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Continuous Glucose Monitoring (CGM) for Type 1 Diabetes

Diabetes Mellitus and Glycaemic Management

Diabetes mellitus is a condition which results in elevated blood glucose levels (hyperglycaemia); clinical signs and symptoms include polydipsia, polyuria, weight loss, fatigue, blurred vision and recurrent infections (Holt, Kumar and Watkins, 2015). Continued elevation of blood glucose contributes to progressive long term micro and macro vascular complications across multiple organ systems potentially leading to renal, nerve and ocular damage, representing a significant contributor to morbidity and mortality (Bilous, Donnelly and Idris, 2021).

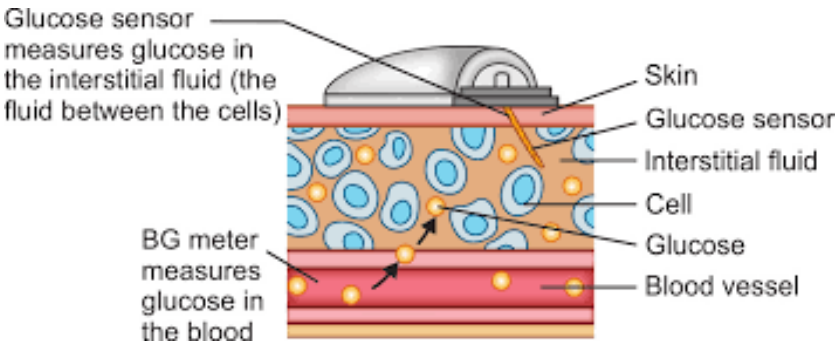
Type 1 diabetes mellitus (T1DM) represents approximately 8-10% of all cases (Holt, Kumar and Watkins, 2015). The pathogenesis of T1DM is complex, principally arising from an autoimmune destruction of insulin secreting beta cells within the pancreas (DiMeglio, Evans-Molina and Oram, 2018).

Optimal glycaemic management, defined as glucose concentrations which mimic those of people without diabetes (normoglycaemia), has long been noted as leading to a reduction in diabetes related complications (DCCT Research Group, 1993). Frequent monitoring of blood glucose via finger prick testing has historically been established as key in achieving effective glycaemic ranges (Kato, Cui and Kato, 2013).

What is Continuous Glucose Monitoring (CGM)?

Technologies are available which now enable people with T1DM to quickly monitor and manage their blood glucose without frequent painful finger pricking, (Leelarathna and Wilmot, 2018;) providing glucose readings with accompanying trend arrows via a subcutaneously implanted device, which measures glucose within the interstitial fluid (Messer *et al.*, 2018) see figure 1.

Figure 1 – CGM example



The device sends the readings to a display device or smartphone and can be worn between 7-14 days depending on the device chosen.

Continuous Glucose Monitoring (CGM) for Type 1 Diabetes

CGM has been shown to be superior to finger prick testing in improving glycaemic management in T1D (reduced HbA1c, reduced hypoglycaemia), particularly for those with elevated HbA1c (Teo *et al* 2021; Leelarathna *et al* 2022). CGM users report improved quality of life and high levels of satisfaction with these technologies (Pickup, *et* al 2015; Lind *et al*, 2017).

CGM provides in-depth data in relation to blood glucose to detect and alert the user to:

- Hypoglycaemic and hyperglycaemic excursions
- Predicted impending hypoglycaemia
- Wide fluctuations in glucose levels (referred to as Glucose variability)

CGM can support the user and their health care team to adjust insulin therapy and provide insight into the effect of behaviours (diet, physical activity) on blood glucose levels (Reddy, Verma and Dungan, 2020).

The quantity of data generated from such devices can be significant and potentially overwhelming for the person with T1D and the healthcare provider, so education and support are essential cornerstones to optimise the use of this technology (Alcantara-Aragon, 2019). Yoo *et* al (2022) demonstrated that users who received structured one-to one education showed better glycaemic outcomes and treatment satisfaction when commencing CGM systems. CGM education should be incorporated into structured education programmes for all people with T1D to ensure that people are empowered to use CGM devices (NICE, 2022).

The development of wearable glucose monitors is a rapidly evolving area of health technology; as device use increases, nurses within primary care will encounter more individuals managing their diabetes with CGM, and so knowledge of such technologies is of importance in the primary care setting.

