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Hybrid closed loop technologies: 5-year implementation strategy

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Foreword

NHS England's vision is to ensure equitable and fair access to diabetes technologies while striving to set the international standard for diabetes care. A recent [King's Fund report \(https://www.kingsfund.org.uk/publications/nhs-compare-health-care-systems-other-countries\)](https://www.kingsfund.org.uk/publications/nhs-compare-health-care-systems-other-countries) comparing the performance of international healthcare systems assessed England as having a high overall score for digital healthcare readiness within diabetes, with strong institutional capacity, proactive attempts to collect data on diabetes through national audits and digital diabetes management tools in clinical guidelines.

The [NHS Long Term Plan \(https://www.longtermplan.nhs.uk/\)](https://www.longtermplan.nhs.uk/) signalled NHS England's intent to improve digital access by including commitments for at least 20% of the type 1 diabetes population being offered a flash glucose monitoring device, and for all pregnant women living with type 1 diabetes to be offered a continuous glucose monitoring (CGM) device for the duration of their pregnancy. The NHS Diabetes Programme has exceeded expectations with over 65% of people living with type 1 diabetes accessing flash glucose monitoring, and 98% of eligible pregnant women having been offered CGM and 78% having accepted. As

a result of this programme, the NHS has seen recorded results for patients' 'time in range' improve significantly, and admissions and time spent in neonatal intensive care units reduce for babies born to mothers living with type 1 diabetes (Feig, et al 2017 ([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)32400-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32400-5/fulltext))).

The mental burden of living with diabetes is significant; with patients and their families having to review complex data and make multiple calculations to optimise insulin dosing. This can be exhausting, can affect people's mood, and frequently leads to burn out. Hybrid closed loop (HCL) systems deliver insulin automatically using a calculation based on continuous glucose measurements. The systems are designed to reduce the mental burden and improve people's quality of life. Use of HCL is also associated with improvements in HbA1c, time in range and hypoglycaemia (Crabtree, et al 2023 (<https://diabetesjournals.org/care/article/46/10/1831/153467/Hybrid-Closed-Loop-Therapy-in-Adults-With-Type-1>)). Ng, et al 2022 (<https://onlinelibrary.wiley.com/doi/abs/10.1111/dme.15015>)).

HCL is the next step in the evolution of diabetes technology as it links CGM with insulin pump technology. However, given clinical capacity constraints in the NHS, and ongoing workforce specialist training requirements, HCL will need a phased implementation over a 5-year period.

Subject to cost-effective prices being agreed with industry suppliers and manufacturers in line with the [NICE technology appraisal recommendation](https://www.nice.org.uk/guidance/ta943) (<https://www.nice.org.uk/guidance/ta943>), this document sets out our strategy for HCL implementation across England.

Professor Partha Kar

NHS England GIRFT Type 1 Diabetes Technology Clinical Lead.

1. Introduction

1.1 Hybrid closed loop (HCL) technologies are the next phase of technical advancement linking continuous glucose monitoring (CGM) and insulin pump technology to provide people living with type 1 diabetes with support 24 hours a day. Sometimes referred to as an 'artificial pancreas', HCL has led to high levels of interest in the technology from people living with type 1 diabetes. This is because the benefits of HCL, including the potential to reduce mental burden and improve quality of life, are well-known.

1.2 National Institute for Health and Care Excellence (NICE) technology appraisals normally expect relevant health bodies to comply with technology appraisal recommendations and make a health technology available for patients

within 3 months of publication of final guidance. NICE agreed to extend the normal period of compliance to 5 years because NHS England submitted a funding variation request that NICE accepted after public consultation.

1.3 NHS England's funding variation request was based on a clinical rationale and focused on eligible patients requiring specialist clinical support to access the technology. This specialist support for adult care is currently concentrated within a limited number of trusts, predominantly larger specialist teaching hospitals, with less availability in smaller specialist trusts and district general hospitals. NICE agreed to the 5-year implementation period to allow the NHS time to train and build specialist competencies within the clinical workforce, and to procure HCL technologies at cost-effective prices. It is not possible to provide HCL in a shorter timeframe given the demand management pressures and capacity constraints that diabetes services are currently experiencing.

1.4 This implementation strategy has been prepared primarily for ICB leads, trust clinical leads working in children, young people and adult services, as well as regional diabetes leads and clinical network leads in their support roles.

