**HIGHLY CONFIDENTIAL**

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## MULTIPLE TECHNOLOGY APPRAISAL

## Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

The following documents are made available to the consultees and commentators:

**1. Appraisal Consultation Document (ACD) as issued to consultees and commentators**

**2. Collated comments on the Appraisal Consultation Document from companies in scope:**

- Advanced Therapeutics UK
- Cambdiab Ltd
- Dexcom International
- Medtronic
- Tandem Diabetes Care Inc.
- Ypsomed Limited

*Note the following additional evidence was received (not included with these papers):*

- Medtronic:
  - Conference abstract 'Automated insulin delivery use in adults with type 1 diabetes (T1D) treated with insulin pump and continuous glucose monitoring (CGM) but not meeting glycemic targets: A randomized controlled trial' Christensen MB et al
  - Protocol for NCT04914910 'The Steno 780G study'

- Tandem Diabetes Care Inc:
  - 'Glycemic Outcomes of Use of CLC Versus PLGS in Type 1 Diabetes: A Randomized Controlled Trial', Brown SA. Diabetes Care 2020;43:1822–1828

**3. Consultee and commentator comments on the Appraisal Consultation Document from:**

- Diabetes UK
- Insulet International Ltd
- JDRF UK
- NHSE (see also under 5, comments received through the NICE website, for further NHSE comments)

Please see also under 5, comments received through the NICE website, for comments from:

- National Children and Young Peoples Diabetes Network
- Diabetes Technology Network UK

**4. Comments on the Appraisal Consultation Document from experts:**

- Professor Partha Kar, National Specialty Advisor, Diabetes with NHS England
- Prof Peter Hindmarsh, clinical expert - Professor of Paediatric Endocrinology
- Dr Sufyan Hussain, clinical expert - Consultant Physician in Diabetes & Endocrinology
    - *Note: the following additional information (not included with these papers) was received via introduction from Dr Hussain* "Findings of the AiDAPT study: a randomised trial of automated insulin delivery in pregnant women with type 1 diabetes". Submitted ahead of publication as academic in confidence.
- Dr Fiona Regan, clinical expert - Paediatric Diabetes Consultant

**5. Comments on the Appraisal Consultation Document received through the NICE website**

**6. External Assessment Group critique of companies' comments on the ACD**

**7. Evidence Assessment Group addendum**

a. EAG addendum
b. EAG Appendix - exploratory paediatric modelling

**8. Log of assumptions used in the calculation of costs**

**9. NICE responses to comments on the Appraisal Consultation Document**

*Any information supplied to NICE which has been marked as confidential, has been redacted. All personal information has also been redacted.*

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Appraisal consultation document

# Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

The Department of Health and Social Care has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using hybrid closed loop systems for managing blood glucose levels in type 1 diabetes in the NHS in England. The diagnostic advisory committee has considered the evidence submitted by the company and the views of non-company consultees and commentators, clinical experts and patient experts.

**This document has been prepared for consultation with the consultees.** It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the consultees and commentators for this appraisal and the public. This document should be read along with the evidence (see the committee papers).

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?



Issue date: January 2023

**Note that this document is not NICE's final guidance on this technology. The recommendations in section 1 may change after consultation.**

After consultation:

- The diagnostics advisory committee will meet again to consider the evidence, this appraisal consultation document and comments from the consultees.
- At that meeting, the committee will also consider comments made by people who are not consultees.
- After considering these comments, the committee will prepare the final appraisal document.
- Subject to any appeal by consultees, the final appraisal document may be used as the basis for NICE's guidance on using hybrid closed loop systems in the NHS in England.

For further details, see NICE's guide to the processes of technology appraisal.

The key dates for this appraisal are:

Closing date for comments: 31 January 2023

Second diagnostics advisory committee meeting: 16 February 2023

Details of membership of the diagnostics advisory committee are given in section 5

# 1 Recommendations

1.1 Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following:

- continuous subcutaneous insulin infusion
- real-time continuous glucose monitoring
- intermittently scanned continuous glucose monitoring.

Hybrid closed loops systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2).

1.2 Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy. Hybrid closed loops systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2).

1.3 Only use hybrid closed loop systems with the support of a trained multidisciplinary team experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring in type 1 diabetes.

1.4 Only use hybrid closed loop systems if the person or their carer:

- understands and is able to use them
- is also attending a type 1 diabetes structured education programme.

1.5 These recommendations are not intended to affect use of hybrid closed loop systems that was started in the NHS before this guidance was published. People using hybrid closed loop systems outside these

recommendations may continue until they and their NHS clinician consider it appropriate to stop. For children and young people, this decision should be made jointly by them, their clinician and their parents or carers.

### Why the committee made these recommendations

Standard care for type 1 diabetes involves regularly measuring blood glucose levels by self-monitoring (blood testing) or by using a continuous glucose monitor (real-time or intermittently scanned). Blood glucose levels are managed with multiple daily insulin injections or by using a pump to inject insulin under the skin (continuous subcutaneous insulin infusion). The aim of treatment is to decrease blood glucose levels and keep them within a healthy range.

Continuously managing blood glucose levels is a substantial mental load for people with type 1 diabetes (and their families or carers). Hybrid closed loop systems automatically deliver insulin using a calculation based on continuous glucose measurements. The systems do not need as much input from the person but manual insulin dosing is still needed sometimes, for example, around mealtimes. So, they may reduce the mental load and improve people's quality of life.

Clinical trial and real-world evidence shows that hybrid closed loop systems are more effective than standard care at maintaining blood glucose levels within a healthy range. Evidence suggests that the systems appear to be more effective for people with higher long-term average blood glucose (HbA1c) levels. But they are also effective for people with average HbA1c levels (the UK average HbA1c for people using a pump is around 64 mmol/mol [8.0%]).

So, to ensure wider access, hybrid closed loop systems are recommended for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition, and have an HbA1c level of around 64 mmol/mol (8.0%) or more. And because blood glucose levels are harder to manage in pregnancy, they are also recommended for people with type 1 diabetes who are pregnant or planning a pregnancy. But because there is some uncertainty in the economic model, they are

only recommended if the companies and NHS England agree a cost-effective price for the systems.

# 2 Information about hybrid closed loop systems

## Clinical need and practice

### Type 1 diabetes

2.1 It is estimated that approximately 400,000 people in the UK are living with type 1 diabetes, including around 29,000 children. In type 1 diabetes, a person's blood glucose level becomes too high (hyperglycaemia) because there is no, or very little, production of insulin by the pancreas. Blood glucose levels can only be regulated by giving insulin to prevent hyperglycaemia. If type 1 diabetes is not well controlled, people are at risk of long-term complications of hyperglycaemia, including microvascular damage such as retinopathy and blindness, nephropathy and neuropathy. They are also at increased risk of macrovascular complications such as ischaemic heart disease, stroke and peripheral vascular disease.

2.2 The goal of treating type 1 diabetes is to keep blood glucose within a healthy range by providing the body with supplemental insulin. If the level of circulating insulin becomes too high, blood glucose levels can become too low leading to hypoglycaemia (also known as a hypo).

2.3 Managing type 1 diabetes usually involves:

- lifestyle adjustments
- regularly measuring blood glucose levels
- multiple daily insulin injections
- continuous subcutaneous insulin infusion (CSII)
- periodic assessment of blood glucose control.

Blood glucose monitoring can be done by self-monitoring (capillary blood testing), or by real-time continuous (rtCGM) or intermittently scanned

continuous glucose monitors (isCGM). Long-term monitoring of blood glucose control can be done by measuring HbA1c level, which is the average plasma glucose over the last 3 months. Time in range is a measure of blood glucose control that shows the percentage of time a person spends within a target glucose range (3.9 to 10 mmol/litre). Time below range (less than 3.9 mmol/litre) is associated with increased risk of severe hypoglycaemia, while time above range (more than 10 mmol/litre) indicates increased risks of complications and diabetic ketoacidosis.

2.4 NICE's recommendations on blood and plasma glucose in type 1 and type 2 diabetes in children and young people, type 1 diabetes in adults and diabetes in pregnancy recommend that people with type 1 diabetes should aim for a target HbA1c level of 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications from diabetes.

## The interventions

2.5 Hybrid closed loop (HCL) systems use a mathematical algorithm to automatically deliver insulin in response to continuously monitored interstitial fluid glucose levels. They use a combination of real-time glucose monitoring from a CGM device and a control algorithm to direct insulin delivery through CSII. Different HCL systems are available and some are built by combining interoperable devices from different companies. Because of the large number of combinations of components available to the NHS, this appraisal considers HCL systems as a class of technologies rather than individual components or systems. Expert advice received by NICE during scoping suggested that in practice, minimal differences in outcomes would be expected between systems if used as intended. The choice of components or system is based on a person's preference. Any systems available in the future need to be able to show interoperability and be equivalent to current systems in terms of patient benefits.

2.6 At the time of scoping the following systems and interoperable combination systems were available:

- The smart guard control algorithm (Medtronic) with the guardian CGM sensor (Medtronic) and either the Minimed 670G or 780G insulin pump (Medtronic). These components are not available for use with components from other companies.
- Control-IQ control algorithm (Tandem Diabetes Care) with Dexcom G6 CGM sensor (Dexcom) and t:slimX2 insulin pump (Tandem Diabetes Care).
- CamAPS FX control algorithm (Camdiab) with Dexcom G6 CGM sensor (Dexcom) and either the Dana RS or Dana-I insulin pump (Advanced Therapeutics UK Ltd).
- Omnipod 5 automated insulin delivery system (Insulet) with Dexcom G6 CGM sensor (Dexcom) and Omnipod tubeless insulin pod (Insulet).

This is not an exhaustive list and other systems and interoperable component systems are available.

### The comparators

2.7 There are 2 comparators:

- rtCGM with CSII (non-integrated)
- isCGM with CSII (non-integrated).

## Price

2.8 A range of HCL systems are available from different companies. Individual components of different systems are sometimes combined. The external assessment group received NHS supply chain costs for the various systems at current prices. The appraisal model base case used an unweighted average of the 4-year cost from various companies. This resulted in a 4-year total cost of £22,975 and an average annual cost of £5,744.

2.9 To give an incremental cost-effectiveness ratio of £20,000 per quality-adjusted life year gained, the companies will need to agree a discount with NHS England, on behalf of the relevant health bodies, for HCL systems available to the NHS. The size of the discount is commercial in confidence.

# 3 Committee discussion

The diagnostics advisory committee considered evidence from a number of sources. See the committee papers for full details of the evidence.

## Clinical need

### People with type 1 diabetes, families and carers

3.1 Patient experts explained that the mental load of living with diabetes is significant. This is because people with diabetes (and their parents or carers) look at a lot of data and have to make a lot of calculations and decisions about their insulin dose every day. This can be exhausting, affect people's mood and frequently leads to burn out. People with diabetes and their families can also be woken by continuous glucose monitor (CGM) alarms, causing sleep disruption. The patient experts explained that managing glucose levels is a lot of work and can affect home life, education, training or work. Although a CGM and continuous subcutaneous insulin infusion (CSII) can help maintain blood glucose control, if they are not integrated then this still involves substantial user input, which can be a mental burden. A parent of a child with diabetes said that the mental burden significantly affected their quality of life. They highlighted that children are less able to recognise the symptoms of hypoglycaemia and hyperglycaemia, and this is a constant worry for parents when they are apart from their children. They also explained that disrupted sleep was a significant problem, with parents waking multiple times a night to monitor their child's blood sugar and administer glucose or insulin. The committee concluded that managing type 1 diabetes is a substantial mental burden on people with diabetes and their families. It

further concluded that automated technologies such as hybrid closed loop (HCL) systems can reduce some of the burden, and improve quality of life for people, their families and carers.

## Inequalities

### Access to technology and care

3.2 Access to technology and appropriate care was highlighted by patient experts as a major concern, and they explained that the process was often slow, frustrating and demoralising. Patient and clinical experts said that there is a postcode lottery in access to technology. Also they noted that there are inequality issues related to family background and socioeconomic status. Clinical experts said that the automation offered by HCL systems could help reduce some of the inequalities for people who find it difficult to maintain healthy blood glucose levels because of a language barrier, a lower level of education or a learning disability, for example. A clinical expert said that NHS England (NHSE) has set out priorities for access to help reduce these healthcare inequalities. A clinical expert also highlighted that the effective use of technologies was an important consideration. They said that improvements to the availability of and access to patient training were needed. They noted that many centres were limited because they do not have enough trained staff in their clinical teams to provide this. The committee concluded that improvements were needed to make sure there was no postcode lottery in access to technology and care. It further concluded that people should be supported to use the systems.

## Clinical effectiveness

### Evidence and generalisability

3.3 The external assessment group (EAG) used 3 different sources to assess the clinical effectiveness of HCL systems. These were randomised controlled trials (RCTs), NHSE study data from adults (the NHSE adult

pilot study), and NHSE study data from children and young people (the NHSE children and young adult pilot study). A clinical expert said that they had some concerns about patient recruitment in the RCTs. They noted that people in RCTs usually have more motivation and a better ability to self-manage their diabetes than some people with diabetes in the NHS. The committee also heard that the RCTs were small in terms of patient numbers and were heterogeneous. Most RCTs included children and young adults. A clinical expert said that most people using CSII in their clinics were adults. The EAG said that the NHSE pilot studies had limitations, because they were non-randomised with a before and after study design and no control group. But the clinical experts explained that the strengths of the pilot studies were that they included a broader range of people than are usually recruited to RCTs. One clinical expert explained that the NHSE adult pilot study selected centres from around the country, but these were skewed towards adults in lower socioeconomic areas. Some clinical experts and committee members said that the populations in the NHSE pilot studies were a better reflection of populations in NHS practice. This was because they included people who may find it difficult to meet glucose targets and who may experience more severe physical and psychological effects of type 1 diabetes. The committee concluded that both the RCTs and the NHSE adult pilot study were not fully generalisable to the type 1 diabetes population in the NHS.

## Baseline characteristics

3.4 The baseline HbA1c levels differed between the RCTs and the NHSE adult pilot study. The people in the RCTs had lower HbA1c levels at baseline (56 mmol/mol to 67 mmol/mol [7.3% to 8.3%]) than in the NHSE adult pilot study (around 79 mmol/mol [9.4%]). A clinical expert explained that National Diabetes Audit data shows that over 65% of people with type 1 diabetes have an HbA1c of over 58 mmol/mol (7.5%). Clinical experts explained that people with higher HbA1c levels at baseline would be expected to have a greater reduction after treatment. The network

meta-analysis showed that HCL systems were associated with a decrease in HbA1c of 3.1 mmol/mol (-0.29 percentage points) compared with CSII plus CGM. But the NHSE adult pilot study reported a decrease in HbA1c of 16.2 mmol/mol (-1.5 percentage points). Some clinical experts said that they preferred the NHSE adult pilot baseline and HbA1c effect, because this was a better representation of real-world NHS practice. The committee concluded that for many people with type 1 diabetes in the NHS, the baseline HbA1c would likely be higher than that reported in the RCTs, so HCL systems may reduce HbA1c more than that estimated from the RCT network meta-analysis. But the extent of the difference was highly uncertain. The committee further concluded that differences in baseline HbA1c levels between the RCTs and NHSE pilot studies led to substantial differences in the reported HbA1c change.

## Population subgroups

### Children

3.5 The EAG's subgroup analyses showed that in the RCT children and young adults (under 18 years) subgroup, the change in HbA1c for HCL systems was greater (-0.31 percentage points, 95% CI -0.43 to -0.20) than the adult subgroup (-0.24 percentage points, 95% CI -0.32 to -0.15). The NHSE children and young people pilot had a lower baseline HbA1c of around 62 mmol/mol (7.9%) compared with the adult pilot study. The decrease in HbA1c after using HCL systems was also lower than the adult pilot, at 7 mmol/mol (-0.7 percentage points) after using HCL systems for 6 months. Data was not presented on age groups specified in the NICE scope for HCL in type 1 diabetes (that is, 5 years and below, 6 to 11 years and 12 to 19 years). A clinical expert explained that in the NHSE children and young people pilot, child age subgroups were not reported because of the low numbers of children in certain age groups that were using devices.

### Pregnancy

3.6 There was only 1 small study on HCL systems' effectiveness in pregnancy. The EAG said that it was difficult to draw firm conclusions in this population. But the committee thought that there could be greater benefits of HCL systems in pregnancy, because blood glucose control is harder to maintain and there is a risk to both the mother and unborn baby. A clinical expert said that HbA1c is a less effective clinical measure of diabetes control in pregnancy. The committee noted that it would be difficult to do studies of HCL systems in pregnancy because the duration of pregnancy is relatively short. This would complicate study design and data collection. The committee concluded that there was a lack of evidence in pregnancy and relevant studies would be difficult to do. It further concluded that the effectiveness of HCL systems in pregnancy would likely be greater than in the overall population.