Real time and Intermittently Scanned CGM (rtCGM – isCGM)

rtCGM systems automatically transmit a continual stream of real time and predictive glucose data (numerical and trends) enabling alerts and alarms via a receiver, smartphone or smart watch (Milne, 2022).

isCGM, commonly referred to as ‘flash’ provides the same type of data but requires the user to scan (or ‘flash’) the sensor to obtain a reading; alarms are available for isCGM but only sound when the sensor is scanned (Edelman, 2018; NHS, 2021). isCGM systems must be scanned at least 8 hourly to obtain sufficient data for a complete glucose profile: 6 scans or more enabling enhanced data (Milne, 2022). A summary of commonly available NHS funded CGM devices is shown in table 1.

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Table 1 (adapted from Marks, 2022; Milne, 2022 and DSN Nurse Forum 2022):

	Freestyle Libre (2)	Dexcom ONE	GlucoRx AiDEX	GlucoMen Day
Device image				
CGM Type	isCGM	rtCGM	rtCGM	rtCGM
Sensor wear time	14 days	10 days	14 days	14 days
Sensor warm up time	60 minutes	120 minutes	60 minutes	55 minutes
High and low alarms	Yes	Yes	Yes	Yes
Predictive alarms	No	No	No	Yes
Calibration needed	No	No	No	Every 48 hrs
Data share with health care practitioner	LibreView	Clarity	CGM viewer	GlucoLog web
Data share with friends / family	Yes	No	Yes	Yes
Wear site	Upper arm	Buttocks /abdomen / upper arm	Abdomen / upper arm	Lower back / abdomen / upper arm

Access to CGM

Until recently, access to CGM systems was variable (DUK, 2019; Crabtree *et al* 2022).

Now all adults with T1D should be offered a choice of rtCGM or isCGM based on their individual needs, preferences, characteristics and the functionality of the device; if multiple devices meet the individuals' requirements, the device with the lowest cost should be selected. NICE (2022) detail the considerations for device selection as part of shared decision making process which should include:

- Accuracy of the device
- Whether the device provides predictive alerts or alarms and if these need to be shared with anyone else (for example, a carer)
- Whether using the device requires access to particular technologies (such as a smartphone and up-to-date phone software)
- How easy the device is to use and take readings from, including for people with limited dexterity
- Fear, frequency, awareness and severity of hypoglycaemia

- Psychosocial factors
- The person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function)
- Whether, how often, and how the device needs to be calibrated, and how easy it is for the person to do this themselves
- How data can be collected, compatibility of the device with other technology, and whether data can be shared with the person's healthcare provider to help inform treatment
- Whether the device will affect the person's ability to do their job
- How unpredictable the person's activity and blood glucose levels are and whether erratic blood glucose is affecting their quality of life
- Whether the person has situations when symptoms of hypoglycaemia cannot be communicated or can be confused (for example, during exercise)
- Clinical factors that may make devices easier or harder to use
- Frequency of sensor replacement
- Sensitivities to the device, for example local skin reactions
- Body image concerns

CGM data

Figure 2 shows typical data from a CGM device; in this example, a smartphone shows the current sensor reading, trend arrow, high- and low alarm levels and trends over the selected numbers of hours represented as a graph.

Figure 2 – DexcomONE smartphone data display

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Trend arrows show the rate of sensor glucose rise or fall allowing for the prediction of impending hypo and hyperglycaemia. Trend arrows for each CGM system show different rates of glycaemic change (e.g., while a double up arrow conveys a rise of > 3 mg/dL/minute for Dexcom rtCGM systems, the isCGM Freestyle Libre system does not have a double up arrow); guidelines for trend arrow-based insulin dose adjustments are specific to each system and users should familiarise themselves accordingly (Marks *et al,* 2022).

Retrospective CGM data is reported in a standardized format known as the ambulatory glucose profile (AGP). The AGP captures the mean sensor glucose, glucose variability (fluctuations in glucose levels), percentage of CGM wear time, and the percentage of time in range (TIR), above range (TAR), and below range (TBR) (Marks *et al* 2022), figure 3 details the targets for these parameters (Wilmot *et al*, 2020). CGM data and the APG (figure 4) can be viewed and shared with clinicians and in some cases friends and family via web-based data sharing.

