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A practical approach to continuous glucose monitoring (rtCGM) and FreeStyle Libre systems (isCGM) in children and young people with Type 1 diabetes

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ABSTRACT

Real-time continuous glucose monitoring (rtCGM) and FreeStyle Libre glucose monitoring systems (isCGM) are new evolving technologies used in the management of Type 1 diabetes. They offer potential to improve diabetes control and reduce hypoglycaemia. rtCGM can be linked to insulin pump providing hybrid closed loop therapy. Families of children and young people are keen to have the benefit from these technologies. These are relatively expensive so it is important that health care professionals, families of children and young people (CYP) with diabetes are adequately trained in the use of these devices. Health care professionals need to be able to make patient selection based on individual needs and preferences to achieve maximum benefit.

Association of Children's Diabetes Clinicians (ACDC) developed a comprehensive guideline in 2017 to help identify which patients may be most likely to benefit and how these technologies may be practically implemented. Since then new technologies have been introduced and the use of GCM has expanded in routine clinical practice.

This article, aims to provide a practical approach and help identify which patients may be most likely to benefit and how the technology may be implemented in order to maximise the clinical benefits.

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1. Introduction

Real-time continuous glucose monitoring (rtCGM) and FreeStyle Libre glucose monitoring systems (isCGM) are evolving technologies that may help both professionals and families manage diabetes in children and young people (CYP). The technology offers the potential to improve glycaemic control, reduce the incidence of hypoglycaemia, and reduces the anxiety that concern regarding hypoglycaemia can induce.

Additionally rtCGM can be linked to insulin pump therapy whereby the sensor can suspend insulin delivery when the glucose is falling or low and increase basal rate or give extra bolus doses if predicted glucose readings are rising (hybrid closed loop systems) Many families are keen to have the opportunity to benefit from these technologies. However, they are relatively expensive and although costs are similar to insulin pump therapy there may be conflicts with commissioners/funders who are concerned about constrained budgets.

Association of Children's Diabetes Clinicians (ACDC), published practical guidelines for managing CYP with rtCGM and FreeStyle Libre in 2017 [2]. Since then newer technologies including hybrid closed loop systems have been introduced in the market. Although these newer technologies are ever evolving, they have shown promising outcomes in terms of improving diabetes control, reducing hypoglycaemia and fear of hypoglycaemia [1]. This article aims to provide a practical approach and help identify patients that may be most likely to benefit and how the technology may be implemented in order to maximise the clinical benefits.

2. rtCGM

rtCGM continuously measures interstitial glucose (rather than capillary blood glucose), and provides a continuous real-time display on the device's handset or a smart phone device. There are three main rtCGM systems currently available (Dexcom G6 and G5, Medtrum Touch Care Nano and Medtronic Guardian 3/4 sensor). A disposable sensor, replaced regularly, attached to a transmitter, is inserted under the skin. With some systems glucose readings can be displayed on the accompanying insulin pump (if the user has one) or transmitted to the CYP/parents' mobile phone. rtCGM systems have alarms which can alert the user to both low and high glucose levels and alert them when the glucose levels are rising or falling above certain thresholds. These thresholds can be adjusted to suit the individual. rtCGM systems also have a series of trend arrows which can indicate how rapidly the glucose is rising or falling. These can be used to alter mealtime doses of insulin and they can also be used to anticipate and prevent hypoglycaemia and hyperglycaemia.

Mean absolute relative difference (MARD) is a metric used to assess CGM accuracy. Lower MARD means that CGM readings are closer to the reference glucose values. Higher percentage indicates larger discrepancies between them. The MARD score and accuracy does vary according to the level of the interstitial glucose and may also fluctuate during the lifetime of the sensor - typically declining as the sensor ages.

The treatment "loop" for patients with diabetes tries to mimic the pancreatic function as best we can. This involves, glucose monitoring device (blood glucose meter or CGM) and the ability to calculate the insulin dose required and its delivery (an insulin pen or a pump). "Closing the loop" would require all these functions to be fulfilled automatically. JDRF research has identified 6 key steps in the journey toward fully automated closed loop [3]. Fig. 1 summarises the 6 steps as outlined by JDRF

Currently, there are hybrid closed loop systems available for use where part of the loop requires manual intervention. The Medtronic 670G and Tandem t slim X2 insulin pump with control -IQ technology can be linked to the sensor and have an in-built algorithm which will alter the basal insulin dose. They have predictive low and high glucose minimiser [4,5]. Tandem t slim X2 with control -IQ technology has an ability to give extra bolus doses as well. Insulin boluses for carbohydrate intake are still delivered by the users. It uses treat to range predictive algorithm. Medtronic 670G uses treat to target proportional integral derivative (PID) with insulin feedback. Medtronic 780G which also has an ability to give extra boluses. Uses same algorithm as Medtronic 670G. It is the upgraded version of Medtronic 670G and is available in the UK for commercial use [6].

