Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee

Briefing Paper for APC

NICE Guideline NG28: Type 2 diabetes in adults: management – Continuous Glucose Monitoring

Recommendations for local implementation

Terminology:

Continuous glucose monitoring (real-time continuous glucose monitoring) - rtCGM
Flash glucose monitoring (intermittently scanned continuous glucose monitoring) - isCGM.
Intermittent capillary blood glucose monitoring (self-monitoring of blood glucose) – SMBG
NICE Guideline Committee - NGC
Scope of guidance - Adults (18 years and older) with Type 2 Diabetes

NICE Guideline	*Type 2 diabetes in adults: diagnosis and management* *NG 28* Recommendations 1.6.10 to 1.6.18 Continuous Glucose Monitoring	
Available at	https://www.nice.org.uk/guidance/ng28	
Date of issue	7th May2023	Version 5

Description of technology

Self-monitoring of blood glucose by capillary blood glucose devices

Self-monitoring of blood glucose is an integral part of therapy in diabetes treated with insulin, it involves the measurement of blood glucose concentration by people with diabetes or their carer using self-monitoring devices such as test strips. Capillary blood glucose monitoring involves pricking the finger with a lancet device to obtain a small blood sample at certain times of the day. The drop of blood is then applied to a test strip which is inserted into a blood glucose meter for automated determination of the glucose concentration in the blood sample at the time of the test.

This method of measuring blood glucose control of diabetes is inexpensive compared to the newer technologies. It is more inconvenient and painful for the user and provides limited information on blood glucose levels providing “fixed” data points during the day. Frequency of testing is dependent on the needs for the person. NICE recommend testing 4 times a day before each meal and bed, plus before driving. Many patients may need to test more frequently than this. (1)

Real time Continuous glucose monitoring (rtCGM)

This involves measuring interstitial fluid glucose levels throughout the day and night. A continuous glucose monitor typically comprises a disposable sensor with a tiny cannula inserted into the skin to measure glucose levels, and a transmitter connected to the sensor that sends real time readings wirelessly to a receiver or a smart device that

displays results. The user can obtain real-time data as well as trends, they can then analyse data and respond to changes in real-time or can make changes to insulin delivery, dose or timing based on retrospective data or trends. Some systems allow sharing of the data with their family/carers and health care professionals. Calibration is required for some continuous glucose monitors; hence they are used in conjunction with capillary blood testing. Most monitors can send alerts for high or low glucose levels and rapid rate of change of glucose levels.

Continuous glucose monitoring provides the user access to thousands of data points per day, as well as data trends and analysis and glucose level predictions. It also allows the user access to glucose level 'alerts' for out-or-range low or high glucose levels. (2)

NICE committee recognise that there is no evidence that rtCGM is cost effective for Type 2 diabetes. This is therefore NOT recommended in the guidance but as the rtCGM market is becoming more competitive, if an rtCGM device is equal or less than isCGM then it would be an acceptable alternative. (1)

Intermittently scanned glucose monitoring (isCGM)

Intermittently scanned continuous glucose monitoring, also known as flash glucose monitoring, involves wearing a sensor just under the skin (usually in the upper arm) that automatically monitors interstitial fluid glucose levels. A sensor can be used for up to 2 weeks. A reader or a mobile device with the appropriate app installed can be used to scan the sensor to obtain real-time data as well as trends by scanning the sensor with a reader device (including smart phones). The information provided gives a glucose level and information regarding the rate of change of glucose levels glucose readings. A reader or smart phone with the appropriate app installed can be used to scan the sensor to obtain real time data as well as glucose trends. The information provided gives a sensor glucose level and information regarding direction of glucose level including its rate of change. This rate is indicated as an upward, downward, or oblique arrow. The Freestyle Libre 2 does not have a predictive low or high alarm, but it can be set to alert on high or low glucose settings. This is no longer an isCGM but has now been upgraded to be a rtCGM.

Role of SMBG in patients on CGM

Historically, CGM was used as an adjunct to fingerstick blood glucose testing. Now, most systems (intermittent and real-time) are more accurate and "non-adjunctive," enabling treatment decisions without finger stick blood glucose confirmation if symptoms match glucose levels. However, patients still need to have access to blood glucose meters and test strips during start-up for some CGM devices (the first 30-120 minutes when glucose data are not available) and for when symptoms do not match CGM-reported glucose levels. The requirement for the test strips use will be significantly less when a patient is using CGM.

Type 2 diabetes

Management of blood glucose is a core component of diabetes care.

Complications of Type 2 diabetes

If type 2 diabetes is not well controlled, patients are at risk of long-term complications of hyperglycaemia including microvascular damage such as retinopathy and blindness, nephropathy, neuropathy and are at increased risk of macrovascular complications such as ischaemic heart disease, stroke, and peripheral vascular disease.

Type 2 diabetes in pregnancy is linked to an increased risk of foetal complications such as still birth, neonatal death, malformation, and foetal macrosomia (infant large for gestational age) and maternal complications.

Hypoglycaemia is a common complication in the treatment of type 2 diabetes in which a person's blood glucose is usually below 4 millimoles per litre. In severe hypoglycaemia (defined as having low blood glucose levels that requires assistance from another person to treat.) symptoms can be life threatening and may require emergency treatment and admission to hospital.

People living with type 2 diabetes who have frequent hypos may experience hypoglycaemia unawareness, a situation in which symptoms of hypoglycaemia are not noticed. Loss of hypo awareness is dangerous because people can experience severe hypoglycaemia without recognizing early warning signs. Fear of hypos also contributes to patients underdosing on insulin, erring on the higher blood glucose levels to avoid further

NICE recommendations[1]

Recommendations adults with Type 2 diabetes

1.6.17 Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to adults with type 2 diabetes on multiple daily insulin injections (MDI) if any of the following apply:

- they have recurrent hypoglycaemia or severe hypoglycaemia.
- they have impaired hypoglycaemia awareness.
- they have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)
- they would otherwise be advised to self-measure at least 8 times a day.

For guidance on continuous glucose monitoring (CGM) for pregnant women, see the NICE guideline on diabetes in pregnancy

1.6.18 Offer isCGM to adults with insulin-treated type 2 diabetes who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose.

1.6.19 Consider real-time continuous glucose monitoring (rtCGM) as an alternative to isCGM for adults with insulin-treated type 2 diabetes if it is available for the same or lower cost.

1.6.20 CGM should be provided by a team with expertise in its use, as part of supporting people to self-manage their diabetes.

1.6.21 Advise adults with type 2 diabetes who are using CGM that they will still need to take capillary blood glucose measurements (although they can do this much less often). Explain that is because:

- they will need to use capillary blood glucose measurements to check the accuracy of their CGM device.
- they will need capillary blood glucose monitoring as a back-up (for example when their blood glucose levels are changing quickly or if the device stops working).

Provide them with enough test strips to take capillary blood glucose measurements as needed.

1.6.22 If a person is offered rtCGM or isCGM but cannot or does not want to use any of these devices, offer capillary blood glucose monitoring.

1.6.23 Ensure CGM is part of the education provided to adults with type 2 diabetes who are using it (see the section on education).

1.6.24 Monitor and review the person's use of CGM as part of reviewing their diabetes care plan (see the section on individualised care).

1.6.25 If there are concerns about the way a person is using the CGM device:

- ask if they are having problems using their device.
- look at ways to address any problems and concerns to improve their use of the device, including further education and emotional and psychological support.

1.6.26 Commissioners, providers and healthcare professionals should address inequalities in CGM access and uptake by:

- monitoring who is using CGM
- identifying groups who are eligible but who have a lower uptake.
- making plans to engage with these groups to encourage them to consider CGM.

To NOTE:

- The Area Prescribing Committee (APC) have already recommended that some people with type 2 diabetes currently are recommended to have access to CGM in line with NICE guidance. Those:

  •Who are on insulin, have a learning disability, and are on a learning disability register in line with NHSE guidance (2)

  •Those who are pregnant, on insulin and have severe hypoglycaemia or difficulties managing their blood glucose levels. (NICE N28) and see Surrey PAD

- NICE defines multiple daily insulin injections (MDI) as two or more daily insulin injections, which could either be a basal-bolus regimen or more than one daily insulin injection.

Decision making framework (DMF)

National guidance and priorities

Whilst there is not a legal obligation to fund the recommendations in NICE guidelines in the same way as a NICE Technology Appraisal (TA) or Highly Specialised Technologies Evaluation (HST), healthcare professionals are expected to take NICE guidelines fully into account, alongside the individual needs, preferences, and values of their patients. Each published NICE guideline includes the summary of responsibilities for professionals, practitioners, commissioners, and providers of healthcare relating to the guideline.

The ICS is still expected to have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services and considering their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

The ICS has a statuary duty to ensure decisions are taken to safeguard financial sustainability.

Clinical effectiveness

Most studies from the evidence review for NICE NG28, compared rtCGM against SMBG but a few compared isCGM to SMBG. No studies compared rtCGM with isCGM.

Treatment effectiveness was characterised using a range of outcomes including reduction in HbA1c levels, severe hypoglycaemic events, non-severe hypoglycaemic events, fear of hypoglycaemia, quality of life and patient preferences for different methods of monitoring.