## Economic model and cost effectiveness

### Baseline characteristics and HbA1c effects

3.7 In its base-case model, for the key baseline characteristics the EAG used data from the 2019 to 2020 National Diabetes Audit subgroup for those on CSII. The baseline HbA1c from this data was 64 mmol/mol (8.0%) and the EAG applied the estimated HbA1c decrease from the RCT network meta-analysis of 3.1 mmol/mol (-0.29 percentage points). In separate scenario analyses the EAG used the NHSE adult pilot study baseline characteristics, with an HbA1c baseline of 79 mmol/mol (9.4%), and applied the HbA1c decrease from either the RCT network meta-analysis (3.1 mmol/mol [-0.29 percentage points]) or the NHSE pilot (16.2 mmol/mol [-1.5 percentage points]). The committee heard that when the NHSE adult pilot baseline characteristics and HbA1c effect were used, the resulting incremental cost-effectiveness ratio (ICER) was substantially lower than the base case (£12,398 compared with £178,925 per quality-adjusted life year [QALY] gained). The EAG provided an analysis of HbA1c net improvement using both the National Diabetes Audit CSII

patient baseline characteristics and the NHSE adult pilot baseline characteristics. The committee said that this was useful to help understand how the ICER would change with different changes in HbA1c. The committee noted that a baseline HbA1c of 79 mmol/mol (9.4%) and a reduction of 16.2 mmol/mol (-1.5 percentage points) showed HCL systems to be cost effective. But it said that using this data in the model would be equivalent to restricting HCL system access to people with much higher than average HbA1c levels. The committee preferred a baseline HbA1c of 64 mmol/mol (8.0%) for use in the model as this widens access to people who cannot maintain their target HbA1c resulting in them having an HbA1c of around 64 mmol/mol (8.0%). The committee said that that the change in HbA1c reported in the NHSE adult study pilot was a good representation of what could be achieved for people with higher HbA1c levels. It also noted that the RCTs showed that people with lower HbA1c levels could also benefit. The committee concluded that with a baseline HbA1c of 64 mmol/mol (8.0%), the expected reduction in HbA1c after HCL system use could be greater than 3.1 mmol/mol (-0.29 percentage points) but would be lower than the 16.2 mmol/mol (-1.5 percentage points) from the NHSE pilot. But it was unclear where in this range the effect estimate would lie. Without any directly observed data, a decrease of 3.1 mmol/mol (-0.29 percentage points) was a reasonable estimate. It further concluded that the change in HbA1c substantially affected the ICER, and therefore whether HCL systems could be considered cost effective.

## Comparators

3.8 The population in the economic model was people on a single technology (CSII, rtCGM, or isCGM). In the model they could then move to a non-integrated system or to HCL. The comparators used for the economic modelling were rtCGM plus CSII (non-integrated) and isCGM plus CSII (non-integrated). NICE's guideline on type 1 diabetes in adults recommends that people should be offered either rtCGM or isCGM, based

on their individual preferences. A clinical expert explained that around 80% of people now have a CGM device. In the economic model base case, the EAG grouped the comparator technologies together as CGM plus CSII and assumed 90% of people were on isCGM and 10% were on rtCGM. Clinical experts explained that in the clinical-effectiveness evidence, when it was reported, all comparators in the RCTs used rtCGM. They also said that rtCGM and isCGM are not the same in terms of cost or clinical effectiveness. So the model may have underestimated the cost effectiveness of HCL systems by comparing them with the clinical effectiveness of rtCGM, but with the lower cost of isCGM. But some experts said that the performance of the newer isCGMs is closer to that of rtCGMs. Although the comparator in the assessment was CGM plus CSII, clinical experts explained that there is a delay in getting people onto CSII, with around 75% of people with diabetes nationally not having CSII. It concluded that although this may have underestimated the cost effectiveness of HCL systems, it was likely that if HCL systems were recommended, they would displace both rtCGM plus CSII (non-integrated) and isCGM plus CSII (non-integrated).

## Uncaptured benefits

3.9 In the economic model, non-severe hypoglycaemic events and severe hypoglycaemic events were only included in a scenario analysis. The EAG said that there was high uncertainty around these annual event rates. When hypoglycaemic events were included, the ICERs were reduced and ranged from £120,679 per QALY gained to £170,193 per QALY gained, depending on the annual event rate and what source the EAG used for the hypoglycaemic event disutility values. In the EAG's exploratory modelling for children and young people, a scenario analysis included the quality of life effects of using HCL systems. This considered the improvements reported in the hypoglycaemia fear survey. The hypoglycaemia fear survey is an 18-item questionnaire that assesses the levels of fear related to hypoglycaemia. Each item is measured on a

5-point scale from 0 (never) to 4 (almost always). Individual item scores can highlight someone's major concerns about hypoglycaemia. This reduced the ICER of the NHSE children and young people pilot scenario (which used the NHSE children and young people pilot baseline characteristics and HbA1c change). A further scenario analysis tripled the quality of life effects reported in the hypoglycaemia fear survey and applied this for 15 years to account for 2 parents having a similar quality of life improvement. This reduced the ICER further still (see section 3.11). However, clinical experts expressed concerns that the reduced mental burden and familial or carer anxiety that HCL systems provide may not be captured adequately in the model. The committee understood that there was no quantitative evidence that could be used to estimate the value of these potential quality of life benefits. The committee agreed that there were potential quality of life benefits of HCL systems not captured in the model, including the effect on learning and education, ability to work, mental burden and fear of hypoglycaemic events. The committee concluded that these uncaptured benefits were likely to undervalue the effect of HCL systems on quality of life.

### Time horizon and long-term effects

3.10 In the base-case economic model, the time horizon was 60 years and the effect on HbA1c was assumed to last for the duration of the model. The time horizon and HbA1c effect duration were key drivers of the model results. Scenarios that reduced the time horizon or duration of the HbA1c effect all resulted in higher ICERs. Some clinical experts said that they would expect the improvements in HbA1c to be maintained. The EAG said that the incidence of kidney and eye complications may be overestimated in the model, and there was uncertainty around the modelling of these long-term effects. The committee concluded although there were uncertainties in the modelling of long-term effects and that this may have overestimated the cost effectiveness, they agreed with the time horizon of 60 years and the lasting HbA1c effect.

## Cost effectiveness for children

3.11 The EAG's exploratory modelling in children and young people showed that HCL systems appear to be more cost effective than in adults, with a base-case ICER of £168,196 per QALY gained. When the analysis was limited to the RCTs in children, the ICER was reduced to £116,256 per QALY gained. In a scenario that used the NHSE children and young people pilot baseline characteristics and HbA1c decrease of 7 mmol/mol (-0.7 percentage points), there was a substantial reduction in the ICER to £54,727 per QALY gained. The EAG said that there was some uncertainty in the results of the exploratory modelling in children. This was because of uncertainty around the modelled long-term survival and also uncertainty around how much clinical data from children was used in the model. The committee concluded that although there was some uncertainty, HCL systems are likely to be more cost effective for children than adults.

## Cost effectiveness in pregnancy

3.12 There was a lack of evidence about the cost effectiveness of HCL systems in managing blood glucose in pregnancy for people with type 1 diabetes. But the committee recalled that the effectiveness of HCL systems in pregnancy would likely be greater than in the overall population (see section 3.6). So HCL systems would likely be cost effective when used in pregnancy and for people planning a pregnancy.

## Costs in the economic model

3.13 The committee considered an analysis including confidential prices submitted to NHS supply chain by the companies. It noted that use of these prices resulted in lower ICERs but not to within the range that would be considered a cost-effective use of NHS resources by NICE. The committee also considered a threshold analysis on average 4-year costs to help them understand the effect of costs of HCL systems on the ICER (see section 2). It noted that relatively small reductions in costs resulted in

large reductions in the ICER. The committee concluded that the cost of the HCL systems was a key driver of the cost-effectiveness results.

## ICER per QALY gained

3.14 NICE's guide to the methods of technology appraisal 2013 notes that above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of a technology as an effective use of NHS resources will take into account the degree of certainty around the ICER. The committee will be more cautious about recommending a technology if it is less certain about the ICERs presented. The committee noted the following aspects of the model affect the ICER:

- uncaptured benefits in the economic model related to reduced mental burden, and parent and carer anxiety
- rates of hypoglycaemic events and the disutility and cost of these
- rates of eye and kidney complications
- what baseline HbA1c level should be used in the model
- what the HbA1c effect size should be after use of HCL systems (which depends on the baseline level)
- duration of the HbA1c effect
- modelling of longer-term effects when using the base-case time horizon of 60 years
- effectiveness of isCGM with CSII compared with HCL systems.

Many of the scenarios tested by the EAG resulted in ICERs much higher than NICE would consider to be cost effective. There is uncertainty around the assumptions that should be used in the base case, so there is a risk of decision error. So it agreed that an acceptable ICER would be around £20,000 per QALY gained.

## Other factors

### Innovation

3.15 The committee considered whether HCL systems are innovative. It noted that these systems enhance existing devices by using an algorithm to integrate rtCGM data with CSII. The committee concluded that although HCL systems provide an alternative treatment option for people with type 1 diabetes, the level of innovation is not sufficient to justify consideration of a higher ICER (over £20,000 per QALY gained).

## Conclusion

3.16 The committee said that the clinical-effectiveness evidence showed that HCL systems are likely to improve blood glucose control in type 1 diabetes. This effect appears to be greater for people with higher baseline HbA1c levels, although the extent of the true effect is uncertain. The committee noted that HCL systems are also effective for people with lower baseline HbA1c levels of around 64 mmol/mol (8.0%). The committee also said that HCL systems are likely to be more cost effective for children than adults. It also noted that HCL systems are likely to be cost effective when used in pregnancy and for people planning a pregnancy. It noted the many uncaptured benefits in terms of reduced mental burden, reduced parent and carer anxiety, and improved quality of life. These would be expected to decrease the ICER, although it was uncertain by how much. So, there is uncertainty in the cost-effectiveness analyses with wide ranging ICERs depending on the scenarios tested. The committee concluded that at the current average price, HCL systems are unlikely to be cost effective, but it recognised the potential benefits to people. It concluded that despite the uncertainty, if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2), HCL systems should be recommended for:

- people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0%)
- people who are pregnant or planning a pregnancy.

# 4 Implementation

4.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication. The normal period of compliance, of 3 months, is likely to be extended for this technology because NICE is awaiting a funding variation request from relevant health bodies. If received NICE will consult on this if appropriate. This extension is made under Section 7(5) of the Regulations.

4.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.

4.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has type 1 diabetes and the doctor responsible for their care thinks that a hybrid closed loop system is the right treatment, it should be available for use, in line with NICE's recommendations.

# 5 Committee members and NICE project team

## Committee members

This topic was considered by the diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each diagnostics advisory committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

## Chair

**Brian Shine**

Chair, diagnostics advisory committee

## NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

**Tosin Oladapo and Simon Webster**

Technical leads

**Frances Nixon**

Technical adviser

**Donna Barnes and Toni Gasse**

Project managers

ISBN: [to be added at publication]

NICE National Institute for Health and Care Excellence

**DIAGNOSTICS ASSESSMENT PROGRAMME**

**Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes**

**Diagnostics Consultation Document – Comments from companies in scope**

**Diagnostics Advisory Committee: 24 May 2023**

# Contents



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| 1 | **Advanced Therapeutics (UK)**<br><br>Submitted via the web | Advanced Therapeutics (UK) Ltd Response to Nice HCL Appraisal<br><br>Hybrid Closed loop systems use an algorithm that takes CGM data and calculates how much insulin needs to be delivered to the patient at that particular time.<br><br>Because the CamAPS FX algorithm is constantly monitoring a patient's metabolic progress (re BG levels) it can be causing the pump to make many small altering dosage deliveries every hour via multiple small bolus adjustments instead of using the Dana pump's basal rate function. The algorithm also "learns" how that dose delivery has affected the patient's blood glucose levels and reacts accordingly.<br><br>It is vitally important in this respect that the insulin dose the algorithm has requested to be delivered is actually delivered so that it can calculate future doses accurately. |

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| | | Pump delivery accuracy varies from one manufacturer's pump to another. With the Dana-i the bolus delivery accuracy at 0.04iu is ±4%. One tubed pump for example has a bolus delivery accuracy of ±30 (as stated in the manufacturers user guide as per their website).<br><br>Some tubeless pumps show delivery accuracy levels of ±0.05iu at a delivery rate of <1.0iu.<br>It is not the purpose of a hybrid closed loop algorithm to correct deficiencies in the accuracy of delivery of the insulin pump component of the system.<br><br>A NICE expert put forward an opinion (see Section 2.5 of the appraisal consultation document) that the pump used in a closed loop system is immaterial, but we would suggest that delivery accuracy has not been understood nor taken into account. A different UK expert who has studied this aspect of insulin pump use (Prof N Oliver) shares a different view in the co-authored paper below (1).<br><br>In two studies (Ziegler 2020(2) and Giardot 2020(3)) the Ypsopump fairs badly. In the Giardot paper (basal delivery), the Ypsopump demonstrated the largest error of all devices at the lowest dose of 0.1 iu/h. Similarly for a bolus of 0.1 iu Ziegler demonstrated the Ypsopump to have the widest range of values for a tubed pump well outside the ±15% they were looking for - not dissimilar to Omnipod. The Giarodot paper entitled "All Insulin Pumps are Not Equivalent" quotes their observations to be similar to the ±30% error reported by the manufacturer Ypsomed. The four studies show pumps to be inaccurate at low levels which is something clinicians should bear in mind when initiating pump therapy involving small doses of insulin. and two of them involve Ypsopump specifically.<br><br>Summary<br>- Closed loop systems consist of 3 main components, a glucose sensor, algorithm, and insulin pump. In closed loop systems, insulin delivery can be altered frequently every few minutes with varying small doses, aiming to emulate a healthy pancreas. The effectiveness of these systems depends upon each of the components performing its task to the highest level of accuracy. The algorithm is the brain of the system which controls the pump based on sensor readings. If a sensor performs with a varying or low degree of accuracy the glucose levels would likely adversely be affected due to incorrect insulin delivery. Conversely, if insulin pumps vary in the ability to deliver small doses insulin accurately, the glucose levels would likely adversely be affected due to incorrect delivery of insulin. Based on the evidence below, it cannot be assumed that insulin pumps are equivalent in terms of accuracy when delivering lower doses of insulin.<br><br>Studies<br><br>1. Ralph Ziegler, Nick Oliver, et al. Evaluation of the Accuracy of Current Tubeless Pumps for Continuous Subcutaneous Insulin Infusion. Diabetes Technology & Therapeutics Volume 23, Number 5, 2021 |

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| | | "With regard to the use of pumps in artificial pancreas systems, short-term accuracy is especially important, because insulin delivery is frequently adapted to current glucose levels".<br><br>2. Ralph Ziegler et al. Accuracy assessment of bolus and basal rate delivery of different insulin pump systems used in insulin pump therapy of children and adolescents. Pediatric Diabetes. 2020;21:649–656<br>"Considerable differences in insulin delivery accuracy were observed between the tested pumps. In general, when using very low doses, accuracy of insulin delivery is limited in most insulin pumps. This should be considered for CSII therapy in children".<br><br>3. Sylvain Girardot et al. All Insulin Pumps Are Not Equivalent: A Bench Test Assessment for Several Basal Rates. Diabetes Technology & Therapeutics Volume 22, Number 6, 2020<br>CSII imprecision could be due to a variability in volume and/or frequency of strokes for every pump. Some models appear better adapted for the smallest insulin needs, or for inclusion in a CLS".<br><br>4. Katharina Laubner et al. Comparative Dose Accuracy of Durable and Patch Insulin Pumps Under Laboratory Conditions. Diabetes Technology & Therapeutics Volume Volume 21, Number 7, 2019<br>"This study demonstrates low accuracy for basal rates and single bolus deliveries at low insulin doses for both pump models. Clinicians should be aware of this variability when initiating insulin pump therapy especially in insulin-sensitive patients with low insulin dose requirements".<br><br>Re the comment Ypsopump being more cost effective when used in a closed loop system, was the extra cost of insulin cart use taken into consideration?<br><br>Based on an average adult in England, using an Ypsomed Pumpcart over 4 years will cost approximately £452 more than insulin from a 10ml vial as used for the Dana-i. It would be useful to know the exact overall cost difference once all factors are considered such as their more expensive consumables and their delivery charge.<br><br>Calculation as per the following: (Insulin costs as per the BNF)<br><br>Insulin daily requirement: 0.75u/kg/day (EMC states adults and children will require 0.5-1.0u/kg/day)<br>Average adult weight UK: 79kg (average male in England weighs 85.4kg and female 72.1kg)<br>Average TDD: 59.25 units/day<br>Novorapid 10ml vial (1000units): £14.08<br>Novorapid 5x1.6ml Pumpcart (800 units): £15.10 |

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| | | Annual insulin use: 59.25 x 365 = 21626 units<br>Novorapid vial: 21626 units requires 22 vials x £14.08 = £310<br>Pumpcart: 21626 units requires 28 pumpcarts x £15.10 = £423<br><br>Annual difference: £113/year<br>4-year difference: £452<br><br>In addition, we have been informed by our customers that Ypsomed infusion sets and basic Ypsomed cartridges are more expensive than the Dana equivalents. Can NICE confirm that these additional costs have been considered. |
| 2 | **CamDiab** | **1 Introduction**<br><br>We present the following two pieces of evidence in relation to "Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes [DAP55]":<br>• Cognitive development in children linked to hyperglycaemia<br>• Costs used by health economic model |
| 3 | CamDiab | **2 Cognitive development in children linked to hyperglycaemia**<br><br>We have reservations about the current recommendation to limit the provision of HCL therapy to children and young people with an HbA1c of 8.0% or above.<br><br>HbA1c is not necessarily reflective of glycaemic variability, meaning that even with an HbA1c <8.0%, children and young people may be experiencing periods of clinically significant hypo- and hyperglycaemia. When using HCL therapy, children have significantly higher variability of insulin requirements compared to adolescents and adults, reflecting their underlying higher glycaemic variability and closed-loop's ability to address this by adjusting insulin delivery accordingly (doi: 10.2337/dc18- 2625).<br><br>The "Questions on the external assessment report for clinical experts" section recognises the negative impact of hypoglycaemia on learning, **but does not appear to take into account more recent evidence on the negative effects of hyperglycaemia on cognitive ability and brain development**. In her 2021 longitudinal study (doi: 10.2337/dc20-2125), Mauras et al showed that children (mean age 7 years at baseline) with type 1 diabetes had lower cognitive scores and lower total, grey and white matter brain volumes than age-matched controls and that these differences were associated with metrics of hyperglycaemia and persisted over time. |

