NHS
Norfolk and Waveney
Integrated Care Board

Norfolk and Waveney Integrated Care Board
Continuous Glucose Monitoring for Adults with Type 1 Diabetes
Implementation Plan

Document Control:

For Use In:	All 3 acute trusts – QEHKL, JPUH and NNUH		
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Previous Titles for this Document: *

Previous Title/Amalgamated Titles	Date Revised
None	Not applicable

Note which Trust, where applicable.

Distribution Control *

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

This document was developed in consultation with members of the NWICB technologies group. The group is made up of clinicians who specialise in the area of diabetes technologies from each acute trust and members of the NWICB medicines optimisation team with representation from the NWIC diabetes programme team. The process has had oversight from the EoE NHS Diabetes Leads.

Provider organisation management and finance teams have also been consulted.

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g., changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents *

This document is a standard operating procedure applicable to NNUH, QEHKL and JPUH; please refer to local Trust's procedural documents for further guidance.

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1) Commissioning Summary

NHS Norfolk and Waveney Integrated Care Board (ICB), also termed '*the Commissioner*' in this document, commissions use of Continuous Glucose Monitoring (CGM) if clinically appropriate and within the recommendations of this implementation plan for adults with Type 1 Diabetes:

- Patients with pancreatic disease who are insulin dependent: follow Type 1 Diabetes CGM pathway
- Patients with Cystic Fibrosis who are insulin dependent: follow Type 1 Diabetes CGM pathway
- Young people transitioned to adult service (16-25 years old): if already established on CGM - continue the existing CGM system (isCGM /RT-CGM). Only consider switching to alternative CGM system if clinical need identified and assessed by MDT.
- Patients with Type 1 diabetes not under specialist care deemed to have problematic hypoglycaemia[1] by primary care MDT should be referred to specialist secondary care service for assessment of eligibility of CGM and initiation of appropriate CGM.
- If there is a clinical need to share data with carers or family for any reason e.g. physical impairment; learning difficulties; vulnerable or frail adult: consider CGM system that allows data sharing

Consideration of CGM initiation will be undertaken at the next diabetes clinical review or if admitted to hospital

2) Scope

This implementation plan applies to all patients for whom Norfolk and Waveney ICB has responsibility for including:

People provided with primary medical services by GP practices which are members of the ICB and people usually resident in the area covered by the ICB and not provided with primary medical services by any ICB

Where a person with diabetes resides in the Norfolk and Waveney ICB area and is seen in specialist services out of the Norfolk and Waveney ICB area and where the purpose of the clinical consultation requires assessment for CGM, then this implementation should be followed.

The clinical responsibility for applying this implementation plan to a presenting patient, rests with the clinician who is responsible for the patient at that point in the treatment pathway. This should be done in consideration of the patient's individual clinical circumstances, their place on the management pathway and following discussions with the patient.

Where a patient's clinical presentation does not clearly meet the requirements for secondary care referral within the context of this implementation plan, and where a GP is uncertain or concerned about the appropriate treatment/management pathway, referral for Advice and Guidance should be considered as an alternative to a referral for clinical assessment.

There may be occasions when a GP referral is made for specialist assessment which appears to meet the implementation plan requirements, but which on specialist clinical examination either does not meet the clinical criteria for the intervention or is not considered clinically suitable for the intervention. Such patients should be discharged without the intervention.

For patients who do not fall within the eligibility criteria set out in the implementation plan, but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration. The referring clinician should the consult the Commissioner's 'Operational Policy' for Individual Funding Requests document for further guidance on this process.