Cam APS Fx is an android app which manages glucose using a similar approach. It uses treat to target Adaptive Model Predictive Control (MPC). It has been extensively used in clinical trials. It is compatible with Dana Diabecare RS insulin pump and Dexcom G6 CGM. It is approved for clinical use in the UK and EU. There are substantial differences in the settings used in different system's algorithms. These differences have implications for optimising insulin doses settings. The main features of the various CGM systems are outlined in Table 1.

The hybrid closed loop systems have shown consistent improvement in HbA1c and TIR in clinical studies [7,8]. Real world use of these systems have exposed some issues around the usability. Some of the issues are related to high target glucose range (6.7 mmol/l), post prandial glucose excursions due to issues with carbohydrate counting and insulin absorption. Use of Medtronic 670G requires considerable user input to remain in auto mode. One third of users discontinued the use of auto mode within the first year in one prospective observational study [9]. However, a recent study of 30 patients who were initiated on Medtronic 670 G found that >85% of users were still using auto mode at 12 months. This study population comprised of users who were on MDI and Medtronic 670G was their first experience of pump use.

3. FreeStyle Libre (is CGM)

The FreeStyle Libre system displays the (interstitial) glucose level when scanned or "flashed" across the sensor, and unlike rtCGM systems, does not have an ability to show realtime data unless scanned. Older version of Free Style libre system did not have alarms to alert the patient to high or low glucose. The FreeStyle Libre 2 System is a device with alarms capability and is approved for the management of diabetes in children age 4. The alarms can be set to alert at a low and high

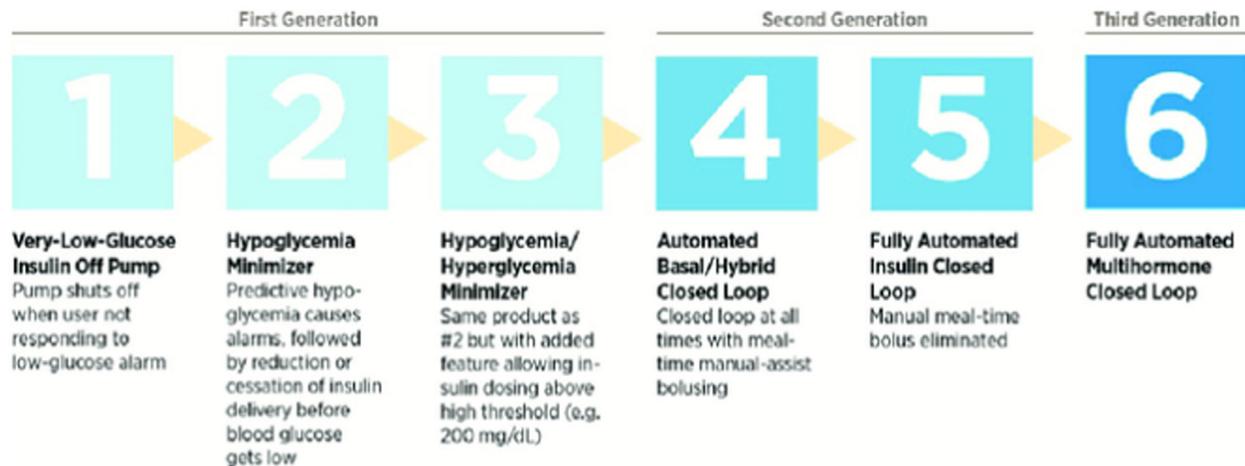


Fig. 1 – The 6 developmental stages of artificial pancreas device systems (copyright JDRF).

reading. The user will have to scan the sensor to obtain the reading. Free Style Libre doesn't have predictive high or low alerts. Insulin boluses for carbohydrate intake are still delivered by the users. Mobile phones with near field communication can also be used to scan the sensor and transmit glucose to permitted users. It has trend arrows and displays glucose variation over the preceding 24 h but only stores data for up to 8 h therefore, if not scanned within that time, the data is lost. The sensor doesn't need any calibration and functions for 14 days, before automatically shutting down. There is limited literature on the FreeStyle Libre and its effect on HbA1c outcomes in children, with small non randomised observational studies suggesting improvement. NICE guidance does not currently cover the use of the FreeStyle Libre system, but NHS England has laid out the criteria for reimbursing the cost of FreeStyle Libre to CCGs. It is estimated that this criteria will be fulfilled by approximately 20–30 % of the population with Type 1 diabetes in England. It is the cheapest of the available technologies with similar accuracy as the Dexcom G6 and there is high degree of reported user satisfaction in CYP [10 11]. It has not been approved for use with any hybrid closed loop systems.