Figure 3. Time in Range (TIR) targets (Wilmot *et al*, 2020 adapted from Battelino *et al* 2019)

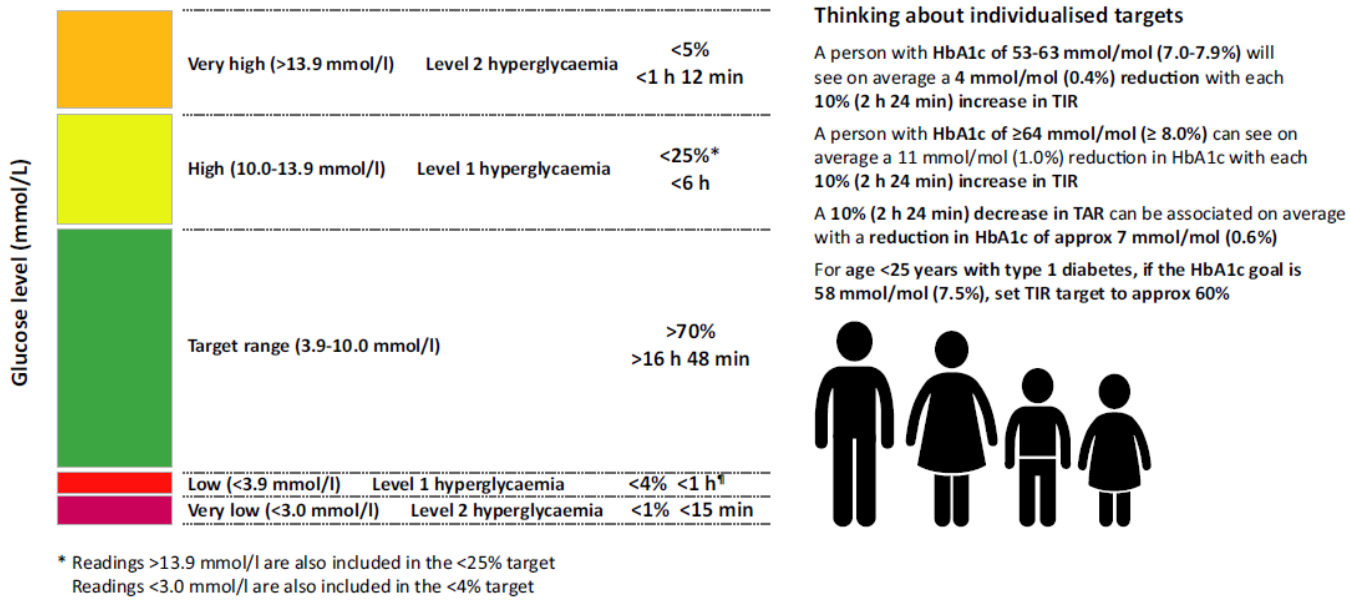

Figure 4. Libre View data from Abbott Freestyle Libre isCGM

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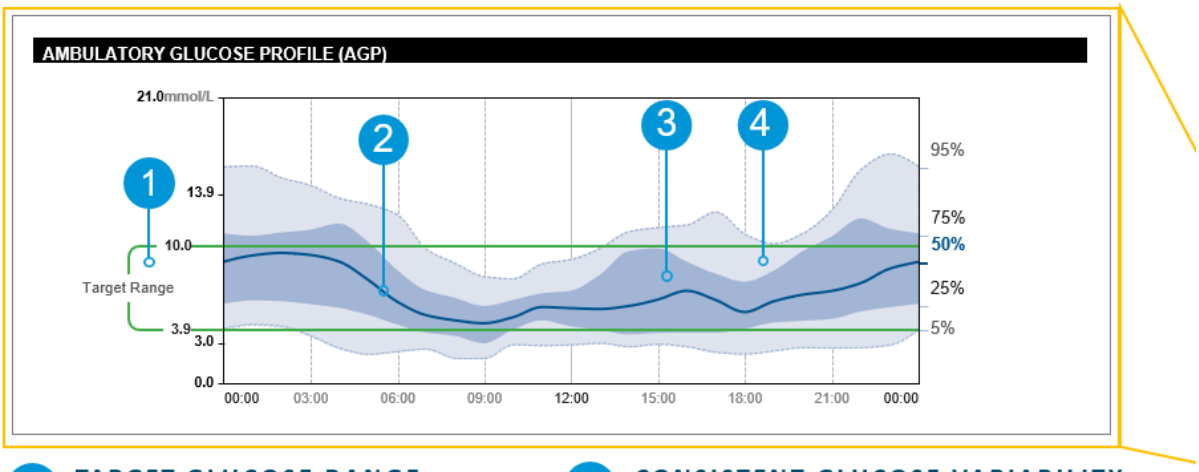

1 TARGET GLUCOSE RANGE

This is where the user wants to be as much as possible.