1. **rtCGM vs SMBG**

Ten studies examined the use of rtCGM in comparison to SMBG. Outcomes ranged from high to very low quality. Many of the studies used populations with both type1 and type2 diabetes. Some studies also provided limited information about their inclusion criteria, making it difficult to establish what specific population was included in the study. This is potentially important, as people who have had type 2 diabetes for a long period of time often present with similar characteristics to those with type 1 diabetes. The effects of rtCGM may therefore differ depending on how long the participants in each study have had type 2 diabetes. These differences in populations may have led to the high levels of heterogeneity that were seen between studies for many of the outcomes. This led to wide confidence intervals for many of the pooled estimates, resulting in uncertainty about the effects of rtCGM.

2. **isCGM vs SMBG**

There are four documented studies in the NG28 NICE guidelines that review isCGM for managing adults with type 2 diabetes. Most of these studies are short of <6 months, poor quality and with a small patient size using insulin and non-insulin treatments.

There was a difference in the effectiveness of using isCGM depending on whether the patient was using insulin or not with most effect for those using insulin.

One study by Wada (2020) explored the use of isCGM in patients with type 2 diabetes NOT using insulin. (1)

HbA1c

Comparing SMBG and isCGM there were limited effects of the different types of glucose monitoring. There were only 3 studies referenced by NICE comparing the use of isCGM and SMBG. It was noted from these studies that the greater effect for isCGM than SMBG was often seen up to 3 months but beyond this time the evidence could not be differentiated. (1)

This shows that short term CGM in patients may be a cost-effective use of resources. (1)

Figure 6: HbA1c (% change from baseline) <3 months (MD<0 favours isCGM)

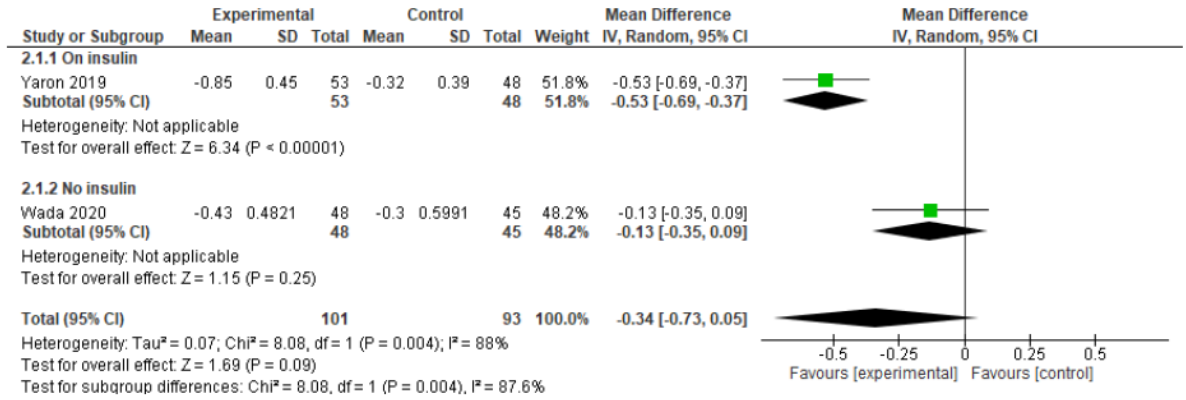
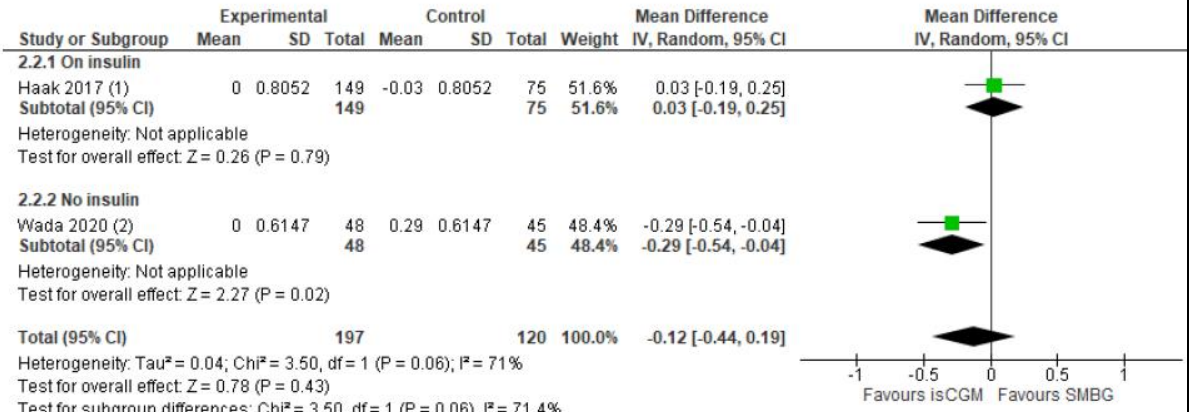


Figure 7: HbA1c (% change from baseline) 3-6 months (MD<0 favours isCGM)



Footnotes

(1) Adjusted mean difference provided by the study. Data was adjusted for imbalances in baseline measurements

(2) Mean difference calculated by the study using baseline values, time and group as covariates

Time In Range (TIR)

The committee agreed that outcomes such as HbA1c and time in range were important for measuring a person's blood sugar levels over time. HbA1c is limited as a specific outcome to define the effectiveness of a monitoring technique by it reflecting the previous 3 months of therapy, whereas time in range is a measurement over a shorter time period. The committee considered time in range to be a better measure than HbA1c as it captures variation over time and can be used to highlight hypoglycaemia and hyperglycaemia, whereas HbA1c gives an average value and does not indicate how often hypoglycaemia or hyperglycaemia occurs. The committee thought that time in range was an important measure when assessing the clinical effectiveness of CGM interventions. However, while there was evidence for both HbA1c and time in range for comparisons between isCGM and SMBG, there was no evidence for time in range for comparisons between rtCGM and SMBG.

Hypoglycaemia

Hypoglycaemic events were raised as one of the most important and concerning outcomes for people who have type 2 diabetes, and so the potential to reduce these events is crucial. The evidence showed reductions in nocturnal hypoglycaemic events and nocturnal time spent in hypoglycaemia with isCGM, although it only showed small reductions in the number of total hypoglycaemic events, with effects less than the minimally important differences (MID).

Quality of life

The evidence review showed that the outcomes do not greatly favour the use of CGM in type 2 diabetes relating to improvement in HbA1c but do greatly favour the use of CGM relating to quality of life and anxiety reduction.

The NGC noted that the evidence for CGM was limited. The NGC highlighted that, in their experience, in current practice there are people with type 2 diabetes who use isCGM and have good outcomes, including those who use insulin and those who do not.

The committee thought that the difference between the evidence and their experience was likely due to the age of some of the studies and the rapid advancements in technology which means that most of the studies do not reflect the most recent versions of CGM devices. **They therefore based their recommendations on their experience as well as the evidence**.

The NGC were aware that with the large number of people who have type 2 diabetes, a recommendation offering everyone the use of CGM would result in high costs to the NHS. They decided that recommendations should be aimed at people who use insulin to manage their diabetes, particularly those who use multiple daily insulin injections. Although CGM can also provide useful information for people who do not use insulin, evidence showed, this group may not receive as much benefit as those who do.

Summary of the evidence for the outcomes that the NICE guidelines review group investigated:

Cohort of T2DM recommended for CGM	NICE guideline group comments
On insulin	Evidence that isCGM was cost effective for those using insulin, but not for those not using insulin. Therefore, recommendations restricted to those using insulin.
Poorly controlled HbA1c	Evidence suggested that isCGM had minimal effects on HbA1c values especially beyond 3 months.
Recurrent or severe hypoglycaemia	Evidence showed reductions in nocturnal hypoglycaemic events and nocturnal time spent in hypoglycaemia with isCGM, although it only showed small reductions in the number of total hypoglycaemic events, with effects less than the meaningful clinical important differences (MIDs)
Impaired hypoglycaemia awareness	**No evidence** was identified for this specific group, the committee thought that it was important to include people with impaired hypoglycaemic awareness in the recommendations because of the potential serious effects of hypoglycaemic episodes. However, they did not recommend specific methods for assessing impaired hypoglycaemic awareness. This is because validated methods for assessing impaired hypoglycaemic awareness in people with type 2 diabetes (such as the GOLD or Clarke scores) are not always available in primary care.

Condition or disability that means they cannot self-monitor	There was no specific evidence for this group, but the committee thought that by giving this group of people access to isCGM, they will no longer have to rely on others to monitor their diabetes, potentially increasing their independence.
Self-testing blood glucose ≥ 8 per day	Recommendations for this as this aligns with funding requirements for NHS England recommendations for Flash Glucose Monitoring in T1DM
Needing help from a care worker or healthcare professional to monitor BG	Helps to provide sufficient, reliable, recordings against which a person's insulin schedule can be adjusted. This will help HCPs to develop a treatment plan to ensure that the person is given insulin at the most effective times, reducing the risk of hypoglycaemic events between home visits.

The NICE guideline committee recognises that the studies reviewed are older and the age of the studies may not reflect recent advances in isCGM. Since the NICE review, more evidence has been published.