4. Time-in range and HbA1c

As the use of CGM has expanded in clinical practice, a need for a metric other than HbA1c has arisen. HbA1c is used to assess glycaemic control and is the key marker for long term outcomes in patients with Type 1 and Type 2 diabetes. But it lacks the ability to provide insight into day to day glycaemic excursions. Use of CGM has an ability to warn users of hypo and hyperglycaemia and it provides data for day to day glycaemic variability. In February 2019, advanced technologies and treatment for diabetes (ATTD) congress convened an international expert panel to provide guidance to clinicians and patients which will help in interpreting and reporting the CGM data. They concluded that retrospective analysis of CGM data using standardised ambulatory glucose profile should be used to help patients set their glycaemic goals. Other metrics such as time in range (time spent between 3.9

and 10 mmol/L) can also be used as a clinical target and an outcome measure together with HbA1c [12]

5. Which patient group would benefit most from CGM use?

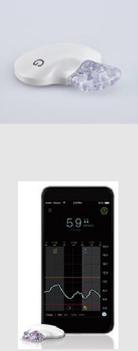
NICE made recommendations as to when rtCGM may be appropriate [13]. Further NICE diagnostics guidance (DG21) made recommendations regarding the use of sensor augmented pump therapy [14]. A Medtech Innovation Briefing (MIB 51) has also been produced to address the fact that the Veo system discussed in DG21 has been replaced by the Medtronic 640G. ADA and ISPAD have released similar guidance for the appropriate use of technology including CGM devices for children and young people [15,16].

Technological developments are moving rapidly and much of the evidence NICE considered related to technology now superseded by more sophisticated devices. More recent studies tend to show improved results but it is unclear whether this is related to technological advances or whether the technology is being used more effectively. Latest evidence has shown more promising results with use of CGM leading to improvement in control which was irrespective of mode of insulin delivery [17].

It has been shown that rtCGM use leads to reduction in HbA1c both with insulin pump therapy (CSII) and multiple daily injections (MDI) [18]. Improvement was approximately 0.3–0.5% HbA1c in the majority of studies [19,20]

There is evidence of improved outcomes in individuals with well-controlled diabetes (HbA1c < 7.5%) and also in those with poorer metabolic control and higher baseline HbA1c > 8% [21,22]. There was a strong correlation with the frequency of sensor usage; those who used sensors most consistently had the best incremental outcomes [22–24]. The highest efficacy is seen with usage > 60% of the time. Only a few studies included children with very high HbA1c (above 11–12%) but suggested that there was little benefit from CGM in those with HbA1c > 10.0% [25]. Regular CGM use in those with HbA1c > 10% is therefore not recommended. SELFY study is the recent UK based paediatric study which has evaluated

Table 1 – Characteristics of CGM and Freestyle libre systems.

| | Medtronic | | Dexcom G6 and G5 | Medtrum – TouchCare Nano CGM | Freestyle Libre system |
|---------------------------------|---|------------|--|--|---|
| | Guardian 3 | Guardian 4 | | | |
| Standalone systems |  | |  | |  |
| Integrated pumps | 670 G 780 G | | Tandem t:slimX2 Dana RS pump with CAMAPS FX | Touch care Nano pump | None |
| Site | 2–13 Abdomen and buttocks 14 + Abdomen and arms | | Abdomen, arms and buttocks | Abdomen, buttocks and arms | Arms |
| MARD Score | 10.9% -paediatrics | | 9%- paediatrics | No data for paediatrics (9% in adults) | 9%- paediatrics |
| Sensor Glucose measurement | Every 5 min | | 5 min | 2 min | Every 1 min when flashed |
| Licence | All ages for the sensor | | 2 and above | 2 and above | 4 and above |
| Duration | 7 days | | 10 days | 14 days | 14 days |
| Calibration | yes | No | No | Yes | No |
| Alarms | Yes | | Yes | Yes | Yes |
| Trend Arrows | yes | | Yes | Yes | Yes |
| Charging | Transmitter should be charged after 6 days of usage | | Receiver needs to be charged every 2 days | Transmitter needs charging after each sensor session (every 14 days) | A fully charged reader battery will last up to 7 days |
| Waterproofing | Pump and transmitter are waterproof. 670G is waterproof upto 12 feet for up to 24 h | | Pump is water proof for upto 3 feet for 30 min and transmitter are waterproof for 8 feet | Waterproof up to depth of 8 feet for upto 60 min | Reader is not water resistant. Sensor is |
| Compatible downloading software | Carelink and Tidepool | | Clarity, Diasend, Tidepool | Easysense | Librelink, Diasend , Tidepool |
| Data sharing | Up to 5 people with Carelink connect web app for guardian 4 sensor | | Up to 10 people with dexcom follow app. | Medtrum easy touch mobile app-Unlimited followers | Up to 20 people with libre link app |

