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DIABETES, ENDOCRINOLOGY, OBESITY

Hybrid closed loop rollout – pregnancy

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Disclosures

- **Speakers honoraria from:** OmniaMed, Novo Nordisk, ABCD DTN UK, ABCD, SBK

- **Travel/accommodation/registration expenses from**:
  - CONCEPTT, AiDAPT
  - ABCD Diabetes Technology Network (UK)
  - SBK

- **Advisory board:** Abbott (Libre)

- **Trial Management Group/Data & Safety Monitoring Board**
  - AiDAPT study (Closed loop in pregnant women with T1D, Norwich) (TMG)
  - AP-Renal (Closed loop in adults with T2D requiring dialysis, Cambridge) (DSMB)
  - CLEAR study (Closing the loop in adults with type 1 diabetes, Cambridge) (DSMB) (2021)

Pregnancy in diabetes

- Pregnant women with type 1 diabetes have an increased risk of adverse pregnancy outcomes
- Increased time in pregnancy-specific glucose target range (3.5-7.8 mmol/l) is associated with reduced risk of adverse pregnancy outcomes

- Pregnancy is a priority area for HCL implementation
- NICE Technology appraisal guidance TA943 Dec 2023

> 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 implementation plan.

Feig D et al, Lancet 2017 390: 2347-2359 Battelino T et al. Diabetes Care 2019;42:1593-1603

‘Pregnancy-specific’ hybrid closed loop

- Hybrid closed loop algorithms are different – most have been designed to achieve non-pregnant glucose targets
- NHSE Saving Babies Lives Care Bundle (2025) defines a pregnancy-specific hybrid closed loop system as ‘having:
  - a licence for use in pregnancy
  - a glucose target of ≤5 mmol/L
  - evidence of a clinically relevant improvement in maternal glucose outcomes (>5% increased time in the pregnancy glucose target range of 3.5–7.8 mmol/L compared to standard care with CGM and standard insulin delivery by multiple daily injections (MDI) / pump).’

https://www.england.nhs.uk/long-read/saving-babies-lives-version-3-2/.

Currently CamAPS FX is the only pregnancy specific hybrid closed loop

	CamAPS FX	Medtronic 780G SmartGuard	Tandem Control IQ	Omnipod 5 SmartAdjust
Licence for use in pregnancy	✓	✓	✗	✗
Glucose target of ≤5 mmol/L	✓ (4.4-11 mmol/l)	✗ (lowest 5.5 mmol/l)	✗ (‘sleep’ target range 6.25-6.7 mmol/l)	✗ (lowest 6.1 mmol/l)
Evidence of a clinically relevant improvement in maternal glucose outcomes	✓ AiDAPT RCT +10.5% TIRp	✗ CRISTAL RCT No difference in TIRp	✓ CIRCUIT RCT +12.5% TIRp	✗ No RCT

AiDAPT: Lee T et al N Engl J Med 2023; 389:1566-1578; CRISTAL: Benhalima K et al, Lancet Diabetes and Endocrinology, June 2024; CIRCUIT Donovan LE et al, JAMA Oct 2025 JAMA. doi:10.1001/jama.2025.19578

Ambitions for hybrid closed loop in pregnancy (England)

6.2 Women with Type 1 diabetes should be offered a pregnancy-specific HCL system ….and be provided with appropriate education and support to use this. (Saving Babies Lives Care Bundle)

