NHS North East London
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North East London implementation document for continuous glucose sensors for adults with insulin-treated type 2 diabetes

Document control	
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Scope and rationale

The National Institute for Health and Care Excellence (NICE) Guideline for adults with type 2 diabetes (NG28) was amended in June 2022 to include access to continuous glucose monitoring (CGM) technologies for a specific cohort of adults living with type 2 diabetes. This document is based upon the Type 2 diabetes in adults: management NICE guideline [NG28] to aid local implementation in North-East London (NEL) for adults with type 2 diabetes to help ensure equitable access.

This implementation document is for use by secondary care, community diabetes specialist services and primary care diabetes health care professionals to assess if people aged ≥18 years living with type 2 diabetes are suitable for intermittently scanned Continuous Glucose Monitoring (isCGM, commonly referred to as 'flash') or real time Continuous Glucose Monitoring (rtCGM).

This document is based upon the work started by the pan-London implementation group for continuous glucose sensors for adults with type 2 diabetes and is intended to aid local implementation in NEL for people with type 2.

Capacity of Services

It has been recognised that capacity to prescribe and monitor of CGM in all eligible patients in specialist services and primary care will not be immediately available in North East London. Risk stratification and phasing of access has been identified in this document. Resourcing for primary care to support implementation and ongoing review, as well as prescribing education support are to be determined. Currently, secondary care or community diabetes specialist teams will be initiating and providing ongoing monitoring including patient support for any queries or issues.

NICE guidance and criteria for isCGM or rtCGM for non-pregnant people (NG28)

Offer CGM to adults with type 2 diabetes on multiple daily insulin injections if any of the following apply (see eligibility flowchart for clinicians below):

- 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 (CBG) but could use an CGM device (or have it scanned for them)
- they would otherwise be advised to self-measure at least 8 times a day.

Offer CGM 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.

When choosing a CGM device, clinicians and individuals should use shared decision making to identify the individual's needs and preferences and an appropriate device should be offered to meet these. Not all devices will be suitable for all individuals e.g. due to contra-indications. If multiple devices meet an individual's needs and preferences, the device with the lowest cost should be offered. See appendix 1 for more information

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

Ensure CGM is part of the education provided to adults with type 2 diabetes who are using it.

Monitor and review the person's use of CGM as part of reviewing their diabetes care plan.
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.

Prescribing of test strips and lancets for Capillary Blood Glucose (CBG) testing:

Everyone living with type 2 diabetes and using CGM will still require ongoing FP10 prescriptions for CBG testing (lancets and strips). This is to ensure a safe mechanism of glucose testing is available should the CGM device or reader fail/damaged/lost, and to facilitate glucose testing when use of the CGM device is not appropriate.

Ongoing prescribing of lancet and strips for CBG testing is to ensure a safe mechanism of glucose testing should the CGM device or reader fail/be damaged/lost, and to facilitate glucose testing when use of the CGM is not appropriate. Ongoing capillary blood glucose testing has been incorporated into the cost assumptions for CGM FP10 prescriptions.

Some CGM devices also require additional adjunctive blood glucose testing or testing for calibration, or to confirm hypoglycaemia.

In addition, for individuals with diabetes who drive group 1 vehicles (motorbikes, cars and light vehicles), the Driver and Vehicle Licensing Agency (DVLA) rules state that those with interstitial glucose monitoring systems (rtCGM or isCGM) may need to carry out CBG testing in certain circumstances . Individuals with type 2 diabetes who drive group 2 vehicles cannot rely on interstitial glucose testing before or whilst driving and will therefore require ongoing regular FP10 prescriptions for CBG testing kit (lancets and strips).

Overall the revised NICE guidance on access to CGM may result in a reduction in the need for CBG, however, ongoing use will be determined by the individual's clinical circumstances. The information in Appendix 1 provides a general guide as to how often an adult person living with type