1.5 The NHS Diabetes Programme has worked collaboratively with a range of partners since the development, initiation and evaluation of the HCL pilot. These include NICE, Association of British Clinical Diabetologists (ABCD), Diabetes UK and Juvenile Diabetes Research Foundation (JDRF). The NHS Diabetes Programme team have also carried out an extensive engagement exercise with the diabetes leadership community. A series of webinars have been held with regional teams, clinical networks, integrated care board (ICB) and trust clinical leads for both adult and children and young people's services to seek feedback on the proposed HCL implementation plan. All NHS regions across England have been actively engaged, with good attendance (over 850 stakeholders participating) and positive feedback received.

1.6 As a result, NHS England understands that the vast majority of paediatric units are in a position to engage in the early mobilisation stages of HCL implementation. Around 60 diabetes centres that provide care to the adult population have expressed interest in becoming 'early adoption sites' across the country. All ICBs are asked to confirm through high-level delivery plans the names of trusts that will support HCL implementation in the early phase of programme rollout, starting from April 2024.

1.7 Ensuring equitable access to technology and appropriate care is a key goal for NHS England, clinical experts and patient representative groups, and therefore an equality health impact assessment (EHIA) has been prepared to try

to mitigate complexities related to population demographics such as age, deprivation, ethnic diversity, language, income and access to technology (for example, smartphone, internet and broadband).

1.8 The implementation strategy will be overseen by the HCL Expert Advisory Group, the membership of which is:

- NHS England GIRFT Type 1 Diabetes Technology clinical lead
- NHS England Diabetes Children and Young Adults clinical lead
- ABCD Diabetes Technology Network representative
- National Children and Young People's Diabetes Clinical Network clinical lead
- Diabetes UK representative
- JDRF representative
- Diabetes Specialist Nursing Forum UK representative
- Regional and/or ICB representative
- NHS England Diabetes Programme director
- NHS England HCL Programme lead
- NHS England GIRFT Project and analytical lead

2. Purpose and principles

2.1 Purpose

2.1.1 This implementation strategy is designed to ensure that eligible patients across England receive equitable and fair access to HCL technologies which are provided at cost-effective prices as set out in [Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes: Technology appraisal guidance \[TA943\]](https://www.nice.org.uk/guidance/ta943) (<https://www.nice.org.uk/guidance/ta943>).

2.1.2 It sets out guidance on how local ICB leaders can develop plans to meet the needs of their populations who meet the recommended NICE eligibility criteria. These include:

- adults living with type 1 diabetes who have an HbA1c of 58 mmol/mol (7.5%) or more, or have disabling hypoglycaemia despite best possible management with at least one of the following:
 - continuous subcutaneous insulin infusion (CSII)
 - real-time CGM
 - intermittently scanned CGM
- children and young people living with type 1 diabetes
- women, trans men and non-binary people living with type 1 diabetes who are pregnant or planning to become pregnant.

HCL systems are only recommended for the above populations if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies. Should NHS England be able to agree cost-effective prices with industry suppliers and manufacturers in line with the NICE technology appraisal recommendation, then it will work with NHS Supply Chain to establish a national framework of HCL technologies for ICBs and providers to purchase from.

2.1.3 The strategy focuses on improving population health outcomes, ensuring equitable access to HCL and reducing health inequalities. It also acknowledges the current state of readiness different NHS providers are at in terms of their levels of specialist support; while prioritising focus where patient need is greatest and to those people who are likely to benefit most.

2.1.4 Key elements of the implementation strategy include: workforce capacity and competencies; patient and professional education; commercial requirements; resources to support mobilisation; ICB reimbursements for HCL technologies; and activity and outcomes reporting.

2.2 Principles

2.2.1 The HCL implementation strategy is underpinned by 6 overarching guiding principles. These have been agreed with key partners to ensure access to clinically and cost-effective technologies is provided in a fair, transparent and equitable manner.

Overarching principles for the HCL implementation strategy

Principle 1: HCL technologies will be initially rolled out to type 1 diabetes patients where the need is greatest and to those who are likely to benefit most.

Principle 2: HCL technologies will be delivered from specialist centres with paediatric units regarded as the optimal place to start implementation.

Principle 3: Education and training is a vital component in supporting wider access to HCL technologies and will be at the heart of the rollout. Professional and patient representative groups, specialist centres and manufacturers will all need to align to provide this.

Principle 4: HCL technologies will be phased into the NHS in both an equitable and sustainable manner to avoid exacerbation of existing health inequalities.

Principle 5: NHS bodies will only purchase HCL technologies in line with the recommendation set out in the NICE technology appraisal. NHS England reserves the right to undertake further commercial activity to ensure HCL systems continue to deliver value for the NHS as new technology emerges.

Principle 6: The phased implementation of HCL will be transparent and supported by data. A robust process for monitoring and reporting uptake will be formalised through the National Diabetes Audit and National Paediatric Diabetes Audit.

