

**Norfolk and Waveney Integrated Care Board  
Continuous Glucose Monitoring in Children and Young People  
Implementation Plan**

**Document Control:**

<b>For Use In:</b>	All 3 acute trusts – QEHL, JPUH and NNUH		
	For use in children and young people’s diabetes services.		
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<b>Document Author:</b>	Heather Leishman, Clinical Programme Manager – Diabetes, N&W ICB Matt Williams: Paediatric Diabetes Specialist Nurse, QEHL Dr Vipin Datta: Paediatric Consultant, NNUH Dr Himal Gurung: Paediatric Consultant, JPUH		
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<b>Approval Date:</b>	16 September 2022	<b>Date to be reviewed by:</b> This document remains current after this date but will be under review	The document is live and will be regularly updated based on technology changes and with a plan to regularly review within the Diabetes Technology Group.
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Version	Date	Author	Reason/Change
1	2023.02.09	Dr Vipin Datta, Dr Himal Gurung, Matt Williams	First version

Author: Heather Leishman, Clinical Programme Manager, Diabetes, NWICB

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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Printed copies of this document should be considered out of date.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 NWICB Diabetes Page - 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 NWICB diabetes programme team. The process has had oversight from the EoE NHSE Diabetes Lead.

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, QEHL and JPUH; please refer to local Trust's procedural documents for further guidance.

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## 1) Commissioning Summary

Norfolk and Waveney ICB also termed 'the commissioner' in this document will **fund** the provision of Continuous Glucose Monitoring systems (CGM) if clinically appropriate and within the recommendations of this implementation plan as follows:

All children and young people (CYP) with type 1 diabetes mellitus are eligible for:

- Real time continuous glucose monitoring (rtCGM)
- OR**
- Intermittently scanned continuous glucose monitoring (isCGM also known as Flash Glucose Monitoring) if unable to use rtCGM or express a clear preference for isCGM)

## 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 outside of the Norfolk and Waveney ICB area and where the purpose of the clinical consultation requires assessment for CGM, then this implementation plan 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 then consult the Commissioner's 'Operational Policy' for Individual Funding Requests

document for further guidance on this process.

<https://www.knowledgeanglia.nhs.uk/LinkClick.aspx?fileticket=pa0yGRi0Ool%3d&portalid=1>

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

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

This implementation plan applies to children and young people under the care of paediatric diabetes services with a diagnosis of type 1 diabetes mellitus.

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

Patient groups not within the scope of this implementation plan include pregnant people with insulin dependent diabetes mellitus, people managed within an adult diabetes service or those with a diagnosis of diabetes mellitus who does not require insulin to manage their disease.

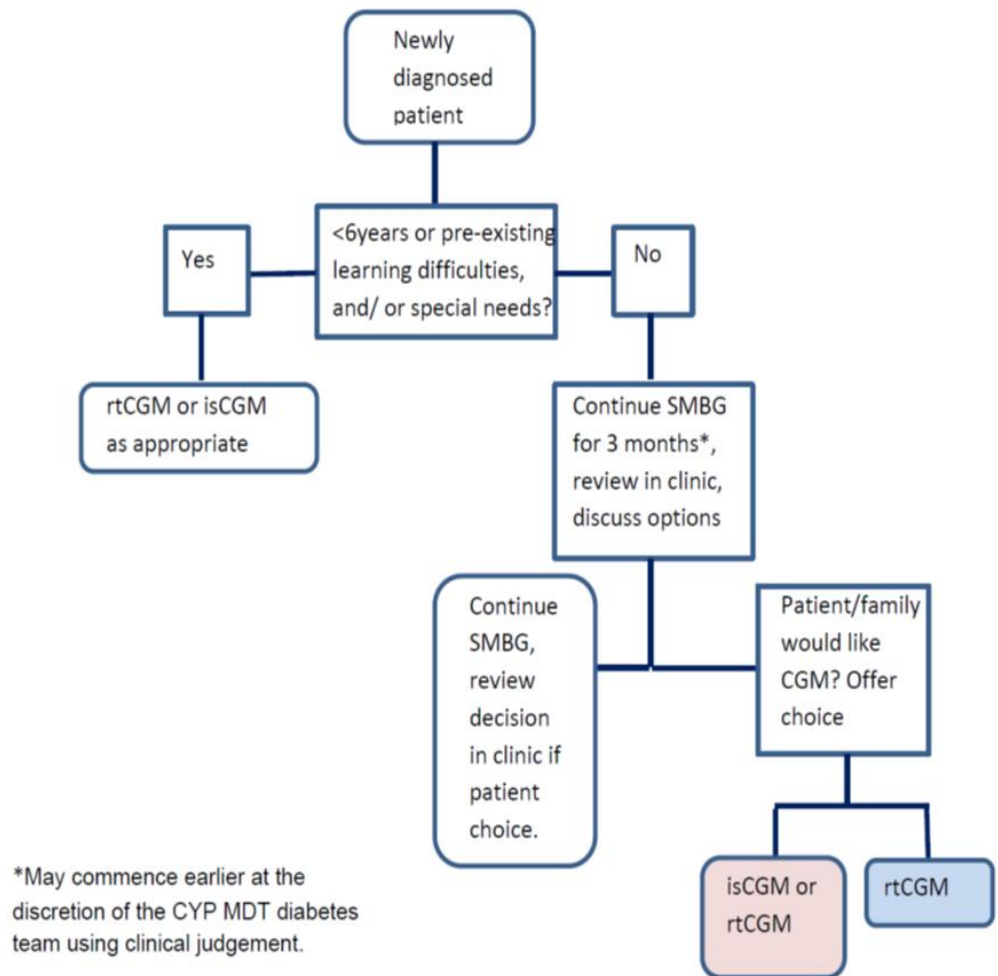
Additional implementation plans are also available for people with a diagnosis of diabetes who use insulin to manage their disease;