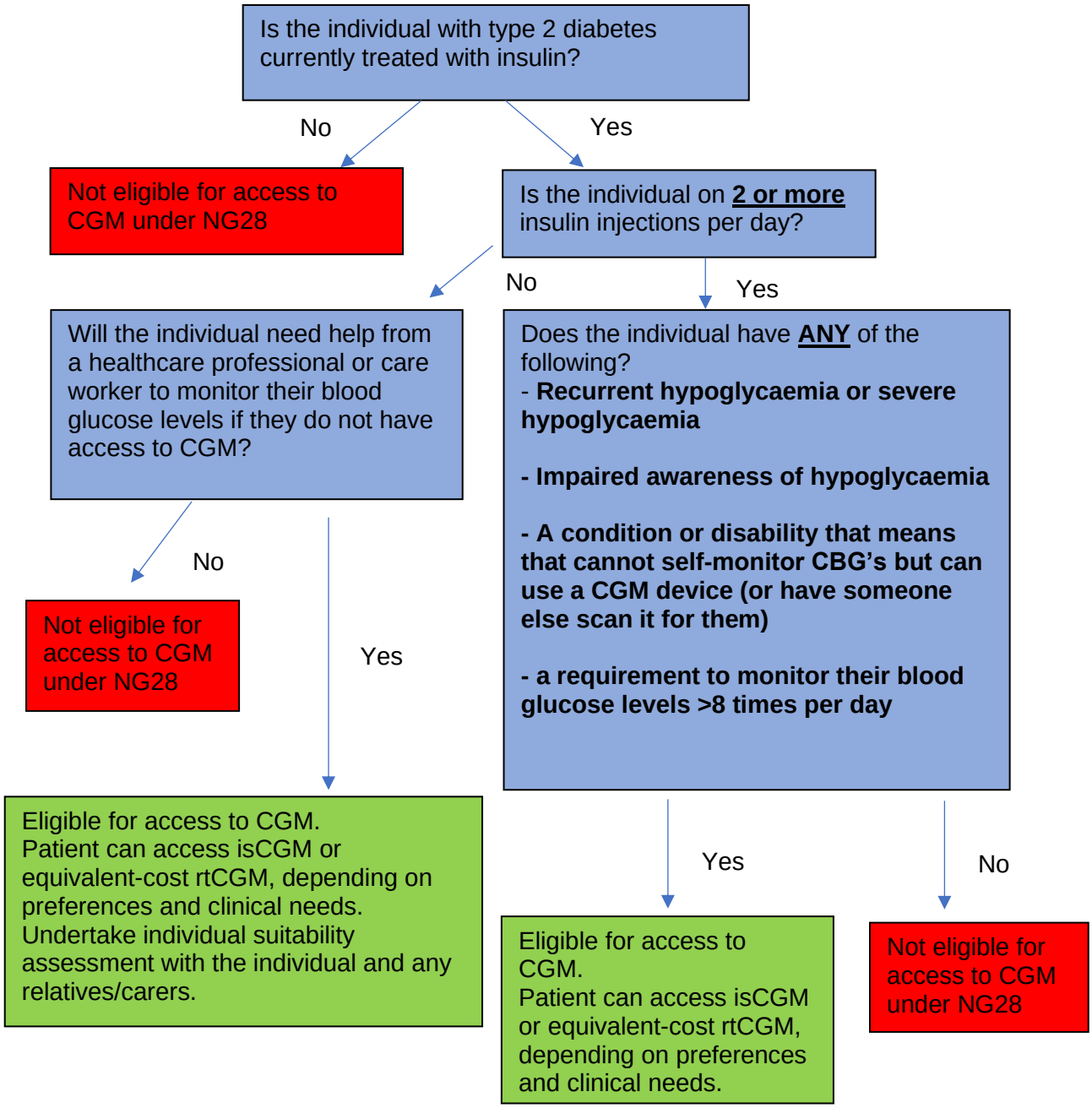
2 diabetes may need to test but this may differ depending on individual circumstances, particularly if their device requires adjunctive capillary blood glucose testing for calibration or confirmation, to confirm hypoglycaemia or in line with driving requirements. The quantity required should be jointly reviewed regularly by the prescriber and the individual with type 2 diabetes to ensure an appropriate number of test strips and lancets are prescribed. Please note once opened, most test strips have an expiry date of between 3-6months dependent on the brand and therefore it is recommended not to prescribe more than 3 months of test strips at any one time.

Individuals can continue to use their current CBG meter alongside the CGM device. The brand chosen should reflect choices on the NEL formulary, the functionality required and patient choice.

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

Eligibility flowchart for clinicians

NICE NG28 sets out the eligibility criteria for CGM in adults with type 2 diabetes as follows:



NICE guidance and criteria for rtCGM for pregnant women who are on insulin therapy (NG3)

Consider CGM for pregnant women who are on insulin therapy but do not have type 1 diabetes, if:

- they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) or
- they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control.

For pregnant women who are using CGM, a member of the joint diabetes and antenatal care team with expertise in these systems should provide education and support (including advising women about sources of out-of-hours support).

Additional information:

- It is recognised that people with type 2 diabetes on insulin requiring further management (e.g. multiple daily injections, raised HbA1c levels, persistent hypoglycaemia etc) will be accessing secondary care or specialist community services periodically as well as regularly accessing primary care services. Some individuals will rarely engage with any healthcare services and may be frequent attenders to emergency services and/or have significant mental health burden.