2.2.2 Principle 1: HCL technologies will be initially rolled out to type 1 diabetes patients where the need is greatest and to those who are likely to benefit most. This should be informed by the best available evidence, local decision-making and clinical judgement. This is an important consideration in areas where there are clinical workforce capacity constraints and limited specialist clinical support to access the technology. Where specialist clinical support is limited, consideration should be given to initially focusing on the following populations, as set out in the NHS England funding variation request accepted by NICE following public consultation:

- Children and young people: NICE has expressed in the [technology appraisal guidance \(https://www.nice.org.uk/guidance/ta943\)](https://www.nice.org.uk/guidance/ta943) that HCL systems could provide children and young people, and their families, with more freedom and help to reduce the mental burden on parents and carers. As a result, the committee thought that HCL systems could benefit all children and young people living with type 1 diabetes irrespective of their HbA1c level. Clinical experts have explained that HCL systems could have added benefits for children and young people. For example, HCL technologies can help:
 - younger children who may not recognise symptoms of hypoglycaemia and may also have unpredictable eating patterns, frequent unscheduled activity and changing insulin requirements associated with growth
 - older children with glucose management during the physiological changes that happen at puberty.
- Women, trans men and non-binary people who are pregnant or planning a pregnancy: NICE also reported that the effectiveness of HCL systems in pregnancy would likely be greater than in the general adult population.

Although not used in the NICE meta-analysis, the recently published Automated insulin Delivery Amongst Pregnant women with Type 1 diabetes (AiDAPT) trial (<https://www.nejm.org/doi/10.1056/NEJMoa2303911>) has shown a statistically significant increase in time in the pregnancy-specific target range in the group of women using HCL compared with the group having standard insulin delivery.

- Adults already using insulin pumps who want to transition to an HCL system. NICE recommends HCL for adults living with type 1 diabetes who have an HbA1c of 58 mmol/mol (7.5%) or more. In geographies where there is limited specialist support, local systems may consider initially prioritising HCL access to existing users of insulin pumps. Clinical experts have advised that in the early phase of HCL implementation adults wishing to access HCL should be experienced in the use of diabetes technologies (for example, insulin pump and/or CGM device). Experts reference the Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus: Technology appraisal [TA151] (<https://www.nice.org.uk/Guidance/TA151>), which is still not fully implemented despite being mandated in 2008, with an estimated 69,000 patients eligible for treatment. The National Diabetes Audit has captured 26,000 people living with type 1 diabetes who are insulin pump users. This population may wish to move to HCL, could already be accessing compatible technology and be supported by clinical teams, with the appropriate specialist expertise, to transition from using insulin pumps to HCL. Over time, as specialist clinical workforce capacity grows in adult services, access to HCL should be extended to people who want to start using a pump for the first time.

2.2.3 Principle 2: HCL technologies will be delivered from specialist centres with paediatric units regarded as the optimal place to start implementation.

Trusts should only provide HCL systems if they have the support of a trained multidisciplinary team experienced in CSII and CGM in type 1 diabetes. As a result of NHS England's engagement with stakeholders, it is only right to acknowledge that it will take time to build workforce capacity and enhance clinical competencies within most adult services' clinical teams. This is a key reason why a phased implementation over a 5-year period was accepted by NICE.

2.2.4 It has also been established through our engagement (and most notably through the National Children and Young People's Diabetes Clinical Network) that paediatric units across the country are generally regarded as being in a better position to start implementing HCL in comparison to the majority of adult services. This is because the majority of paediatric units have access to specialist trained clinical staff, with greater experience of providing insulin pumps as this now forms part of a routine offer in paediatric diabetes care. Many paediatric units are already providing HCL to their patients. NHS England encourages ICBs and

paediatric units to consider prioritising children and young people, one of the initial population cohorts recommended by NICE, for access to HCL in the early stages of HCL implementation.

2.2.5 NHS England encourages proactive conversations between local ICB leaders and providers of children, young people and adult diabetes services to agree a delivery plan for their local population. If a specialist diabetes centre is unable to provide access to HCL for the eligible population across the ICB geography, then consideration needs to be given to how a lead trust can support neighbouring trusts by providing training and other support to upskill their clinical workforce. NHS England will assist the Diabetes Technology Network in the dissemination of professional guidelines that will help ICBs and clinical teams to decide how best to take forward HCL in their geographies.

2.2.6 Principle 3: Education and training is a vital component in supporting wider access to HCL technologies and will be at the heart of the rollout.