the use of Freestyle Libre. It showed improvement in time spent in the range of almost 10% compared to SMBG and improvement in HbA1c. Recent studies in adolescents and children have shown improvement in glycaemic control with the use of isCGM for those with HbA1c > 7% [11].

Anxiety and fear of hypoglycaemia, which can impact overall diabetes control, may be reduced by CGM [26]. Use of CGM to address parental anxiety was supported by the ACDC guideline group provided that a recognised assessment tool was employed and improvement documented. *Children's Hypoglycaemia Fear Survey* (CHFS) and the parental measure, *Hypoglycaemia Fear Survey - Parent* (HFS-P) which has also been adapted for parents of very young children (HFS-PYC) are recommended [27,28]. There is no defined clinical cut-off but a mean score of 2 or over on the worry subscale may indicate the need for consideration of CGM.

Clinical bottomline:

1. rtCGM can be considered for any patient irrespective of age, sex, ethnic or educational background and socioeconomic status who meet NICE criteria.
2. rtCGM can be considered in children on CSII or MDI therapy
3. CGM can be considered in individuals where anxiety or fear of hypoglycaemia is high in both the patient and parents, supported by the use of CHFS and HSF-P worry surveys.
4. 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.

5.1. How does CGM reduce hypoglycaemic risk in children?

Hypoglycaemia is a key limitation to good glycaemic control and CGM may be beneficial [18,21]. rtCGM improves hypoglycaemia though similar to HbA1c not all studies demonstrated improvement. Numerous systematic reviews and several meta-analyses have been undertaken [18]. Most demonstrated that periods of time spent in hypoglycaemia were shorter [18]. In studies where hypoglycaemia reduction was defined as the primary point (rather than improved HbA1c), there was significant improvement in rates of hypoglycaemia. Several studies with predictive low glucose suspend have reported a reduction in the rate and severity of hypoglycaemia, particularly in nocturnal hypoglycaemia [29]. Fear of hypoglycaemia is also reduced with SAPT. Some studies suggested improvement in quality of life (QOL).

Younger children in particular are unable to recognise and respond to hypoglycaemia, and CGM can be useful in hypoglycaemia detection. rtCGM studies in pre-school children confirmed that the majority of hypoglycaemia events were asymptomatic [29]. Only 32% were detected even when glucose levels were checked 10 times per day. Hypoglycaemia unawareness is common with up to 29% in of those aged 6 months to 19 years demonstrating impaired awareness of hypoglycaemia[30]. The risk of hypoglycaemic seizures is greatest in such children. A history of hypoglycaemic seizure

adversely affects glycaemic control, predisposes to further seizures and increases parental anxiety. In adolescents, fear of further hypoglycaemic seizures and embarrassment regarding such incidents significantly affects control [31]. Nocturnal hypoglycaemia also occurs frequently in children. Historical studies have reported a prevalence of up to 40% on any given night [32]. Almost half of these episodes go undetected by patients or carers. The JDRF study recorded hypoglycaemic events during 8.5% of nights and on almost a quarter of those nights hypoglycaemia persisted for 2 h [33].

It is important that where CGM is considered for hypoglycaemia unawareness, it should be assessed using one of the following tools to objectively assess hypoglycaemia unawareness and document improvement

- *Clarke Score*– An 8 item questionnaire adapted for children [29]. A score of ≥ 4 suggests hypoglycaemia unawareness.
- *Gold Scale* – A single question “do you know when your hypos are commencing?” on a Likert scale. A score of ≥ 4 suggests impaired awareness [34].