Evidence post NICE Review:

1. An Oregon Health Authority evidence base review concluded (4):

    - We have **very low confidence** regarding the impact of CGM on the incidence of severe hypoglycaemia requiring intervention, due primarily to very low rates of reported events in all study groups.
    - We have **low confidence** that CGM are associated with greater reductions in HbA1c over time compared with SMBG. This rating is based on statistically significant findings in 2 US-based RCTs of rtCGM and 1 non-US-based RCT of isCGM that found no between-group differences.
    - We have **low confidence** regarding the comparative impact of CGM on QoL due to mixed results across multiple general and diabetes-specific scales. QoL scores were generally indicative of positive feelings about diabetes treatment and daily functioning across all study groups and scales.
    - There were no eligible studies that reported health resource utilization outcomes.
    - We have **moderate confidence** that AEs attributed to CGM use are infrequent, mostly mild intensity (e.g., skin rash reactions to sensor adhesives), and treatable. Reported events generally do not lead to study or device discontinuation.

2. Evidence from a Canada's Drug and Health Technology Agency (CADTH) Health Technology Review in September 2022 reviewed evidence for rtCGM vs SMBG and showed (5):

- Results from 5 systematic reviews and 1 randomized controlled study suggest that in adult patients, rtCGM may be favoured over SMBG in improving glycated haemoglobin levels, and in lowering time with extreme low or high blood glucose levels. However, the evidence is uncertain due to limited quality evidence.
- In adults, limited safety evidence suggests that rtCGM is safe with low rates of adverse events.
- A cost-effectiveness analysis conducted in Spain found that rtCGM is not a cost-effective option compared to SMBG in adults with type 2 diabetes mellitus.

The NICE evidence review showed the greatest benefit for isCGM was in reducing nocturnal hypoglycaemia and improved quality of life. It had minimal effect on HbA1c.

Where the evidence favoured either isCGM or SMBG, many of the statistical outcomes were less than the minimally important differences (MIDs), suggesting that there were limited effects of the different types of glucose monitoring. Where there was a difference, the greater effect for CGM than SMBG was often seen up to 3 months, but beyond 3 months the evidence could not differentiate between the different monitoring techniques.

The research publications of CGM in Type 2 diabetes are limited but the evidence base is growing and studies of CGM and behaviour change in Type 2 diabetes are ongoing. More long-term studies are needed to assess the clinical effectiveness of CGM on outcomes in people with type 2 diabetes.

Patient safety

- A small number of users may have difficulties inserting the CGM, discomfort wearing it, alarm fatigue and a mismatch of expectations in terms of accuracy or performance.
- Irritation and complications of the skin (degrees of allergic contact dermatitis) may occur from the use of adhesive on the skin with CGM devices.
- The frequency of skin problems is generally mild and infrequent. (6)
- Some CGM devices have alerts which can be set up to help people to alert them if their blood glucose levels are low or high.

Patient factors

- isCGM offers the ability to people with diabetes to share their data on blood glucose control with their healthcare professional and family/carers.
- Use of CGM reduces the need for frequent finger prick testing for self-monitoring of blood glucose.
- NICE recommends that the decision to use an isCGM device should be decided by the healthcare professional and person with diabetes.
- Patient and/or carer education is important and must cover how to use the CGM devices and associated Apps, sharing of data with healthcare professional, family and carers if needed, ordering the sensor and transmitter, and what to do if the sensor is faulty. A lot of education is online and easily accessible.
- isCGM devices can be purchased by members of the public directly from the manufacturers. The manufacturers of CGM provide comprehensive patient support

helplines and on-line education for both NHS and private patients. This though can lead to inequalities for patients who cannot afford to buy the technology.

- Initiation of isCGM in patients by the diabetes teams is carried out both individually and in groups, both face to face and sometimes virtually.
- A receiver to read the CGM results is available for Freestyle Libre 2 and Dexcom ONE for people who do not have a Smartphone.
- People who are Group 1 drivers can now use CGM for the purpose of driving to ensure they are safe to drive. (7)
- **Freestyle Libre 2 can now be used as a rtCGM at no extra cost using a smartphone but NOT a reader. If a reader is used, then the Freestyle Libre 2 behaves as a isCGM.**

Equality & diversity

NICE recommends that commissioners, providers, and healthcare professionals should address inequalities in CGM access and uptake by:

- monitoring who is using CGM
- identifying groups who are eligible but who have a lower uptake
- making plans to engage with these groups to encourage them to consider CGM.

NICE Cost-effectiveness assessment

The main outcomes of interest in the health economic analysis that NICE looked for are:

- Health-related quality of life.
- Adverse events.
- Mortality. (No data found in adults or children)
- HbA1c.
- Time spent in target glucose range (TIR)*
- Hypoglycaemia (including severe hypoglycaemia and nocturnal hypoglycaemia)

Fear of hypoglycaemia and patient preferences for different methods of monitoring were also considered in the health economic analysis. (1)

For the economic analysis, a systematic literature search was undertaken to identify published health economic evidence relevant to the review questions. The health economic evidence study selection considered 14 primary studies. One of these was the Healthcare Improvement Scotland (2018) study which had relevant evidence relating to people with type 2 diabetes in the UK.

The economic analysis was undertaken using a computer program called the IQVIA CORE Diabetes model (CDM) version 9.5 to study the economics. This program predicts how diabetes gets worse over time using a series of connected parts called Markov sub models. This model has been proven to give accurate results.

The economic analysis results showed that isCGM was cost-effective compared with SMBG at a threshold of £20,000 per QALY, while rtCGM was not cost-effective even if we increased the threshold to £30,000 per QALY.

The annual cost per patient of CGM used by NICE in their cost-effectiveness analysis were:

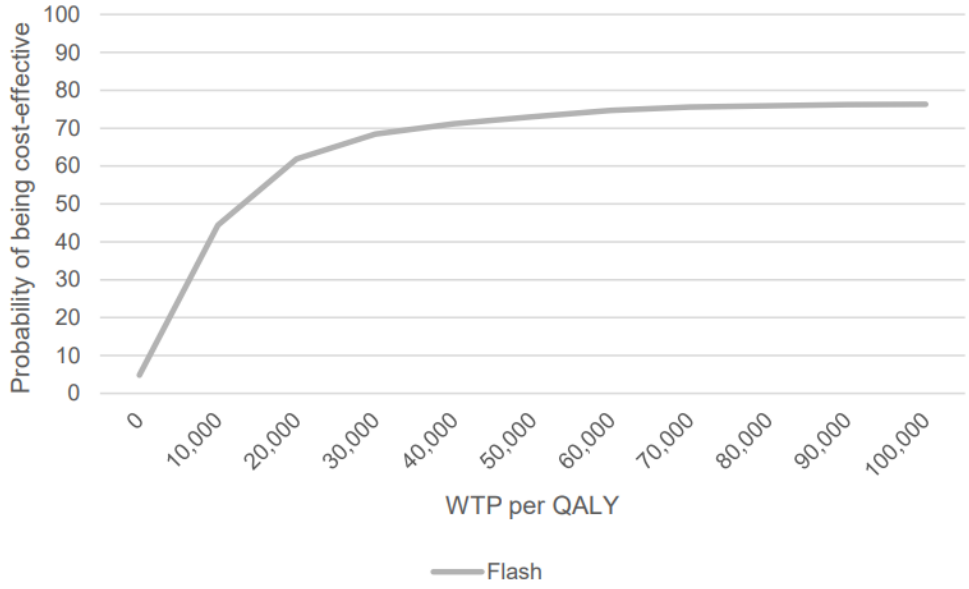
isCGM	£910
rtCGM	£2,000

The NGC carried out a probabilistic sensitivity analysis. The results were reported below in table HE017, and the cost-effectiveness acceptability curves (CEAC) are shown in the graph below(HE002). The probability of isCGM being cost-effective is about 65% at a threshold of £20,000 per QALY. As the threshold value increases, the probability also increases. However, the maximum value is around 80%, indicating that there is much uncertainty around the results

Table HE017: Summary findings of probabilistic sensitivity analyses (isCGM vs. SMBG)

Sensitivity analyses	Costs		QALYs		ICER (vs SMBG)
	IsCGM	SMBG	IsCGM	SMBG	
Probabilistic sensitivity analyses	24,499	19,367	7.505	7.086	12,240

Figure HE002: Cost-effectiveness acceptability curve in probabilistic sensitivity analyses



The cost-effectiveness analysis by NICE has limitations in that it could not differentiate insulin and non-insulin treated T2DM patients in most studies, and that the studies with rtCGM were with rtCGM devices that would not normally be used in T2DM. More research needs to be available to assess cost-effectiveness for non-insulin treated diabetes.

From the evidence, the NGC concluded that rtCGM did not seem to be a cost-effective option for people with type 2 diabetes. isCGM appeared to be cost-effective compared with SMBG at a threshold of £20,000 per QALY, and the results remained robust across all sensitivity analyses. However, the cost-effectiveness of isCGM may only be applicable to insulin-treated type 2 diabetes population in the UK from the evidence available to the NGC.

NICE cost-effectiveness analysis was not able to demonstrate short term cost benefits to the health economy in terms of hospital admissions, ambulance call outs etc. The committee based their recommendations in terms of benefit in outcomes on hypoglycaemia reductions and improved quality of life.

Post NICE NG28, more studies have been undertaken to investigate the cost-effectiveness of CGM in adults with type 2 diabetes.