- Diabetes technologies during pregnancy
- Diabetes technologies for adults with type 1 and type 2 diabetes

### **3) Processes/Pathways**

We propose 2 pathways, one for newly diagnosed patients, this will include a period where they will use SMBG, it is felt that it is still important that CYP and their families/carers are aware of how to undertake finger-prick blood glucose monitoring to ensure competency as this will be needed in case of sensor error or other issues with either isCGM or rtCGM and one for established patients who are either using MDI or insulin pump therapy.

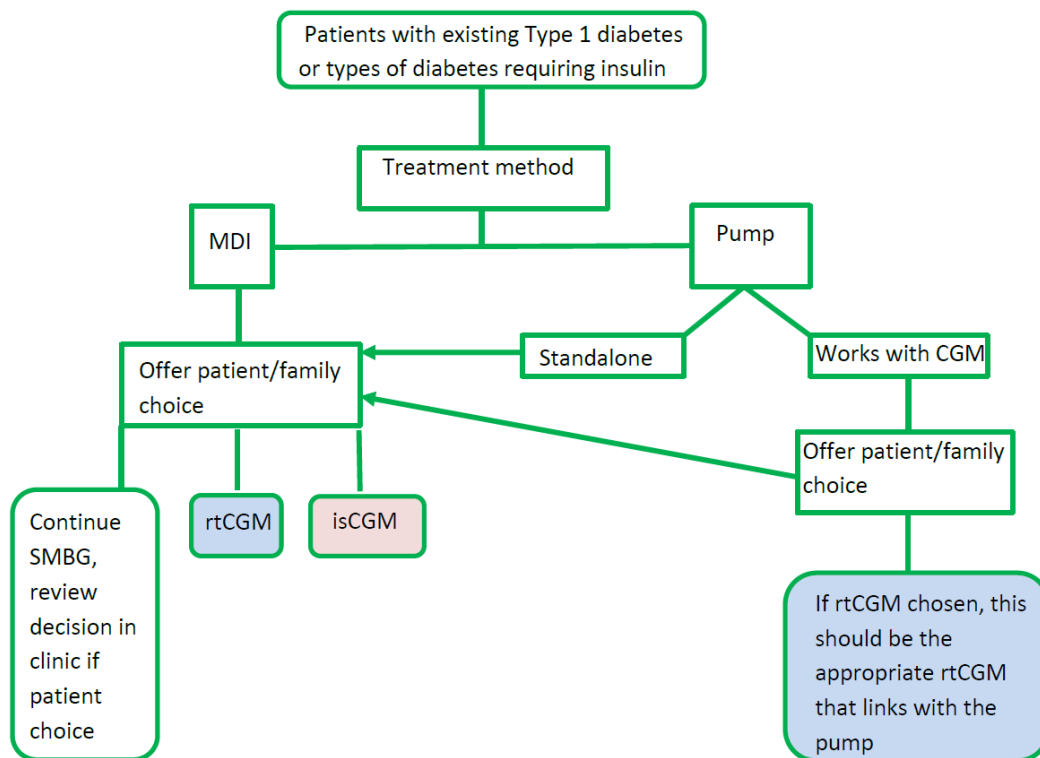
Pathway for CYP newly diagnosed with type 1 diabetes and rare types of diabetes requiring insulin



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

<b>Key:</b>
Started by CYP diabetes team, system prescribed by primary care
Started by CYP diabetes team, funding from ICB

Pathway for CYP with existing type 1 diabetes and rare types of diabetes requiring insulin.



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

<b>Key:</b>
Started by CYP diabetes team, system prescribed by primary care
Started by CYP diabetes team, funding from ICB

**4) Patient Eligibility**

Author: Heather Leishman, Clinical Programme Manager, Diabetes, NWICB

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All CYP with type 1 diabetes are eligible for real time continuous glucose monitoring(rtCGM). CYP should be offered:

1. A choice of rtCGM device based on individual preferences, needs, characteristics and the functionality of devices available.
2. Intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') if aged 4 years and over and unable to use rtCGM or express a clear preference for isCGM.
3. Education to support CYP and their families and carers to use chosen device.

**Note:** Use of rtCGM and isCGM (FlashGM) during pregnancy is covered by a separate commissioning implementation plan: Continuous Glucose Monitoring during Pregnancy for People with Insulin Treated Diabetes Mellitus.