2024/25

Preparation and early implementation

2025/26

>60% of pregnant women with Type 1 diabetes offered HCL

2026/27

>95% of pregnant women with Type 1 diabetes offered HCL

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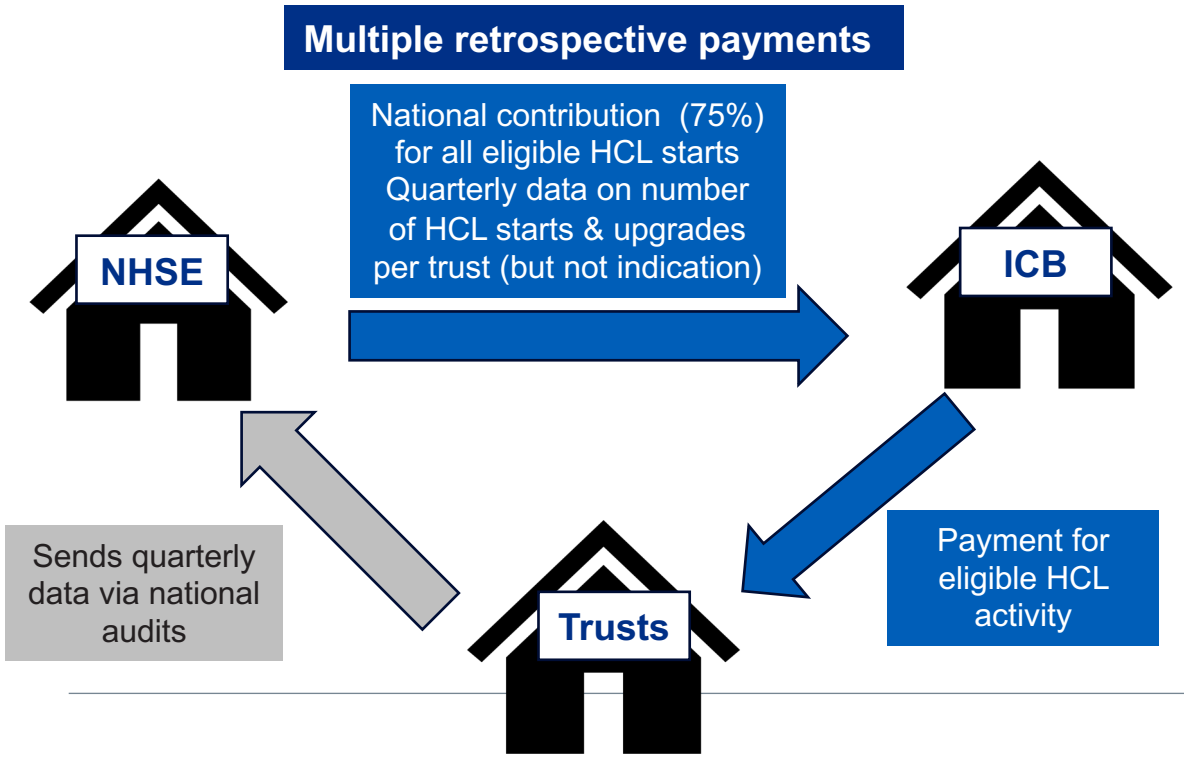
Funding considerations

- Women who are pregnant (or planning pregnancy)
  - On MDI
  - On non-pregnancy specific hybrid closed loop system or open loop

Funding for HCL in pregnancy in England

There are **two sources of national funding** to contribute to the rollout of HCL in pregnancy:

Each ICB will have a maximum funding envelope (indicative allocation) that they claim within each year. This contributes towards the costs of HCL systems for those that are eligible across the ICBs local type 1 diabetes population. **Payment is based on activity reported** to the national diabetes audits.



'*Pregnancy Pump Switching Fund*' for pregnant women who are already using an insulin pump when they become pregnant that is incompatible with pregnancy-specific HCL. **Allocated to ICBs up front** in May 2025 and was included with funding labelled as '*fixed HCL allocation for eligible activity not captured by reporting*'. Plan to continue in 2026-2027.

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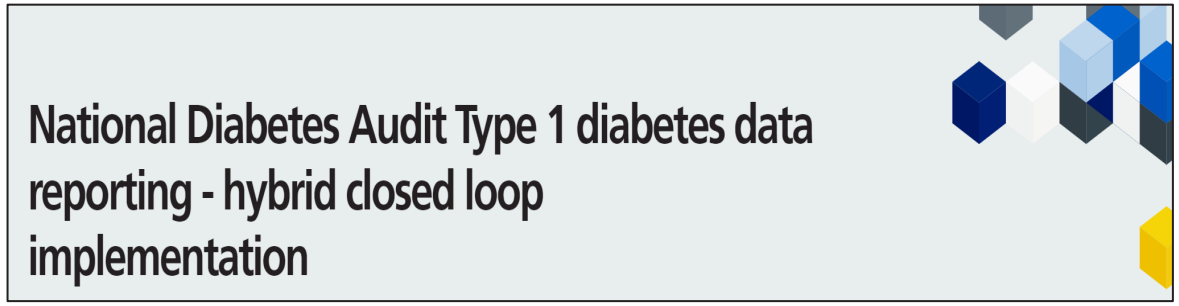
Reporting requirements for HCL in England

Trusts should submit data to two national audit datasets – one to claim national reimbursement and the other to help track outcomes.