Professional and patient representative groups, specialist centres and manufacturers will all need to align to provide this. The Diabetes Technology Network has produced a series of educational videos to support clinical teams. The videos cover themes such as: what is HCL; choosing your HCL; getting started on HCL; HCL essentials; and HCL and exercise. Such resources will be made available via the [Association of British Clinical Diabetologists](https://abcd.care/) (<https://abcd.care/>) website. The National Children and Young People's Diabetes Clinical Network also held an educational training day on 3 November 2023 to improve understanding of HCL systems, optimising their use and improving clinician confidence to support priority populations. NHS England will work with its partners to learn from these educational resources and understand what other educational requirements are needed, to inform the development of a comprehensive package of ongoing educational support.

2.2.7 HCL suppliers and manufacturers will also provide clinician and patient training and educational resources. Further information is detailed in section 4.2.4.

2.2.8 Principle 4: HCL technologies will be phased into the NHS in both an equitable and sustainable manner to avoid exacerbation of existing health inequalities. The NHS Diabetes Programme will draw on its experience and adopt similar approaches used in the rollout of flash and CGM to ensure equitable access to HCL. Automatic administration of insulin, as required 24 hours a day, should help people who find it difficult to maintain healthy blood glucose levels. Local plans need to be in place to ensure people living in economically deprived communities; certain Black, Asian and minority ethnic populations; people who have low educational attainment levels; and people with limited or no ability to speak English receive equal access to HCL. NHS England will commission the

production of educational resources and other patient-facing materials in the top 10 non-English languages spoken in England to support people. Industry suppliers and manufacturers are also offering to provide support. For individuals who may struggle to engage with written communications, local plans should consider how access to interpreting services, translation and easy read materials can be made available to support a range of populations (for example, older adults who do not speak English as a first language).

2.2.9 Principle 5: NHS bodies will only purchase HCL technologies in line with the recommendation set out in the NICE technology appraisal. NHS England reserves the right to undertake further commercial activity to ensure HCL systems continue to deliver value for the NHS as new technology emerges. A range of HCL systems are available from different companies. Individual components of different systems are sometimes combined. NHS Supply Chain provided costs for the various technologies at April 2023 prices. Following external assessment, NICE concluded that companies will need to agree discounts with NHS England, on behalf of the relevant health bodies, for HCL systems to become available on the NHS. Further negotiations are required with manufacturers to receive company discounts so the NICE threshold of £20,000 per quality-adjusted life year (QALY) gained can be secured for the NHS.

2.2.10 Principle 6: The phased implementation of HCL will be transparent and supported by data. A robust process for monitoring and reporting uptake will be formalised through the National Diabetes Audit and National Paediatric Diabetes Audit. Key metrics have been agreed to measure and monitor HCL uptake, population outcomes and progress against addressing health inequalities. Trusts will need to submit comprehensive baseline technology data (on insulin pumps, CGM and HCL devices) to the audits via the relevant part of the patient and care section of the submission portal.

2.2.11 NHS England will produce quarterly updates on HCL activity, as captured through the national audits, at ICB and national level. NHS England will also produce routine monitoring data, via dashboards and evaluation of outcomes reports, to inform local quality improvement initiatives aimed at reducing unwarranted variation in HCL access and addressing health inequalities.

3. What is the NHS going to do?

3.1 Establish a national framework of HCL technologies for ICBs and providers to purchase from

3.1.1 Following the conclusion of a commercial tendering exercise led by NHS Supply Chain, NHS England will work collaboratively with NHS Supply Chain to promote a national framework of HCL technologies for ICBs and providers to purchase from. This will comprise different components of HCL systems (for example, compatible insulin pumps, CGM devices and combined technologies) for ICBs or providers to buy to meet the needs of their local population.

3.1.2 Companies offering cost-effective prices at the level specified by the NICE Appraisal Committee will feature on the national framework of HCL technologies. This will be reinforced by commercial agreements with individual suppliers. NHS Supply Chain, with clinical input from NHS England, will develop scenarios where ICBs and providers can purchase a combination of different technologies at cost-effective prices through the framework to meet the needs of the eligible population.

3.2 NHS England will contribute to the costs of HCL and offer reimbursement funding

3.2.1 ICBs are responsible for the implementation of HCL and ensuring equitable access to the technology is achieved for their local population. From 2024/25, NHS England will make available capped funding to all ICBs, from which they can request reimbursement for 75% of the estimated incremental costs of HCL as a contribution to the cost of the technology and operational delivery of the service. The level of reimbursement for activity has been calculated by estimating the increase in costs associated with providing HCL to a larger population, and taking into account the greater use of staff time, provision of new or upgraded equipment as required (for example, compatible insulin pumps, CGM devices and combined technologies) and consumables. Each ICB's maximum funding will be calculated using data from the National Diabetes Audit and National Paediatric Diabetes Audit on the total eligible population. NHS England will review HCL activity and make retrospective quarterly reimbursements to ICBs as Service Development Funding, based on their activity returns submitted to the audits. Where ICBs are not claiming the maximum amount in year, NHS England may, by exception and with the agreement of regional teams, reallocate underspend to other ICBs. Allocations in respect of quarter 4 will be made before year end using estimated activity based on run-rate.