POST NICE: Evidence for Health Economic Outcomes

Summary of evidence table: Please see appendix 2

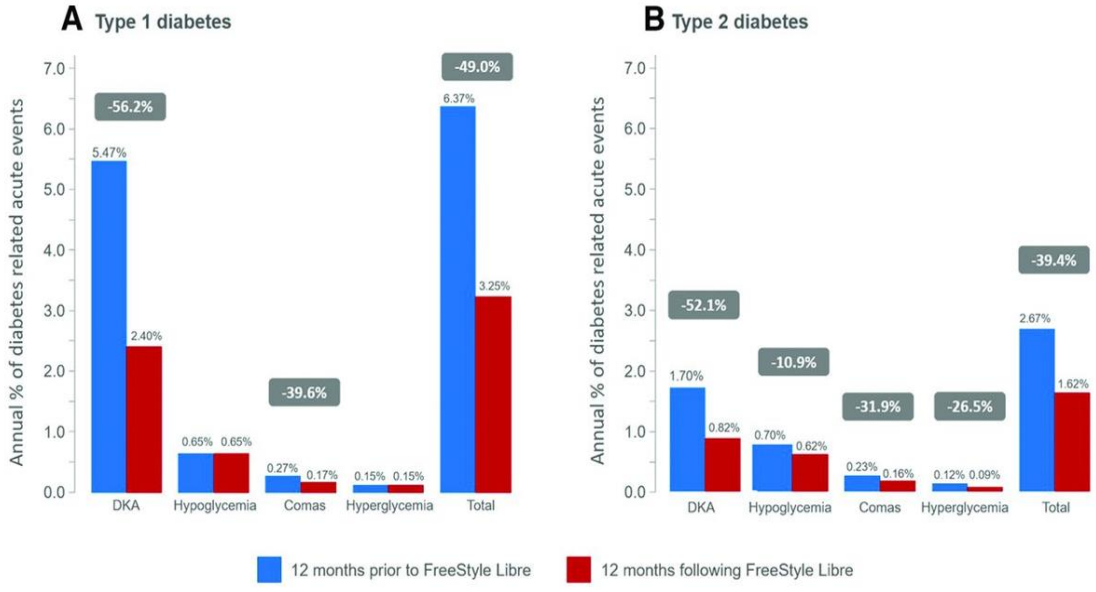
RELIEF STUDY

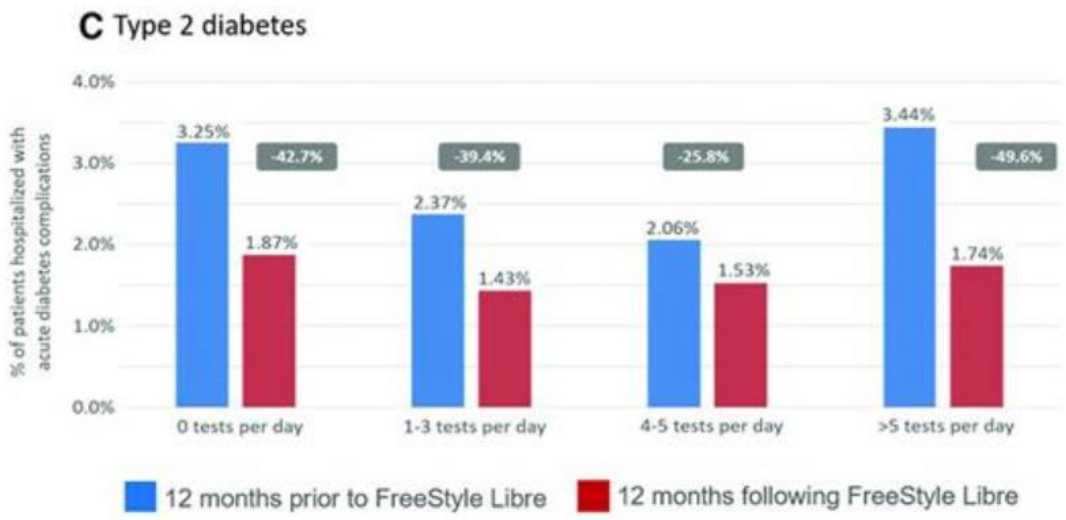
One of the largest studies recently published was retrospective cohort study conducted in France which looked at rates of hospitalisation for acute diabetes complications before and after initiation of isCGM (8).

The study included 31,446 people with T1 diabetes and 41,027 people with Type 2 diabetes who were initiated with Freestyle libre (FSL).

Hospitalizations for DKA, severe hypoglycaemia, diabetes-related coma, and hyperglycaemia were recorded for the 12 months before and 24 months after FSL initiation.

The graphs below show the drop in rates for these outcomes.





The table below shows the change in the number of events per 1000 patients.

	Nature of acute diabetes complication	12 months before FreeStyle Libre initiation*	12 months after FreeStyle Libre initiation*	Change in number of events*
Type 1 diabetes (n=33,165)	Hospitalization for hypoglycemia	7.1	6.8	-0.3
	Hospitalization for coma	2.8	1.7	-1.1
	Hospitalization for DKA	63.9	29.3	-34.6
	Hospitalization for hyperglycemia	1.5	1.7	+0.2
	Hospitalization for at least one acute event	65.4	33.6	-31.8
Type 2 diabetes (n=40,846)	Hospitalization for hypoglycemia	7.6	6.8	-0.8
	Hospitalization for coma	2.5	1.7	-0.8
	Hospitalization for DKA	19.8	11.2	-8.6
	Hospitalization for hyperglycemia	1.2	0.9	-0.3
	Hospitalization for at least one acute event	27.5	16.8	-10.7
Total (n=74,011)	Hospitalization for hypoglycemia	7.3	6.8	-0.5
	Hospitalization for coma	2.6	1.7	-0.9
	Hospitalization for DKA	39.5	19.3	-20.2
	Hospitalization for hyperglycemia	1.4	1.3	-0.1
	Hospitalization for at least one acute event	44.5	24.3	-20.2

* Data are number of events per 1,000 patient years in the 12 months before and after first prescription of FreeStyle Libre sensors.

In the 2-year follow-up, after FSL initiation, hospitalisations for adverse drug events were reduced by 49% and by 48% for people with T1 and T2 diabetes respectively, driven by reductions in DKA.

After 2 years, estimated mean consumption of blood glucose test strips had fallen after 2 years by -82% and by -84% in type 1 diabetes mellitus and type 2 diabetes mellitus,

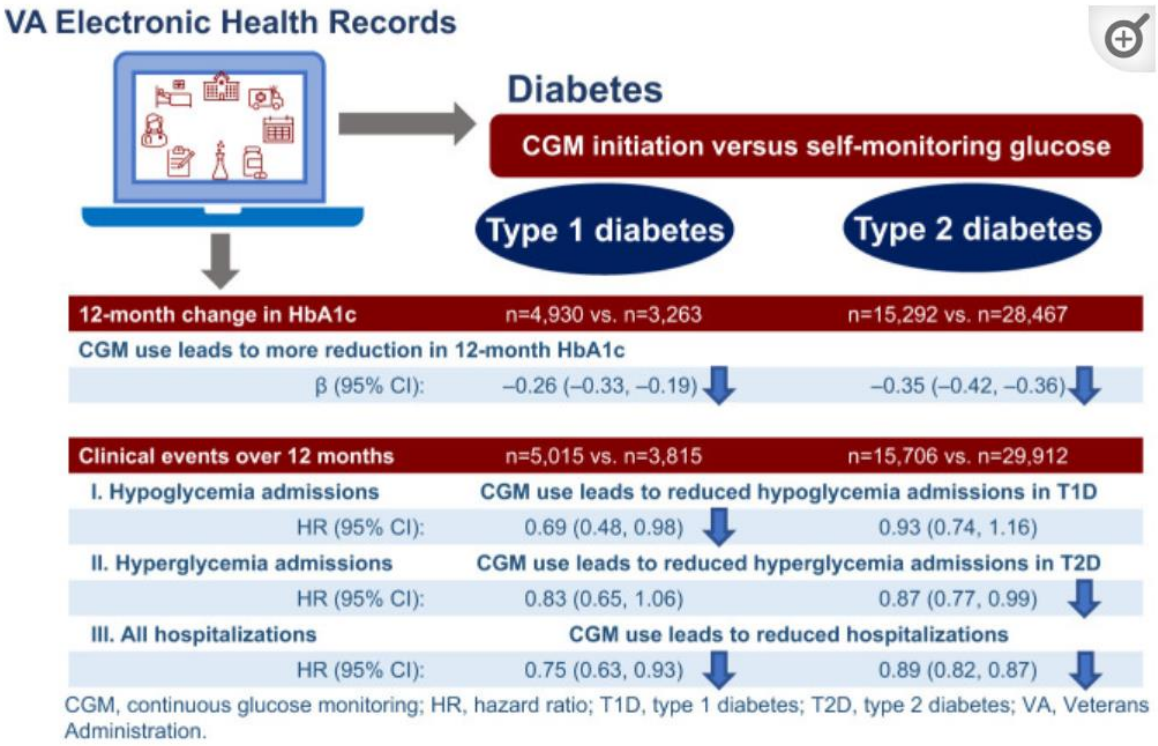
Amongst the whole study population, hospitalisations rates for hypoglycaemia and hyperglycaemia fell by 6.4% and 13%, respectively, with a decrease mainly observed in type 2 diabetes (−10.8% and −26.5%).

Although the percentage drop-in hospitalisation rates fell, the actual numbers are relatively small.

VETERENS STUDY

A retrospective observational cohort study within the USA Veterans Affairs Health Care System was undertaken to determine the benefit of starting continuous glucose monitoring (CGM) in adult-onset type 1 diabetes (T1D) and type 2 diabetes (T2D) regarding longer-term glucose control and serious clinical events.
The study compared glucose control and hypoglycaemia- or hyperglycaemia-related admission to an emergency room or hospital and all-cause hospitalisation between users of CGM and nonusers, over 12 months.