Hypoglycaemic risk may be increased both at the time of exercise and also in the 24 h following activity [35]. rtCGM has been used successfully during physical exercise in adolescents, noting unrecognised hypoglycaemia and post-exercise nocturnal hypoglycaemia [36]. Experience of CGM in diabetes sports camps suggest that sensors are well tolerated during exercise. In well-controlled young adults the handling of glucose excursions during exercise appears to be improved [35].

There are no RCTs for the FreeStyle Libre in children and little published evidence at present. One study in adults examined the incidence of hypoglycaemia. Time spent in hypoglycaemia was reduced from 3.4 h daily to 2.0 h daily with individuals flashing the glucose reading a mean 15 times daily [37]. A recent trial in children attending a summer camp has shown that use of isCGM alone is non inferior to SMBG for making treatment decisions and improved time spent in range [38].

Clinical bottomline:

1. rtCGM/is CGM should be considered in any child of any age who has had a hypoglycaemic seizure, frequent and nocturnal hypoglycaemia.
2. rtCGM/isCGM should be considered in all young children (neonates, infants and preschool children) and in all children of any age with cognitive or neurodevelopmental problems that impair their ability either to recognise or to respond to hypoglycaemia.
3. rtCGM/isCGM should be considered in situations where individuals have unawareness of hypoglycaemia, with evidence from Clarke score and Gold scale.
4. rtCGM should be considered for exercise in children and young people who are competing or exercising regularly; those who have had a severe episode of hypoglycaemia or unpredictable hypoglycaemia following sporting activity and cannot resume activity; those in whom there is

concern regarding overcompensation with additional carbohydrate for activity; high endurance sporting activities where it is difficult to test blood glucose.

rtCGM systems have an ability to provide predictive low and high glucose alerts. Thresholds can be adjusted according to individual patient needs. iCGM lacks this feature. This needs to be kept in mind when considering CGM for a particular individual. rtCGM might be clinically more suitable option for those having frequent nocturnal hypoglycaemia or seizures.

5.2. Is there any value in using intermittent CGM?

Intermittent use of CGM sensors (rt CGM and is CGM) can be used as a diagnostic tool for the following conditions:

- Suspected nocturnal hypoglycaemia
- Unrecognised hypoglycaemia
- HbA1c above individualised target despite intensified insulin therapy
- Persistent disabling hypoglycaemia

Evidence supports the intermittent use of CGM as an educational/motivational tool in poorly controlled adolescents in certain circumstances. In a cohort of patients, mean age 14 years, when offered a month of CGM support, HbA1c improved from 9.3% to 8.8% (0.5% improvement). However individuals with HbA1c > 10% at the outset did not improve [25]. Diagnostic use in those with HbA1c > 10% should therefore only be considered in exceptional circumstances.

Clinical bottomline:

1. Intermittent or diagnostic CGM should be considered for suspected nocturnal or unrecognised hypoglycaemia. Diagnostic CGM to suggest period of significant hypoglycaemia for which they are unaware i.e. periods with glucose < 2.6 mmol/l for > 20 min during waking day.
2. Intermittent CGM can also be used as an educational/motivational tool in adolescents with poor glycaemic control, but only when HbA1c < 10% (86 mmol/mol).

6. What are the limitations of using CGM systems?

All of the systems measure interstitial glucose rather than capillary blood glucose. It takes 5–10 min for them to equilibrate. As a consequence, when the blood glucose is rising or falling rapidly, there may be a noticeable difference in readings. If the glucose is falling, the sensor interstitial glucose may lag behind the capillary glucose, with the sensor suggesting a higher glucose reading than the capillary reading. Conversely when the blood glucose is rising rapidly the sensor may indicate a lower reading than capillary samples. When making judgements about insulin administration, it is advisable particularly when the blood glucose is rising or falling, that it is confirmed by a finger prick measurement.

CGM may not be suitable for all patients as a significant number of CYP decline to be involved in studies. Importantly, use of CGM may decline over time. In studies <50% of individuals used CGM > 70% of the time and at 1 year, 41% had discontinued use altogether [39]. The reasons for discontinuing are not clear, but could be physical issues (e.g. skin irritation, pain), effort of use or effect on QOL (e.g. alarms). Successful use of CGM and SAPT is likely to require intensive support and education [40]. Similar results have been reported with the use of hybrid closed loop systems when used in real life [41].

Clinical bottomline:

1. CGM measures interstitial glucose which can have a 5–10 min lag behind capillary readings. Consider using capillary blood samples (finger prick) to make decisions on insulin administration when the blood glucose is undergoing rapid change (increasing or decreasing rapidly) or at high or low extremes.
2. CGM may not be suitable for all patients, and the patient can reduce engagement with its use over time. Diabetes teams should anticipate this and provide intensive support and education.