NDA SS: Data required quarterly (next submission deadline 15 January 2026) to claim national funding for eligible HCL activity

National Diabetes Audit Type 1 diabetes data reporting - hybrid closed loop implementation - NHS England Digital

NPID: Data required annually (by February each year) to track technology usage in pregnancy and associated outcomes. Asks pregnancy-specific HCL (CamAPS FX), standard and other HCL systems at booking and 28 weeks of gestation.
This data will inform annual fixed allocations and help NHS England to track switches to pregnancy-specific HCL systems
National Pregnancy in Diabetes Audit - NHS England Digital

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Promising progress to date

Hybrid Closed Loop starts due to pregnancy and pregnancy planning:

- There are usually approximately 2,000 Type 1 pregnancies a year reported to the National Pregnancy in Diabetes (NPID) Audit.
- In 2024/25 ‘pregnancy’ was recorded as the reason for 655 HCL starts which was equivalent to

~33% of type 1 diabetes pregnancies. Does not include those already on HCL prior to April 2024.

	Total Q1-Q4 2024/25		
HCL start meets criteria:	All	*Pump to HCL*	*No pump to HCL*
Pregnancy	655	*136*	*519*
Pregnancy Planning	531	*125*	*406*
Other Adult HCL starts	8,421	*3,891*	*4,530*
Proportion of adult HCL starts due to pregnancy and pregnancy planning criteria	12.3%	*6.3%*	*17.0%*

- So far, in 2025/26 ‘pregnancy’ has been reported as the reason for 271 HCL starts.

Source: GIRFT analysis of NDA and NPDA data - England only. Unpublished
Please note: Data reflects recording of the criteria as a reason for a HCL start. Where an adult met other criteria e.g HbA1c >58mmol/mol and the pregnancy questions weren’t answered, or where HCL starts were due to pregnancy / pregnancy planning, but trust sites did not correctly record and submit data, they won’t be included in these counts. They are therefore likely to be underestimates of HCL use in pregnancy.

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Practicalities

- If starting hybrid closed loop or system renewal, if considering pregnancy in the next 4 years consider pregnancy-specific system or system with no upfront costs (e.g. Omnipod 5)
- Services need to have in place:
  - At least one named HCL diabetes consultant and at least one named HCL diabetes specialist nurse/midwife/dietitian within the antenatal clinic
  - Training as appropriate for all health care professionals involved in care in the use of the pregnancy-specific HCL system
- Hardware
  - If no compatible mobile phone, request the YpsoMed Digital essentials pack
  - If wishes to use pregnancy-specific system for pregnancy only and then revert, consider loaning a pump (instructions for reuse and cleaning available)

Practicalities

- Training
  - DAFNE hybrid closed loop essentials
  - In-app training
  - In-person training
    - Can be done by device company educator. Hospital diabetes educator should be present or available
    - Can be done in groups (provided suitable for the woman and no delay)
    - Can be done face to face or online (provided suitable for the woman)
- Safety
  - Must understand the pump only contains rapid-acting insulin. If cannula/infusion set fails ketosis/ketoacidosis can develop very quickly
  - DKA in pregnancy carries a risk of fetal death (Diguisto, Strachan, 2022)
  - Unexplained hyperglycaemia/sick day rules. Carry glucose & ketone meter & strips, rapid acting insulin pen and needles.
  - Set changes
    - Perform early in the day,never before bed
    - For those changing from Omnipod, emphasize tubing primed BEFORE cannula inserted

Practicalities

- Initial support
  - Contact every 2-3 days for at least first week, including at first cannula change, until confident
- Equity of access
  - Some will have particular needs (e.g. learning difficulty or disability, numeracy or literacy difficulties, neurodivergent, mental health conditions, difficultly communicating in English etc)
  - Every effort should be made to support use of pregnancy-specific HCL provided this can be done safely

Resources to support delivery

Clinical resources:

- DTN Best Practice guidance on HCL in pregnancy – due shortly
- A 2-page HCL in pregnancy Factsheet, developed by the Diabetes Specialist Nurse Forum
- Elearning for Health module on the management of diabetes in pregnancy to support SBLCB: Safety Action 6

Implementation resources - on the National Diabetes Programme FutureNHS workspace:

- A step by step guide for ICBs on HCL in pregnancy, setting out the following key steps:
  1. Understand local data
  2. Identify available national funding
  3. Local prioritisation of HCL implementation across local type 1 population
  4. Clinical engagement and readiness
  5. Register with NHS supply Chain framework
  6. Engage suppliers and explore the support they can offer
  7. National audit submissions
  8. Pay providers for activity
  9. Local monitoring and review
- National and regional HCL pregnancy webinar recordings.
- There is also an FAQ document with key information about national funding and data reporting.

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