- It is recognised that there is significant inequality in outcomes for people from non-white ethnic minorities and more deprivation.

- It is recognised that applying stringent clinical criteria to access to technology can exacerbate inequality, and this document attempts to keep pathways simple for healthcare users and clinicians alike.

Recurrent severe hypoglycaemia, hypoglycaemic unaware:

- *Severe hypoglycaemia* is defined by NG28 as ‘episodes of hypoglycaemia that require assistance from another person to treat’.
- *Recurrent hypoglycaemia* is defined by NG28 as ‘frequent events of hypoglycaemia that occur each week or month and have an impact on quality of life’.
- *Impaired hypoglycaemia* awareness can be defined as ‘loss of subjective awareness of a falling blood glucose in time to take action to avoid a severe hypoglycaemic episode’.[1]

Clinicians should undertake an individual assessment to determine if their hypoglycaemia is problematic for them and whether use of CGM would be of benefit in prevention, identification and treatment of the hypoglycaemia. This may also involve medication changes to help reduce hypoglycaemia risk. Impaired hypoglycaemic awareness should be formally assessed via use of either Gold or Clarke scores. A Gold score of ≥4 and/or a Clarke score of ≥4 indicates impaired hypoglycaemic awareness (see Appendix 2).

[1] Pedersen-Bjergaard, U. et al. Severe hypoglycaemia in 1076 adult patients with type 1 diabetes: influence of risk markers and selection. Diabetes Metab. Res. Rev. 20, 479–486 (2004)

Initiation: education and risk stratification

People with insulin-treated type 2 diabetes should be classified according to clinician judgement into the following categories, where red and amber will be managed by secondary care or community diabetes specialist teams. *Consider a type 2 diabetes specialist multidisciplinary (MDT) discussion and risk assessment where additional clinical support is required.*

Red: one to one initiation
People with insulin treated type 2 diabetes who are likely to struggle with either the device or the education resources available. This may include people who have a learning disability (or neurodiversity), have a mental health history or who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose.

Amber: group initiation
People with insulin treated type 2 diabetes who would not be suitable for online resources and may need a face to face group consultation to aid safe initiation of technology. They may need closer clinical review after initiation. This may include people with insulin-treated type 2 diabetes where English is not their first language.

Green: people with insulin treated type 2 diabetes who meet the NICE criteria and/or are already familiar with glucose sensing devices and would be suitable to be directed towards online resources including webinars, video and industry literature. A contact number/email details of their secondary care or community diabetes specialist team should be provided, if they have any issues, particularly with skin irritation etc.

Suggested process for people with insulin treated type 2 diabetes regularly or periodically accessing secondary care

Risk stratification and phasing of access:

Due to capacity limitations and education/training needs within NEL ICS, the following approach may be used for risk stratification and prioritisation of access to CGM for individuals with type 2 diabetes (in descending order, greatest clinical benefit first):

1. Individuals with impaired hypoglycaemic awareness (as defined by Gold/Clarke score ≥4) and individuals with a history of severe hypoglycaemia.

2. Individuals with a cognitive or physical impairment that are unable to monitor CBG's themselves.

3. Individuals with problematic recurrent hypoglycaemia (but no impaired awareness of hypoglycaemia or history of severe hypoglycaemia).

4. Individuals who would otherwise be advised to self-monitor CBG's ≥8 times per day.

5. Insulin-treated adults who would otherwise need help from a care worker or HCP to monitor their blood glucose.

Process for implementation:

1. Identify people with insulin treated type 2 diabetes who meet the NICE guidelines for CGM and risk stratify as above during routine outpatient consultation for proposed use of CGM device from the list of devices (appendix 1) according to patient choice and clinical criteria.

Complete the Initiation/Transfer document (accessible via NEL Primary Care Portal) ideally with the patient and obtain patient signature/implied consent.

2. The clinician should risk stratify the person with type 2 diabetes according to the Red/Amber/Green classification above to ascertain the appropriate route for initiation. Use the flowchart in appendix 3 to guide the appropriate device.

3. For those identified as Red, they should have a one to one initiation with a suitably trained member of staff. For those identified as Amber, they would be suitable for a group initiation. For those identified as Green, they are suitable for directing to online resources only and must be given contact details of their secondary care or community diabetes specialist team for any queries or issues.

4. In secondary care, prescribe 2 months of sensors using either trust pharmacy outpatient prescription or FP10.

5. The review schedule after initiation should be determined by the initiating clinician and would generally follow the above red/amber/green risk classification. This may include ensuring that the device is being used, data is being uploaded and then the Initiation/Transfer document is sent to or stored by the patient's GP to continue with the prescription (electronically in most cases).

