months). When ongoing eligibility is demonstrated (beyond 4-6 months), general practitioners will be asked to maintain ongoing supply of sensors together with any other established diabetes medication

requirements. A Blueteq proforma is completed to demonstrate eligibility for use of FGM, and again at annual review to ensure eligibility for continuation.

People who self-funded FGM prior to availability on the NHS will be assessed for NHS eligibility in accordance with the above arrangements, including:

1. demonstrating that they met one of the clinical criteria prior to commencing use of FGM AND
2. demonstrating:
    a. completion of any necessary assessment tools
    b. that they satisfy the continuation criteria above

If the diabetes team are assured that eligible patients meet the parameters below, ongoing eligibility may be determined at an earlier stage, this will need to be individualised to the patient's circumstances:

a. FGM use has been optimised and patient is both competent and confident with use
b. the sensor is worn for more than 70% of the time with scanning at least 8 times a day
c. attendance at annual education event (the initiation session counts for year 1)
d. improvement in HbA1c since self-funding commenced

Where a patient is not able to immediately demonstrate the above parameters further support and education will be offered with re-assessment at 4-6 months in accordance with the arrangements outlined above.

Real-time Continuous Glucose Monitoring

Consideration for real-time CGM will be undertaken as clinical need arises following failure of alternative management options.

Real-time CGM with alarms may be offered to children and young people with type 1 diabetes who have one of the following indications:

a. Recurrent severe hypoglycaemia - defined as more than 1 episode of hypoglycaemia, within a 6-month period, that:
    i. has required third party assistance due to a reduced conscious level needing treatment with oral glucose gel or intra-muscular (IM) glucagon and
    ii. is a diabetic emergency and
    iii. is a very infrequent event

b. Impaired awareness of hypoglycaemia associated with adverse consequences (for example seizures or anxiety) – assessed using:
    i. the Clarke Hypoglycaemic Index and Gold Score necessitating a score of >4 and ≥ 4 respectively and
    ii. the Hypoglycaemia Fear Questionnaire necessitating a mean score of 2 or over on the worry subscale of the Children's Hypoglycaemia Fear Survey (CHFS) and Hypoglycaemia Fear Survey – Parent (HFS-P) and/or a mean score of 3 or over on the Parents of Young Children HFS-PYC.

c. Inability to recognise, or communicate about, symptoms of hypoglycaemia (for example because of cognitive or neurological disabilities)

Real-time CGM may be considered for neonates, infants and children under 4 years of age where there are persistent difficulties with blood glucose control. It may also be considered for children and young people with type 1 diabetes who have demonstrated insufficient benefit from FGM and who meet one of the following indications:

a. Impaired awareness of hypoglycaemia (including nocturnal, unrecognised, recent, or where associated with significant anxiety/fear) evidenced by FGM

b. High levels of physical activity (eg. sport at a regional, national or international level) or recurrent severe hypoglycaemia following activity that cannot be resumed

c. Comorbidities/other treatments causing persistent difficulties with blood glucose control

d. Hyperglycaemia despite insulin adjustment and additional support

Eligibility for ongoing use of rtCGM will be assessed at **1 month** and **3 months** and will require demonstration of:

1-month assessment:

a. wearing CGM for more than 5 days per week and

b. family attendance at education session and 1-week follow-up session

3-month assessment:

a. wearing CGM for more than 5 days per week and

b. clinic attendance at least twice in the first 6 months and then at least 3 times a year thereafter

c. reduced number of SMBG tests

d. improved self-management evidenced by one or more of the following parameters and depending on the reason for commencement:

i. Improved HbA1c (>5 mmol/mol if ≥ 58 mmol/mol pre-rtCGM)

ii. Improved time in defined patient range

iii. Reduced number of hypoglycaemic events or time in hypoglycaemia (<4 mmol/l)

iv. Reduced time in hyperglycaemia (>14mmol/l)

v. Improved hypoglycaemic awareness - necessitating an improvement from baseline (pre-rtCGM) in one or more of the following assessment tools: Clarke Hypoglycaemic Index, Gold Score or Hypoglycaemia Fear Questionnaire

vi. Improvement in psycho-social well-being – necessitating an improvement from baseline in the PedsQL

Notes regarding rtCGM:

1. All eligible CYP will have a months' trial with a loan system before being provided with their own personal CGM system
2. The multidisciplinary specialist team will determine the appropriate choice of CGM in consideration of age, ability to link to insulin pump, potential benefit from predictive low glucose suspend technology and cost-effectiveness
3. If CGM is to be commenced in addition to insulin pump therapy, CGM should be commenced prior to the insulin pump
4. Some patients, within the identified cohorts, may require diagnostic CGM over a short period of time to inform better management; such patients may not be offered CGM for long-term use

The Paediatric Diabetes Team is responsible for determining eligibility for rtCGM, initiating use (including education) and device and consumable supply throughout the period of use by the child. A Blueteq proforma is completed to demonstrate eligibility for use of rtCGM, with annual review to ensure eligibility for continuation.

CGM/FGM Systems and Schools

- An individualised care plan should be put in place for every child on CGM.
- Structured education should be provided for nursery and teaching staff supervising the child.
- Consideration should be given to adjusting alarm thresholds if disruptive at school.
- Expectations between parents and staff at preschool/school need to be clearly agreed to avoid conflict.

CGM/FGM and Driving

- Patients using CGM and/or FGM monitoring should be made aware of the requirement to also test their blood glucose in accordance with DVLA rules.

The Practicalities of Implementation

During implementation the following are considered:

- All children should have a month's trial with a loan system before being provided with their own personal CGM system
- It is important to consider the CGM system type for age and whether aiming to link to insulin pump therapy for sensor augmented pump therapy and potential benefit from predictive low glucose suspend technology (in which case the integrated Minimed Paradigm Veo insulin pump and CGM system may be used)
- 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

CYP and their carers commencing CGM must commit to formal CGM training. They are given a 3-hour long education session on practical aspects and the assessment and interpretation of results, as well as the day to day management based on CGM trends. This includes:

- Getting started with the CGM system
- Understanding the basic knowledge of the CGM system
- Learn to identify and understand trends and patterns
- Learn to actively use target glucose range

- Optimise the effect of CGM using trend arrows
- How to use the total dose percentage adjustment tool
- How to use the insulin sensitivity factor tool (ISF)
- How to use the Ambulatory Glucose Profile (AGP)
- Diasend/Software downloads

Written information is provided to reinforce this training and the family are reviewed 1 week later. Regular skills assessments are performed to ensure the CYP and their carers are getting the most out of their device. They must then commit to CGM download with diabetes team contact (minimum monthly in the first 6 months) and subsequent regular downloads.

References

1. NICE NICE Guideline NG18 - Diabetes (type 1 & type 2) in children and young people: diagnosis and management. National Institute of Clinical Excellence, 2015.

2. NICE NICE Diagnostics Guidance DG21 - Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system). https://www.nice.org.uk/guidance/dg21, 2016.

3. NICE NICE Medtech innovation briefing MIB51- MiniMed 640G system with SmartGuard for managing blood glucose levels in people with type 1 diabetes. https://www.nice.org.uk/advice/mib51, 2016.

4. Flash Glucose Monitoring: National arrangements for funding of relevant diabetes patients. March 2019. https://www.england.nhs.uk/publication/flash-glucose-monitoring-national-arrangements-for-funding-of-relevant-diabetes-patients/

Appendices

Appendix 1: Clarke Hypoglycaemia Index Score

Score ≥4 = hypoglycaemia unawareness

1) Check the category that best describes you: (check only one)

- ☐ I always have symptoms when my blood sugar is low 0
- ☐ I sometimes have symptoms when my blood sugar is low 1
- ☐ I no longer have symptoms when my blood sugar is low 1

2) Have you lost some of the symptoms that used to occur when your blood sugar was low?

- ☐ yes 1
- ☐ no 0

3) In the past 6 months how often have you had moderate hypoglycaemia episodes? (Episodes where you might feel confused, disoriented, or lethargic and were unable to treat yourself)

☐ never 0 ☐ once or twice 1 ☐ every other month 1
☐ once a month 1 ☐ more than once a month 1

4) In the past year how often have you had severe hypoglycaemia episodes? (Episodes where you were unconscious or had a seizure and needed glucagon or intravenous glucose)

☐ never 0 ☐ 1 time 1 ☐ 2 times 1 ☐ 3 times 1 ☐ ≥4 times 1

5) How often in the last month have you had readings <70mg/dL (or < 3.5mmol/L) with symptoms?