The results showed a reduced risk of admission to an emergency room or hospital for hyperglycaemia and of all-cause hospitalisation for people with type 2 diabetes but there was no significant reduction for hypoglycaemia.



CGM, continuous glucose monitoring; HR, hazard ratio; T1D, type 1 diabetes; T2D, type 2 diabetes; VA, Veterans Administration.

Table 3—Comparison of glycemic control over 12 months among CGM users and nonusers with T1D or T2D

Analysis	CGM users			Non-CGM users			Weighted difference in differences	
	Before baseline	After baseline	Difference	Before baseline	After baseline	Difference	Estimate (95% CI)	*P*
T1D (CGM users, *n* = 4,930; nonusers, *n* = 3,263)								
Mean (SD) HbA_{1c} at 6 months, %	8.54 (1.45)	8.26 (1.33)	−0.28	8.39 (1.56)	8.36 (1.55)	−0.03	**−0.26 (−0.31, −0.21)**	**<0.001**
Mean (SD) HbA_{1c} at 12 months, %	8.54 (1.45)	8.22 (1.35)	−0.32	8.39 (1.56)	8.39 (1.55)	0.0	**−0.26 (−0.33, −0.19)**	**<0.001**
HbA_{1c} <7%, %	11.5	14.8	+3.3	16.5	16.4	−0.1	3.4 (−17.7, 24.5)	0.75
HbA_{1c} <8%, %	38.9	47.0	+8.1	43.2	44.5	+1.3	**6.9 (0.1, 13.6)**	**<0.05**
HbA_{1c} <9%, %	66.0	75.7	+9.7	70.0	69.9	−0.1	**9.7 (7.7, 11.8)**	**<0.001**
T2D (CGM users, *n* = 15,292; nonusers, *n* = 28,467)								
Mean (SD) HbA_{1c} at 6 months, %	8.70 (1.71)	8.17 (1.42)	−0.53	8.26 (1.61)	8.13 (1.58)	−0.13	**−0.39 (−0.42, −0.36)**	**<0.001**
Mean (SD) HbA_{1c} at 12 months, %	8.70 (1.71)	8.21 (1.46)	−0.49	8.26 (1.61)	8.10 (1.60)	−0.16	**−0.35 (−0.40, −0.31)**	**<0.001**
HbA1c <7%, %	12.2	17.2	+5.0	19.2	23.7	+4.5	0.4 (−8.2, 9.0)	0.92
HbA1c <8%, %	36.6	49.6	+13.0	49.1	54.7	+5.6	**7.4 (4.6, 10.2)**	**<0.001**
HbA1c <9%, %	63.1	76.2	+13.1	73.2	76.3	+3.1	**10.0 (9.1, 10.9)**	**<0.001**

Abbreviations: CGM, continuous glucose monitoring; CI, confidence interval; HbA1c, hemoglobin A1c (%); n, sample size; mo, months; T1D, type 1 diabetes; T2D, type 2 diabetes. *P* values <0.05 and associated estimates are in bold. Values presented before or after baseline as mean (SD) or percentage. Sample size is slightly reduced for HbA_{1c} outcomes because those included must have either a preindex HbA_{1c} value, a 6-month postindex value, or a 12-month postindex value. Difference-in-differences estimates reflect LMMs and GEEs with HbA_{1c} status within 6 months before and 12 months after the index date adjusted by overlap weighting from PS models. The reference group for comparisons is CGM nonusers. To convert HbA_{1c} from percentage to mmol/mol, use the formula HbA_{1c}, mmol/mol = (HbA1c, % − 2.152) ÷ 0.09148.

The study found that for the people with type 2 diabetes, there was a significant drop in HbA1c in CGM users with Type 2 diabetes compared with nonusers at 6 (0.39%; 95% CI 0.42, 0.36%) and 12 (0.35%; 95% CI 0.40, 0.31%) months.
No difference in risk of admission for hypoglycaemia, was seen between CGM users and nonusers, but there was a reduction in risk of hyperglycaemia in CGM users (HR 0.87; 95% CI 0.77, 0.99). The risk of all-cause hospitalisation was reduced in CGM users (HR 0.89; 95% CI 0.83, 0.97). (9)

Another recent study investigated whether the use of CGM in people with type 2 diabetes using insulin therapy, would reduce the risk of diabetes-related hospitalisations and concomitant costs. The study found initiation of rCGM (Dexcom G6) among people with T2 diabetes using intensive insulin therapy was associated with a significant reduction in diabetes-related emergency department and inpatient visits and related hospitalisation costs. Expanded use of rtCGM could augment these benefits and result in further cost reductions. This study was however conducted with sponsorship from Dexcom. (10)

Benefit of rCGM on psychosocial outcomes in patients with type 2 diabetes:

A small study with 174 patients, examined the impact of real-time continuous glucose monitoring (rtCGM) on psychosocial outcomes in adults with insulin-using type 2 diabetes.

rtCGM in adults with T2D and on insulin, was associated with significant improvements in diabetes-related psychosocial outcomes over six months. Gains were significantly greater among participants reporting impaired hypoglycaemia awareness and those with higher HbA1c at baseline, thus providing the evidence regarding which users might likely benefit the most. (11)

COST-UTILITY ANALYSIS STUDY

A recent retrospective cohort study carried out a cost-effectiveness analysis of rt-CGM versus SMBG in patients with T2D on insulin therapy in the UK. Results showed that rt-CGM was associated with increased quality-adjusted life expectancy of 0.731 quality-

adjusted life years (QALYs) and increased mean total lifetime costs of £2694, and an incremental cost-effectiveness ratio of £3684 per QALY compared with SMBG. Key drivers of outcomes included HbA1c reduction and reduced fingerpick testing quality of life benefit. Over patient lifetimes, rt-CGM was associated with improved clinical outcomes and is highly likely to be cost effective versus SMBG in people with T2D on insulin therapy in the UK. (12)

META-ANALYSIS: improvements in Glycaemic Control

Jancev et al conducted a systematic review and meta-analysis is to provide a comprehensive overview of the effect of CGM on glycaemic control in adults with type 2 diabetes. The review used Embase, MEDLINE, Web of Science, Scopus and ClinicalTrials.gov from inception until 2 May 2023. Randomised control trials were included investigating real-time CGM (rtCGM) or intermittently scanned CGM (isCGM) compared with self-monitoring of blood glucose (SMBG) in adults with type 2 diabetes. The review found that CGM use compared with SMBG was associated with improvements in glycaemic control in adults with type 2 diabetes (see table below) with a reduction of 3.43 mmol/mol (−0.31%) in HbA1c. This effect was comparable among users of insulin and other oral agents. Furthermore, CGM was associated with a +6.36% increase in TIR and a decrease of −0.66% in TBR, −5.86% in TAR and −1.47% in glycaemic variability. However, all studies were open label. In addition, outcome data on incident severe hypoglycaemia and incident microvascular and macrovascular complications were scarce. (13)

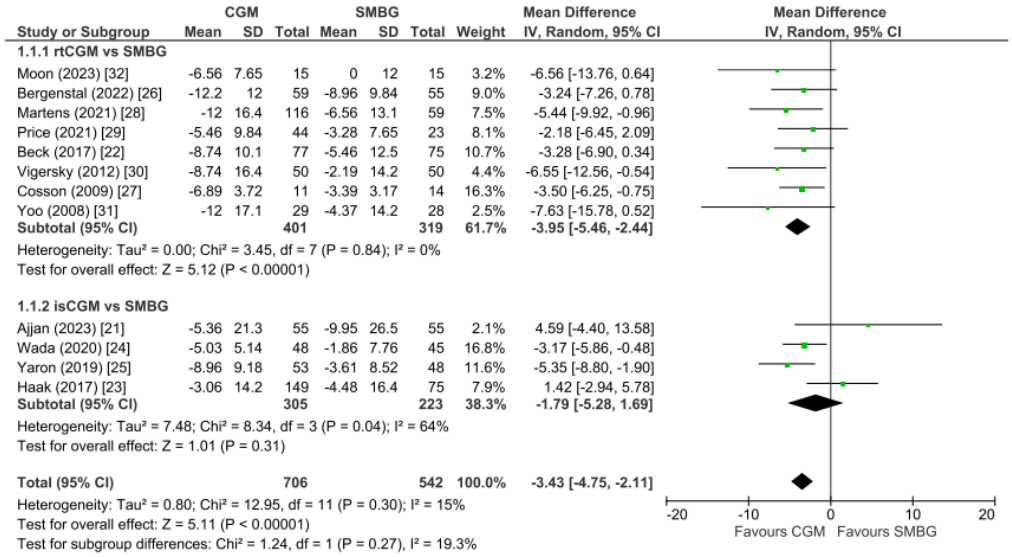


Fig. 1 Forest plot of pooled analysis of change in HbA_{1c} (mmol/mol) in individuals with type 2 diabetes using rtCGM or isCGM compared with SMBG

The table below shows a summary of all the post NICE NG28 studies above. More robust evidence for CGM use in adults with T2 diabetes is needed. More long-term real-world studies need to be undertaken to show evidence for outcome and cost benefit to the NHS.