2 MEDIAN LINE

The dark blue **median line** traces the **average glucose** across the day. It swings upwards or downwards at different times.

3 CONSISTENT GLUCOSE VARIABILITY

The darker blue shaded band, **also known as the interquartile range (IQR),** shows the 50% of glucose readings that are **most consistent** across each day.

4 LESS COMMON VARIABILITY

The lighter shaded band indicates glucose readings that are **less-common across** the average day.

Images are for illustrative purposes only. Not actual patient data.
Bergenstal RM, et al. *Diabetes Technol Ther*. 2013; 15: 198-211

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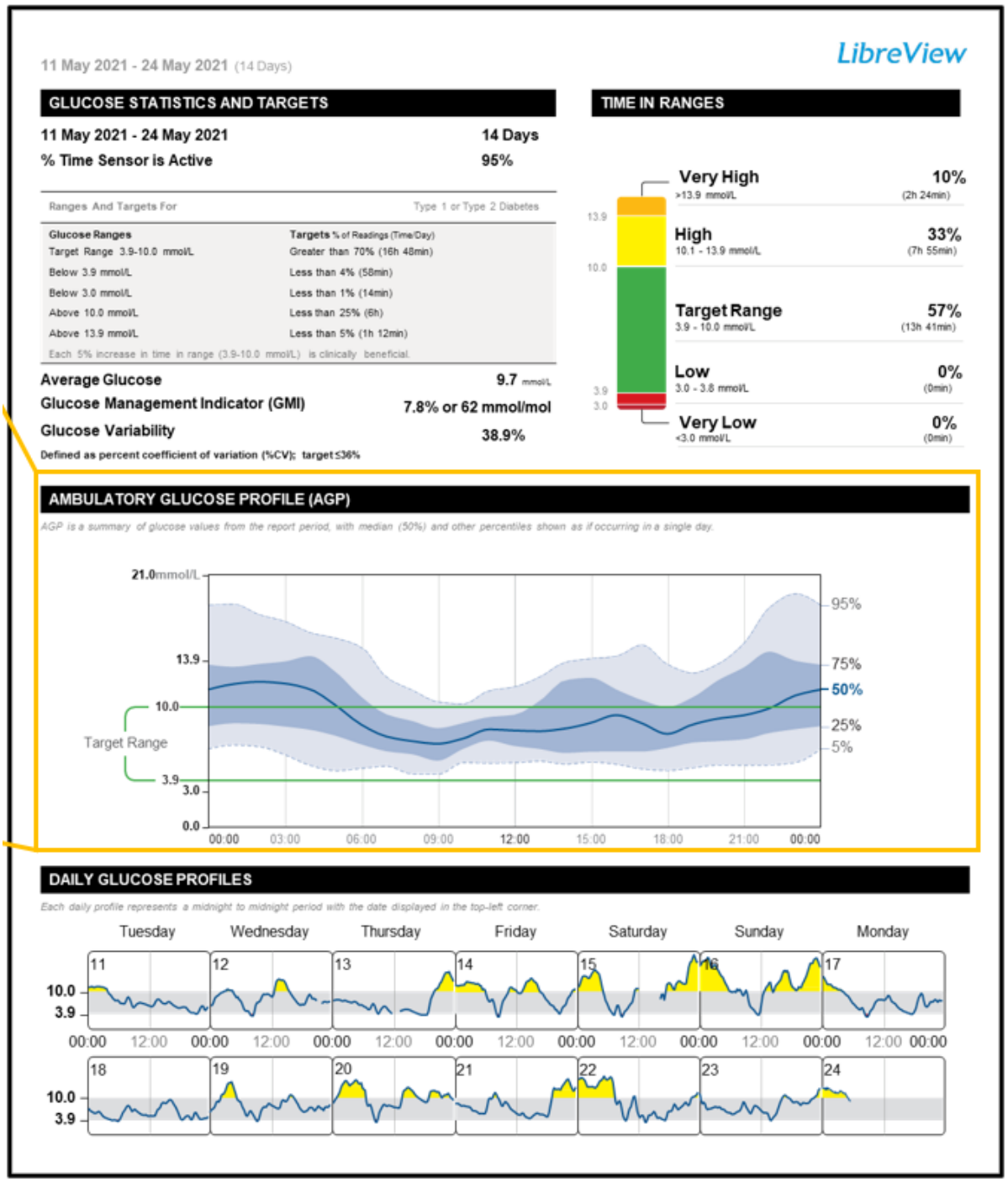