☐ never ☐ 1 to 3 times ☐ 1 time/week
☐ 2 to 3 times/week ☐ 4 to 5 times/week almost daily

6) How often in the last month have you had readings < 70mg/dL without symptoms?

☐ never ☐ 1 to 3 times ☐ 1 time/week
☐ 2 to 3 times/week ☐ 4 to 5 times/week ☐ almost daily

Score 1 if reading <3.5 with no symptoms

7) How low does your blood sugar need to go before you feel symptoms?

- ☐ 3.4-3.9mmol/L 0
- ☐ 2.8-3.3mmol/L 1
- ☐ 2.2-2.7 mmol/L 1
- ☐ < 2.2mmol/L 1

8) To what extent can you tell by your symptoms that your blood sugar is low?

- ☐ Never 1
- ☐ rarely 1
- ☐ sometimes 1
- ☐ often 1
- ☐ always 0

Gold Score

"Do you know when your hypos are commencing?"

Always aware							Never aware
Awareness	1	2	3	4	5	6	7

Appendix 2: Hypoglycaemia fear questionnaires

There is no defined clinical cut-off for the hypoglycaemia fear questionnaires. However, a mean score of 2 or over on the worry subscale of the Children's Hypoglycaemia Fear Survey (CHFS) and Hypoglycaemia Fear Survey - Parent (HFS-P), and mean score of 3 or over on the Parents of Young Children HSF-PYC, would indicate the need for consideration of CGM. Additionally, if there was one very highly rated element (rated 'often' or above; 3 or over on CHSF and HSF-P, 4 or over on HSF-PYC) despite a mean score lower than 2 on CHSF and HSF-P or 3 on HSF-PYC, this may prompt consideration of CGM.

Hypoglycaemia Fear Questionnaire – Parent

This survey is intended to find out more about how low blood sugar makes your child feel and behave. Please answer the following questions as frankly as possible.

Behaviour – Below is a list of things that people whose children have diabetes do in order to avoid low blood sugar. Circle one of the numbers to the right that best describes what you do during your daily routine to avoid your child having low blood sugar

	Never	Rarely	Sometimes	Often	Very often
1. Feed my child large snacks at bedtime	1	2	3	4	5
2. Avoid allowing my child to be away from me when his/her sugar is likely to be low	1	2	3	4	5
3. Try to run a little high to be on the safe side	1	2	3	4	5
4. Keep my child's sugar higher when he/she will be away from me	1	2	3	4	5
5. Feed my child as soon as I feel or see the first signs of low blood sugar	1	2	3	4	5
6. Reduce my child's insulin when I think his/her blood sugar is low	1	2	3	4	5
7. Keep my child's blood sugar higher when I know he/she is planning to be at a long event (e.g. school, party)	1	2	3	4	5
8. Always carry fast-acting sugar	1	2	3	4	5
9. Don't allow my child to play excessively when I think his/her blood sugar is low	1	2	3	4	5
10. Check my child's blood sugar often when he/she is planning to be at a long event (e.g., school, party)	1	2	3	4	5

Worry – below is a list of concerns people whose children have diabetes sometimes have. Please read each item carefully (do not skip any). Circle one of the numbers to the right that best describes how often you worry about each item because of low blood sugar

	Never	Rarely	Sometimes	Often	Very often
11. Not recognizing that my child is having a hypoglycaemic event	1	2	3	4	5
12. Not having food or fruit juice with me for my child	1	2	3	4	5
13. Having my child dizzy or pass out in public	1	2	3	4	5
14. Feeling that my child will have a low blood sugar while he/she is asleep	1	2	3	4	5
15. My child embarrassing him/herself in front of friends/family in a social situation	1	2	3	4	5
16. My child having a low blood sugar when he/she is away from me	1	2	3	4	5
17. My child being disoriented	1	2	3	4	5
18. My child losing control	1	2	3	4	5
19. No one being around to help my child during a hypoglycemic event	1	2	3	4	5
20. My child making a mistake or having an accident at day care/school	1	2	3	4	5
21. My child getting a bad evaluation at day care/school because of something that happens when his/her sugar is low	1	2	3	4	5
22. My child having seizures	1	2	3	4	5
23. My child developing long-term complications from frequent low blood sugars	1	2	3	4	5
24. My child feeling light headed or faint	1	2	3	4	5
25. My child having an insulin reaction	1	2	3	4	5
26. My child having a hypoglycemic event while I'm driving	1	2	3	4	5

Hypoglycaemia Fear Questionnaire – Patient

This survey is intended to find out more about how low blood sugar makes you feel and behave. Please answer the following questions as frankly as possible.