3.2.2 For ICBs to be eligible to receive HCL reimbursement payments they must abide by the following criteria:

1. ICBs will only receive reimbursements for technologies purchased from the national framework of HCL technologies hosted by NHS Supply Chain, once the framework is established in the 2024/25 financial year. In the interim period, local systems still have the option to engage with technology companies using existing supply chain frameworks, so the purchase of cost-effective HCL systems can continue or start without delay. NHS Supply Chain will continue to support systems to achieve best value.
2. To access the funds, diabetes centres and paediatric units providing HCL will need to update their returns to the National Diabetes Audit and National Paediatric Diabetes Audit by 29 March 2024 to show their baseline position, with the expectation that they will continue to routinely submit quarterly data to the audits. This will establish baseline data on existing prescribing of open loop pumps, real-time CGM and HCL. Where baseline or quarterly returns have not been completed this could delay and potentially affect reimbursements from NHS England. Before passing the HCL funding to providers, ICBs should satisfy themselves that the provider is completing their quarterly National Diabetes Audit and National Paediatric Diabetes Audit returns.
3. NHS England will create the quarterly data return to track HCL prescribing activity and use it for the purpose of reconciling reimbursement payments for individual ICBs. ICB reimbursements will be made on a quarterly basis as adjustments to ICB Service Development Fund allocations. This funding will be ring-fenced for HCL with ICBs responsible for ensuring funds due to hospital trusts are transferred. Block contracts should not be used to support the administration of these funds between ICBs and trusts.
4. ICBs must have developed a high-level local delivery plan setting out how they will meet the needs of the local eligible population and achieve equality of access over the 5-year period.
5. Finally, NICE recommended in March 2023 that all people living with type 1 diabetes should be offered continuous glucose monitors. It has been the responsibility of ICBs to provide these monitors for people living with type 1 diabetes since April 2021, with funding included in ICB core allocations. It is expected that ICBs will cover any additional costs relating to their provision to support HCL prescribing.

3.3 ICB delivery plans will set out how they will meet the needs of the local eligible population and achieve equality of access

3.3.1 Each ICB will develop a high-level local delivery plan for the next 5 years and set out how the needs of the NICE recommended eligible population (see section 2.1.2) will be met and equality of access achieved. This is an important consideration in areas where there are clinical workforce capacity constraints and limited specialist clinical support available to access the technology.

3.3.2 Where access to specialist clinical support is limited, consideration should be given to initially focusing on areas of greatest need and people who are likely to benefit most. In section 2.2.2, we describe the first of 6 principles underpinning this strategy, and provide a rationale for why ICBs lacking specialist clinical support should consider an initial focus on the following populations in the early stages of HCL implementation:

- children
- young people
- women, trans men and non-binary people who are pregnant or planning a pregnancy
- adults already using insulin pumps who want to transition to an HCL system.

Over time, as the specialist clinical workforce capacity grows in adult services, access to HCL should be extended to people who want to start using a pump for the first time. The professional representative bodies will produce guidelines to support ICBs with HCL implementation.

3.3.3 High-level ICB delivery plans should consist of no more than 3 sides of A4, be submitted to NHS England by 28 February 2024 and will:

1. **Describe local population need** – including: profiling local trends in type 1 diabetes technology access by age, ethnicity, indices of multiple deprivation, sex; population cohorts to be prioritised in the early stages of mobilisation; and how equality of access will be achieved during the 5-year implementation phase.
2. **Confirm the names of the acute trusts within the ICB area that intend to provide HCL in the early phase of mobilisation.** Insights from our stakeholder engagement have informed us that paediatric units across the country are in a more advanced state of readiness to start HCL implementation in comparison to adult services. Therefore, it is anticipated that the vast majority of paediatric units will be in a position to provide HCL to their patients from April 2024.
3. **ICB delivery plans will also need to confirm the state of readiness of diabetes centres providing specialist services to eligible adults living**

with type 1 diabetes. If some diabetes centres are not in a position to provide HCL to their patients within an ICB area from April 2024, the plan will need to set out how and when the needs of the eligible adult population will be served. As a result of NHS England's engagement with clinical leads and networks, there is a growing consensus that a 'hub and spoke' model would help mobilise the programme. The hub and spoke approach has worked effectively in some regions in terms of CGM adoption. There is flexibility in the model for this to be delivered at ICB or clinical network level. This approach also builds on learning from the HCL pilot programme where the NHS Diabetes Programme team worked with diabetes specialist centres, largely comprising teaching hospitals across England, to trial the rollout of HCL in a real-world setting. For the adult population, diabetes centres onboarded as early adoption sites will be supported by NHS England to perform the role of a specialist hub – if required locally. Support from specialist hubs could include:

- providing leadership, expertise and training to neighbouring spoke trusts to enable them to develop their own workforce competencies, skill sets, and helping them build their workforce capacity to provide HCL and insulin pumps for their own eligible patients.
 - providing access to HCL to eligible patients registered with neighbouring spoke trusts that lack the specialist expertise to provide HCL. This potentially could include patients registered in different ICB areas within a region.
4. Delivery plans will need to have local trust approval, be signed off by a senior ICB leader and provide details for local clinical leads (both adult and children and young people's services) and ICB finance lead to support the processing of payments.

3.4 Mobilisation funding to support the implementation of HCL

3.4.1 NHS England released a £2.5 million HCL mobilisation fund to systems via ICB allocations in December 2023. This fund provides each ICB with £60,000 this financial year for pass-through to specialist providers; to support the release of clinical time to help finalise local implementation plans, provide or participate in essential workforce training, and establish hub and spoke arrangements where required. This funding should also support diabetes units and paediatric centres to submit baseline data to the National Diabetes Audit and National Paediatric Diabetes Audit by 29 March 2024. It can also support trust administration costs associated with onboarding a new cohort of HCL patients.

3.5 Support for people living with type 1 diabetes

3.5.1 It is recommended that all patients will be offered face-to-face diabetes structured education and management training.

3.5.2 It is recommended that all patients will also be offered digital access to diabetes education, information and self-management support.

3.5.3 HCL patient education will be strongly encouraged before the individual is prescribed the product. Once prescribed, as part of the onboarding process, patients will also be encouraged to participate in training in HCL management. This will be delivered or supported by the product manufacturer subject to commercial agreements being confirmed.

3.6 Professional training on HCL management

3.6.1 NHS England expects manufacturers to provide training on their HCL systems to healthcare professionals who prescribe, initiate or support maintenance of HCL for their patients.

3.6.2 Trusts will also be expected to ensure their staff are suitably trained.

3.6.3 Diabetes centres that agree to become HCL early adopters, and provide a specialist hub service locally, should offer training and support on HCL and insulin pump management to agreed neighbouring trusts, where required, to help them build their own workforce competencies. ICBs should use the mobilisation fund to support appropriate trust clinical staff to provide, receive or participate in training.

3.6.4 NHS England will also work with professional representative bodies like the Diabetes Technology Network, and structured education and self-management support providers to ensure HCL training modules are tailored and readily available to clinicians and people living with type 1 diabetes.

3.7 Data reporting, monitoring and evaluation

3.7.1 The development of a robust reporting process via the National Diabetes Audit and National Paediatric Diabetes Audit is in the advanced stages of planning. NHS England and the National Diabetes Audit team have identified key metrics to measure and monitor HCL uptake levels, population outcomes and progress in addressing health inequalities.

3.7.2 Trusts will need to submit comprehensive baseline technology data (on insulin pumps, CGM and HCL devices) to the National Diabetes Audit and National Paediatric Diabetes Audit, via the relevant part of the patient and care

section of the submission portal, by 29 March 2024 for ICBs to access HCL reimbursement funding. This is because HCL prescribing activity will be used to reconcile reimbursement payments to ICBs on a quarterly basis. Therefore, there is also a requirement for trusts to return a quarterly data return so reimbursements can be made to local organisations.

3.7.3 NHS England will produce routine monitoring data, via dashboards and evaluation of outcomes reports, to inform local quality improvement initiatives aimed at reducing unwarranted variation and addressing health inequalities.

3.8 HCL supply and distribution

3.8.1 The supply and distribution of HCL systems will be confirmed by NHS Supply Chain once the competitive tendering process has concluded and contracts with all suppliers have been signed.

4. Delivering the strategy

4.1 Governance

4.1.1 HCL rollout will have robust and transparent governance processes accountable to the Diabetes Programme Board. The 5-year implementation strategy will undergo stringent review by NHS England to ensure the equitable rollout of the technology. A governance chart is set out in the appendix.

4.1.2 An outline of the strategic approach and delivery plan was presented to NICE in support of the variation request submitted. Following further consultation on the strategy and justification for phased implementation, NICE approved NHS England's funding variation request. The approach and delivery plan were also endorsed by the Diabetes Programme Board on 11 September 2023, with the implementation strategy approved on 4 December 2023.