For definition of the term 'exceptional clinical circumstances' please refer to the definitions section of this document.

https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=pa0yGRi0OoI%3d&portalid=1

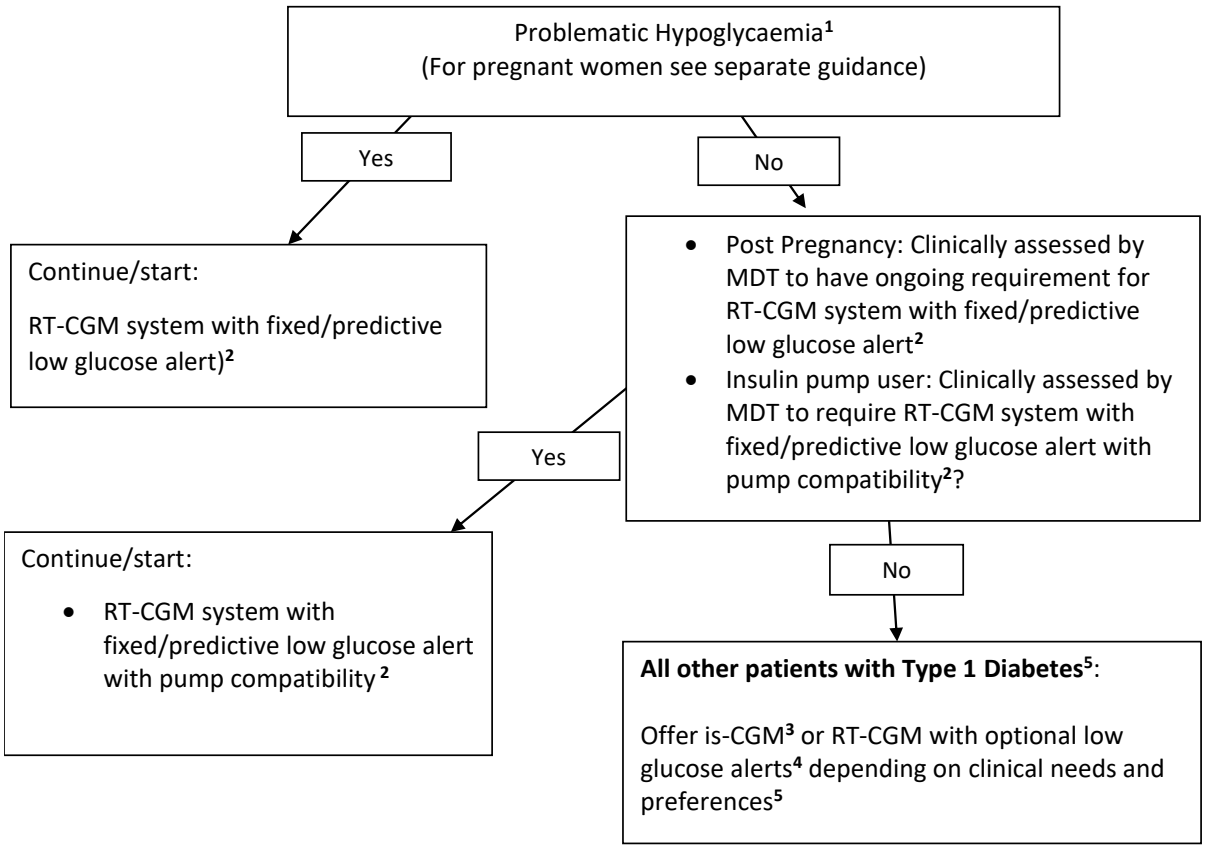
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=nhkGxSJHmOc%3d&portalid=1

The purpose of this implementation plan is to determine eligibility for CGM depending on presenting circumstances.