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| | | **Arguably, it is therefore of high importance to reduce time in hyperglycaemia for all children with T1D, regardless of baseline HbA1c, to facilitate optimal brain development and allow children and young people to reach their full potential**. In the paediatric age-group, HCL therapy improves glycaemic control primarily by reducing time in hyperglycaemia and is therefore well-placed to address this important issue. |
| 4 | CamDiab | **3 Costs used by health economic model**<br><br>When the original submission by CamDiab was made in June 2022, the cost of CamAPS FX app was £840 pa when working with Dana-I pump (Sooil, South Korea). Since then the cost of the CamAPS FX was reduced to one-off cost of £800 over 4 years (i.e. £200 pa, **i.e. the cost was reduced four-fold**) when working with YpsoPump (Ypsomed, Switzerland).<br><br>Additionally, the CamAPS FX will be available from March 2023 in the UK with FreeStyle Libre 3 (Abbott Diabetes Care, USA). The cost of FreeStyle Libre 3 is at par with iCGM and thus **the premium cost of CGM compared to iCGM used by the health economic model does not apply when contrasting HCL vs comparator**.<br><br>The present health economic calculations using RCTs data are flawed in any case: The health economic efficacy assessment utilised exclusively RCTs which applied CGM in the comparator group but costed iCGM in the comparator for the health economic calculations. This is incorrect unless it can be demonstrated that a therapy with iCGM and CGM provide the same outcomes. This is not the case, no such evidence exists. **The health economic calculations should have used CGM in the comparator and not iCGM.** |
| 5 | **Dexcom International** | The EAG committee draft recommendations state that HCLs are recommended as an option for managing blood glucose levels for people with T1D who have difficulty managing their diabetes and who had an average HbA1c of 8.0% (64mmol/mol). This recommendation excludes people with diabetes with A1c below 8.0% (6.5 – 7.9).<br><br>NICE's own recommendations is that people with T1D should aim for a target HbA1c level of 6.5% or lower (48 mmol/mol) to minimize the risk of long-term complications. The Diabetes Control and Complications Trial (DCCT), a prospective randomized controlled trial of intensive (mean A1C about 7.0% [53 mmol/mol]) versus standard (mean A1C about 9.0% [75 mmol/mol]) glycemic control in patients with type 1 diabetes, showed that better glycemic control is associated with 50–76% reductions in rates of development and progression of microvascular (retinopathy, neuropathy, and diabetic kidney disease) complications. https://diabetesjournals.org/care/article/42/Supplement_1/S61/30946/6-Glycemic-Targets-Standards-of-Medical-Care-in. EDIC trial has demonstrated long-term microvascular benefits over two decades following DCCT. Similar results are seen in the long-term follow-up of UKPDS type 2 diabetes cohort. |

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| | | Thus, evidence suggests that achieving A1c targets of <7.0% has been shown to reduce microvascular complications of both type 1 and type 2 diabetes when initiated early in the course of disease. Committee's decision to cap HCLs to patients at HbA1c ≥8.0% will exclude diabetic patients with HbA1c in the range of 7.0 to 8.0% as well as moderate to high-risk population i.e., < 7.0% who experiences hypoglycemia.<br><br>Additionally, short term complications produced by high glucose variability (GV) or glucose excursions should be considered. People with diabetes (PWD) with HBA1c < 8.0% may experience short-term glycemic variability with episodes of hypo- and hyperglycemia. A1c is a good indicator if patients with diabetes are always on the high blood glucose levels but it does not measure GV (ACCORD trial: https://diabetesjournals.org/care/article/43/6/1169/35683)<br><br>PWD have glycemic variability where night-time insulin requirements are variable than daytime for not just adults but children as well as adolescents. These glycemic variations have been well addressed by HCLs ( doi: 10.2337/dc15-2623); (doi: 10.2337/dc18-2625). |
| 6 | Dexcom International | • "Problematic hypoglycemia" should be an independent indication. HCLs has shown to be effective in vulnerable sub-populations which are at moderate to high risk of hypoglycemia. According to Anderson study (DTT 2019), HCLs when compared to SAP therapy were safe and effective for treating people with type 1 diabetes by reducing the risk and frequency of hypoglycemia while improving time in range and reducing hyperglycemia. The % TBR (3.9 mmol/l) decreased significantly in HCLs than in SAPs (7.2% ± 5.3% to 2.0% ±1.4% vs (5.8% ± 4.7% to 4.8% ± 4.5%); p=0.001<br>• We would like to point out that time below range (<3.9 mmol/l) should be used as a proxy for hypoglycemia. Eight RCTs were used in the network Meta-analyses (NMA) to assess time below range (TBR) (<3.9 mmol/l) when comparing HCL to CSII+CGM. The draft MTA assessment report states (page 87), that the time <3.9 mmol/L is small at baseline (<6%) in both arms, implying not much room for change. The report comments that studies had small effect size and occasionally reached statistical significance however 4 studies showed statistical significance for time below range favoring HCLs. It should be noted that any time in this hypoglycemic range <3.9 mmol/l (<70 mg/dl) is not good for the patient and any decrease in this hypoglycemia time is a better outcome. The relative decreases in TBR are important to note (e.g., Tauschman 2018 showed a -23% relative decrease in TBR) even when the absolute decreases are small. Or the relative difference in TBR is large between groups at end of study (e.g., Benhamou 2019, Kariyawasam 2022) ~50% better for HCL. Thus indicating that HCLs showed better relative differences in TBR when compared to CSII+CGM. |
| 7 | Dexcom International | • It is concerning to use the same base case from the EAG report for evaluating the cost-effectiveness of HCL systems in patients with type 1 DM (ICER of 179k GBP/QALY) despite the existing flaws in the modelling approach including misappropriation of clinical evidence of rtCGM+CSII to isCGM+CSII, lack of QoL benefits for HCL, and exclusion of SHE and NSHE events from the base case. |

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<tr><th>Comment Number</th><th>Name and organisation</th><th>Stakeholder Comment</th></tr>
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<li>QoL benefits of HCL systems and impact on cost-effectiveness analysis: The components of quality-of-life benefits that are expected with the use of HCL by patients with Type 1 DM include improvement in quality-adjusted life years due to reduction in diabetes complications, avoidance of diabetes-specific disutilities (Fear of Hypo), and additional utility benefits due to improvement in the process of care( avoidance of fingersticks, reduction in day to day diabetes burden and decision making, disease stress). The current cost-effectiveness model only captures the QoL benefit from the avoidance of microvascular and macrovascular complications and does not consider any additional QoL benefits due to improvement in the process of care. The current draft guidance includes positive language that acknowledges the patients, carers, and clinical experts' perspectives on the improvement in the quality of life of patients and their families, however, no attempt was made to quantify the additional benefits and incorporate them in the cost-effectiveness assumptions. The scenario analyses done by EAG only consider a utility due to the avoidance of acute events (severe hypoglycaemia). The previous assessments by NICE for use of insulin pumps (TA151) set the standard of testing additional utility values due to a reduction in disease burden. Similar to TA151, the EAG could have used assumed utility values of 0.005-0.05 QALY for the expected improvement in the process of care and its impact on patients’ QoL. The table below provides multiple scenarios, and it clearly shows that the inclusion of even a small additional utility will reduce the ICER significantly. Assuming a utility of 0.01 for the HCL systems will reduce the ICER by 50% (from £177,814/QALY to £83,425/QALY).</li>
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**Table: Impact of QoL benefits of HCL systems on ICER**

| | Net Costs | Life expectancy (years) | HCL QoL benefit Utility (annual) | QoL*Life expectancy | Net QALY | ICER |
|---|---|---|---|---|---|---|
| **Current Base Case** | 28,628 | 18.216 | 0 | 0 | 0.161 | £177,814 |
| Scenario 1 | 28,628 | 18.216 | 0.005 | 0.09108 | 0.25208 | £113,567 |
| Scenario 2 | 28,628 | 18.216 | 0.01 | 0.18216 | 0.34316 | £83,425 |
| Scenario 3 | 28,628 | 18.216 | 0.015 | 0.27324 | 0.43424 | £65,927 |
| Scenario 4 | 28,628 | 18.216 | 0.02 | 0.36432 | 0.52532 | £54,496 |
| Scenario 5 | 28,628 | 18.216 | 0.025 | 0.4554 | 0.6164 | £46,444 |
| Scenario 6 | 28,628 | 18.216 | 0.03 | 0.54648 | 0.70748 | £40,465 |
| Scenario 7 | 28,628 | 18.216 | 0.035 | 0.63756 | 0.79856 | £35,850 |
| Scenario 8 | 28,628 | 18.216 | 0.04 | 0.72864 | 0.88964 | £32,179 |
| Scenario 9 | 28,628 | 18.216 | 0.045 | 0.81972 | 0.98072 | £29,191 |

<ul>
<li>The relationship between HbA1c level at baseline and treatment effect: Previous studies have shown a dose-response relationship between HbA1c at baseline and the expected improvement in glycaemic control manifested by a drop in HbA1c at follow-up. The combined mean HbA1c at baseline for the RCTs’ populations in the NMA is 7.6%. The draft recommendations suggest a cutoff point of 8% HbA1c for eligibility for HCL. The base case assumption around the treatment effect should be higher than 0.29. The NHSE study shows that patients with baseline HbA1c of 9.4 experienced</li>
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| | | a 1.5 drop on average. The expected drop in HbA1c in patients with 8% should be a value between 0.29 and 1.5%. It is important to update the base case for cost-effectiveness evaluation to reflect the expected clinical effect.<br><br>• Distributional Cost-effectiveness analysis to address health inequalities: The committee highlighted the clinical experts' opinions on the value of automation offered by HCL systems. This automation of diabetes and insulin management can help reduce some of the inequalities for people with poorly controlled diabetes due to language barriers, a lower level of education, or a learning disability. We believe that cost-effectiveness analyses should incorporate the impact of different interventions on the social distribution of health. It is important to understand how the current standard of care could be affecting the outcomes of patients with lower socioeconomic status, lower educational levels, or with learning disabilities who are facing challenges with managing their diabetes that results in poor outcomes. |
| 8a | **Medtronic** | **Consultation question 1: has all of the relevant evidence been taken into account?**<br><br>**The EAG concluded that "*the relevance of the RCT populations and outcome measure results for the decision problem is debatable and not easy to judge"***<br><br>We agree with the EAG conclusions that *"the relevance of the RCT populations and outcome measure results for the decision problem is debatable and not easy to judge"*. The studies included in the network meta-analysis (NMA) are not reflective of the currently available hybrid closed loop (HCL) technologies nor the average HbA1c levels of people with T1D in NHS England.<br><br>The effect size from the NMA used in the base case, shows a very modest reduction in HbA1c of 0.29% which is at odds with the much larger reduction in HbA1c achieved with current advanced algorithm hybrid closed loop (AHCL) technologies as reported in more recent studies[1–5]) and the substantial body of real-world evidence including the recent NHS England observational study in approximately 900 people with Type 1 diabetes.<br><br>NICE health technology evaluations: the manual (PMG36) states that: *"In general, all model parameter values used in base-case, sensitivity, scenario and subgroup analyses should be both **clinically plausible** and should use methods that are consistent with the data. Results from analyses that do not meet these criteria will not usually be suitable for decision making.*<br><br>**We suggest that the 0.29% effect size from the NMA is not clinically plausible and is substantially lower than that observed in clinical practice in NHS England. We are concerned that the efficacy outcomes in the base case are based solely on this pessimistic effect size of 0.29%.** |

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| | | We are concerned that the studies included in the NMA are not representative for the population defined in draft recommendation because the relevant evidence for HCL with a baseline HbA1c ≥8 has not been included and the most recent, clinically relevant evidence has not been considered.<br><br>No weighting has been given to RCT data with a baseline HbA1c>8%. The inclusion of this evidence in populations with higher baseline HbA1c is essential for the NMA as the reductions in HbA1c increase with increasing baseline HbA1c.<br><br>**We ask the committee to give more weighting to this body of evidence to help address the uncertainty in the effect size and determining the true ICER.**<br><br>The following RCTs have not been captured in the review and may be of interest<br><br>• The recently published **ADAPT RCT[1]** included UK participants and investigated the effect of AHCL on HbA1c compared with multiple day injections (MDI) plus flash glucose monitoring (FGM) or continuous glucose monitoring (CGM) in sub-optimally controlled adult patients with T1D. The HbA1c reduction in intervention arm of ADAPT was 1.4% greater than the comparator which reflects the standard of care in NHS England. This is a remarkably similar reduction in HbA1c to that seen in the NHS England observational study and was achieved regardless of starting technology. This effect is also over 5 times higher than the 0.29% reported in the network meta-analysis.<br><br>• The results from **NCT04914910** have been shared with NICE as Academic in Confidence [AIC] ahead of publication. The RCT compared an automated insulin delivery (AID) system with insulin pump and CGM / isCGM, usual care (UC).<br><br>[redacted] |

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| | | **We ask the Committee to consider that the NMA findings need to be put into perspective with ADAPT and NCT04914910 to account for the higher effect size observed in HCL users with baseline HbA1c ≥8%** |
| 8b | Medtronic | **Key limitations of the network meta-analysis are as follows:**<br>• The average baseline HbA1c in the studies included in the network meta-analysis is 7.5% which is not in line with the HbA1c stated in scope which specifies studies with a baseline HbA1c >8%.<br>• 63% of Type 1 in NHS England have HbA1c>7.5% (National Diabetes Audit 2021), while the participants in the selected studies for the NMA were a well-controlled population with a baseline HbA1c of 7.5% before introduction of the HCL system.<br>• The study selection for the NMA is not representative of the newest generation of MiniMed 780G and Control-IQ hybrid closed loop technologies currently in use in NHS England, which correct for hyperglycaemia. Control-IQ is not represented in any of the studies and MiniMed780G is the intervention in adults in only 1/12 of the studies. This 780G study is not powered to measure HbA1c as it is a safety study, not clinical effectiveness.<br>• Studies included are mainly safety studies with 11/12 studies having Time in Range (TIR) as the primary endpoint; these studies were not powered to measure HbA1c reduction as the sample sizes were too small.<br>• HbA1c reduction is greater from higher starting point so has a non-linear relationship. Most of the studies selected for NMA were not powered for the secondary endpoint of HbA1c and assumptions re TIR conversion to HbA1c are not validated and should be interpreted with caution.<br>• As described the MTA assessment report, studies were heterogeneous in terms of population, age groups, gender, RCT design (parallel cross over), numbers of participants and variable adjustment methods for determining mean difference between intervention and comparators. Studies did not consistently describe comparators. Cross-over studies did not provide data at different cross-over time points. |
| 8c | Medtronic | **Uncaptured Quality of life benefits**<br><br>The committee agreed that there were potential quality of life benefits of HCL systems not captured in the model, including the effect on learning and education, ability to work, mental burden and fear of hypoglycaemic events. The committee concluded |

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| | | that these uncaptured benefits were likely to undervalue the effect of HCL systems on quality of life. This has the effect of falsely inflating the ICER.<br><br>This was considered in the economic modelling for the diagnostic guidance on sensor augmented pumps, DG21. They reported that the ICER changed substantially when a utility increment of 0.0329 was applied to represent a reduction in fear of hypoglycaemia.<br><br>**We ask that the Committee take account of these uncaptured benefits and consider a willingness to pay threshold of up to £30,000/ QALY.** |
| 9 | Medtronic | **Consultation Question 2: Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?**<br><br>**Clinical Effectiveness**<br><br>The EAG concluded that ***"the relevance of the RCT populations and outcome measure results for the decision problem is debatable and not easy to judge".***<br><br>*We suggest that the interpretation of the results is factually incorrect as the key driver of the effect size, baseline HbA1c, is not taken into account and data for populations with higher HbA1c has not been taken into account in the recommendation despite availability of more recent RCT and rea-_l world evidence*<br><br>**We ask the Committee to interpret the NMA results in statistical context of:**<br><br>a) The effect estimate of 0.29% reduction in HbA1c applies to a population with average baseline HbA1c of 7.5%.<br><br>b) The results from NCT04914910 and the NHS England pilot data confirm that baseline HbA1c is a key driver of the effect size observed with HCL therapy. As suggested by regression modelling (Pickup et al 20196) and the most recent evidence, for the population in scope of the draft recommendation with a baseline HbA1c>8%, the reduction of HbA1c is approximately 1%.<br><br>c) The NMA relies on RCT data only and the real-world evidence (RWE) effectiveness should be considered in balance.<br><br>**Base case assumptions** |