HbA1c is the current gold standard marker of plasma glucose concentrations over the previous 8-12 weeks and is widely used to estimate the efficacy of diabetes management interventions; HbA1c levels in isolation do not reflect day-to-day glucose variability. CGM data allows the observation of daily variations in glucose, time in glycaemic target range and time in hypoglycaemia. This data in addition to HbA1c can enhance diabetes management and self-care; TIR is now an integral component of diabetes risk assessment and therapy. (Chehregosha *et al* 2020; Wilmot *et al* 2020).

CGM Accuracy

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People using CGM should continue to finger-prick test (but frequency can be significantly reduced) in order to:

- Check the accuracy of the device
- Act as a backup in the case of device failure or rapidly changing blood glucose
- Check blood glucose levels when symptoms do not correlate with readings
- Ensure safety to drive for group 2 drivers (buses and large lorries / commercial drivers). Group 1 drivers can use CGM readings unless the reading is 4.0mmol/l or less, where a finger prick check is required.

(DVLA, 2019; NICE, 2022)

Glucose levels in the interstitial fluid are closely correlated with, but not identical to blood glucose levels via finger-prick testing; glucose flows down a concentration gradient between the vascular space and the interstitial fluid creating a delay in CGM readings in comparison to finger prick testing known as 'lag time'; when glucose levels are not changing rapidly, there is a minimal difference but when levels are rising or falling rapidly, CGM may read falsely high or low leading to potential over or undertreatment of hypo / hyperglycaemia. Lag time for isCGM (Abbott Freestyle Libre 2) is typically 2.4 minutes (in adults) and 2.1 minutes in children and for rtCGM approximately 4 -5 minutes depending on the device (Alva et al 2022; Marks et al, 2022, Milne 2022).

A common example of device interference is 'compression hypoglycaemia' where direct pressure is applied to the sensor (for example during sleep) which reduces perfusion to the sensor resulting in false hypoglycaemia; user and clinicians should be mindful of device location when interpreting results; removal of pressure will quickly normalise CGM values (Forlenza, 2017).

Support for CGM use in clinical practice

Regardless of the device chosen, the importance of support and education regarding CGM use is central to ensuring user engagement; increased wear times are associated with greater glycaemic benefit; the frequency of user interaction and appropriate use of data is of vital importance. (Barnard-Kelly and Polonsky, 2020). Figure 5 provides 'Nine tips' to optimise initiation of CGM systems for people with T1D.

Box 2: Nine tips to improve glucose control using CGM (Barnard-Kelly and Polonsky, 2020)

- Wear CGM as much as possible – use CGM to see how food and insulin affect glucose levels
- Share data in a way that works – set boundaries and language that is preferred
- Make alerts and alarms friends not foes

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- Review CGM results regularly (data sharing reports) to observe patters of highs and lows
- Know personal glucose targets – it may take time for levels to improve
- Ensure a plan is in place for preventing and responding to hypoglycaemia
- Test out what harms and helps glucose levels
- Use trend arrows to understand what is going on – trend arrows can give insight into the direction and speed of glucose changes
- Be reminded why committing to CGM is important

Conclusion:

CGM is a technology which is now standard of care for people living with Type 1 diabetes, with potential usage for other forms of diabetes or where monitoring of blood glucose levels is required. Crabtree (2022) posits that as technology evolves and improves, finger prick testing may soon be seen as outdated and impractical, similar to the current perception today of urine testing for blood glucose monitoring. With this in mind, practice nurses will increasingly encounter people with these devices meaning knowledge of CGM, the data generated and the support needed for people living with T1D will become of key importance in contemporary nursing practice.

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Abbott UK for image permissions

Dexcom UK for image permissions

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