CGM (rtCGM and isCGM) should be provided by a team with expertise in its use, as part of supporting children and young people to self-manage their diabetes.

Use of CGM should be monitored and reviewed as part of reviewing the CYP diabetes care plan. This should include explanation of the importance of continuously wearing the device.

CYP not using their CGM device at least 70% of the time should be:

- Asked if they are having problems with the device
- Offered ways to address any problems or concerns to improve use of the device, including further education, emotional and psychological support.

Specialist diabetes teams at provider trusts are responsible for:

- Determining eligibility for rtCGM and isCGM (FlashGM)
- Choosing a CGM device using shared decision making to identify the CYP needs and preferences.

**Where multiple devices meet the needs and preferences, offer the device with the lowest cost**

- Initiating use of the chosen device (including offer of education)
- rtCGM device and consumable supply throughout the period of use by the CYP

A small number of rtCGM systems are included in the Drug Tariff and therefore available to prescribe on FP10. Primary care prescribing could be considered on an individual basis if in agreement with patient's general practitioner.



Where CGM is determined appropriate for the CYP, communicate with general practitioners to inform them that CGM has been initiated and:

- To reduce the quantity of blood glucose test strips prescribed to 1 box every 3 months or on request. Noting that quantity can be increased dependent on individual patient needs.
- Where isCGM (FlashGM) is initiated communicate the need for ongoing supply of sensors.

General practice teams are responsible for:

Reducing prescribing of blood glucose test strips to 1 box every 3 months or on request, in line with secondary care advice

- Quantity can be increased dependent on individual patient needs.
- Ketone test strips should continue to be prescribed without change.

Ongoing prescribing of isCGM (FlashGM) sensors, when isCGM is determined appropriate by secondary care.

People who self-funded CGM prior to availability on the NHS will be assessed for NHS eligibility in accordance with the above.

- For patients who meet these criteria, there will be no retrospective funding of any intervention or service costs incurred in advance of assessment of eligibility in accordance with this implementation plan.
- Patients who do not meet these criteria will not be eligible for NHS funding of CGM or any other associated costs.

Specialist diabetes teams are required to complete a Blueteq proforma to demonstrate eligibility for use of rtCGM, with annual continuation forms completed thereafter.

## **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 and mentoring from other experienced clinicians 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 patient identifier (or funding number) and send the form to the Norfolk Tariff address at [norfolkontariff@nhs.net](mailto:norfolkontariff@nhs.net)

## **Applying for a funding number for continuous glucose monitoring**

For patients 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.

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Author: Heather Leishman, Clinical Programme Manager, Diabetes, NWICB

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## **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.

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Author: Heather Leishman, Clinical Programme Manager, Diabetes, NWICB

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.

National Institute for Health and Clinical Excellence (2015, updated 2022). *Diabetes (type 1 and type 2) in children and young people: diagnosis and management*. NICE Guideline 18. Available at:

<https://www.nice.org.uk/guidance/ng18/resources/diabetes-type-1-and-type-2-in-children-and-young-people-diagnosis-and-management-pdf-1837278149317>

## 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 paediatric 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)

<b>Title/topic</b>	Diabetes Technologies Implementation Plans (Phase 1)
<b>Status</b>	This assessment related to phase 1 of the diabetes technologies implementation plans where all eligible people are under specialist services care.
<b>Impact and Evidence</b>	
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	
<b>Age:</b> 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.	
<b>Disability:</b> 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.	
<b>Gender reassignment (including transgender):</b> Gender will not affect access to diabetes technologies.	
<b>Marriage and civil partnership:</b> Partnership status will not affect access to diabetes technologies	
<b>Pregnancy and maternity:</b> 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).	
<b>Race:</b> 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.	
<b>Sex:</b> Implementation of diabetes technologies in phase 1 is available equally to all sexes.	
<b>Sexual orientation:</b> Diabetes technologies in phase 1 will be available to all people	
<b>Carers:</b> 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.	
<b>Other disadvantaged groups:</b> 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.	

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<b>Health Inequalities</b>	<b>Yes/No</b>	<b>Evidence</b>
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.
<b>FREDA Principles/Human Rights</b>	<b>Question</b>	<b>Response</b>
<b>Fairness</b> – 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.
<b>Respect</b> – 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.

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<p><b>Equality</b> – right not to be discriminated against based on your protected characteristic</p>	<p>How will this process ensure that people are not discriminated against and have their needs met and identified?</p> <p>How will this affect a person's right to freedom of thought, conscience and religion?</p>	<p>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.</p>
<p><b>Dignity</b> – the right not to be treated in a degrading way</p>	<p>How will you ensure that individuals are not being treated in an inhuman or degrading way?</p>	<p>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.</p>
<p><b>Autonomy</b> – right to respect for private &amp; family life; being able to make informed decisions and choices</p>	<p>How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?</p>	<p>Access to technologies in diabetes self-care of diabetes improves access to data to help inform self-care and decision making</p>
<p><b>Right to Life</b></p>	<p>Will or could it affect someone's right to life? How?</p>	<p>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.</p>

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<b>Right to liberty</b>	Will or could someone be deprived of their liberty? How?	The technologies give people liberty.
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