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| | | The base case takes the effect size from the NMA where studies have a mean HbA1c of 7.5% at the baseline and selects a different baseline HbA1c of 8% from the National Diabetes Audit of people on insulin pumps. HbA1c reduction is greater from higher starting point so has a non-linear relationship therefore selecting a higher baseline HbA1c then applying the effect size from a NMA with a lower average HbA1c is incorrect methodology and requires an adjustment of the effect size to account for the higher baseline HbA1c.<br><br>**<u>Cost Effectiveness</u>**<br><br>The EAG produced a threshold analysis to calculate the price that gives an ICER of £20,000 however this is provided to the Committee as a confidential appendix and has not been shared within the consultation so we do not have the opportunity to comment on this analysis.<br><br>**As this threshold analysis is likely to inform pricing discussions with NHS England, we ask that it is shared with consultees along with the preferred assumption for the ICER of the Committee.**<br><br>At the committee meeting, the EAG presented the HbA1c net improvement threshold analyses (fig 1) using both the national diabetes audit CSII patient baseline characteristics (HbA1c 8.0%) and the NHSE adult pilot baseline characteristics (HbA1c 9.4%)<br><br>Using the NHSE adult pilot baseline characteristics data and HbA1c change (-1.5%) results in a large decrease in the ICER from the base case (£12,398 compared with £179k per QALY gained).<br><br>[redacted], the 1.4 % reduction reported in the ADAPT RCT and the 1.5% reduction reported in the NHS England pilot study, **we ask the Committee to consider a mid-point estimate reduction in HbA1c of around 1%** (estimated from Figure 1; NB: this threshold analysis chart (fig1) was presented to the committee however exact numbers have not been shared as part of the consultation).<br><br>Figure 1 |

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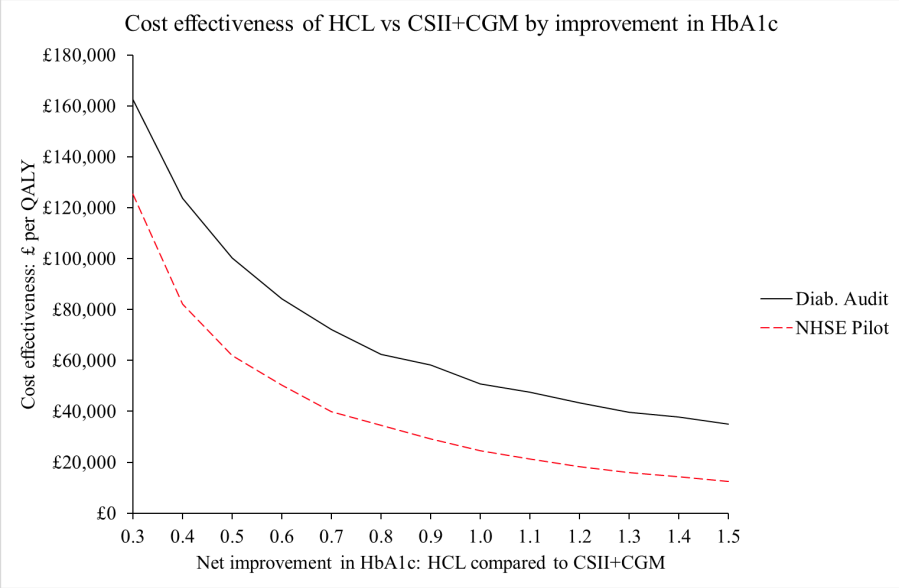
| | |  <br><br>**Additional factors likely to reduce the ICER further are:**<br><br>• Uncaptured disutilities in the model for hypoglycaemia, mental burden and patient and carer anxiety, the true ICER is likely to be lower than this.<br><br>• Clinical experts have advised the committee that the cost of HCL for those on rt-CGM / CSII are over estimated as most CSII currently have an algorithm embedded at no extra cost.<br><br>• Costs for isCGM have been incorrectly applied to outcome effects of rtCGM, which has the effect of inflating the ICER. |

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| | | • Input costs for severe hypoglycaemic events may be an underestimation. The base case assumed a cost of £628 for those requiring medical attention. The National Schedule of NHS Costs 2020-217 reported costs on HRGs KB01B, KB01C, KB01D, KB01F, KB02G and KB01H: Diabetes with Hypoglycaemic Disorders, with CC Score 0 - 8+. Reference costs ranged from £516 to £772 with a weighted average £688 for non-elective short stay and £3,020 for non-elective long stay.<br><br>**Change of comparators from scope**<br><br>Given the change of the scope after the Committee meeting, including MDI with isCGM as a comparator we ask the Committee to explicitly put the current base case into perspective of outcomes being driven by baseline HbA1c, and discuss the 10-fold lower ICER when using the NHSE observational study outcomes and the ADAPT results in the base case analysis of clinical and cost effectiveness. |
| 10 | Medtronic | **Consultation question 3: are the provisional recommendations sound and a suitable basis for guidance to the NHS?**<br><br>We agree that the provisional recommendations are sound with regards to offering access to people who are having difficulty managing their condition despite optimal management with at least 1 of the following: continuous subcutaneous insulin infusion, real-time continuous glucose monitoring, intermittently scanned continuous glucose monitoring.<br><br>The committee preferred a baseline HbA1c of 64 mmol/mol (8.0%) for use in the model as this widens access to people who cannot maintain their target HbA1c resulting in them having an HbA1c of around 64 mmol/mol (8.0%).<br><br>We agree with the committee's preference for the lower baseline HbA1c however, even at this lower level, this may preclude some people from accessing HCL therapy who work exceptionally hard to maintain HbA1below this level.<br><br>The HbA1c target level for control in adults in the current NICE guideline NG17 is 6.5% and achieving this level of control can involve a significant burden in terms of quality of life. Restricting access to HCL to those with HbA1c around 8% means that those below that level would need to lose control in order to access HCL therapy. |
| 11 | Medtronic | **Consultation Question 4: Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** |

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| | | We agree with the widening of the recommendations to people who are on isCGM or rtCGM alone as restricting the recommendations to those already on a pump would build on the existing inequity of access that exists with pumps. |
| 12 | Medtronic | **Committee papers EAG Comments on Assessment Report p365**<br><br>In response to a consultee comment (committee papers p365) the EAG responded that *"It is not appropriate to separately model the cost effectiveness of HCL against CSII+rtCGM and CSII+isCGM as* ***this could result in perverse incentives for patients to seek to adopt the more costly CSII+rtCGM".***<br><br>It is unclear what is meant by perverse incentives. Please provide the rationale for not evaluating the separate comparators in terms of NICE methods where clinical effectiveness is evaluated independently from cost effectiveness.<br><br>The recently published NICE Guidance on CGM for T1 recommends that adults with type 1 diabetes are offered a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring, based on their individual preferences, needs, characteristics, and the functionality of the devices available" so the description of "perverse incentive" in relationship to rtCGM is entirely inappropriate.<br><br>RtCGM and isCGM have a different clinical outcomes as reflected by evidence base including the very recent publication of 24-month results from the randomised ALERTT1 trial [ref] and it is inappropriate to assume the same efficacy for isCGM and rtCGM as was done for the base case.<br><br>**Given that CSII+rtCGM and CSII+isCGM have not been modelled separately and this has resulted in an inflated ICER, we ask the committee to make allowance for this when deciding on their preferred ICER.** |
| 13 | Medtronic | **ACD Page 6, para 3.** *"Any systems available in the future need to be able to show interoperability and be equivalent to current systems in terms of patient benefits".*<br><br>We suggest that this sentence is amended for clarification to "*Any systems available in the future need to be able to show* ***data*** *interoperability and be equivalent to current systems in terms of patient benefits".* |
| 14 | Medtronic | 1) Choudhary P, Kolassa R, Keuthage W, et al. Advanced hybrid closed loop therapy versus conventional treatment in adults with type 1 diabetes (ADAPT): a randomised controlled study. *Lancet Diabetes Endocrinol*. 2022;10(10):720-731. doi:10.1016/S2213-8587(22)00212-1 |

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| | | 2) Arrieta A, Battelino T, Scaramuzza AE, et al. Comparison of MiniMed TM 780G system performance in users aged below and above 15 years: Evidence from 12,870 real-world users. *Diabetes Obes Metab*. Published online April 11, 2022:dom.14714. doi:10.1111/dom.14714<br>3) Ekhlaspour L, Town M, Raghinaru D, Lum JW, Brown SA, Buckingham BA. Glycemic Outcomes in Baseline Hemoglobin A1C Subgroups in the International Diabetes Closed-Loop Trial. *Diabetes Technol Ther*. 2022;24(8):588-591. doi:10.1089/dia.2021.0524<br>4) Breton MD, Kovatchev BP. One Year Real-World Use of the Control-IQ Advanced Hybrid Closed-Loop Technology. *Diabetes Technol Ther*. 2021;23(9):601-608. doi:10.1089/dia.2021.0097<br>5) Castañeda J, Mathieu C, Aanstoot HJ, et al. Predictors of time in target glucose range in real-world users of the MiniMed 780G system. *Diabetes Obes Metab*. 2022;24(11):2212-2221. doi:10.1111/dom.14807<br>6) Pickup JC. Is insulin pump therapy effective in Type 1 diabetes? *Diabet Med.* 2019;36(3):269-278. doi:10.1111/dme.13793<br>7) https://www.england.nhs.uk/publication/2020-21-national-cost-collection-data-publication/ accessed Jan23 |
| 15 | **Tandem Diabetes Care Inc** | We request that NICE consider the following additional information:<br><br>In response to EAG's comment that the Breton et al (2020) study was not included when reviewing hybrid closed loop (HCL) vs predive low glucose suspend (PLGS) because "> 10% not on prior intervention pump or monitor, results were not reported separately/stratified by prior intervention)" – please refer to page 17 of the supplementary appendix with the stratification by prior therapy, which is available at: https://www.nejm.org/doi/suppl/10.1056/NEJMoa2004736/suppl_file/nejmoa2004736_appendix.pdf<br><br>A study that should have been included in the clinical review of RCTs comparing HCL to PLGS:<br>Brown SA, Beck RW, Raghinaru D, Buckingham BA, Laffel LM, et al. Glycemic Outcomes of Use of CLC Versus PLGS in Type 1 Diabetes: A Randomized Controlled Trial. Diabetes Care 2020;43:1822-1828. https://doi.org/10.2337/dc20-0124<br><br>Supplemental appendix is available at:<br>https://diabetesjournals.figshare.com/articles/figure/Glycemic_Outcomes_of_Use_of_CLC_vs_PLGS_in_Type_1_Diabetes_A_Randomized_Controlled_Trial/12240968 |
| 16 | Tandem Diabetes Care Inc | We are concerned with NICE's Recommendation 1.1, which recommends hybrid closed loop systems for people with Type 1 diabetes who are having difficulty managing their condition and have an average HbA1c level of 8.0% and higher for the following reasons: |

| Comment Number | Name and organisation | Stakeholder Comment |
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| | | • The randomized controlled trials (RCTs) used to determine the clinical benefit for the cost-effectiveness model's base case (-0.28% HbA1c) had an average baseline HbA1c of 7.5%.<br><br>• NICE guidelines (NG3, NG17, NG18) recommend a target goal of HbA1c goal of 6.5% or lower for people with Type 1 diabetes to minimize risk of long-term complications. Thus, limiting hybrid closed loop system access to people with 8.0% or higher excludes a large segment of the population with Type 1 diabetes who would greatly benefit from reaching target goal.<br><br>  • The Diabetes Control and Complications Trial (DCCT) found intensive therapy (mean HbA1c about 7%) delays the onset and slows the progression of retinopathy, nephropathy, and neuropathy by 35% to 76% compared to standard therapy (mean HbA1c about 9%).[1] These microvascular benefits persist for two decades as seen with follow up of DCCT cohorts in the Epidemiology of Diabetes Intervention and Complications (EDIC) study.[2]<br><br>  • Based on the National Diabetes Audit, about 2/3 of the population with Type 1 diabetes in NHS England have HbA1c > 7.5%.<br><br>  • A threshold of HbA1c of 8.0% or greater may result in perverse incentives to poorly manage glycemic levels to become eligible for hybrid closed loop systems.<br><br>[1] Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977–986. DOI: 10.1056/NEJM199309303291401<br>[2] Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group. Effect of intensive diabetes therapy on the progression of diabetic retinopathy in patients with type 1 diabetes: 18 years of follow-up in the DCCT/EDIC. Diabetes 2015;64:631–642. |
| 17 | Tandem Diabetes Care Inc | We are concerned that the base case cost-effectiveness model significantly underestimates the quality of life (QOL) benefit of hybrid closed loop systems, resulting in a much larger ICER (£179K/QALY) than expected. The base case does not account for hypoglycemic events nor other uncaptured QOL benefits, such as improved sleep, decreased mental burden, ability to work, etc. While the scenario analysis includes severe and non-severe hypoglycemia events and disutility values based on reported improvements in the Hypoglycemia Fear Survey, which improved ICERs (ranging from £121K/QALY to £170K/QALY), QOL benefits for hybrid closed loop systems remain underestimated due to uncaptured benefits. Additionally, severe and non-severe hypoglycemia becomes an increasing concern when targeting an HbA1c goal of 6.5% and lower. Since cost-effectiveness results from the base case are used to inform decision-making and policy, we urge NICE to consider |

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| | | this significant model limitation when determining the pricing required for hybrid closed loop systems to be considered "cost-effective." |
| 18 | **Ypsomed Limited**<br><br>Submitted via the web | Ypsomed are overall delighted by the announcement by NICE of the proposed guidelines on the future availability of closed loop systems for people living with T1 Diabetes in England. We welcome the step forward in accelerating the access of new technologies to support those living with Type 1 diabetes, their families, and carers.<br><br>The novel way in which the NHS Hybrid Closed Loop pilot was designed to provide NICE with real-world data to support recommendations is commended.<br><br>The following feedback from Ypsomed highlights the need for clarity in the recommendations to ensure guidance is interpreted and implemented to avoid health inequalities in relation to the use of Diabetes Tech being exacerbated. |
| 19 | Ypsomed Limited | Recommendations 1.2<br><br>• Clearly state in the guidance which commercially available systems are licensed for use in pregnancy. |
| 20 | Ypsomed Limited | Recommendations 1.3<br><br>• Approx 30-40% NHS trusts procure Diabetes Tech via the NHS Supply Chain National Tender, the remaining ICS have their own preferred pump list. Recommend a national pricing and procurement infrastructure to aid adoption and uptake whilst minimising 'postcode lottery' of access. Thus, ensuring equitable access to the same portfolio of products. |
| 21 | Ypsomed Limited | Recommendations 1.3<br><br>There is a need to increase capacity and capability of the healthcare professionals who will be implementing and supporting the use of the HCL systems. |
| 22 | Ypsomed Limited | Recommendations 1.4<br><br>• Structured education needs to be widely available in a format that is accessible to the majority, non-traditional methods of implementation should be considered. It is established that structured education can be a barrier to accessing diabetes technologies. |
| 23 | Ypsomed Limited | Recommendations 1.5<br><br>• How will existing HCL users be assessed at renewal? If HbA1c has improved and is lower than 8% will the system be renewed or removed?<br>• PWD who are currently using self-funded ''DIY' HCL systems, with HbA1Cs less than 8% won't meet the criteria, how will they be assessed? |

| Comment Number | Name and organisation | Stakeholder Comment |
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| 24 | Ypsomed Limited | Section 2.1 Type 1 diabetes<br><br>• The quantitative research doesn't accurately describe the reduced burden on mental health of PWD and their families and carers. It is necessary to take into consideration such things as the improvement in sleep disturbance/deprivation, burn out of carers, days lost at work / school etc. in addition to the reduction in HbA1c |
| 25 | Ypsomed Limited | Section 2.6 The interventions<br><br>• The report should include all current commercially available Hybrid Closed Loop Systems in England – Ypsopump with Cam APS FX and Dexcom G6 or FSL3 is not listed whereby others that are not currently commercially available are listed. Recommend listing all commercially available systems at time of publication. |
| 26 | Ypsomed Limited | Section 2.6 The interventions<br>• Clearly state in the guidance which commercially available systems are licensed for use in pregnancy and young |
| 27 | Ypsomed Limited | Section 2.8 Price<br>Ypsomed understands the NHS is experiencing the most severe funding pressures in its 70-year history. Balancing rising demand whilst commissioning new technologies poses a great challenge. Ypsomed's mylife Loop system comprising of Ypsopump + Dexcom G6 or Freestyle Libre 3 + CamAPS FX algorithm is priced between [redacted] (depending on the choice of sensor used) for a 4-year period. The mylife Loop system cost [redacted]. |
| 28 | Ypsomed Limited | Section 3.2 Committee discussion - Access to technology and care<br><br>• Approx 30-40% NHS trusts procure Diabetes Tech via the NHS Supply Chain National Tender, the remaining ICS have their own preferred pump list. Recommend a national pricing and procurement infrastructure to aid adoption and uptake whilst minimising 'postcode lottery' of access. Thus, ensuring equitable access to the same portfolio of products. |
| 29 | Ypsomed Limited | Section 3.2 Committee discussion - Access to technology and care<br><br>NHS England is currently undertaking an Assessment of: Blood glucose and ketone meters, testing strips and associated consumables, provided a clear rationale for doing so, NHS England may issue one or more commissioning recommendations covering topics, including but not limited to:<br>• Products it considers the NHS should prioritise for use<br>• Guidance and/or resources to enable patients to safely change products, where clinically appropriate; and/or<br>• Improvement opportunities |