Suggested implementation for people with insulin treated type 2 diabetes that are accessing primary care alone:

1. The person with type 2 diabetes should be classified according to the Red/Amber/Green classification as above. This may be during an annual review or opportunistic consultation.

2. For those identified as Red, these individuals would need to be either referred to or discussed with a type 2 diabetes specialist MDT for risk assessment and to develop a bespoke plan for glucose sensor initiation if deemed appropriate.

3. For those identified as Amber, these individuals would need face to face support in initiating glucose sensor therapy safely. This can be through the community diabetes services.

4. For those identified as Green, these individuals could be directed to online resources alone, with contacts for community diabetes services if problems arise.

Appendix 1: recommended CGM devices

NICE NG28 guideline states that eligible individuals living with type 2 diabetes should be offered isCGM or rtCGM as an alternative if it is available for the same or a lower cost.

List 1 below details the currently available isCGM device and rtCGM devices available on FP10 (as per the NHS Drug Tariff January 2024).

List 1: rtCGM available on FP10

Device name	Key features of device	Minimum CGB testing required	Estimated annual cost per individual[3]
Abbott FreeStyle Libre 2 **Note device is classified as isCGM for those using device via a FreeStyle Libre 2 Reader device (non-smartphone users)**	14-day sensor, no transmitter required Optional reader device if no smartphone access Optional low and high glucose alerts Data sharing with healthcare team, friends/relatives/carers via LibreLink App	Minimum 200 strips and lancets per annum	£912.50 (sensors)[1] CBG testing: - £52 p.a.[2]
Abbott FreeStyle Libre 2 Plus **Note device is classified as isCGM for those using device via a FreeStyle Libre 2 Reader device (non-smartphone users)**	15-day sensor, no transmitter required Optional reader device if no smartphone access Optional low and high glucose alerts Data sharing with healthcare team, friends/relatives/carers via LibreLink App	Minimum 200 strips and lancets per annum	£912.50 (sensors)[4] CBG testing: - £52 p.a.[2]
Dexcom ONE	10-day sensor, 90-day transmitter Optional reader device if no smartphone access Data sharing with HCP's only (via Dexcom Clarity software).	Minimum 200 strips and lancets per annum	£900 (sensors and transmitters)[5] CBG testing: - £52 p.a.[2]
Dexcom ONE +	No separate transmitter required	Minimum 200 strips and lancets per annum	£898.92 (sensor)[6]
GlucoRX AiDEX	14-day sensor, 4-year transmitter Data sharing with HCP's and relatives/carers.	Minimum 200 strips and lancets per annum	£778.74 (sensors and transmitter)[7] CBG testing: - £52 p.a.[2]
GlucoMen Day – **discontinued**			

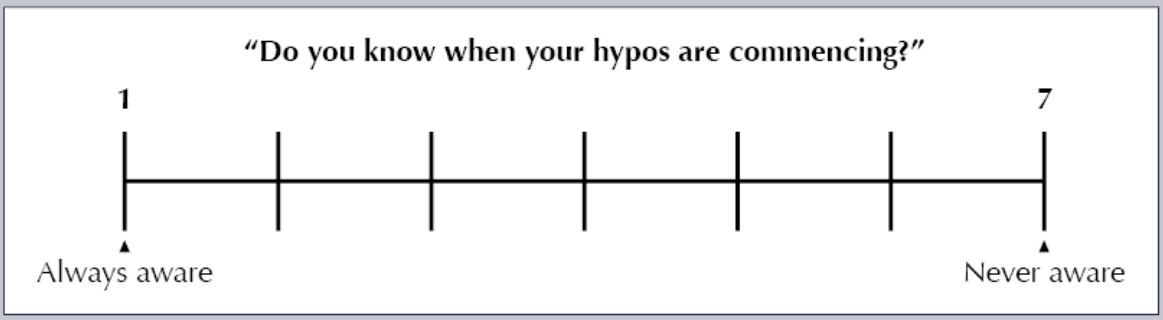
[1] Cost as per National Drug Tariff April 2024. £35.00 per 14-day sensor – 26 sensors per annum. No transmitter.
[2] Based on use of 4 test strips and lancets per day at a cost of £0.26 per unit.
[3] Cost as per National Drug Tariff April 2024.
[4] Cost as per National Drug Tariff April 2024. £37.50 per 15-day sensor – 24 sensors per annum. No transmitter.
[5] £23 per 10-day sensor (36 sensors per annum); £18 per 3-month transmitter (4 transmitters per annum)
[6] £24.97 per sensor working (36 sensors per annum)
[7] £29.76 per 14-day sensor – 26 sensors per annum. £19.95 per 4-year transmitter - assume £4.98 p.a

Appendix 2: Gold and Clarke scores

Gold Score

Gold score[2]

A score of ≥4 suggests impaired hypoglycaemia awareness; ≤2=normal awareness; 3=borderline.