The following implementation plans are also available for people with a diagnosis of diabetes who use insulin to manage their disease;

- Diabetes technologies for adults with type 2 diabetes
- CGM for Children and Young People
- Pregnancy

3) Processes/Pathways



4) Key Points as above:

1. Problematic hypoglycaemia defined as:

- ≥ 1episode of severe hypoglycaemia needing third party assistance in preceding 12 months
- Impaired hypoglycaemia awareness (Clarke Score/ Gold score ≥4)
- Extreme fear of hypoglycaemia

2. RT-CGM systems with fixed/predictive low glucose alert feature currently include:

- Abbott Freestyle Libre 3
- DEXCOM G5
- DEXCOM G6
- Medtronic Guardian 3
- Medtronic Guardian 4
- Medtrum Touch Care Nano

3. isCGM system currently include:

- Abbott Freestyle Libre 1
- Abbott Freestyle Libre 2

4. RT-CGM systems with optional low glucose alert feature currently include:

- DEXCOM ONE
- GlucoRX Aidex
- Glucomen Day

5. **All other patients with Type 1 Diabetes: Considerations for using** isCGM or RT-CGM with optional low glucose alerts[4]:

Offer individual a choice of isCGM or RT-CGM based on individual preference or need of scanning or real-time data display

If individual prefers or requires (for e.g., certain occupation etc.) RT-CGM, offer a device that meets the following criteria:

A. Optional high and low glucose alerts
B. The RT-CGM system does not need to have connectivity/compatibility to a hybrid-closed loop or CSII system
C. The RT CGM system allows individual to view their own RT-CGM data and share data with healthcare professionals, but does not feature a relative, friend or carer data-sharing system.

If individual is unable to tolerate a system due to physical issues e.g., adhesion issues, local allergic reaction etc. an alternative device should be offered

5) Further Information for Clinicians

Transition from Children/Young People Services to Adult Services

When a person transfers from the children to the young adult services, a clinical assessment will be made on the most appropriate technologies to be used by that person going forwards.

Disposal of Technologies

Norfolk and Waveney ICS/ICB are waiting for a national position on the disposal of the form of clinical waste. In the intervening time, please refer to disposal guidelines, set out by the manufacturers of the devices you are recommending.

De-Prescribing of Blood Glucose Monitoring Strips

When a technology is prescribed, the number of blood glucose strips to be prescribed by the General Practitioner needs to be reduced to 4 bottles of 50 test strips per year. A letter needs to be sent to the GP requesting this change.

Training of Healthcare Professionals

A link to the training platform can be found here: HCP Education | ABCD (Diabetes Care) Ltd.
In addition, there needs to be access to training on the individual technological devices that are being recommended by the clinician. The healthcare professional should also attend face to face training from other with the correct competencies.

Training of Devices

Patient/parent education on all systems will be provided by the MDT

Driving Advice

Diabetes mellitus: assessing fitness to drive - GOV.UK (www.gov.uk)

Technologies that are not prescribed

When a clinician is giving the patient a technology that is not prescribed on FP10, they will need to complete the following proforma to obtain and patient identifier (or funding number) and send the form to the Norfolk Tariff address at norfolkontariff@nhs.net

Applying for a funding number for continuous glucose monitoring

When a patient with diabetes and who requires CGM, a purchase order number will need to be obtained from the Medicines Optimisation team. To do this, complete this form and follow the instructions to submit :
https://nww.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=OMvVnGqIDb0%3d&tabid=2283&portalid=1&mid=3378

Any problems with the link above please try to access the form via Knowledge Anglia.

The supplier of the monitor will require the Purchase Order number. If this is not done, then the monitor will be charged to your Trust rather than the Medicines Management team. At the current time, it is the Medicines Management team budget that covers the cost of the monitors. This will be updated when this changes in the future.

This process also helps the system understand the level of demand for the monitors.

The Norfolk and Waveney Formulary of diabetes technologies

The following link is a list of devices relating to diabetes technologies that have been agreed for use in the system.

https://www.norfolkandwaveneyformulary.nhs.uk/Mobile/chaptersSubDetails.asp?FormularySectionID=6&SubSectionRef=06.01.06&SubSectionID=B100

6) Definitions

Exceptional - refers to a person who demonstrates characteristics, which are highly unusual, uncommon, or rare.