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| | | We recommend that a similar assessment is conducted for the final guidance for hybrid closed loop systems to expand appropriate access without limitations. |
| 30 | Ypsomed Limited | Section 3.4 Committee discussion - Baseline characteristics<br><br>• People with T1 Diabetes with HbA1c lower than 8% may be experiencing repeated hypoglycaemic events that impact heavily on QOL, a HCL system would benefit them.<br>• People with T1 Diabetes and carers of people with T1 Diabetes who have worked tirelessly, often at a detriment to their QOL and gained HbA1c less than 8% are being excluded from a system that would benefit them by reducing the burden of management.<br>• How will existing Hybrid Closed Loop users be assessed at renewal? If HbA1c has improved and is lower than 8% will the system be renewed or removed?<br>• People with T1 Diabetes who are currently using self-funded ‘‘DIY’ HCL systems, with HbA1Cs less than 8% won’t meet the criteria, how will they be assessed? |
| 31 | Ypsomed Limited | Section 3.5 Committee discussion - Children<br><br>• Clearly state in the guidance which commercially available systems are licensed for use in the young. |
| 32 | Ypsomed Limited | Section 3.6 committee discussion - Pregnancy<br><br>• Clearly state in the guidance which commercially available systems are licensed for use in pregnancy. |
| 33 | Ypsomed Limited | Section 3.9 committee discussion – uncaptured benefits<br><br>• HCL systems can benefit those with learning difficulties, Diabetes burnout, impaired cognitive function due to age or illness. |
| 34 | Ypsomed Limited | Section 4.3 implementation<br><br>• There is a need to increase the capacity and capability of the skilled healthcare professionals who are implementing and supporting the use of the HCL systems. |

NICE National Institute for Health and Care Excellence

**DIAGNOSTICS ASSESSMENT PROGRAMME**

**Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes**

**Diagnostics Consultation Document – Comments**

**Diagnostics Advisory Committee: 24 May 2023**

# Contents



| Comment Number | Name and organisation | Stakeholder Comment |
|---|---|---|
| 1 | **Diabetes UK** | We broadly welcome these draft recommendations, which have the potential to open access to this next-generation, life-changing medical technology to a significant number of people with type 1 diabetes for the first time. We also strongly support the appraisal encompassing systems and not individual components or devices, in order to future-proof the recommendations and account for new, interoperable systems that are being developed and will offer greater choice.<br><br>As the evidence assessed during this appraisal has clearly demonstrated, hybrid closed-loop systems can help to significantly improve blood glucose levels and time-in-range. This reduces the risk of hypoglycaemia and devasting long-term complications such as sight loss and limb amputations. Furthermore, this technology greatly reduces the daily mental burden of having the condition and automates a considerable amount of the calculations and processes that people with diabetes, their families and carers rely on for self-management.<br><br>Given that the baseline characteristics from the randomised control trials and real world data reviewed by the committee were not fully generalisable to the type 1 diabetes population in the country, we are glad that the decision was made to use the average HbA1c for insulin pump users as per the National Diabetes Audit as a cut-off for access. We feel that this is a sensible compromise to widen access to as many people as possible.<br><br>However, we are also very concerned that some sub-groups – particularly children and young people – and other factors such as hypoglycaemia unawareness and quality of life are not given due consideration in this broad approach to the type 1 population. |

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| 2 | Diabetes UK | We disagree with the lack of specific recommendations for children and young people. It appears contradictory that the committee agree that hybrid closed-loop systems are likely to be more cost effective for children than adults, and also note the greater impact of benefits such as reduction in hypoglycaemia fear scores, yet have been unable to make recommendations for them.<br><br>The proposed HbA1c cut-off will exclude many children and young people with type 1 diabetes currently being given access to a technology that will help them, their parents and carers live healthier and happier lives. We recognise the limitations of the economic modelling in the appraisal but feel it is vital that this group are given the chance to optimise their management at earliest opportunity with this technology in order to gain the greatest benefits. The economic models used are not sufficient to assess the full benefits to children, some diagnosed as young as toddlers, who will live with the condition the longest and have a heightened risk of developing long-term complications.<br><br>In response to the comment about the lack of evidence on the quality of life benefits we would highlight the study recently published which is based on the NHS England pilot for children and young people. This included over 250 children and young people aged between 1-18 and, as well as significant improvements in HbA1c and time-in-range, found that average fear of hypoglycaemia score in parents or carers fell from 56.5 before the pilot to 45.2 after 6 months, with a greater decrease of an average of 64.9 to 57.5 in those older than 12 years old. The average sleep-related impairment T-score in participants over 8 years old also fell from 56.6 to 54.9 and the parent and carer sleep disturbance T-score fell from 60.1 to 56.1 – both of which are statistically significant. These life-changing improvements in quality of life for children and young people, their parents and carers must be reflected in the recommendations.<br>Reference: https://onlinelibrary.wiley.com/doi/abs/10.1111/dme.15015 |
| 3 | Diabetes UK | Furthermore, the current NICE criteria for an insulin pump in TA151 is to offer them to people with type 1 diabetes if they experience repeated and unpredictable hypoglycaemia or have HbA1c of 69mmol/mol (8.5%), which is similar to the draft recommendations for hybrid closed-loop systems.<br><br>However, this criteria for insulin pumps does not apply to children under 12, who can be offered pump therapy if multiple daily injections are deemed inappropriate or impractical. In light of this we think that there are additional grounds to make a recommendation for this group to be offered hybrid closed-loop regardless of their HbA1c – as they should already be given a choice of CGM and are eligible for a pump under existing guidance. |
| 4 | Diabetes UK | As stated above, it is positive that the committee has agreed on a relatively low HbA1c cut-off for access to this technology but feel that using this as the primary criteria does not account for the needs of all the type 1 population and benefits hybrid closed-loop can offer.<br><br>Firstly, we would refer back to NICE guidelines for type 1 diabetes in adults (NG17) and children (NG18) which advises a target HbA1c of 48 mmol/mol to reduce the risk of long term complications. This is significantly below the 64 mmol/mol recommended here, and though we appreciate that there are other factors to consider in this appraisal, it is important to remember that many more people could benefit from it. |

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| 5 | Diabetes UK | It is also notable that the mental load of self-managing type 1 diabetes is highlighted as a key concern in committee discussions but not reflected in recommendations. Insights gathered by Diabetes UK found that one in four people with type 1 diabetes experience severe diabetes distress, which is the emotional toll resulting from living with diabetes and the burden of relentless daily self-management.<br><br>Many people with high levels of diabetes distress tend to have a higher HbA1c but more optimal management does not necessarily indicate lower levels of diabetes distress. We believe that the recommendations must be mindful of people who may be reaching a HbA1c of under 64mmol/mol but going through great difficulty to do so, and allow clinicians to consider diabetes distress as an additional criterion.<br><br>Another potential unintended effect of using a target HbA1c alone as a criterion is that it could encourage people who are desperate to use the technology to improve their self-management and quality of life, but just under the cut-off, to worsen their management in order to become eligible. We are aware that this occurred in the past when strict criteria based on HbA1c was used to decide access to Flash glucose monitoring technology.<br><br>Reference: https://www.diabetes.org.uk/resources-s3/2019-03/0506%20Diabetes%20UK%20Australian%20Handbook_P4_FINAL_1.pdf |
| 6 | Diabetes UK | As well as inclusion of diabetes distress, we think that the recommendations should be extended to people who experience severe hypoglycaemia and hypoglycaemia-unawareness – as they are another group that could benefit substantially from this technology.<br><br>Tighter control of blood glucose levels using insulin can increase the risk of hypoglycaemia. The additional stability that hybrid closed-loop provides by improving the amount of time-in-range, as well as reducing time spent in the hypoglycaemia range, can help many people who have a HbA1c below 64 mmol/mol but experience the negative effects of regular periods of very low blood sugars.<br><br>There are also practical considerations for people with type 1 diabetes such as those who need to avoid severe hypoglycaemia for driving licences or employment. Making explicit reference to hypoglycaemia in the recommendations will allow for a more nuanced and effective application of the technology that is better able to consider the individual needs and circumstances of people. |
| 7 | Diabetes UK | We are concerned that making attendance of a structured diabetes education course a mandatory requirement may exclude many people, particularly those who already experience health inequalities. Good education is of course essential to good self-management but this has to be flexible and able to fit around the needs of people's circumstances. Currently, access to structured education is not equally available to all with type 1 diabetes for a range of reasons including long waiting lists, some courses only being available during working hours when some people do not have access to paid leave.<br><br>We agree there should be appropriate training for people living with diabetes, their carers and healthcare professionals to ensure that the systems are understood and used safely and effectively, but this can be delivered in quicker and more flexible ways as evidenced in the NHSE pilot. |

| Comment Number | Name and organisation | Stakeholder Comment |
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| | | We believe that good training, education and support can be provided by diabetes teams on the use of hybrid closed-loop technology without specifying diabetes structured education programmes. Due to the current access issues, this may serve as an additional barrier to those who can benefit from it. |
| 8 | Diabetes UK | It is important to ensure that this guidance makes this technology available to those at most risk of experiencing health inequalities and maximises the potential benefits of automation that hybrid closed-loop systems allow.<br><br>As the clinical experts on the committee note, the technology can reduce some of the inequalities for people who find it difficult to keep their blood glucose levels in target range because of factors like language barriers due to learning disabilities or not speaking English as a first language. Elderly people in residential care homes represent another commonly under-represented group who could greatly benefit from this.<br><br>Many people with type 1 diabetes who have been able to get hybrid closed-loop systems to date tend to already be very knowledgeable about diabetes technology and have the financial and social resources to get access. As this guidance is implemented services should be mindful of this and take action to avoid exacerbating any potential health inequalities. |
| 9 | Diabetes UK | We welcome recommendations for pregnant women and those planning pregnancy as they are a key sub-group who stand to benefit from this technology. |
| 10 | Diabetes UK | The language used in the document should aim to be person-centred and not use terms such as "not well controlled" in preference for others like "not managed within target ranges" to avoid the impression that they are imparting judgement on people living with diabetes.<br><br>Reference: https://www.england.nhs.uk/wp-content/uploads/2018/06/language-matters.pdf |
| 11 | Diabetes UK | In addition to the current draft recommendations we suggest that the committee consider if there should be consideration of non-tech options as back-up in case of technology failure and capacity for healthcare professionals to follow-up on their patients regularly, working together to optimise it. |
| 12 | **Insulet International Ltd** | Insulet International welcome the approach by NICE for a class level approach to HCL evaluation, and for class recommendations to be issued.<br><br>People living with T1D require insulin to stay alive. They therefore need to interact with their diabetes technology every day. It is estimated that people with T1D make an average of 180 decisions per day related to the management of their condition (Latts 2019) and some of this burden can be alleviated through the use of technology Although AID systems are similar in their use, the features and benefits differ depending on the specific AID technology. These differences include tubed and tubeless form factors, differing sensor compatibility and differences in algorithm design and behaviour. In combination, these differences can significantly impact on how an individual interacts with their technology |

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| | | **Offering choice in diabetes management technology to PWD, both in terms of technology type and available range within a class, is therefore critical to achieving effective diabetes care and we welcome the acknowledgement of this by NICE within the ACD.**<br><br>Reference:<br>• Alleviating the burden of diabetes with AI – THINK Blog, Latts 2019 |
| 13 | Insulet International Ltd | At recommendation 1.1, applying an 8% HbA1c as the sole clinical criteria to be considered for HCL technology will significantly restrict access (and this is indeed the opposite of the Committee's intention "to ensure wider access" as written on p4 of the ACD). We request acknowledgement of additional clinical criteria beyond a sole HbA1c measurement considered in recommendation 1.1 and flexibility in approach to clinical decision making.<br><br>For example, TA151 includes a recommendation for a minimum HbA1c or for a person to have experienced hypoglycaemia that is having a significant adverse effect on QoL.<br><br>We suggest that NICE considers amending the clinical criteria for access in 1.1 to recommend use from;<br>"for people who are having difficulty managing their condition **and** have an average HbA1C of…… to<br>"for people who are having difficulty managing their condition ***or*** have an average HbA1c of….." |
| 14 | Insulet International Ltd | Whilst we fully acknowledge the need for an individual and/or their carer to understand and be able to use HCL technology, we wish to flag that the additional requirement at draft recommendation 1.4 to be "also attending a T1D structured education programme" will likely create a barrier and further restrict access.<br><br>Clinicians working across the UK have previously shared with us that the need to attend structured education programmes can create unintended barriers to access. Funding for these courses is variable, many people may have attended one previously, and it may not be possible for an individual to attend one of these courses, for example, because of language or course location.<br><br>We consider that the assessment of education requirements should sit with the clinical team responsible for delivering diabetes care. We absolutely agree that there a need for appropriate education, but we consider this "structured" and live attendance requirement to be a potential barrier as currently written, rather than supportive of effective and efficient care delivery. For example, the local clinical team may determine that virtual or online courses may be more appropriate and the guidance should support flexibility in education delivery.<br><br>We request that NICE revises its language at 1.4 so that the second bullet point reads "*has received appropriate education on T1D to support use of this technology*". |
| 15 | Insulet International Ltd | We consider there are significant issues remaining with the CEA which have not been adequately addressed by NICE. As a result, in its current form, this ACD could have significant negative impact on the diabetes communities' access to HCL technology. |

| Comment Number | Name and organisation | Stakeholder Comment |
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| | | In light of the significant uncertainty in the CEA, unresolved disputes across multiple economic model inputs raised across multiple stakeholders, including NHS England, and many benefits remaining uncaptured (e.g., impact of NSHE on quality of life, benefits relating to mental health burden and parent/carer anxiety), we are challenged to understand how the Committee can only recommend use of HCL technology if companies agree a "cost effective" price with NHS England.<br><br>The requirement for a cost-effectiveness price agreed with NHS England at recommendation 1.1 and 1.2 is based on what we believe to be a flawed CEA. Affordability needs to be discussed in the framework of value, and if we are determining value via a cost effectiveness model, then that model needs to adequately capture value. |
| 16 | Insulet International Ltd | It is unclear how cost effectiveness will be determined by NHS England given the significant uncertainty surrounding multiple model inputs and the conclusions drawn from the CEA.<br><br>It is also unclear how cost effectiveness will be determined by NHS England because no process or information has been shared with industry regarding this critical step. We request that NICE and NHS England rectify this situation and clarify the process transparently to industry, prior to any final recommendations being issued that could have significant negative impact on access to effective technology across the NHS. |
| 17 | Insulet International Ltd | When looking at the EAC report and its response to stakeholder feedback, ten of the eleven stakeholders that replied made similar challenges to the CEA on at least one or more of the observations we identified . Despite this consensus across stakeholders, including clinician and patient associations and NHS England itself, limited changes to model inputs or additional analyses appear to have been carried out by the EAC in response.<br><br>In our feedback on the EAC report we had requested that additional analyses be carried out to model the improvements in quality of life associated with use of HCL systems, either by applying a theoretical utility gain or the differences in health-related quality of life that have been reported. From reviewing the consultation paperwork, this request does not seem to have been addressed by NICE. |
| 18 | Insulet International Ltd | During the Committee's discussions at its November meeting, it was clear that many members considered the NHS England pilot data to be more applicable to NHS clinical experience vs RCT data included in the NMA, and the impact of applying these data in the model is significant. However, it appears in the consultation documentation that these NHS England pilot data were not applied in the final economic analysis identified by the Committee as most appropriate to drive NICE's conclusions.<br><br>We request that NICE reconsider why these NHS England data were not included in the final considerations on the cost effectiveness of HCL technology. |
| 19 | Insulet International Ltd | The key parameters affecting the ICER are documented within the ACD, with the cost of HCL systems identified as being 1 of 9 key drivers of the cost-effectiveness results.<br><br>We therefore find it disappointing that the Committee's conclusion defaults to the cost of the technology being the issue when the CEA has not adequately captured the value of this technology and its impact on people living with T1D. |