4.1.3 The adherence to good corporate governance will continue into the implementation phase and will be supported by the establishment of an expert advisory group, for which members have already been recruited. The advisory group will comprise diabetes clinical experts from children, young people and adult services, and professional and patient representative groups. It will provide expert input, oversight and advice throughout the programme lifecycle.

4.1.4 Capturing, sharing and learning from knowledge gained by clinical leaders throughout the implementation phase is a key guiding principle for the NHS Diabetes Programme and was adopted during the rollout of other technologies like flash glucose and CGM. The NHS Diabetes Programme will utilise

established engagement channels with diabetes clinical leads nationwide, the Diabetes Programme Board and the expert reference group, to obtain a consensus on good practice approaches and agree future amendments to the strategy when appropriate.

4.2 Roles and responsibilities

4.2.1 NHS England:

- provide overall leadership for the programme and manage the interface between ICBs, acute trusts, regional teams, professional and patient representative groups
- oversee the management of the HCL programme from a national perspective
- develop and manage the governance process – including consulting the HCL Expert Advisory Group, creating an HCL delivery group to oversee operational delivery, reporting to the Diabetes Programme Board, and capturing local insights from diabetes centres on progress in implementation at collaborative sessions with early adoption sites
- oversee the HCL mobilisation fund allocations process
- oversee the ICB HCL reimbursements funding allocations process
- implement and manage a robust national reporting framework via the National Diabetes Audit and National Paediatric Diabetes Audit
- model exemplary new NHS England matrix working with designated leads confirmed in NHS England strategic finance, commercial, medicines value and access unit, and transformation teams (both dedicated data analytical lead and communications lead) to oversee the delivery of the implementation strategy
- agree local HCL delivery plans with ICB leads and trust clinical leads.

4.2.2 Acute trusts:

- Providers of adults' diabetes care:
 - identify clinical leadership within the trust for HCL
 - confirm with regional teams and describe in ICB delivery plans whether the trust:
 - will be in a position to provide HCL in the early stages of mobilisation; and
 - is in a position and required to provide specialist clinical support to neighbouring trusts (as a specialist hub); or
 - requires access to specialist clinical support from a neighbouring diabetes centre to provide HCL to their patients (as a spoke trust)

- trusts to return baseline technology data (on insulin pumps, CGM and HCL devices) to the National Diabetes Audit by 29 March 2024 and make quarterly submissions as part of routine HCL reporting
 - ICBs are strongly encouraged to purchase technology on behalf of all trusts
 - trusts to utilise available resources, professional training, patient information, education and self-management support (including in-person and digital services).
- Providers of children and young people's services:
 - identify clinical leadership within the trust for HCL
 - confirm with regional teams and describe in ICB delivery plans if paediatric units are in a position to implement HCL from April 2024
 - trusts to return baseline technology data (on insulin pumps, CGM and HCL devices) to the National Paediatric Diabetes Audit by 29 March 2024 and make quarterly submissions as part of routine HCL reporting
 - ICBs are strongly encouraged to purchase technology on behalf of all trusts
 - trusts to utilise available resources, professional training, patient information, education and self-management support (including in-person and digital services).

4.2.3 Integrated care boards:

- engage clinical and patient leaders to determine the optimal approach to implementing HCL to meet the needs of the eligible population
- develop ICB delivery plans by 28 February 2024 setting out how they will meet the needs of the local eligible population and achieve equality of access over the 5-year period. ICB delivery plans will also confirm if a 'hub and spoke' approach is required within the ICB geography, the trusts involved and the nature of the support (for example, workforce training for clinical staff, HCL referral pathway). It is recommended local memorandum of understanding (MoUs) are established to confirm hub and spoke arrangements where required
- ensure the distribution of mobilisation funding to local trusts to help them prepare for HCL implementation and to cover associated training and administrative costs
- champion the national framework of HCL technologies for purchasing systems. ICBs are strongly encouraged to purchase technology on behalf of all trusts
- identify a finance lead to support the administration of the ICB HCL reimbursements funding and manage funding transfers to individual trusts
- regularly review activity and outcomes data and monitor progress in addressing unwarranted variation and health inequalities

- ICBs are encouraged to work with local stakeholders, including primary care, to develop the following in line with existing ICB policies and governance structures to ensure equitable access:
 - robust and inclusive communications, supported by an engagement plan, with content and channels that reach all parts of the community
 - local systems to utilise data, information and support tools available to ICBs to co-ordinate local activities to enable improvement.