Clarke Score Webpage link: [Clarke Score – IN A NUTSHELL]

Clarke score[3]

Answers provide a rating of either A (aware) or R (reduced). Four or more R ratings suggests impaired hypoglycaemia awareness; ≤2=normal awareness; 3=borderline.

Question	Rating (A or R)
1. Check the category that best describes you (check one only): ❑ I always have symptoms when my blood sugar is low (A) ❑ I sometimes have symptoms when my blood sugar is low (R) ❑ I no longer have symptoms when my blood sugar is low (R)	
2. Have you lost some of the symptoms that used to occur when your blood sugar was low? ❑ Yes (R) ❑ No (A)	
3. In the past **six months**, how often have you had moderate hypoglycemia episodes? (episodes where you might feel confused, disoriented, or lethargic and were unable to treat yourself) ❑ Never (A) ❑ Once or twice (R) ❑ Every other month (R) ❑ Once a month (R) ❑ More than once a month (R)	
4. In the past **year**, how often have you had severe hypoglycemic episodes? (episodes where you were unconscious or had a seizure and needed glucagon or intravenous glucose) _____ (A if never; R if one or more. If ≥12, conclude impaired awareness irrespective of other answers)	
5. How often in the last month have you had blood sugar readings under 3.9 mmol/L **with symptoms**? ❑ Never ❑ 1–3 times ❑ 1 per week ❑ 2–3 per week ❑ >4–5 per week ❑ >Almost daily (see question 6 for scoring)	
6. How often in the last month have you had blood sugar readings under 3.9 mmol/L **without symptoms**? ❑ Never ❑ 1–3 times ❑ 1 per week ❑ 2–3 per week ❑ >4–5 per week ❑ >Almost daily (R = answer to Q5 < answer to Q6. A = answer to Q6 < answer to Q5)	
7. How low does your blood sugar need to go before you feel symptoms? ❑ 3.4–3.8 mmol/L (A) ❑ 2.8–3.3 mmol/L (A) ❑ 2.2–2.7 mmol/L (R) ❑ Under 2.2 mmol/L (R)	
8. To what extent can you tell by your symptoms that your blood sugar is low? ❑ Never (R) ❑ Rarely (R) ❑ Sometimes (R) ❑ Often (A) ❑ Always (A)	

[2] Gold, A. E., Macleod, K. M. & Frier, B. M. Frequency of severe hypoglycemia in patients with type I diabetes with impaired awareness of hypoglycemia. Diabetes Care 17, 697–703 (1994).
[3] Clarke, W. L. et al. Reduced awareness of hypoglycemia in adults with IDDM: a prospective study of hypoglycemic frequency and associated symptoms. Diabetes Care 18, 517–522 (1995).

Appendix 3: flow chart for selection of CGM devices

Type 2 FlowChart V0.1 draft.pptx

Appendix 4: NEL CGM Type 2 Diabetes Initiation / transfer of care form

T2DM CGM pathway transfer of care (NEL)

Appendix 5: resources

1. Initiation and transfer of prescribing of continuous glucose monitors (CGM) for adults living with type 2 diabetes in North East London. Available at: https://primarycare.northeastlondon.icb.nhs.uk/home/meds/medicines-guidelines-diabetes/

2. DTN-UK Education modules on continuous glucose monitoring. Available at: https://abcd.care/dtn-education/continuous-glucose-monitoring

3. EDEN: Implementing glucose sensing in primary care training package. Register at: https://www.glucose-sensing.com/

4. Dexcom Education Hub. Real-time continuous glucose monitoring. Available at: https://uk.provider.dexcom.com/education-and-resources/rt-cgm-education

5. Dexcom ONE training and resources. Available at: https://uk.provider.dexcom.com/products/dexcom-one/training-and-resources?UNLID=504640407202355162430

6. GlucoRx AiDEX Hub. Available at: https://www.glucorx.co.uk/glucorx-aidex-hub/

7. FreeStyle Libre https://pro.freestyle.abbott/uk-en/home/primary-care.html

8. Eden training modules (for FreeStyle Libre) https://www.edendiabetes.com/news-blog/new-flash-glucose-monitoring-elearning

9. https://cpd.diabetes.org.uk/diabetes-technology