Exceptional clinical circumstances are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional, when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (i.e., similar patients). A patient with exceptional clinical circumstances will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.

A Similar Patient is a patient who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of more than one similar patient indicates that a decision regarding the commissioning of a service development or commissioning policy is required of the Commissioner.

An individual funding request (IFR) is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment.

An in-year service development is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Such unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded because of either delaying or aborting other planned developments.

The term “where appropriate” within this document means that clinical judgement is exercised in determining which aspects of the policy guidance can be applied to individual patients depending on their condition; ability to tolerate the listed treatment; and whether they have already undergone that treatment.

Diabetes mellitus (DM) is a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced. Such a deficiency results in increased concentrations of glucose (sugar) in the blood, which in turn damages many of the body's systems, in particular the blood vessels and nerves.

There are two different forms of diabetes:

1) **Type 1 diabetes** in which the pancreas fails to produce the insulin which is essential for survival. This form develops most frequently in children and adolescents but is being increasingly noted later in life.

2) **Type 2 diabetes** which results from the body's inability to respond properly to the action of insulin produced by the pancreas. Type 2 diabetes is much more common and accounts for around 90% of all diabetes cases worldwide. It occurs most frequently in adults but is being noted increasingly in adolescents as well.

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

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

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

Self-monitoring blood glucose (SMBG) involves a skin prick to draw blood and the application of a chemically active test-strip to the blood. The test-strip is inserted into a meter which provides a reading for the concentration of glucose in the blood at that time. This is the standard method of measuring and monitoring blood glucose in patients with diabetes, particularly those who use insulin to manage their disease.

Insulin pumps are small electronic devices that deliver regular insulin to the body throughout the day and night; also termed **Continuous Subcutaneous Insulin Infusion (CSII).** There are 2 types of insulin pump – a tethered pump and a patch pump. Both are attached to the body by a tiny tube called a cannula which sits just under the skin. Insulin pumps may be used with or without CGM.

Hypoglycaemia is where the level of glucose (sugar) in the blood drops to less than 4mmol/l; it mainly affects people with diabetes, especially those using insulin.

Severe hypoglycaemia is episodes of hypoglycaemia that require assistance from another person to treat.

Recurrent hypoglycaemia is frequent events of hypoglycaemia that occur each week or month and have an impact on quality of life.

Hyperglycaemia is where the level of glucose (sugar) in the blood is excessively high; it mainly affects people with diabetes and if it persists can cause damage to the body's internal organs.

Nocturnal hypoglycaemia is an episode of abnormally low blood glucose (sugar) occurring at night-time during sleep.

HbA1c, is a measurement in the blood that represents the average blood glucose (sugar) levels for the last two to three months. A high HbA1c means there is too much glucose (sugar) in the blood indicating that diabetes control is suboptimal.

Multiple daily injections are two or more daily insulin injections, which could be a basal-bolus regimen or more than one daily insulin injection.

7) References.

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8) Monitoring Compliance

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring

The audit results are to be discussed at relevant diabetes team and governance meetings to review the results and recommendations for further action.

Then sent to the Diabetes Programme Board who will ensure that the actions and recommendations are suitable and sufficient.

9) Equality Impact Assessment (EIA)