Behaviour – Below is a list of things that people who have diabetes do in order to avoid low blood sugar. Circle one of the numbers to the right that best describes what you do during your daily routine to avoid having low blood sugar

	Never	Rarely	Sometimes	Often	Very often
1. Eat large snacks at bedtime	1	2	3	4	5
2. Avoid being alone when my sugar is likely to be low	1	2	3	4	5
3. Try to run a little high to be on the safe side	1	2	3	4	5
4. Keep my sugar higher when I will be alone for a while	1	2	3	4	5
5. Eat something as soon as I feel the first signs of low blood sugar	1	2	3	4	5
6. Reduce my insulin when I think my blood sugar is low	1	2	3	4	5
7. Keep my blood sugar higher when I know I am planning to be at a long event (e.g. school, party)	1	2	3	4	5
8. Always carry fast-acting sugar	1	2	3	4	5
9. Avoid a lot of exercise when I think my blood sugar is low	1	2	3	4	5
10. Check my blood sugar often when I am planning to be at a long event (e.g., school, party)	1	2	3	4	5

Worry – below is a list of concerns people who have diabetes sometimes have. Please read each item carefully (do not skip any). Circle one of the numbers to the right that best describes how often you worry about each item because of low blood sugar

	Never	Rarely	Sometimes	Often	Very often
11. Not recognizing/realising that I am having a hypoglycemic event	1	2	3	4	5
12. Not having food or fruit juice with me	1	2	3	4	5
13. Feeling dizzy or passing out in public	1	2	3	4	5
14. Having a low blood sugar while I am asleep	1	2	3	4	5
15. Embarrassing myself in front of friends/family in a social situation	1	2	3	4	5
16. Having a hypoglycaemia while I am alone	1	2	3	4	5

17. Appearing stupid or drunk	1	2	3	4	5
18. Losing control	1	2	3	4	5
19. No one being around to help me during a hypoglycemic event	1	2	3	4	5
20. Making a mistake or having an accident at school	1	2	3	4	5
21. Getting a bad evaluation at /school because of something that happens when my sugar is low	1	2	3	4	5
22. Having seizures	1	2	3	4	5
23. Developing long-term complications from frequent low blood sugars	1	2	3	4	5
24. Feeling light headed or faint	1	2	3	4	5
25. Having an insulin reaction	1	2	3	4	5

Appendix 3: FGM – Patient/parent agreement

You/your child are eligible to receive the Freestyle Libre device on prescription. We (Worcestershire Paediatric Diabetes team) are happy to start this process by arranging prescriptions for you for the first 6 months. However, we have agreed with the Clinical Commissioning Groups (who fund the prescriptions) that patients will be reviewed at 4-6 months to see whether ongoing prescriptions can be justified. Continued prescriptions are reliant on achieving the following criteria:

1. That you have attended one of our education sessions about the Freestyle Libre device. **The date of your education session is the:**
2. That you agree to scan the Freestyle Libre device no less than 8 times per day and use the sensor >70% of the time.
3. That you attend a structured education event once a year (a session on the Freestyle Libre will count for the first year).
4. That you attend clinic twice in the first 6 months (as per normal) and then at least 3 times a year (National recommendations say Children and Young People with Type 1 diabetes should be seen in clinic 4 times a year).
5. That we see evidence that the Freestyle Libre device is improving your diabetes self-management by satisfying one of the following:
    I. If your HbA1c is 58 mmol/mol or above before starting, this improves by at least 5 mmol/mol by 4-6 months, or
    II. A reduction in time spent hyperglycaemic (levels >14 mmol/l), or
    III. An improvement in the total time your blood glucose level is in range, or
    IV. Your hypo awareness (if unaware), fear of hypos, number of hypos or total time spent hypo improves, or
    V. There is an improvement in your psychological wellbeing.

Once satisfying these review criteria we will write to your GP advising that you continue to receive the Freestyle Libre device on prescription. Please note, the above criteria will also be used to allow us to recommend continuation/stopping prescriptions in the future.