6.1. When might we need to withdraw the use of CGM on a patient?

CGM systems are funded by the NHS providing patients fall within the scope of the National Institute of Clinical Excellence (NICE) guidance and NHS criteria for funding Freestyle Libre systems CGM systems are a cost to the NHS. Costs of CGM are typically £3200–£3500 a year. Freestyle Libre is cheaper and costs £900 per patient per year. Whilst they can be very valuable, if they are used infrequently, if there is insufficient engagement in the structured education process required to maximise benefit, or the intended benefits are not realised then they should be withdrawn. Evidence shows that sensor wear of >60% of the time is associated with improvement in HbA1c. rtCGM use during the 1st month was predictive of longer term use of rtCGM 6 months later [36]. If HbA1c was > 7.5% at initiation of sensor use for poor glycaemic control, it would be reasonable to expect an improvement of 0.5% [2]. In cases where HbA1c was < 7.5%, maintenance of HbA1c would be expected along with a reduction in hypoglycaemia or hypoglycaemia unawareness

Clinical bottomline:

1. CGM systems are expensive and requires good engagement by the patient in order to ensure it is a cost-effective strategy.
2. Diabetes teams should ensure regular follow up and discontinue CGM when appropriate.

7. Practical implementation

It is suggested that patients have a trial period with a loan rtCGM system before they are provided with their own personal system because studies with the best clinical outcomes

were those where there was a “run-in” period. In studies with no trial period, subsequent drop out and discontinuation of CGM was high – up to 50% [36]. In younger patients approximately 20% of the patients discontinued rtCGM during the trial phase due to sensor problems. Higher treatment adherence prior to rtCGM was associated with improved adherence. Of those who completed the trial phase and continued with rtCGM therapy, only 40% were using it on a regular basis after six months. The frequency with which rtCGM was used in the first month of therapy was a strong predictor of the likelihood that individuals will continue to use it after six months [36].

In younger children hybrid closed loop therapy may have advantages but children on MDI and other CSII systems still benefit from CGM. If CGM (rt CGM or isCGM) is being considered in addition to the initiation of insulin pump therapy (in patients on MDI), then CGM should be commenced before CSII to achieve optimal adherence [22].

A recent systemic review has concluded that use of sensor augmented pumps and hybrid closed loop therapies with predicted low glucose suspend features are helpful in preventing hypoglycaemia, improving quality of life by reducing fear of hypoglycaemia. They have also shown modest improvement in improving time spent in range and HbA1c [1].

Trials for closed loop therapy have also shown promising results with patients spending more time in range and improvement in HbA1c.

An initial training is likely to ensure maximum benefit is derived. Patients and carers need to commit to training in CGM, including the practical aspects, the assessment and interpretation of results, as well as the day to day management based on CGM trends. Skill test scores for CGM correlate with the degree of improvement. It is important that training for schools is provided and that agreed care plans are in place to avoid the potential for conflict with school due to unrealistic parental expectations. Use of isCGM has shown improved quality of life and reduced diabetes distress in adult population [42]. In children and adolescents, structural diabetes education programme with combined used of flash glucose monitoring improved diabetes related stress score [43].

The ACDC Guideline Group has produced a freely available 4 step educational training package with patient education materials to facilitate education tailored to the specific devices [2].

8. Summary

Real-time CGM with alarms, benefits motivated individuals who are committed to full-time sensor wear. Both CGM and FreeStyle Libre help support improvements in HbA1c and reduce hypoglycaemia. To maximize the clinical benefit, careful patient selection and training is required. It is least effective where diabetes is not well controlled and is not an alternative to investing time and energy in managing diabetes day to day. It does not “automate” diabetes management but is known to reduce diabetes related distress and burden of care especially when linked to a pump (hybrid closed loop therapy) Some families find the additional burden of care it creates unhelpful and there is a high drop-out rate in sensor usage. Freestyle Libre is more acceptable to use by CYP so

should be offered to those who fulfill the NHS tariff criteria. Use of rt CGM to be limited for those who have significant hypoglycaemia and there is clinical need for predictive hypoglycaemia alert and or being considered for hybrid closed loop therapy. It is not appropriate for all patients but provides a valuable tool to support diabetes management for many families.

CGM is definitely the future of diabetes management and may herald the end of SMBG. It has potential to improve diabetes control, reduce the burden of care for CYP living with diabetes.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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