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| 20 | Insulet International Ltd | We consider that to conclude that HCL systems are unlikely to be cost effective, you would have to believe the following:<br><br>• That the effect Automated Insulin Delivery (AID) has on glycaemic control is small and the impact on hypoglycaemia is very modest.<br>• That people with T1D live in a world where hypoglycaemia isn't that common and that the impact of having hypoglycaemic events on quality of life is actually quite trivial.<br>• That the reduction in the mental burden of managing diabetes that AID can deliver is entirely unimportant.<br><br>We do not consider this to be consistent with the Committee's opinion, and request that the Committee reconsider its conclusions in light of the testimony from PWD received, NHS England pilot data, and available published literature as cited by multiple stakeholders (including ourselves and the ABCD DTN) when commenting on the EAC report. |
| 21 | Insulet International Ltd | Within our EAC report feedback we had referred to HbA1c of participants across the NMA studies being already below, or close to, target HbA1c and the baseline rate and absolute treatment effect on non-severe hypoglycaemia, both of which may not be generalisable to all people with T1D.<br><br>We also continue to believe that the representation of the impact on hypoglycaemia on quality of life in the CEA plays down the true impact on people with T1D and could be better represented. We would like to make reference to the comment made by ABCD DTN-UK that Gordon 2020 was a study that excluded those with problematic hypoglycaemia. The small impact on quality of life estimated by this study may not be generalisable for all people with T1D. As a result, the starting point for the analyses on hypoglycaemia is a small treatment effect on numbers of hypoglycaemic events applied to a low assessment of the impact they have on quality of life.<br><br>The NHS England pilot study reported that use of HCL systems was associated with a substantial reduction in the proportion of people reporting diabetes-related distress, from 70.8% to 43.1% (P=0.001) and a reduction in mean Gold score from 2.2 to 1.9 (P<0.001). Additionally, 95% reported that the system had a positive impact on their quality of life. With Omnipod® 5, adults experienced a significant reduction in diabetes distress (p<0.0001) on the Type 1 Diabetes Distress Scale (T1DDS) (Polonsky 2022). This type of evidence indicates that the impact on mental burden of diabetes is an important factor without which the cost effectiveness of HCL cannot reliably be estimated.<br><br>We request that NICE reconsider the model inputs to more adequately capture the impact of T1D and the value of this technology.<br><br>Reference:<br>• Gordon J.,et al. Relationship between hypoglycaemia, body mass index and quality of life among patients with type 1 diabetes: Observations from the DEPICT clinical trial programme. Diabetes Obes Metab 2020;22(5):857-65<br><br>• Polonsky W., et al. How introduction of automated insulin delivery systems may influence psychosocial outcomes in adults with type 1 diabetes: Findings from the first investigation with the Omnipod® 5 System. Diabetes Research and Clinical Practice (190). 2022. |
| 22 | Insulet International Ltd | In our comments submitted on the EAC report we shared our feedback that the EAC had applied a very conservative approach to some of the model costs, which are also driving an underestimate of effect. Reflecting across the similar feedback shared across |

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| | | multiple stakeholders, we do not consider the EAG response that the costs applied were simply those from previous assessments and that the impact of NSHE "could affect the analyses" to be satisfactory. We request that the NICE team review this.<br><br>**Cost of stroke:** The EAC applies the cost for stroke in the year of the event at £4,728 and £175 in subsequent years. To provide comparison, average per patient costs of £15,000 -£30,000 (Youman et al. 2002), and separately £13,452 in year one to £17,963 after five years (Xu et al. 2018) have been reported in the published literature.<br><br>**Cost of Non-Severe Hypoglycaemic Events (NSHE):** The EAC has assumed NSHE have no cost to the NHS. Brod et al (2011) and Orozco-Beltran et al. (2014) report that 8% - 25% of NSHE are associated with additional HCP appointments in people with T1D. Considering the frequency of NSHE, this could represent a substantial cost to the NHS.<br><br>• Youman P, Wilson K, Harraf F, Kalra L. The economic burden of stroke in the United Kingdom. Pharmacoeconomics. 2003;21 Suppl 1:43-50<br>• Xu XM, Vestesson E, Paley L, Desikan A, Wonderling D, Hoffman A, Wolfe CD, Rudd AG, Bray BD. The economic burden of stroke care in England, Wales and Northern Ireland: Using a national stroke register to estimate and report patient-level health economic outcomes in stroke. Eur Stroke J. 2018 Mar;3(1):82-91<br>• Brod M, Christensen T, Thomsen TL, Bushnell DM. The impact of non-severe hypoglycemic events on work productivity and diabetes management. Value Health. 2011 Jul-Aug;14(5):665-71<br>• Orozco-Beltrán D, Mezquita-Raya P, Ramírez de Arellano A, Galán M. Self-reported frequency and impact of hypoglycemic events in Spain. Diabetes Ther. 2014 Jun;5(1):155-68. |
| 23 | Insulet International Ltd | The value of HCL systems is derived from the algorithm which automates many of the insulin dosing decisions within a 24h period. Using NICE's executable model, we adjusted the base case inputs so only the comparator was 100% CSII+rtCGM. This resulted in a cost difference over 60-years of £1,427 and an ICER of £8,919/QALY.<br><br>We request that NICE and its EAC explore this approach themselves and give due consideration to isolating the impact of the new innovation under evaluation within CEA. |
| 24 | Insulet International Ltd | In the Committee presentation slides, it is clearly stated that "NICE has no fixed threshold" (slides included in consultation paperwork released by NICE). In the ACD, NICE has specified a fixed threshold of £20k/QALY in its ACD. This is an inconsistent approach by NICE.<br><br>We also find it challenging to accept that HCL technology is not considered innovative by NICE. What would be required for medical technology to be considered innovative by NICE? We request that NICE revises this fixed approach to its QALY threshold to determine cost effectiveness. |
| 25 | Insulet International Ltd | Due to the interoperable nature of different HCL system components across AID system providers and a swiftly changing landscape, agreeing a "system" price with NHS England is challenging for the vast majority of AID systems available. |

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| | | Interoperability enables choice to people with diabetes and their healthcare providers, it is therefore important that any negotiation framework does not give preference to systems with fixed combination of pump and sensor.<br><br>We therefore wish to flag to NICE, that a clear and robust process for negotiation has not been set out and therefore there is no good foundation for fair negotiations with NHS England to date. |
| 26 | **JDRF, the type 1 diabetes research charity** | JDRF is delighted that NICE has drafted recommendations approving hybrid closed loop (HCL) systems for use by people with type 1 diabetes.<br><br>Below are some case studies of those using HCL and the benefits it brings, not just to the person with type 1 diabetes, but to those around them (names have been changed):<br><br>Claire's son is 14 years old, and has had T1 since he was 2 years old. As a toddler it was very challenging and traumatic, he wasn't able to go to nursery as staff there didn't want to have to inject him. She describes it as "like having a newborn baby all the time." HCL (Dexcom G6 and Tandem T-Slim) has given them their lives back. He now has an average HbA1c of 5.7%. “Less sugar intake to treat hypos, so his teeth aren't compromised. He's now in better health, with better moods; he's sports mad and can now play in football matches.” His mum is less on edge as she knows the pump is working in the background, one step ahead. She had put her career on hold to care for him, and has now been able to go back to full time employment as not having to worry about him all the time.<br><br>Patricia has been using HCL for a year. Since using HCL her Time in Range has gone from 54% to 75-95% on a daily basis. It has reduced the mental burden of constant decision making; her improved clinical outcomes are reflected in her day to day life: she was able to get a promotion, and her mood is more stable. She found that whilst on just an insulin pump, her glucose levels were yo-yoing daily from 2mmols/L to 17mmols/L. The hybrid closed loop system has smoothed all this out. |
| 27 | JDRF, the type 1 diabetes research charity | 1.1 JDRF is concerned that the draft recommendation only recommends hybrid closed loop (HCL) for those with a HbA1c of 8% or more. There are so many other factors that should be taken into account with regards to type 1 diabetes management – all of which impact ongoing self-care, such as severe hypoglycaemia, hypo-unawareness, fear of hypos, and diabetes distress.<br><br>Diabetes-specific emotional distress can be defined as the experience of emotional problems related to living with diabetes and its treatment.[1] The study Evaluating the relationships of hypoglycaemia and HbA1c with screening-detected diabetes distress in type 1 diabetes[2] states that a significant proportion of people who achieve target HbA1c with minimal hypoglycaemia do so at the expense of significant diabetes distress. This suggests that those who don’t meet the proposed criteria of a HbA1c of 8% or over may be experiencing diabetes distress, and thus may not be able maintain their target HbA1c in the long term.<br><br>Therefore, JDRF recommends changing the wording from “Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more” to “Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition OR have an average HbA1c of around 64 mmol/mol (8.0%) or more.” |

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| | | A person with type 1 relates the impact of hypoglycaemia: “The impact of hypos on daily life for someone with type 1 is difficult to articulate. If you are aware of your hypos, when you are experiencing a hypo fear of it progressing to a medical emergency that you cannot rescue yourself from is real, and fear that 'this one' might kill me can be terrifying, especially as my brain isn't working properly and I can't think rationally. 'Dead in Bed' Syndrome is rare but real. As I am unaware of being hypo these fears can be present throughout my waking days. I am not aware of my hypos until my glucose is very low, at which point I feel very panicky and vulnerable. What if I become unconscious? I'm unlikely to die but I'm vulnerable and the normal fear - together with hypo-brain irrational fear - is intense. Using my hybrid closed loop system protects me from most hypos and the predictive alerts of its CGM let me know if I do become hypo, long before I would be aware of it. I can then take action before it gets serious.”<br><br>Kathleen shares her experience of hypoglycaemia: “In a hypo your brain stops working, and you need to take time to stop and recover. A mild hypo can leave you hungry, shaky, confused and tired. If you treat it quickly, in about 30 minutes you feel better. There is a lot of anxiety around hypos, will one happen when driving, walking, when in a meeting or a lecture? They are very disruptive.”<br><br>The paper “Self-reported non-severe hypoglycaemic events in Europe” states that the rate of self-reported non-severe hypoglycaemia is reported as 94 per year per patient in a general population, showing the burden of living with type 1.[3]<br><br>The burden of managing type 1 diabetes is summarised here by a supporter: “The burden of managing type 1 is relentless - you have to do all the things even on holiday, at Christmas, on your birthday, when you're unwell, when you're busy. It feels like a heavier burden when I don't achieve my treatment targets despite my best efforts. Using hybrid closed loop means that many of the treatment decisions are made automatically, which helps relieve the burden, and I spend more time in target glucose range, which lifts the burden further still.” |
| 28 | JDRF, the type 1 diabetes research charity | 1.1 JDRF is concerned that the requirement to have already been using an insulin pump, flash glucose monitoring or continuous glucose monitoring to qualify for a HCL system will disadvantage those who have been unable to obtain those devices. We know that a number of ICB’s are not yet following NICE’s NG17 and NG18 guidelines on glucose monitoring, and that there are waiting lists for pumps around the country.<br><br>JDRF’s 2020 Pathway to Choice report[4], the National Paediatric Diabetes Audit and the National Diabetes Audit have found that those from a lower socioeconomic background, and those from black, Asian and minority ethnic communities are much less likely to use diabetes technologies. By having a requirement to already be on an existing device to access HCL will mean many in these communities will be unable to obtain the systems.<br><br>We feel that if this requirement remains in the recommendation, there should be a clear pathway to obtain a pump/glucose monitor that leads to access to a HCL system within a certain time period. |
| 29 | JDRF, the type 1 diabetes research charity | 1.2 JDRF is delighted to see HCL systems recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy. |

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| 30 | JDRF, the type 1 diabetes research charity | 1.4 JDRF is concerned about the requirement for the person with type 1 to be "attending a type 1 diabetes structured education programme". Structured education programmes for type 1 diabetes offered by the NHS usually only last for a week, so it is not possible to be continually "attending" one. Secondly, we feel this should not be a mandatory requirement. Many people with type 1 diabetes are unable to attend formal structured education programmes as they are unable to take time off work or school to attend. We suggest this criteria be changed to being trained on the appropriate HCL device. If this recommendation was intended to state that people should attend structured education on how to use a hybrid closed loop system then that should be clarified. Further, the NHSE pilot showed that even with no education on its use, some people can still gain significant clinical benefit from using a HCL system. |
| 31 | JDRF, the type 1 diabetes research charity | References<br>[1] Longitudinal relationship between diabetes-specific emotional distress and follow-up $HbA_{1c}$ in adults with Type 1 diabetes mellitus; Strandberg et al; April 2015 https://onlinelibrary.wiley.com/doi/10.1111/dme.12781#dme12781-bib-0001<br>2 Evaluating the relationships of hypoglycaemia and HbA1c with screening-detected diabetes distress in type 1 diabetes; Todd et al; Dec 2017<br>https://onlinelibrary.wiley.com/doi/10.1002/edm2.3<br><br>[3] Self-reported non-severe hypoglycaemic events in Europe; Östenson et al; Jan 2014 https://pubmed.ncbi.nlm.nih.gov/23796113/<br><br>[4]JDRF, Pathway to Choice, February 2020 https://jdrf.org.uk/wp-content/uploads/2020/02/jdrf-pathway-to-choice-brochure-FINAL.pdf |
| 32 | **NHSE – Office of the CSO** | Type 1 Diabetes and Gestational Diabetes are more common in black and ethnic minorities these groups were better represented in the NHS 'Real World Pilot' than the RTCs. |
| 33 | NHSE – Office of the CSO | We are concerned that there was very limited evidence of use pre- or during pregnancy and the effectiveness of HCL in pregnant women remains unclear, we would therefore like to see this cohort excluded from recommendations until evidence for this group is better evaluated in further trials. |
| 34 | NHSE – Office of the CSO | As outlined by the clinical experts we also have some concerns about recruitment bias of patients in RCTs. Participants in RCTs usually have higher levels of motivation and better ability to self-manage. Given that type 1 diabetes is more common in black and ethnic groups, evidence shows these groups are less likely to participate in RTCs therefore results may be biased to motivated white Caucasian populations. |
| 35 | NHSE – Office of the CSO | Given the experts comments on the changing physiology of Children between ages of 0-6yrs 7-11yrs and 12-18yrs we would want any recommendations for use of HCL and the benefits realised be reflected by specific age groups, if that is possible. We are concerned that there is uncertainty reflected in the modelling for children. |

NICE National Institute for Health and Care Excellence

**DIAGNOSTICS ASSESSMENT PROGRAMME**

**Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes**

**Diagnostics Consultation Document – Comments**

**Diagnostics Advisory Committee: 24 May 2023**

| Comment Number | Name and organisation | Stakeholder Comment |
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| 1 | Partha Kar<br>NHS England – National Specialty Advisor, Diabetes | Overall, the recommendations from the HCL TA are extremely welcome and will have a positive impact on people of all ages living with type one diabetes, improving clinical outcomes and quality of life. |
| 2 | Partha Kar<br>NHS England – National Specialty Advisor, Diabetes | ALIGNMENT WITH TA151 (CHILDREN & YOUNG PEOPLE):<br><br>One fundamental issue is how this aligns with existing TA guidance specifically TA151 for Insulin Pumps. Bearing this in mind?<br><br>A specific aspect, that requires consideration, is **the impact of the guidance on children under the age of 12 years.**<br><br>***We would be grateful if HCL therapy could be considered as a treatment option for all children under the age of 12 years, regardless of their average HbA1c.*** There is an opportunity to align this guidance with the recommendations set out in other NICE documents relating to the management of type 1 diabetes in children, TA151 and NG18. The rationale for this is outlined below.<br><br>Specific challenges in this age group: There are significant additional challenges associated with managing type 1 diabetes in younger children, which have been recognised in previous NICE guidance (TA 151) relating to the use of CSII therapy, where this technology is a recommended treatment option if 'MDI therapy is considered to be impractical or inappropriate'. These challenges include recognising and expressing the symptoms of hypoglycaemia, unpredictability of eating patterns, frequent unscheduled activity, and changing insulin requirements associated with growth. HCL therapy provides additional clinical benefits, compared with standard insulin pump and CGM options, in overcoming these difficulties.<br><br>Minimal additional costs: The additional cost impact of upgrading to a HCL system from rt-CGM and insulin pump therapy, in this age group, will be relatively low. Most of the additional cost comes from switching to a rt-CGM sensor that links with the insulin pump. However, this type of sensor (HCL enabled) is the most suitable type in this age group and provided as standard practice as per NICE guidance (NG18, 2022 update). When deciding on the suitability of different CGM devises, this guidance recommends considering the following factor - 'whether the device provides predictive alerts or alarms and if these need to be shared with anyone else, for example a parent or carer'. For children under the age of 12, it is essential for parents and carers to be able to 'follow' the CGM data to respond to the alarms and make treatment decisions. |

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| | | Impact on parents and carers: Children under the age of 12 years are almost entirely dependent on parents and carers for their diabetes management and therefore the impact of managing diabetes extends beyond the young person to include their family and care provided within schools. Previous NICE guidance (TA 151) recognises that 'Diabetes is a source of stress for all members of an affected person's family and in the case of children can cause intense parental anxiety'. In addition to the impact on quality of life for parents and carers, there are also wider economic considerations. Parents and carers of young children often find themselves facing issues with lost income due to missing workdays or unable to maintain employment due to managing their child's diabetes, particularly when there are issues overnight and where HCL systems are especially helpful.<br><br>Current practice: HCL therapy is already viewed as standard practice in many centres, particularly for very young children, and there is a risk that this guidance will result in a backwards step in paediatric diabetes management. In essence, it will build in the requirement for a high hba1c with the associated long-term effects on metabolic memory and risk of diabetes complications before this technology can be considered.<br><br>Both from a policy implementation and clinical perspective, this alignment needs to be strongly considered.<br><br>In addition, it needs to consider whether this should be offered to anyone ages 12-18 irrespective of HbA1c as data from National audits also show the increasing HbA1c due to challenges in adolescence – as per National Diabetes audits. *(There is continued evidence of lifetime peaks of HbA1c age 19 and DKA age 18)* |
| 3 | Partha Kar<br>NHS England – National Specialty Advisor, Diabetes | ALIGNMENT WITH TA151 (HYPOGLYCAEMIA)<br><br>TA151 allows those with Disabling Hypoglycaemia to have access to Insulin Pumps. As things stand? Based on NG17 & 18, anyone with Type 1 Diabetes can get a CGM- and if disabling hypoglycaemia- a Pump. It makes no clinical sense for that CGM and Pump NOT to be connected- in fact, by default most will. To simplify and align the TAs, it would make sense for this group to be included in the category eligible for Closed Loop technology.<br><br>Our suggestion would be to consider using this -which would help with alignment<br><br>"Attempts to achieve target haemoglobin A1c (HbA1c) levels result in the person experiencing disabling hypoglycaemia with at least 1 of the following:<br>• continuous subcutaneous insulin infusion<br>• real-time continuous glucose monitoring "<br><br>*For the purpose of this guidance, disabling hypoglycaemia should be defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life.* |
| 4 | Partha Kar<br>NHS England – National Specialty Advisor, Diabetes | STRUCTURED EDUCATION PROGAMMES: |