Please sign below to say you have read and understood the above (please ask if you have any questions).

Patient	**Parent**
Signature: ……	Signature: ……
Name: ……	Name: ……
Date:	

Appendix 4: CGM/FGM data and adjusting insulin doses

Dexcom

Total insulin dose percentage adjustment based on trend arrows

Arrow Trend	Description of trend arrow	Action needed
→	Stable: It may go up or down by 0.8 mmol/L in 15 mins	Give dose as calculated
↗	Slowly rising: It may go up by 1.7 mmol/L in 15 mins	Add 10% extra to calculated dose
↑	Rising: It could go up by 2.5 mmol/L in 15 mins	Add 20% extra to calculated dose
↑↑	Rising rapidly: It may go up **more than** 2.5 mmol/L in 15 mins	Add 20-30% extra to calculated dose If glucose >8 mmol/L consider 25-30% but if <8mmol/L consider 20%
↘	Slowly falling: It may go down by 1.7 mmol/L in 15 mins	Take away 10% from calculated dose
↓	Falling rapidly: It could fall by 2.5 mmol/L in 15 mins	Take away 20% from calculated dose
↓↓	Falling very rapidly: It may go down by **more than** 2.5 mmol/L	Take away 20 - 30% from calculated dose
Blank No arrow	If no trend arrow appears: The receiver cannot work out if the glucose is going up or down and how fast	

Correction dose adjustment using the trend arrows

Trend arrow	Maximum change in 15 mins	Glucose in 15 mins (based on starting glucose 12.0mmol/L)	Action needed
→	Glucose is changing up or down (maximum 0.8 mmol/L per min)	Stable 11.2 or 12.8 mmol/L	Give usual correction dose
↘	Falls by maximum of 1.7 mmol/L in 15 mins	10.3 mmol/L	Give usual correction dose
↓	Falls rapidly maximum of 2.5 mmol/L	9.5 mmol/L	Wait until levelled off and glucose is stable
↓↓	Falling very rapidly by more than 2.5 mmol/L	<9.5mmol/L	Wait until levelled off and glucose is stable
↗	Glucose is rising by maximum of 1.7 mmol/L	13.7 mmol/l	Add 10% to correction dose
↑	Rising rapidly by maximum of 2.5 mmol/L	14.5 mmol/L	Add 20% to correction dose
↑↑	Rising very rapidly by more than 2.5 mmol/L	>14.5 mmol/l	Add 25-30% to correction dose

Interpreting Medtronic Minimed 640G device data

Trend Arrows	
↑↓	Blood glucose has been rising or falling by about 1-2mmol/l over the last 20 minutes
↑↑↓↓	Blood glucose has been rising or falling by about 2-3mmol/l over the last 20 minutes
↑↑↑↓↓↓	Blood glucose has been rising or falling greater than 3mmol/l over the last 20 minutes

Interpreting FreeStyle Libre device data and adjusting insulin doses

Total insulin dose percentage adjustment based on trend arrows

Arrow trend before meal time bolus	Description	10-15min timing	Action needed
↑	Glucose is rising quickly (more than 0.1 mmol/L per minute)	1-1.5mmol/L in 10-15 mins	Add 20% of meal time dose as extra
↗	Glucose is rising (between 0.06 - 0.1 mmol/L per minute)	0.6-0.9 mmol/l in 10-15 mins	Add 10% of meal time dose as extra
→	Glucose is changing slowly (less than 0.06/L per minute)	Stable	Give usual meal time dose
↘	Glucose is falling (between 0.06 - 0.1 mmol/L per minute)	0.6-0.9 mmol/l in 10-15 mins	Take 10% off meal time dose
↓	Glucose is falling quickly (more than 0.1 mmol/L per minute)	1-1.5 mmol/L in 10-15 mins	Take 20% off meal time dose