4.2.4 Suppliers:

- to engage in the tender process and provide cost-effective price for their systems
- must provide an information line available to healthcare professionals, patients and carers during core hours (9 am to 5 pm), for technical support on the supplier's products, equipment and services
- suppliers of insulin pumps must provide an emergency contact phone line to patients, at the point of delivery, for resolution of any issues and problems with products. This will be available 24 hours a day, 365 days a year and provide access to a dedicated diabetes product support team
- will be able to support comprehensive clinical staff training to develop expertise among nurse specialists and medical practitioners in terms of the use, functionality and features of equipment and associated products provided under the Framework Agreement. It will be necessary for the supplier to fit in with the local shift systems of staff who require training
- will be expected to deliver training session(s) at each participating trust with sufficient frequency to ensure that all relevant staff have access to training on no longer than an annual basis for the duration of the Framework Agreement, or as and when requested to do so by the diabetes specialist team
- will make available on request educational materials that support the use of their products for the duration of the Framework Agreement. These must include materials that are suitable for healthcare professionals and materials that are suitable for patients. These can include product literature, CDs, DVDs, videos, web-based information. All materials must be provided and/or made accessible free of charge. Materials must be available in languages relevant to each trust's/ICB's population mix and provide appropriate support for people who are visually impaired.
- support for patient training will incorporate advice on the technical use of the system and not be individual specific
- as a minimum, support for patient training (alongside diabetes specialist team) must include:
 - patient pump starts
 - patient CGM starts

- advanced pump education sessions for patients on pumps, and interpretation of data from device.

4.2.5 People living with type 1 diabetes:

- are encouraged to participate in structured education, supported self-management and HCL management training prior to HCL initiation
- to consider participating in surveys evaluating the implementation of HCL so individual experiences can be captured and reflected in the future rollout of the programme.

4.2.6 Professional and patient representative groups:

Diabetes UK:

- to be represented on the National Diabetes Programme Board and HCL Expert Advisory Group, provide subject matter expertise, and contribute to the development of the strategy and its implementation
- feedback to the NHS Diabetes Programme team any insights and learning it has captured during the implementation phase
- develop and support the dissemination of guidelines and other resources
- share with the NHS Diabetes Programme any good practice case studies from local implementation for wider dissemination.

Association of British Clinical Diabetologists:

- to be represented on the HCL Expert Advisory Group, provide subject matter expertise, and contribute to the development of the strategy and its implementation
- feedback to the NHS Diabetes Programme team any insights and learning it has captured during the implementation phase
- develop and support the dissemination of guidelines and training resources
- share with the diabetes programme any good practice case studies from local implementation for wider dissemination.

Juvenile Diabetes Research Foundation (JDRF):

- to be represented on the HCL Expert Advisory Group, provide subject matter expertise, and contribute to the development of the strategy and its implementation
- feedback to the NHS Diabetes Programme team any insights and learning it has captured during the implementation phase
- develop and support the dissemination of guidelines and training resources
- share with the diabetes programme any good practice case studies from local implementation for wider dissemination.

Diabetes Specialist Nurse Forum UK:

- to be represented on the HCL Expert Advisory Group, provide subject matter expertise and contribute to the development of the strategy and its implementation
- feedback to the NHS Diabetes Programme team any insights and learning it has captured during the implementation phase
- develop and support the dissemination of guidelines and training resources
- share with the diabetes programme any good practice case studies from local implementation for wider dissemination.

Appendix: Governance and oversight structure

National Diabetes Programme Board

Key role in providing leadership oversight, reviewing progress reports, monitoring uptake activity, approving the release of funding, and monitoring progress in addressing unwarranted variation and tackling health inequalities.

Subject matter expertise: HCL Expert Advisory Group

Key role in supporting diabetes centres and diabetes paediatric units, and upskilling the workforce.

- NHS England GIRFT Type 1 Diabetes technology clinical lead
- NHS England Diabetes children and young adults clinical lead
- Association of British Clinical Diabetologists' diabetes technology network representative
- National Children and Young People's Diabetes clinical network clinical Lead
- Diabetes UK representative
- Juvenile Diabetes Research Foundation representative
- Diabetes Specialist Nursing Forum UK representative
- Regional and/or ICB representative
- NHS England Diabetes programme director
- NHS England HCL programme lead
- NHS England GIRFT project and analytical lead

Operational delivery: HCL Delivery Group

- NHS England GIRFT Type 1 Diabetes technology clinical lead
- NHS England Diabetes programme director
- NHS England HCL programme lead
- NHS England strategic finance representative

- NHS England medicines value and access representative
- NHS England commercial team representative
- NHS England Transformation Directorate representative, including data analytics and communications
- NHS England Workforce, Training and Education Directorate representative
- NHS Supply Chain representative
- NHS England GIRFT project and analytical manager

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