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| | | Attendance of Type 1 Diabetes structured education programmes must be offered- not made as a mandatory step. The wording should thereby be clear- and not be misinterpreted by systems- causing unintended delays in implementation. Of note? The Closed Loop Real world data collection- and work did NOT involve each patient going through a mandatory structured education programme<br><br>Our experience from data analysis -as regards obstacles to uptake of Insulin Pumps (TA 151) has been education programmes in its present format (face to face alone) and we need to ensure we aren't disadvantaging those who are unable to attend a programme. (e.g., those unable to get time off due to work/carer roles and very often low socioeconomic conditions or proficiency in digital courses or unable to speak English)<br><br>I would suggest changing the wording to "offering approved structured education programmes (face to face or digital) or ensuring person with diabetes demonstrates equivalent competencies in functional insulin dosing". |
| 5 | Partha Kar<br>NHS England – National Specialty Advisor, Diabetes | <u>PREGNANCY:</u><br><br>The implementation of the recommendation poses a question for the committee to consider. Many of the women trying for pregnancy may not fit proposed criteria of HbA1c for access to Closed Loops on its own. What would the committee be recommending post-delivery of the baby? If it is that the women concerned need to come off this technology, it is unlikely to be feasible -from a policy or rational point of view. |
| 6 | Partha Kar<br>NHS England – National Specialty Advisor, Diabetes | <u>PEOPLE ON EXISTING CLOSED LOOPS- AND SELF FUNDED:</u><br><br>It would make sense if those self-funded- are not "penalised" and thus if there is evidence of improvement of HbA1c post self-funding- this should be continued via NHS funding. This prevents thereby any scenario of unaffordability triggering a stopping of parts of the closed loop system- and thus worsening of control—further resulting in return to closed Loops |
| 7 | Partha Kar<br>NHS England – National Specialty Advisor, Diabetes | **Thus, in summary, the request is to consider:**<br>*a) Alignment with TA151 and NG17/18 resulting in ages 0-12 (without any HbA1c cut off) and Disabling Hypos despite treatment -being considered for eligibility*<br>*b) Education programmes and relevant wording to ensure this isn't an obstacle- and does not widen deprivation gaps*<br>*c) Consider age groups 12-18 (without any HbA1c cut off) due to issues associated with adolescence and data showing worsening of control during this phase*<br>*d) Consider pregnancy group- and issues around discontinuation*<br>*e) Consider wording in final recommendations for those -at present- self funding their Closed Loop and showing evidence of benefit* |

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| 8 | Peter Hindmarsh (clinical expert) | General point. The appraisal has considered all the available evidence on hybrid closed loops in children. It might be worth adding to the references the published NHSE Children's pilot<br><br>Ng SM, Wright NP, Yardley D, Campbell F, Randell T, Trevelyan N, Ghatak A, Hindmarsh PC. Real world use of hybrid-closed loop in children and young people with type 1 diabetes mellitus – a National Health Service pilot initiative in England. Diabet Med. 2022; Nov 24:e15015. doi: 10.1111/dme.15015 |
| 9 | Peter Hindmarsh (clinical expert) | General point. The economic case for children is hard to determine given the lack of information on long term outcomes but what has been provided is about the best that can be attained. |
| 10 | Peter Hindmarsh (clinical expert) | The appraisal gives good guidance to the NHS. The position of children should be more along the lines of TA151 so that all children under the age of 12 years should be offered hybrid closed loop probably from diagnosis as Cambridge data show that is effective in this group. For the over 12 years of age then the HbA1c criteria would apply as it does in TA151.<br><br>It would make more sense to make this appraisal the same as TA151 which could be closed. For paediatrics we would then have the following stages<br><br>Age under 12 years<br>Offer hybrid closed loop to all and from diagnosis<br>Second line if this is not taken up offer insulin pump with real time CGM<br>Third line insulin pump plus finger prick glucose testing<br>Fourth line multiple dose insulin injections plus real time CGM<br>Fifth line multiple dose insulin injections plus finger prick glucose testing<br><br>This would bring together this appraisal, TA151 and NG18<br><br>Age over 12 years<br>Offer multiple dose insulin injections with real time CGM to all<br>If HbA1c 8% or above then:<br>Offer insulin pump with real time CGM<br>And if this is unsuccessful:<br>Hybrid closed loop |
| 11 | Peter Hindmarsh (clinical expert) | Do not underestimate the impact of hypoglycaemia on this age group and the fear families have of experiencing hypoglycaemic events. |
| 12 | Peter Hindmarsh (clinical expert) | As mentioned diabetes burden is high for families and carers and this is markedly reduced by hybrid closed loop |
| 13 | Peter Hindmarsh (clinical expert) | There is an argument that the hybrid closed loop is the only way to replace insulin in a physiological manner that is safe in avoidance of hypo and hyper glycaemia. It improves family and carers well being reducing diabetes burden. There is a question if we know that this is the best therapy that replaces insulin that it should be available to all. |

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| 14 | Sufyan Hussain (clinical expert) | Section 1.4 “is also attending a type 1 diabetes structured education programme”<br><br>I am concerned that this recommendation will disadvantage people from lower socio-economic groups (who due to work and carer roles are more likely to struggle to attend an education programme), those from minority groups where proficiency in English and therefore ability to partake in a structured education programme will be affected, and those who have lower digital literacy and less able to participate in online versions of these structured education programmes (from both the groups mentioned and similar to what we have observed during the pandemic with disparities in participation in online education at schools). I would strongly urge the committee to re-word this to ensure disparities in access to digital innovations and technologies are not widened by this recommendation, whilst preserving the ethos of education as a central pillar for diabetes management.<br><br>A potential suggestion is below and is based on clinical experience of working in a large-centre serving one of the most deprived regions in the country and a high prevalence of ethnic groups whilst offering some of the best outcomes for type 1 diabetes in the country based on recent national audit data and supporting technology use in the groups mentioned. This requires other means of supplementing education and empowering individuals using higher frequency of clinic interactions, resources, peer support etc to ensure equivalent competencies in functional insulin dosing / dose-adjustments can be obtained. I would therefore suggest:<br><br>Only use hybrid closed loop systems if the person or their carer:<br><br>• understands and is able to use them<br>• is also attending a type 1 diabetes structured education programme *or demonstrates equivalent competencies in functional insulin dosing, obtained via other means and assessed by a member of the diabetes specialist team.* |

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| 15 | Sufyan Hussain (clinical expert) | Section 1: In addition to the groups mentioned in the draft, for simplicity, I would be grateful if the committee can consider further addition to ensure alignment with prior technology appraisals and prior guidance in this MTA. This would avoid confusion and ensure the technology pathway is aligned with prior guidance and appraisals:<br><br>As recommended:<br><br>1.1 Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following:<br>• continuous subcutaneous insulin infusion<br>• real-time continuous glucose monitoring<br>• intermittently scanned continuous glucose monitoring.<br>Hybrid closed loops systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2).<br><br>1.2 Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy. Hybrid closed loops systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2).<br><br>*Consider addition of the following criteria, which have existing technology appraisal and guidance in place that will potentially enable hybrid-closed loops:*<br><br>*i) Children under the age of 12 years – recommended as a treatment option provided that MDI is considered impractical or inappropriate*<br>*ii) Attempts to achieve target haemoglobin A1c (HbA1c) levels result in the person experiencing disabling hypoglycaemia with at least 1 of the following:*<br>*• continuous subcutaneous insulin infusion*<br>*• real-time continuous glucose monitoring*<br><br>*For the purpose of this guidance, disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life* |

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| | | Explanation:<br>Both groups above are covered by NICE TA 151 for access to CSII. The recent NICE guidance (2022) recommends consideration of rt-CGM for those on CSII systems with HCL options (which in due course is likely to be almost all CSII systems); thereby enabling use of HCL systems in these groups. Intermittently scanned continuous glucose monitoring has not been included in ii) as individuals on MDI with disabling hypoglycaemia should either proceed to rt-CGM or CSII based on existing evidence base and guidance. |
| 16 | Sufyan Hussain (clinical expert) | Section 3.3:<br>"Most RCTs included children and young adults. A clinical expert said that most people using CSII in their clinics were adults."<br><br>This statement may be misleading in the current context. I would suggest removing this as it does not add much value to this section. |
| 17 | Sufyan Hussain (clinical expert) | Section 3.6<br><br>"The committee noted that it would be difficult to do studies of HCL systems in pregnancy because the duration of pregnancy is relatively short. This would complicate study design and data collection. The committee concluded that there was a lack of evidence in pregnancy and relevant studies would be difficult to do."<br><br>In relation to the comments above, I would like to draw the committee's attention to the following please<br><br>https://clinicaltrials.gov/ct2/show/NCT04938557<br><br>This large randomised controlled trial is currently on-going in the UK. Whilst findings are not available publicly yet, it may address some of the questions posed. Therefore, I would like to suggest taking this into consideration and rewording this section please." |

| Comment Number | Name and organisation | Stakeholder Comment |
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| 18 | Fiona Regan (clinical expert) | Section 1.1 Given that all patients with type1 diabetes are advised within NICE guidance to aim for a HbA1c of 48mmol/mol(6.5%) or lower, then any patients unable to achieve this with other methods should be able to access HCL. We know that HCL systems lead to a reduction in HbA1c alongside reduced hypoglycaemic episodes and DKA episodes.<br><br>Given the likely increased benefit for children, all children should be offered access to a HCL system from diagnosis and regardless of their current HbA1c. The report acknowledges the authors have not taken into account the impact on young people and their families in terms of Quality of life, impact on reducing days lost at school/college and days lost in employment for parents. |
| 19 | Fiona Regan (clinical expert) | Section 3.8 The cost analysis is not accurate given that it is assumed that prior to HCL 90% of patients are using the cheaper isCGM rather than the rtCGM. rtCGM is now accessible to all patients with type 1 diabetes. The cost analysis/comparators should look at the cost of rtCGM plus pump and compare this to HCL systems. It makes no sense to say that pumps and rtCGM will be funded but the HCL systems will not, as the additional cost when looking at appropriate comparators is minimal and the evidence clearly shows that HCL systems can make a significant impact on improved glycaemic control. I think the comparators used for analysis needs to be reviewed as this will significantly affect the cost analysis and this fundamental flaw makes the current conclusions and recommendations invalid. |
| 20 | Fiona Regan (clinical expert) | Section 3.9 As mentioned above the uncaptured benefits including missed days of employment (for patients or parents of patients), days in school or college for young patients and quality of life benefits can not be ignored as they have significant financial and mental health impacts. |
| 21 | Fiona Regan (clinical expert) | Section 3.11 The lack of certainty surrounding the modelling for costs in children should not disqualify all children and young people from being able to access HCL systems. This is a group of patients who stand to gain the most from use of the systems. They will have diabetes for longer than any other patients and will therefore be at greatest risk of long term complications. In addition, the uncaptured benefits mentioned above are likely to be greatest in this group of patients. In pre school children unable to vocalise acute side effects and recognise low and high glucose levels these systems stand to make a huge impact on their lives, glycaemic control and the lives of their parents/carers. I find it astonishing that the conclusions of this report fail to mention children and young people in any criteria. |
| 22 | Fiona Regan (clinical expert) | Section 3.16 I find the conclusion reached in the report hard to justify given the flaws in cost analysis mentioned above. If NICE is enabling all patients with type 1 diabetes to access rtCGM it is a logical next step to enable the use of HCL for those not able to reach the desired HbA1c of 48mmol/mol. In addition, the use of HCL systems gives us an opportunity to reduce some of the inequalities in diabetes care. These systems will be user friendly for those with less time and ability to digest and analyse the huge amount of data generated by rtCGM to optimise their glycaemic control and quality of life. |

NICE National Institute for Health and Care Excellence

# DIAGNOSTICS ASSESSMENT PROGRAMME

## Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

## Diagnostics Consultation Document – Comments

## Diagnostics Advisory Committee date: 24 May 2023

**Contents**

## THEME: ACCESS AND EQUALITY

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
|---|---|---|---|---|---|---|
| 49 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | committee-discussion | Access to technology and care | 3.2 | Clinical experts said that the automation offered by HCL systems could help reduce some of the inequalities for people who find it difficult to maintain healthy blood glucose levels because of a language barrier, a lower level of education or a learning disability, for example. | How are people with a lower level of education of a learning disability supposed to understand a closed loop pump which is often very complicated. |
| 83 | | | | | | 3.2<br>There should not be a post code lottery on who gets what, (as I know this personally affects me) and staff in clinical teams should be trained in all available technology in the access involving our care, and in such a way for all to understand, and on going support readily available to all . |
| 84 | | | | | | 4.3<br>I would hope that the doctor responsible for an individuals Diabetic care thinks that when a hybrid closed loop system is the right treatment for a type 1 Diabetic it would be available as quickly as possible for children, and all adults regardless of age. |
| 106 | | committee-discussion | Access to technology and care | 3.1 | | Agree, as a Type 1 fortunate to be using CSCI I read regularly on diabetes forums etc of others who are facing a real fight for access to a pump.<br>There must equal access across all characteristics in all areas of the country with the necessary support from staff to manage safe and effective initiation and follow up care |
| 110 | | recommendations | 1 Recommendations | 1.3 | | There needs to be an option for the person with diabetes to easily change MDTs, if the current MDT do not offer HCL. Their care should not be held back by the inability of hcps or the system. |
| 121 | | | | | | Is it possible to include guidance on how these technologies are proactively offered to target groups by clinicians, in order to tackle inequalities in access (ie. not just limited to those who know they can ask for it)? |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 135 | | committee-discussion | Access to technology and care | 3.2 | | The inequality in terms of pumps, funding and provision, is totally unfair. This needs to be addressed ungently. We are currently in dispute over pump contracts in Cornwall, I have researched the funding for our current pump would be greater in at least 25 other NHS trusts in the country. Pump contracts for children should be more flexible, 4years is too long to be tied to a system when you are growing up, and the technology is changing so fast. |
| 139 | Primary Care Diabetes Society | committee-discussion | Access to technology and care | 3.2 | | NICE should advise that systems actively adopt processes to monitor and guard agains widening health inequalities with access to technologies |
| 177 | | committee-discussion | Access to technology and care | 3.2 | | Often T1Ds will travel considerable distances to attend clinic with the trained staff and the access to the technology they need. The postcode lottery also affects which HCL system the patient will be able to access. |
| 178 | | committee-discussion | Evidence and generalisability | 3.3 | | Especially in newly diagnosed adults the patient is not aware of what technology is available to them, or what they need to do to gain access to it. If one wants an insulin pump or CGM then it is difficult to get access to it as it is a long demoralising process that can seem to be more effort than it is worth. This leads to lower uptake and can cause more complications in the long term. |
| 214 | | committee-discussion | Access to technology and care | 3.2 | | Access to NHS funded HCL technology must be fair and non-discriminatory to all and, therefore, it must not be down to "postcode lottery". |
| 242 | | committee-discussion | Access to technology and care | 3.2 | It further concluded that people should be supported to use the systems. | It is vital that the uptake of HCL should reflect the diversity of the T1 community. It would be a tragedy if the same inequalities in the uptake of CGM are seen with HCL, as the most deprived socioeconomic strata are likely to derive the most benefit.<br><br>Jeyam, A., Gibb, F.W., McKnight, J.A. et al. Flash monitor initiation is associated with improvements in HbA1c levels and DKA rates among people with type 1 diabetes in Scotland: a retrospective nationwide observational study. Diabetologia 65, 159–172 (2022). https://doi.org/10.1007/s00125-021-05578-1 |
| 248 | | | | | | This technology should be made available to those who are actively managing their diabetes and have good control. I have had Type One Diabetes for 20 years and maintain an excellent HBA1C. However, this takes a huge amount of work and mental strain and this technology would make a monumental difference to my quality of life. Please consider making it available to all those who would benefit from it. |
| 254 | | implementation | 4 Implementation | 4.3 | | This needs reiterating to clinics, many still refuse to allow people access to the technology despite meeting the eligibility criteria |
| 279 | | recommendations | 1 Recommendations | 1.3 | continuous subcutaneous insulin infusion and continuous glucose monitoring in type 1 diabetes. | Agree - but does the NHS have resourcing? Several CCGs still deliberately obstruct T1 patients from accessing flash glucose monitoring on the basis that they think it too expensive or unnecessary. |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 282 | | committee-discussion | Access to technology and care | 3.2 | inequalities for people who find it difficult to maintain healthy blood glucose levels because of a language barrier, a lower level of education or a learning disability, for example. | This is true, but also then begs the question as to whether such people, who presumably are the most likely to have poorer control and therefore be eligible, have the required support available to ensure they derive the maximum benefit from a closed loop system. Shouldn't highly competent and proactive T1s also be included so as to more fairly demonstrate the technology's potential? |
| 294 | | committee-discussion | Access to technology and care | 3.2 | Access to technology and appropriate care was highlighted by patient experts as a major concern, and they explained that the process was often slow, frustrating and demoralising. Patient and clinical experts said that there is a postcode lottery in access to technology. Also they noted that there are inequality issues related to family background and socioeconomic status. Clinical experts said that the automation offered by HCL systems could help reduce some of the inequalities for people who find it difficult to maintain healthy blood glucose levels because of a language barrier, a lower level of education or a learning disability, for example. A clinical expert said that NHS England (NHSE) has set out priorities for access to help reduce these healthcare | This is true. We had to apply 3 times for pump funding for our daughter - despite full support from the hospital team, the CCG kept refusing. In the end I had to involve my MP. Not everyone has the the mental resilience or the economic status (access to laptop etc) to be able to do this and it is unfair that you should have to. |