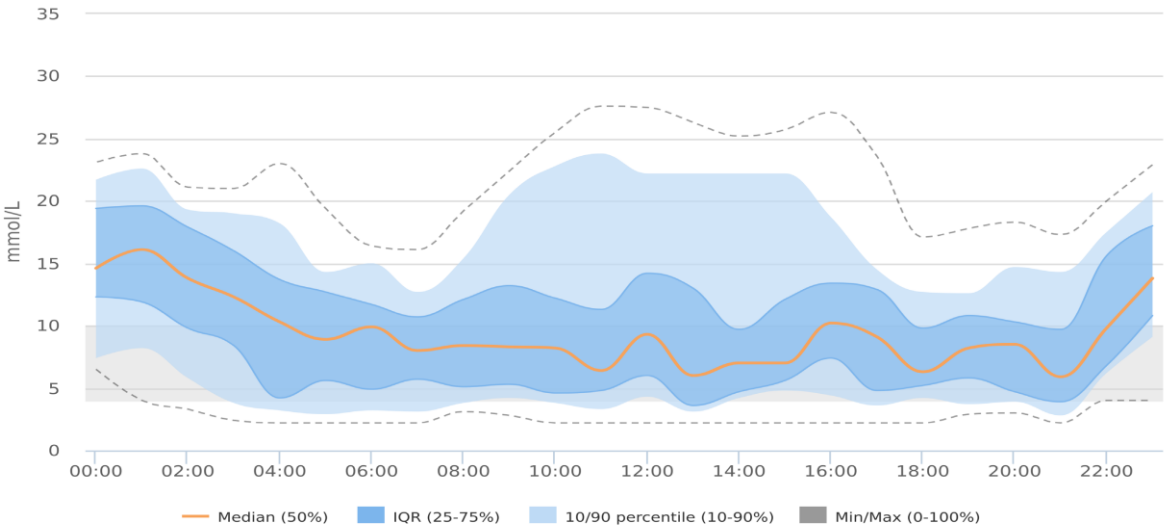
NB: Meal time dose = insulin for CHO + correction dose

Correction dose adjustment using the trend arrows

Trend arrow	Description	Glucose in 15min (based on starting glucose 12.0mmol/L)	Action needed
↑	Glucose is rising quickly (more than 0.1 mmol/L per min)	13.5mmol/L	Add 20% to correction dose
↗	Glucose is rising (between 0.06 - 0.1 mmol/L per min)	12.9 mmol/l	Add 10% to correction dose
→	Glucose is changing slowly (less than 0.06/L per min)	Stable 12.6 or 11.4 mmol/L	Give usual correction dose
↘	Glucose is falling (between 0.06 - 0.1 mmol/L per min)	11.1 mmol/l	Take 10% off correction dose
↓	Glucose is falling quickly (more than 0.1 mmol/L per min)	10.5 mmol/L	Take 20% off correction dose

Ambulatory glucose profile

This shows the glucose values over 14 days
- The orange line shows the median of all the results
- The pale blue area is the 10-90% percentile range
- The dark blue area is the 25-75% range
- The wider these areas the bigger the variation in glucose levels



How to use the AGP:

1. Look at the median glucose line over a 2 week period.
2. How close is the patient to target?
3. What is the variability like i.e. how wide are the glucose levels?
4. How often do they have a hypo or hyper or been close?

Start by looking at the risk of a hypo.
The FreeStyle Libre software will be highlighted as red in a traffic light system

If hypos are a problem look at the common time they occur or are likely to occur.
Think about:

- When did they last have insulin?
- Are they counting carbohydrate correctly?
- Are they within your target range overnight?

Are their glucose levels high most of the time?
Think about:

- Has insulin been omitted?
- Have they given insulin after a meal?
- Are they counting carbohydrates correctly? Are they over treating a hypo?
- Is their basal insulin too low?
- Have they been unwell?
- Does it occur at certain times of the week?

Traffic lights to identify risk of hypos

To help identify which time of the day needs to be looked at more closely a traffic light system has been added with the FreeStyle Libre software i.e.

Red - There is a very high risk of hypo or hyperglycaemic episode (a lot of glucose results away from the goal)

Amber - Moderate or high chance of hypo or hyper (many glucose results further away from target)

Green - Low chance of hypo or hyper (most glucose results closer to target)

Glucose control measure	Assessment		
	Low	Moderate	High
How likely you are to have a low glucose	Less than 10% chance	Between 10-50% chance	Greater than 50% chance
Median glucose (compared to your goal)	Less than goal	Greater than goal	Greater than goal and more than 20% (2.2mmol/L) greater than whole day median
Variability below median (median to 10th percentile	less than 1.9 mmol/L	Between low and high	Not close to median but far enough away not to cause low glucose