Costs to health economy

Section 1: Cost of the technology

a. Annual cost per patient:

FP10 prescribed CGM	IsCGM or rtCGM	Annual cost per patient
GlucoRx Aidex	isCGM	£778
Dexcom One	rtCGM	£912
Freestyle Libre 2	**isCGM**- when used with a reader. **rtCGM**- when used with a smartphone	£912

NOTE**: **Freestyle Libre 2(FSL2) has recently been updated to allow people to use it as a rtCGM if they use a smartphone. When the device is used with a reader then it can only be used as an isCGM device. The cost of FSL2 has not increased. Also, Dexcom ONE can be used as a rtCGM and is the same cost as FSL2)

isCGM – this showed benefit over SMBG in the evidence review. When isCGM was compared to rtCGM, isCGM was more cost-effective but it was noted that if the price of rtCGM is similar then the cost-effectiveness becomes similar for both devices.

b. Price relative to comparable medicines:

SMBG average annual cost used by NICE £436/year, but this could be depending on which BGTS are used and frequency of testing.

Section 2: Current spend.

Current Primary care prescribing:

Annual spend on Freestyle Libre and Dexcom ONE for ALL patient groups but **predominantly used by people with type 1 diabetes** (Mar 23 -Feb 23) - £2,972,151 (there is no prescribing of GlucoRx Aidex)

(**Note** this figure does not include current level of growth and represents the time before CGM was recommended for ALL Type1 patients was recommended in Surrey Heartlands in May 2023.)

Section 3: Cost impact

The cost impact is modelled based on optimal use of the Freestyle Libre 2/Dexcom ONE isCGM.

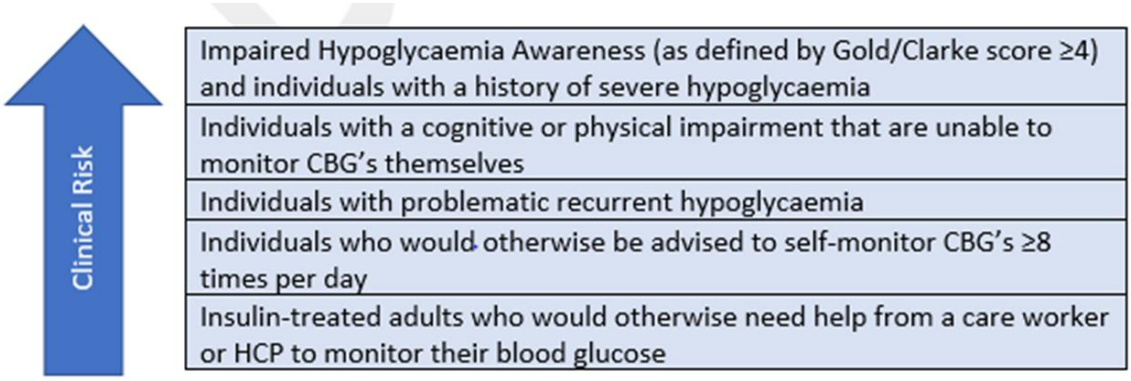
Estimated prevalence of eligible people in Surrey Heartlands (14)

Patient Cohort eligible for isCGM with type 2 diabetes (NG28)	**Estimated prevalence in all type 2 diabetes for patient cohort.**

Frailty and or elderly on MDI (Multiple daily injections/basal bolus)	0.4% (of all T2DM)
People who have a disability (cognitive or physical) that restricts their ability to self-monitor blood glucose	2.5% (of all T2DM) (1% dementia, 1.5% blind)
People with type 2 diabetes who have recurrent or severe hypoglycaemia events.	~30% of cohort with IAH
People needing help from a care worker to administer an insulin injection. (1 or more)	Unknown
Learning disabilities – in line with similar guidance for type 1 diabetes.	0.7% (of all T2DM)
People with type 2 diabetes who have impaired awareness of hypoglycaemia.	10% (T2DM on insulin)
People who would otherwise by advised to self-measure 8 times a day.	~15% (T2DM on insulin)

Robust data is unavailable that can provide accurate numbers for those patients eligible from NICE guidance, for isCGM in Surrey Heartlands. Information from studies and discussions with other ICBs who have access to public health management (PMH) data can help to produce estimates.

London Diabetes Network suggested using a risk stratification for those eligible for CGM:



Cambridgeshire and Peterborough ICS chose the following eligible cohorts for CGM:

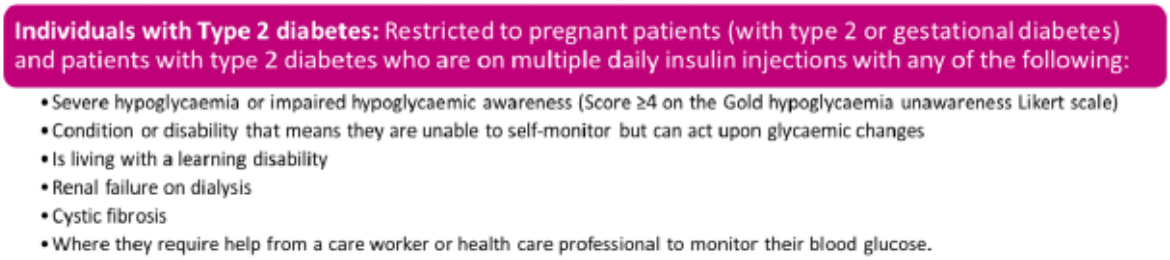


TABLE 1: Estimate of eligible cohorts for CGM in SurreyHeartlands(14,15,16):

What proportion of our T2 population is in eligible cohort?	
Source	% of T2DM population on insulin
UK obs study (Sharma et al, BMJ Open 2015)	23%
Swedish obs study (Norhammar et al, Diabetalogica 2016)	25%
Van Meijel et al, BMJ Open 2020	~ 80% on BD or basal/bolus regimens
Source	% of T2DM population on MDI insulin and eligible high risk cohort
NICE guideline costing template (46% of cohort on MDI of 3.55%)	~1.8%
PHM data, Frimley ICB / Sussex ICB Estimate	5%
NWL obs data (Pearson-Studdard et al, eClinicalMed 2022)	up to 7%
PHM data, Camb & Peterborough ICB (high T2DM prevalance)	~ 10%

To note:

NICE estimated 3.55% of T2DM are on multiple dose insulin (MDI) and around 1.8% of these patients are eligible for CGM.

Published data and PHM profiles suggests this is under estimate.

Some ICBS have access to more accurate public health data to estimate the percentage of patients T2DM patients on MDI who are eligible for CGM.

To estimate cost of CGM, it seems sensible to use Frimley ICS data for Surrey Heartlands as this is a neighbouring ICB and will have a similar population and has access to more accurrate public health data. From the table above, we can assume that **5%** of people with type 2 diabetes on MDI would be eligible for CGM based on NICE NG28 criteria.

Surrey Heartlands:

- Prevalence of T2DM = 4.3%
- 45,605 patients (Diabetes Audit data [NDA] audit data 21/22)
- Patient numbers increasing by 0.1% per year
- Prevalence of T2DM in 5 years (2027/28) = estimate 4.7%
- 51,241 patients (estimate)

TABLE 2: **Costs for patients in 5 years:**

		CGM costs ~£900/patient/ year. Some reduction in BGTS costs ~£160,000 to ~£200,000			
Source	% of T2DM population on MDI insulin and eligible high risk cohort	Patient numbers (5 year projection)	Annual CGM costs if 100% uptake	Annual CGM costs if 80% uptake	Annual CGM costs if 50% uptake
NICE guideline costing template (46% of cohort on MDI of 3.55%)	~1.8%	922	£830,104	£664,083	£415,052
PHM data, Frimley ICB / Sussex ICB Estimate	5%	2,562	£2,305,845	£1,844,676	£1,152,923
NWL obs data (Pearson-Studdard et al, eClinicalMed 2022)	up to 7%	3,587	£3,228,183	£2,582,546	£1,614,092
PHM data, Camb & Peterborough ICB (high T2DM prevalance)	~ 10%	5,124	£4,611,690	£3,689,352	£2,305,845

Using NDA data, if all current eliglibel patients take up the technology straight away, cost to the ICB could be upto £2,305,845 with 100% uptake of the technology. This is significantly more than NICE estimates.

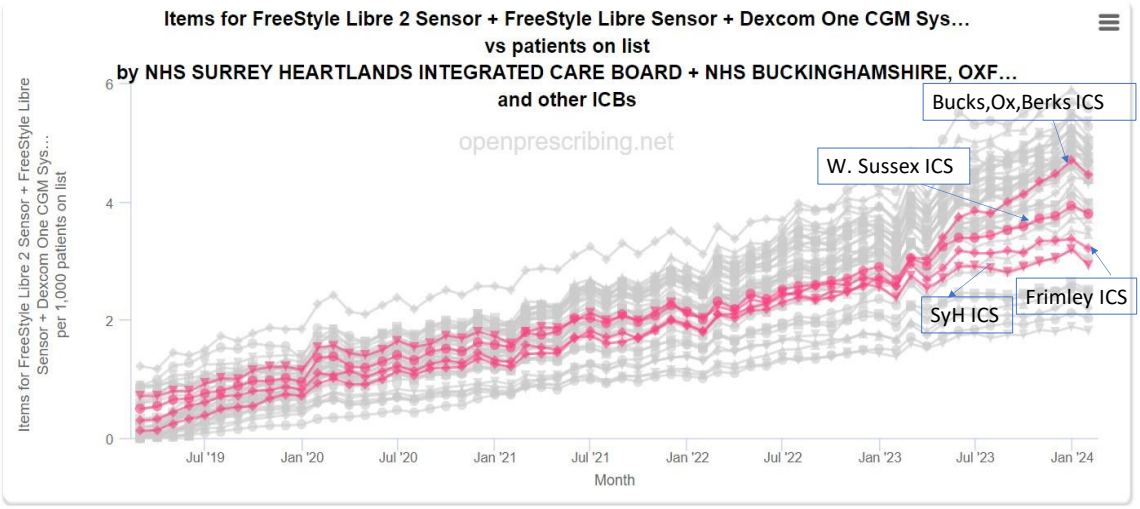
This is because NICE estimates that SyH will have 922 eligible patients vs 2,562 estimated from the Frimley PHM data.