Title/topic	Diabetes Technologies Implementation Plans (Phase 1)
Status	This assessment related to phase 1 of the diabetes technologies implementation plans where all eligible people are under specialist services care.
Impact and Evidence	
In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work	
Age: Paediatrics: The paediatric cohort is within the prioritisation groups (Phase1) Finger pricking in this groups causes distress in the child. Also knowing the child's blood sugars can reduce anxiety in the parent/ carer. All other age groups will be included in line with NICE guidance and rolled out in a phased way. Further details can be found in the implementation plans. Access to technologies in children and young people with type 1 diabetes is specifically highlighted as a key clinical area of health inequalities in the Core 20+5 approach. Access to technologies in the most deprived quintiles and for children and young people from ethnic minority backgrounds are identified as a specific risk.	
Disability: Access to diabetes technologies will be prioritised in adults reviewed at the next diabetes review. Disability should not be a barrier to technologies and many people with disability may benefit from access to technologies.	
Gender reassignment (including transgender): Gender will not affect access to diabetes technologies.	
Marriage and civil partnership: Partnership status will not affect access to diabetes technologies	
Pregnancy and maternity: Women who are pregnant are prioritised for access to diabetes technologies (Phase1). The rationale for this is to reduce to risk to mother and baby as the result of high blood sugars during pregnancy. Further details can be found in the implementation plans. There is a strong evidence base that women with type 1 and type 2 diabetes have improved outcomes when using Continuous Glucose Monitoring (CGM) (CONCEPTT trial).	
Race: Access to technologies in the most deprived quintiles and for children and young people from ethnic minority backgrounds are identified as a specific risk. We need to proactively monitor and ensure that access to technologies is equitable across all ethnic groups.	
Sex: Implementation of diabetes technologies in phase 1 is available equally to all sexes.	
Sexual orientation: Diabetes technologies in phase 1 will be available to all people	
Carers: Implementation of diabetes technologies in Phase 1: Carers would be encouraged to attend clinical appointments relating to the technologies, so that they too can understand the readings and what needs to be done about them, also they may need to understand how to fit the sensors for the technologies and how to support the person they are providing care for. The carers may need support as to what help is available to them.	
Other disadvantaged groups: In Norfolk and Waveney 15.7% of people with type 1 diabetes live in the most deprived quintile. There is a need to ensure that access is equitable across all social groups.	

Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals	Yes	There is a risk that patient initiated follow up could drive inequalities. There is a possibility that people who do not attend their planned clinical review or who are not known to acute services, may be disadvantaged.
Is there any impact for groups or communities living in particular geographical areas?	Yes	There is need to ensure that people who receive their diabetes care in localities other than Norfolk and Waveney have equitable access to technologies
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	People who are unemployed, on low incomes or who have low educational attainment may find it more difficult to access clinics at local hospitals due to the costs of transport or to get time away from work to attend clinics. As the CGM/ Flash is to be offered at the next clinical review, people who struggle to attend clinics or who have regularly defaulted due to poor literacy and other social barriers, may potentially miss the opportunity to access the technologies.
FREDA Principles/Human Rights	**Question**	**Response**
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	The technologies implementation plans are being rolled out in a phased way with prioritisation based on clinical need.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	This activity abides by NHS policies around patient confidentiality.

Equality – right not to be discriminated against based on your protected characteristic	How will this process ensure that people are not discriminated against and have their needs met and identified? How will this affect a person's right to freedom of thought, conscience and religion?	Ultimately all people with type 1 diabetes will have access to CGM technology. During roll out prioritisation will be based on clinical need with every effort made to ensure that uptake is equitable. The programme team will monitor access to technologies for people with type 1 diabetes and type 2 diabetes via the National Diabetes Audit (NDA) Type 1 Dashboard (access to CGM) and the Adolescent and Young adult type 1 diabetes dashboard (access to pumps). Local data sources will be developed to monitor and support equity of access.
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Access to CGM offers the potential to improve quality of life by reducing the need for finger prick testing. For some people using the technologies offers the potential to open up activities and opportunities not previously considered accessible because of the limitations of finger prick testing and diabetes.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	Access to technologies in diabetes self -care of diabetes improves access to data to help inform self- care and decision making
Right to Life	Will or could it affect someone's right to life? How?	For people with diabetes using technologies there is evidence of reduced hypoglycaemia which is a potentially a life- threatening complication of insulin management in diabetes. For people with type 1 and other types of diabetes, insulin is a life requiring treatment and blood glucose monitoring is a necessary part of care.

Right to Liberty	Will or could someone be deprived of their liberty? How?	The technologies give people liberty.