

How do I escalate Technology Use to Hybrid Closed Loops?



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Escalating Technology to Closed-Loop

- Mark Evans has received speakers/writers fees, acted on advisory board and/or had research collaborations with / acted as a triallist for:
 - Eli Lilly
 - NovoNordisk
 - Ypsomed
 - Sanofi
 - Medtronic
 - Dexcom
 - Roche
 - Astra Zeneca
 - Zucara
 - Boehringer Ingelheim
 - Abbott Diabetes Care
 - NGM Pharma
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Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

Technology appraisal guidance [TA943] Published: 19 December 2023 [Register as a stakeholder](#)

“What do I need to know about HCL and the NICE TA as an ST5/6 who will be in a consultant interview in 12 to 18 months”



- “Hardware”
- Service level

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- 1.4 Only use HCL systems with the support of a trained multidisciplinary team experienced in CSII and continuous glucose monitoring in type 1 diabetes.
- 1.5 Only use HCL systems if the person or their carer:
 - is able to use them, and
 - is offered approved face-to-face or digital structured education programmes, or
 - is competent in insulin dosing and adjustments.

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1.1 Hybrid closed loop (HCL) systems are recommended as an option for managing blood glucose levels in type 1 diabetes for adults who have an HbA1c of 58 mmol/mol (7.5%) or more, or have disabling hypoglycaemia, despite best possible management with at least 1 of the following:

- continuous subcutaneous insulin infusion (CSII)
- real-time continuous glucose monitoring
- intermittently scanned ^{1 Recommendation} continuous glucose monitoring.

HCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England, and implemented following [NHS England's and NHS Wales' implementation plans](#).

1.2 HCL systems are recommended as an option for managing blood glucose levels in type 1 diabetes for children and young people. HCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England, and implemented following [NHS England's and NHS Wales' implementation plans](#).

1.3 HCL systems are recommended as an option for managing blood glucose levels in type 1 diabetes for women, trans men and non-binary people who are pregnant or planning to become pregnant. HCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England, and implemented following [NHS England's and NHS Wales' implementation plans](#).

Pathways to Hybrid Closed Loop

Pathway A

Multiple daily injections



Structured education? (DAFNE)

Still meets TA criteria?

Pathway B

Pump waiting list

Processes for identifying, prioritizing, training, following up, problem-solving and then upgrading in due course

Pathway C

TA eligible and already on a pump but not one that loops

Wait for end of 4 year warranty period?

Pathway D

TA eligible and already on a pump that can loop

Pathway E

Self-funding HCL

Pathways, protocols, programmes for Insulin Pump Therapy



Pathways, protocols, programmes for Insulin Pump Therapy

- Approval process (MDT)
- Procurement
- Onboarding
- Out of hours?
- Exit strategy
- Support and identify strugglers

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Processes for identifying, prioritizing, training, following up, problem-solving and then upgrading in due course



“Unfortunately, there’s another elephant in the room.”



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Appendix 1: Eligible Population Assumptions for HCL

Uptake Outcome Scenario (2022/23 - 2027-28)	Description	Total Eligible Patients (152,309)	Eligible Adults (121,020) (>19 years old, including pregnant women)	Eligible Children (31,289) (<19 years old)
Scenario 1 (Medium Adoption)	Adult uptake is a 50% additional uptake on current insulin pump usage in wider Type 1 population. Child reflects expected uptake (HCLs offered to all children).	57,041 (37% of total estimated eligible patients)	38,349 (32% of estimated eligible adults)	18,689 (60% of estimated eligible children)
Scenario 2 (High Adoption)	Adult uptake is a 150% additional uptake on current insulin pump usage in wider Type 1 population. Child reflects expected uptake (HCLs offered to all children).	78,849 (52% of total estimated eligible patients)	60,160 (50% of estimated eligible adults)	18,689 (60% of estimated eligible children)
Scenario 3 (Low Adoption)	Adult uptake reflects current insulin pump uptake in wider Type 1 population after 15 years of availability. Child reflects expected uptake (HCLs offered to all children).	43,621 (29% of total estimated eligible patients)	24,932 (21% of estimated eligible adults)	18,689 (60% of estimated eligible children)

Proportions are presented relative to the estimated patients eligible for HCL as per NICE HTA

Eligible adults includes those with HbA1c >7.5% and pregnant women

NHSE do not have robust data on HbA1c levels of pregnant women, therefore pregnant women have been added to the HbA1c > 7.5% population. This is likely to result in some double counting of the total eligible adult population where pregnant women also have Hb1Ac levels > 7.5%

Scenario descriptions are based on the wider Type 1 adult population

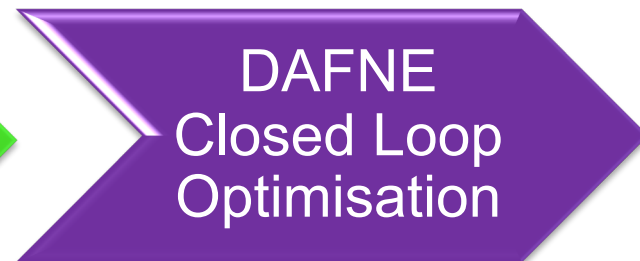


“Onboarding”



DANGER

- Manufacturers to provide device training
- Upskill other centres
- Digital resources



Date published: 22 January, 2024
Date last updated: 22 January, 2024

Hybrid closed loop technologies: 5-year implementation strategy

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. (X)

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. YES!!

Date published: 22 January, 2024
Date last updated: 22 January, 2024

Hybrid closed loop technologies: 5-year implementation strategy

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

Principle 5: NHS bodies will only purchase HCL technologies in line with the recommendations 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. OK

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. YES

Date published: 22 January, 2024
Date last updated: 22 January, 2024

Hybrid closed loop technologies: 5-year implementation strategy

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.

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