This does not take into consideration the potential and speed of uptake of CGM.

The cost of implementing this technology for patients with type diabetes on MDI, **exceeds £100k per place.**

Comparison of CGM prescribing with neighbouring ICSs

- Frimley ICS have made CGM available for a limited number of people per year, in adults with T2 diabetes as per NICE N28 guidance.
- Sussex ICS have not made CGM available for adults with T2 diabetes as per NICE N28 guidance but have since a steady rise in the use of CGM.
- Berkshire, Oxfordshire and Buckinghamshire have made CGM available to all adults with Type 2 diabetes as per NICE NG28 guidance. The increase in CGM uptake has been less than expected by clinicians in the ICB but there has been a steady rise. (see graphs below from OpenPrescribing data)



Using the findings from the RELIEF study to predict outcomes in our own system could potentially help balance out the costs of implementation. (8)

The table below shows the number and costs in the last year Jan-Dec 23, for Surrey Heartlands ICS of some of the outcomes measured in the RELIEF study. Unfortunately, the number of events cannot be attributed to type 1 and type 2 patients, so it is hard to calculate savings accurately, but some savings may be realised albeit not enough to offset the costs of implementation.

	Activity & Unit Costs	Year to Date Cost
Costs for an episode to treat someone admitted with diabetic ketoacidosis (DKA)	£3,317	
Number (1 yr if poss for all number of episodes in table) of diabetic ketoacidosis (DKA) admissions	314	£1,041,539
Costs for an episode to treat someone admitted with diabetic coma	£4,019	
Number of people admitted with diabetic coma	8	£32,148
Costs for an episode to treat someone admitted for hypoglycaemia	£2,824	
Number of people admitted for hypoglycaemia	265	£748,251

Governance and medicolegal implications

At CGM initiation, patients must be told that if they invite their healthcare professional (HCP) to share their data, their data will only be looked at by the HCP when it is needed for instance

during a consultation. They cannot assume that the HCP will be alerted if the data shows any readings that are out of range.

For community nursing teams managing housebound patients, they can use the continuous glucose monitor readings in the same way as SMBG for administering insulin. Any concerns that are identified can then be communicated to the patient's diabetes clinician who can address these in the same way as they would had done had the patient been using SMBG for monitoring their blood glucose levels. The process for managing the blood glucose levels would be the same for CGM as it would for SMBG. The only difference being that the data for blood glucose levels is received in a different format. Responsibilities for reviewing this data would not be changed.

Implementation in Neighbouring ICBs

- Kent - approved clinically as per NICE NG28 criteria but waiting for funding approval.
- Sussex – recommendations have not been agreed and paper yet to be presented to their APC.
- Northwest London- recommendations have not been agreed and paper yet to be presented to their APC. For now, their holding statement advises clinicians not to prescribe CGM or flash glucose monitoring for patients with type 2 diabetes in primary care.
- South-West London have approved for people with type 2 diabetes who fall within one of the following cohorts:
    - People on haemodialysis and on insulin treatment, who are clinically indicated, defined as those requiring monitoring more than 8 times daily, as demonstrated on a meter download or on review, in the last 3 months.
    - People with diabetes associated with cystic fibrosis on insulin treatment.
    - People who are living with a learning disability that is recorded on their GP learning disability register.
- Frimley – approved clinically as per NICE NG28 criteria and are using in a small group of 40 patients each year to understand the benefits.
- Hampshire Isle of wight – approved as per NICE NG28 criteria.
- Buckinghamshire, Oxfordshire, and Berkshire West. – approved as per NICE NG28 criteria.

Stakeholder views

(SEE ALSO APPENDIX 1 FOR VIEWS POST FIRST CONSULTATION)

Prior to wider consultation an engagement meeting was held with clinicians from Surrey Heartlands.

The following was noted from the discussions:

- A consensus on prioritisation of cohorts to receive CGM could not be reached.
- It was suggested a pilot scheme would be beneficial to understand challenges of implementation. Patients in care homes and housebound were recognised as potential cohorts for the pilots. It was noted that currently, district nurses do not have technology that would allow them to upload a patient's data before insulin administration. Also, patients who do not have access to technology such as home Wi-Fi would be at a disadvantage. Care home staff would all need to be upskilled before implementation of any guidance.
- It was highlighted that the lack of diabetes clinicians across the system would mean the current workforce would struggle to manage the extra workload implementation would cause.
- The traffic light status of CGM and the role of secondary care and primary care services was discussed but a conclusion could not be drawn as to which of these services should initiate CGM and timeframes for review. In both secondary care and primary care staff have high workloads and there are increasing staff shortages.

- The current workforce in primary care would need to be upskilled if the NICE guidance was to be implemented. The manufacturers of the CGM devices are willing to help with upskilling the workforce but this would take time.
- It was noted that medico-legal issues should be considered, as if CGM data is shared with GP practice they have a duty of care to review and do something about it if there is a problem, but capacity issues of being able to do this in a timely manner may prove difficult.

Considerations to Implementation

The APC is asked to note the following:

- The NGC recognised the benefits to adults with type 2 diabetes for using isCGM and that implementation of the recommendations from NG28 would result in higher shorter-term costs to the NHS. In the longer term, if patients are more confident in managing their diabetes and better controlled, they will require less appointments from HCPs and develop fewer diabetes complications which cost more for the NHS than the treatment of diabetes.
- Surrey Heartlands ICB currently has financial strains and the ICB has a statuary duty to strive to safeguard financial sustainability. The high cost of implementation would increase the risk of not achieving budget targets. NHS England has not provided any extra funding for ICBs to implement the guidance.
- The workload needed for implementation of CGM in the cohort of patients recommended by NICE NG28 would be only manageable if CGM was initiated by primary and secondary care. Currently, there is a shortage of diabetes clinicians across the system and implementation would increase workload on systems that are already extremely strained. For implementation to be successful, education would need to be provided for staff to be upskilled to interpret and communicate CGM data effectively and comply with NICE guidance NG28 1.6.20. This requires that CGM should be provided by a team with expertise in its use, as part of supporting people to self-manage their diabetes.
- Medicolegal concerns- At CGM initiation, patients must be told that if they invite their healthcare professional (HCP) to share their data, their data will only be looked at by the HCP when it is needed for instance during a consultation as they would SMBG readings. They cannot assume that the HCP will be alerted if the data shows any readings that are out of range. CGM utilisation in remote patient management can lead to reduced clinician time, resulting in cost savings, and offering added convenience for patients.
- NICE's cost-effectiveness and outcome evidence is marginal at £20,000 per QALY for isCGM and £30,000 for rtCGM. (This is based on rtCGM priced at £3000)
- There is limited evidence to show outcomes benefit of CGM use and more research is needed to show benefit.
- The evidence review showed that the outcomes do not greatly favour the use of CGM in type 2 diabetes relating to improvement in HbA1c but greatly favour the use of CGM relating to quality of life and anxiety reduction.
- The NGC thought that the difference between the evidence and their experience was likely due to the age of some of the studies and the rapid advancements in technology which means that most of the studies do not reflect the most recent versions of CGM devices. They therefore based their recommendations on their experience as well as the evidence.
- The RELIEF study (8) and the VETERANS study (9) has demonstrated that the use of CGM can notably decrease adverse events like DKA and hypoglycaemia, which are known causes of hospitalisation, thereby offering potential cost savings

for the healthcare system albeit only small cost savings as actual number of decreased events was small.

The APC is asked to make the following recommendations.

A. In line with NICE NG28, to offer intermittent or real time continuous glucose monitoring to patients with type 2 diabetes who are on multiple daily insulin injections if any of the following apply:

    1. they have impaired hypoglycaemia awareness (Gold/Clarke score ≥4)
    2. they have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them).
    3. they have recurrent hypoglycaemia or severe hypoglycaemia.
    4. they would otherwise be advised to self-measure at least 8 times a day.

B. To continue to offer CGM for adults:
    a. With type 2 diabetes treated with insulin and who are living with a learning disability which is recorded on their GP learning disability register, in line with updated NHS England guidance from November 2020.
    b. Pregnant women with NON Type I Diabetes requiring insulin with problematic severe hypoglycaemia or unstable blood glucose in line with NICE guidance.

C. To recommend the following traffic light status for the use CGM for adults with type 2 diabetes on multiple daily insulin injections for the following CGM **(see accompanying comparison table and choices recommendations):**

    GREEN traffic light status to the following prescribable CGM available on FP10.:

    - Freestyle Libre
    - Freestyle Libre 2
    - Freestyle Libre 2 plus
    - Dexcom One
    - Dexcom One Plus

    Non preferred status to all other prescribable CGM devices: Freestyle Libre (more costly than Freestyle Libre 2/2plus with no added benefit)

    - All hospital only CGM that is not available on FP10 should be assigned a Non-Formulary TLS

D. To recommend the Surrey PAD narrative:

    Continuous glucose monitoring is considered GREEN for adult patients with type 2 diabetes on multiple daily insulin injections if any of the following apply(please see CGM formulary for this cohort of people):

    1. they have impaired hypoglycaemia awareness (Gold/Clarke score ≥4)
    2. they have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their

blood glucose by capillary blood glucose monitoring but could use an CGM device (or have it scanned for them).
3. they have recurrent hypoglycaemia or severe hypoglycaemia.
4. they would otherwise be advised to self-measure at least 8 times a day.

APPENDIX 1

Post first consultation, stakeholders provided more clarity on the cohorts of people with type2 diabetes they would expect to have access to CGM. Some of these cohorts would only require CGM for a limited time. Most of the cohorts suggested were those who would have initiation of CGM in a secondary care setting by specialist teams.

SUGGESTED COHORTS OF PEOPLE WITH TYPE 2 DIABETES TO CONSIDER FOR CGM:

1. Those patients presenting with diabetic foot ulcer/arthropathy presenting in MDT foot clinics and continued care in community podiatry clinics.
2. People with type 2 diabetes on multiple insulin injections daily attending diabetes clinics with specialist teams to start CGM for these patients while discouraging routine referral to specialist care specifically for this purpose.
3. Post bariatric surgery hypoglycaemia patients. This is a small cohort of patients, post-surgery who have serious hypoglycaemia. They may need CGM for only a short period of time.
4. Pancreatic (Type 3c) diabetes - often have more fluctuating and 'brittle' glucose control and clinically behave more like Type 1 diabetes. Due to lack of glucagon secretion, they can also have severe hypos that need monitoring.
5. Housebound patients who as they are more susceptible to episodes of hypoglycaemia and therefore a greater risk of falls.

Meeting with regional Diabetes Lead Dr Gary Tan

Dr Tan addressed some of the concerns that Surrey Heartland clinicians had regarding the implementation of CGM.

He shared his and experiences of other neighbouring ICBs who have approved CGM in patients who fit NG28 criteria (see above). These ICBs have managed to roll out training and education easily and have not had any problems with implementation.

- Workforce:

  Using CGM will likely reduce the frequency of visits by patients as patients can be easily managed remotely using the data produced by the CGM data

platform. The data produced has more information than that provided by self-monitoring and allows patients to bring their blood glucose levels in control faster, **thereby reducing need for clinic appointments.**

- training and education:

  This had been rolled out with help from pharma and one ICB found organising a one-day online training event to be very useful.

  The training and education for those clinicians who do not have an interest in diabetes and are not as familiar with using the data produced by the CGM data platforms, was found to be useful and allayed any reservations they had for using it.

- Initiation:

  In all ICBs that have approved this, primary and secondary care teams have initiated patients. The use of videos and training modules available on manufacturers' websites has streamlined the initiation process, demanding less clinician time than initially expected.

  In neighbouring ICBs, the adoption of this technology has been slower than expected, with fewer patients expressing interest in its utilisation than anticipated.

Appendix 2

Stdy and weblink	Study Design & length	Population/sample size	Intervention	Comparator	Follow up	Primary and secondary outcomes (PO/SO)	Results and comments
Roussel et al: Relief study https://diabetesjournals.org/care/article/44/6/1368/138708/Important-Drop-in-Rate-of-Acute-Diabetes (8)	retrospective study on hospitalisations for acute diabetes complications	74,011 patients with T1DM or T2DM: 88% on MDI (n = 46,828) or a insulin pump (n = 18,593). The remaining 12% had T2DM +basal insulin injection/oral agents.	CGM	Number of hospitalisation before and after initiationon	12 mths and 2 yr follow up	**PO**: Hospitalisations for diabetic ketoacidosis (DKA), severe hypoglycemia, diabetes-related coma, and hyperglycemia were recorded for the 12 months before and after initiation.	As this study was conducted on a single nationwide database, no statistical probability tests were performed to compare the frequency of events before and after FreeStyle Libre system initiation. Hospitalisations for acute diabetes complications fell in type 2 diabetes (39.4%), DKA fell by (52.1%), as did diabetes-related comas (31.9%). Hospitalizations for hypoglycaemia and hyperglycaemia decreased in type 2 diabetes (10.8% and 26.5%,respectively). Persistence with FreeStyle Libre at 12 months was at 98.1%. .

Reaven 2023: USA Veterans Affairs Health Care System Study. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10260873/ (9)	retrospective observational cohort study.	n=4,930 using CGM vs. n=3,263not using CGM, with T1DM and n=15,292 with CGM vs not using CGM n=28,467 with, T2DM	CGM	SMBG	12mths	**PO:** 1. HbA1c 2. hospital admission due to a hypoglycemia event 3. hospital admission due to a hyperglycemia event. 4.all-cause hospitalization **SO:** change in the percentage of patients achieving HbA1c alues below 7%, 8%, and 9% during this time window	1. Decline HbA1c was greater in CGM users with T2D compared with nonusers at 6 mths (-0.39%;95% CI [-0.42, -0.36%]) and 12mths (-0.35%;95% CI [-0.40, -0.31%]). 2. In patients with T2D, no staistically significant difference in risk of admission for hypoglycaemia seen between CGM users and nonusers 3. A statistically signifciant reduction in risk of admission for hyperglycemia in CGM users (HR 0.87; 95% CI 0.77, 0.99). 3.The risk of all-cause hospitalisation was reduced in CGM users (HR 0.89; 95% CI 0.83, 0.97) 4. The percentages of patients with T2D achieving <8 and <9% after 12 months were greater in CGM users than in nonusers
Hannah et al. https://pubmed.ncbi.nlm.nih.gov/38619722/ (10)	retrospective analysis of US healthcare claims data	n= 790	CGM	Hospitalisation 12mths before and after CGM inititation	12mths	Diabetes-related emergency department visit and hospitalisations	Those with ≥ 1 ED visit decreased by 30.0% (p = 0.01) and with ≥ 1 inpatient visit decreased by 41.5% (p < 0.0001)

Soriano et al: https://journals.sagepub.com/doi/abs/10.1177/193229682210994831 (11)	cross sectional observational study	n=174	CGM	Answers to questions before and after CGM	6mths	Diabetes distress, hypoglycemic confidence, hypoglycemic fear, device-related emotional burden, and device-related trust before and after a six-month trial of rtCGM. Hemoglobin A1c (HbA1c) was assessed at the same time points; impaired hypoglycemic awareness (IAH) was assessed at baseline.	Significant improvement observed in hypoglycemic fear (P = .031), hypoglycemic confidence (P < .001), diabetes distress (P < .001), and device-related emotional burden (P < .001).
J. Issitt et al : https://journals.sagepub.com/doi/abs/10.1177/193229682210994831 (12)	retrospective cohort study of insulin treated patients with T2D from the Kaiser Healthcare Delivery System and Diabetes Registry	rtCGM n= 344 and SMBG n=35,736	rtCGM	SMBG	The time horizon used in the analyses was set to the remaining lifetime of the patients (30 years)	Long-term costs and clinical outcomes were estimated using the CORE Diabetes Model, with clinical input data sourced from a retrospective cohort study.	Rt-CGM was associated with an ICER of £3684 per QALY gained. Based on a willingness-to-pay threshold of £20,000, the probability of rt-CGM being cost-effective versus SMBG was 70.8%, and the probability of rt-CGM being cost saving was 38.7%. These findings were robust under a wide range of plausible assumptions around key input parameters

Jancev et al : https://link.springer.com/article/10.1007/s00125-024-06107-6 (13)	Systematic review of open-label studies in adults with type 2 diabetes with or wothout insulin.	12 RCTs comprising 1248 participants, with eight investigating rtCGM and four isCGM.	rtCGM, isCGM	SMBG	N/A	HbA1c and Time in Range (TIR) Sever hypoglycaemia incidence Macrovascular complications	Compared with SMBG, CGM use (rtCGM or isCGM) led to a mean difference (MD) in HbA1c of −3.43 mmol/mol (−0.31%; 95% CI −4.75, −2.11, p<0.00001, I2=15%; moderate certainty. This effect was comparable in studies that included individuals using insulin with or without oral agents (MD −3.27 mmol/mol [−0.30%]; 95% CI −6.22, −0.31, p=0.03, I2=55%) CGM was associated with an increase in TIR (+6.36%; 95% CI +2.48, +10.24, p=0.001, I2=9%) In comparison with SMBG, CGM use led to a non-statistically significant difference in the incidence of severe hypoglycaemia (RR 0.66, 95% CI 0.15, 3.00, p=0.57, I2=0%) and macrovascular complications (RR 1.54, 95% CI 0.42, 5.72, p=0.52, I2=29%).

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VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1	*12 July 23*	*PO*		*Out for first consultation*
V2	*26 July 23*	*PO*		*Post first consultation*
V3	*15 October 23*	*PO*		*Out for consultation after amendments to change the cohort recommended for CGM following first consultation*
V4	*11th March 2024*	*PO*		*Out for consultation after adding in information about outcomes evidence from CGM use in patients with Type 2 diabetes.*
V5	*7th May 2024*	*PO*		*Out for Consultation after adding:* • *clarification of NICE cost-effective analysis,* • *more recent ICS data* • *additional studies investigating cost-effectiveness.* • *Prescribable CGM comparison chart was updated with information about new updated CGM devices.*

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