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| | | | | | inequalities. A clinical expert also highlighted that the effective use of technologies was an important consideration. They said that improvements to the availability of and access to patient training were needed. They noted that many centres were limited because they do not have enough trained staff in their clinical teams to provide this. The committee concluded that improvements were needed to make sure there was no postcode lottery in access to technology and care. It further concluded that people should be supported to use the systems. | |
| 336 | | recommendations | 1 Recommendations | 1.4 | | People learn about their diabetes at different pace, the closed loop gives hope of living a near "normal" life w minimal complications, access to this technology should in my opinion be given to all but at a time when ready to "embrace it and take it on", knowing its available will give hope and motivation, and will help people with diabetes pay attention to all part of diabetes management. Access to all but in a staggered individualised way. |
| 340 | | committee-discussion | Baseline characteristics | 3.4 | | In my view focus should be on access to this technology for all following certain steps, degree of readiness as opposed to focus on individual HbA1c which I believe will lead to short term gain long term loss a "fire fighting / plaster approach". Instead to use this technology to give hope motivation and w the right timing knowledge following a certain pathway -could revolutionize type 1 treatment and optimise outcomes (but the tech could not replace for instance other steps such as knowledge gained from education and support in implementation of all diabetes related tasks |
| 428 | | recommendations | 1 Recommendations | 1.5 | | The clinical trials showed an improvement to the daily lives, physical health and mental health of almost all of the participants with minimal adverse effects, also people who have already been issued with these systems via the NHS provide confirmation of these results, so they should be made available to anyone with |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| | | | | | | type 1 rather than limiting its issue to just pregnant women and those with bad control. |
| 446 | | committee-discussion | Access to technology and care | 3.2 | Access to technology and appropriate care was highlighted by patient experts as a major concern, and they explained that the process was often slow, frustrating and demoralising. | Yes - my daughter is on a one year long waiting list for a pump. This means her having a minimum of 1800 injections whilst she is waiting - which could be avoided. This is very upsetting when her legs are black and blue with bruises. We have a CGM but she still has a hypo most days. |
| 447 | | committee-discussion | Access to technology and care | 3.2 | Patient and clinical experts said that there is a postcode lottery in access to technology. | We are considering moving to a hospital further away which has no waiting list for a pump. This would mean having not so good support for school as it is "out of area". The offer should be the same at all hospitals. |
| 448 | | committee-discussion | Access to technology and care | 3.2 | The committee concluded that improvements were needed to make sure there was no postcode lottery in access to technology and care. | Definitely would agree with this. |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 461 | Children & Young People's Diabetes Team, Somerset Foundation Trust | committee-discussion | Access to technology and care | 3.2 | | Agree, addressing postcode lottery and reducing the time and emotional burdens of attempting individual applications / appeals for funding is vital.<br><br>Some regions have a lower % of patients currently using pump therapy as a result of barriers to access due to inequality issues. In these areas, there will be a potentially greater workload and workforce requirement to safely roll out HCL. There will be more patients who need initial pump training as well as education on the HCL system. Also the training & educational needs of those from a more deprived background may be different.<br><br>There are additional barriers which may need to be addressed - many of our patients do not have a computer / laptop and can't afford an up to date phone, which are practical barriers to effective adoption of HCL. |
| 472 | | committee-discussion | Access to technology and care | 3.2 | | The postcode lottery is definitely an issue which needs addressing. I have heard of diabetics moving their care to different hospitals because they are more likely to receive continuous glucose monitors or pumps elsewhere. This should not be happening and parity across hospitals should be improved. |
| 482 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | HCL offered to a wider group of T1 diabetics will help more patients achieve target HbA1c of 48mmol/mol or lower and thus lower the risk of long term complications |
| 485 | | | | | | In general, this is a fantastic stop forward for Type 1 diabetics and is very welcome. We must hope this can be expanded as soon as possible to the 170,000 type 1 diabetics who are not covered by the recommendations. As an aside, there are many thousands of diabetics using multiple daily injections who might benefit from a pump but who are denied the opportunity under current NICE guidelines. Will these be updated once these recommendations are implemented to allow more of us to at least try using pump and hopefully get better control? There seems to currently be a postcode lottery on pump prescription. |
| 495 | | | | | | This system should be made available to everyone with type 1 Diabetes |
| 545 | | committee-discussion | Access to technology and care | 3.2 | | Some systems require smart phone and that can be excluding those on low incomes |
| 561 | | implementation | 4 Implementation | 4.1 | is likely to be extended | I appreciate the rationale, does this open a postcode lottery as we have seen with CSII and isCGMS? |
| 594 | | recommendations | 1 Recommendations | 1.3 | | These trained teams should have access to a range of HCL systems so most appropriate & acceptible can be offered to the patient. |
| 615 | | recommendations | 1 Recommendations | 1.3 | | While I agree with this comment, the side effect is that (similar to insulin pumps) those people using the hybrid systems will get far more consultant time than those not. This is unfair, and again there is a moral hazard in that if a patient wants more consultant time they just have to manage their diabetes less well. |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 624 | | | | | | I have been living with type 1 diabetes since 1978, when I was 12 years old. In that time I've benefitted from many innovations thanks to the NHS. Recently, there has been a wealth of technology that has provided relief from multiple daily injections, greater flexibility to live a normal life and more relevant information to make choices.<br>There have been occasions where cutting edge tech has not been available through the NHS. This has created, sometimes temporarily, a 2 tier system. Those who can afford to self fund and benefit from better management, and those who can't. Over time the gap grows and the majority may experience worse outcomes and lower quality of life.<br>This latest development of the hybrid closed loop system is in danger of falling into this category. Those who don't qualify and can't self fund will undoubtedly feel left behind and may see their health outcomes suffering.<br>I would urge NICE to consider any possible option to include all people with type 1 diabetes so that nobody is left behind. This will ensure equity across all existing under-represented subgroups.<br>Thank you from a weary, slightly battered, 57 year old with type 1 diabetes. |
| 651 | | implementation | 4 Implementation | 4.1 | | From past experience in seeking funding for CGM, it would seem that NICE recommendations are sometimes ignored, the buck is passed, and excuses are made as to why we can't have something that should be available. Hopefully, this won't happen in this case. |
| 663 | | committee-discussion | Access to technology and care | 3.2 | | If a patient has taken the time to research and read up on a piece of technology and even go as far as having a trial basis of a piece of technology and seeing the benefits and how this fits into their lifestyle, they should be allowed to use that technology, to give them the quality of life they deserve,regardless of costs, more needs to be done in terms of negotiations of "cost effectiveness". What we have also found is that the "paperwork" surrounding funding and being able to access accounts to the technology delays the patient receiving the technology, therefore putting the patient off from having new trials or even becoming interested in any new technology that would help their diabetes. This in turn has an impact in future research, as less people take up any form of technology, there is less data to compile, giving a distorted image of the technology as a whole. |
| 697 | | recommendations | 1 Recommendations | 1.2 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy. | It should be for absolutely everyone with T1 |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 751 | | recommendations | 1 Recommendations | 1.3 | | Some of us no longer have a team of any description, having been discharged against their will. In my case by a consultant claiming that I know far more than him. I am now seen once a year at the GP surgery by a healthcare assistant asking questions from a script, who has absolutely no specialist knowledge.<br>Is this an age thing?<br>This has left us in danger of being left behind, not only within the realm of new technology but with basic improvements in treatment. How are these inequalities going to be addressed? |
| 753 | | committee-discussion | Access to technology and care | 3.2 | | The postcode lottery also applies to access to a “team” something assumed by most diabetes related organisations. Some people are denied access to any specialist care or advice until crisis point is reached. People living in such areas are also disadvantaged. |

## THEME: COMPATABILITY WITH TA151

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 9 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.1 | | For children >12 years and adults, the threshold of HbA1C 8.0% in the draft HCL guidance will allow progression from isCGM to pump therapy (+algorithm) with rtCGM, without meeting criteria for pump therapy set out in NICE TA151 (HbA1C 8.5%).<br><br>https://www.nice.org.uk/guidance/TA151/chapter/1-Guidance<br><br>Given the difference in starting criteria for CSII and HCL, will NICE TA151 be reviewed? |
| 40 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | recommendations | 1 Recommendations | 1.1 | | CSI is currently offered to people with HBA1c of >8.5% and/or disabling hypoglycaemia. In the consultation document they are offering hybrid closed loop system to people with HBA1c>8mmol/L. It does not make sense that a person who wouldn't otherwise qualify for pump would qualify for hybrid closed loop system. |
| 415 | British Society For Paediatric Endocrinology and Diabetes | recommendations | 1 Recommendations | 1.1 | | This is not compatible with current NICE recommendations for pump therapy (TA151), which is only possible in children aged under 12 years, and in those aged 12 years and over with an HbA1c over 69mmol/mol. |
| 666 | NHS England | recommendations | 1 Recommendations | 1.1 | | The proposed HbA1c inclusion threshold is now lower for Hybrid Closed Loop than the threshold set out in NICE TA151 requiring pump prescribing for people living with Type 1 Diabetes. HbA1c threshold needs to be aligned across TA151 and Hybrid Closed Loop MTA. TA151 also recommends access to Pumps for people with Disabling Hypoglycemia and consideration should be given for alignment with this aspect as well. |

**THEME: COMPARATOR**

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 88 | University Hospitals Dorset Diabetes Service | information-about-hybrid-closed-loop-systems | The comparators | 2.7 | | It is interesting that these 2 comparator groups were chosen. Following NICE's March 2022 guidance publication, it would be anticipated that most people with type 1 diabetes now have access to at least a sensor to help with type 1 diabetes management. A much larger group for comparison to HCL use in current clinical practice would therefore have been people with type 1 diabetes on rtCGM or isCGM alone, rather than those using the systems with pumps. Is there any reason why these suggested comparator groups were not chosen? |
| 94 | University Hospitals Dorset Diabetes Service | committee-discussion | Comparators | 3.8 | | See earlier comment on comparator groups chosen. If possible, I think a better comparator group for this guidance would have been HCL outcomes versus patients on a sensor alone, and not necessarily CSII. Even this guidance comment acknowledges that around 75% of people with diabetes nationally are not not on a CSII. On publication of the proposed guidance, it is likely that patients who are not currently on pumps will request access to the HCL systems, and strictly speaking the evidence-based used for the proposed guideline would not potentially cover this group?<br><br>90% isCGM appears to be a reasonable estimate, and this is reflective of our local population at the present time. |
| 602 | Diabetes Technology Network -UK | information-about-hybrid-closed-loop-systems | The comparators | 2.7 | | The recommendation was for people not reaching targets with 1 therapy - so unclear why the comparators are "dual therapy" with non-integrated sensor augmented pump or isCGM+ CSII |

## THEME: COMPLICATIONS

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 104 | | | | | | Background to my comments<br>I have DMO (diabetic Macular oedema) it has severely affected my sight, I am registered as sight impaired.<br>I lead a DMO support group and know many ho are in the same situation as I.<br>Having read the document, I would like to make 2 comments below and would be most grateful if they could be taken into consideration.<br>1) Some who have sight loss find using the various technologies difficult, as the technologies themselves often have no accessibility features. These systems seem to be no different. We are led to wonder whether those that set up CamAPS, Tandem-control IQ,Medtronic 780 or Medtrum Nano have taken the needs of those with poor sight into consideration. Having approached some of the companies involved at various patient exhibitions I have been disappointed to see the lack of thought in this area, bearing in mind that diabetes and sight loss can go hand in hand.<br>We are not asking to be directed to other Apps to help us, but in fact feel that the companies themselves should be catering for those with poor sight themselves.<br>2) Dropping an HbA1c too quickly, especially when retinopathy is present can be very detrimental on eye health. Has this been taken into consideration? I notice that only CampAPs allows for a higher starting target range and those that have a set target range such as the Medtronic of 5.5% may actually cause an issue if the patient is starting with an HbA1c of for example 11%. The greater the drop in HbA1c the greater the risk. Diabeloop which is another looping system set their targets higher because they recognised the risk factor themselves of dropping an HbA1c too quickly. I myself lost my sight when starting on my first insulin pump when my HbA1c was brought down from 10.7% to 7.7% in 3 months and my opthalmologist explained that a quick drop in HbA1c had caused my sight loss which over time led to job loss and the permanent inability to drive. Has an ophthalmologist been invited to comment? I apologize I could not see who was on the committee.<br>Many thanks for all your hard work on this project and kind regards<br>[redacted] |
| 61 | | dap55-diabetes-mta-acd-final-no-acicdocx | | | | Almost half of the individuals with Type 1 Diabetes experience hypoglycaemia during the night. (Coelho et al, 2018). Usually, this event is not followed by any oral health related behavior - e.g. rinsing mouth with water (Antoniszczak et al, 2022) and can contribute to the development of long term oral health complications e.g. caries. Saliva from people with diabetes has increased bacterial load and the rate of saliva flow is decreased. As a result, they are at higher risk of developing tooth decay and periodontitis.<br><br>It has been proved that Patients with HbA1c>8% have higher incidence of caries. Metabolic control has great influence on the development of this condition among people with diabetes (Twetman et al, 2002). Taking into consideration that Hybrid Closed-Loop systems significantly improves metabolic control and reduce the incidence of hypoglycaemia this technology could significantly contribute to savings in |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| | | | | | | the NHS. Not only in diabetes care but simultaneously reduce dental expenditures dedicated to treatment of caries - another and one of the most prevalent chronic diseases - through the limitation of its risk factors.<br><br>As a person living with type 1 diabetes and dentist, I can't emphasize enough how life changing this technology is. Since I have been using it the episodes of hypoglycaemia have significantly reduced and the quality of my life has been improved. Taking into consideration the positive health outcomes and all the benefits Hybrid Closed-Loop systems offer this technology should be offered to every person with Type 1 Diabetes.<br><br>Antoniszczak, D & Thomas, R & Prior, Sarah & Dunseath, G. (2022). "Do you think I brushed my teeth after a 3 a.m. hypo?" - Investigation of Oral Health Behaviors among people with Diabetes Mellitus., [Poster], IDF World Diabetes Congress 2022, 7.12.2022 Lisbon, Portugal, 10.13140/RG.2.2.25988.60800.<br><br>Coelho A, Paula A, Mota M, Laranjo M, Abrantes M, Carrilho F, Ferreira M, Silva M, Botelho F, Carrilho E. Dental caries and bacterial load in saliva and dental biofilm of type 1 diabetics on continuous subcutaneous insulin infusion. J Appl Oral Sci. 2018 Jun 11;26:e20170500. doi: 10.1590/1678-7757-2017-0500. PMID: 29898180; PMCID: PMC6007967.<br><br>Twetman S, Johansson I, Birkhed D, Nederfors T. Caries incidence in young type 1 diabetes mellitus patients in relation to metabolic control and caries-associated risk factors. Caries Res. 2002 Jan-Feb;36(1):31-5. doi: 10.1159/000057587. PMID: 11961327. |
| 481 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.1 | | The long term complications associated with poor management of T1 diabetes are numerous, bleak and make for distressing reading. Giving T1s the tools to improve their long term health outcomes will reduce the financial burden on the NHS in the long term and provide individuals with a better quality of life. |
| 560 | | committee-discussion | Baseline characteristics | 3.4 | would be expected to have a greater reduction after treatment. | Is there a significant risk of Early Worsening of Diabetic Retinopathy? If so, who will this be managed/mitigated? |

## THEME: COST EFFECTIVENESS AND MODEL

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 3 | PrescQIPP CIC | dap55-diabetes-mta-acd-final-no-acicdocx | | | | Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?<br><br>Multiple assumptions have been made in interpreting the RCTs and NHSE pilot studies, and there are significant uncertainties in extrapolating findings to the general population.<br>Therefore, the overall clinical and cost effectiveness of the HCL technology remains unclear. |
| 4 | PrescQIPP CIC | dap55-diabetes-mta-acd-final-no-acicdocx | | | | Are the recommendations sound, and a suitable basis for guidance to the NHS?<br><br>We do not think that the current recommendations are suitable for implementation in the NHS.<br><br>The economic modelling for this guidance does not demonstrate cost-effectiveness for the majority of type 1 patients, and breaches NICE's usual threshold for an ICER of between £20,000-30,000. The data is not generalisable to the whole population and is based on assumptions and several unquantifiable and uncertain potential benefits. The financial risk of this approach appears to have been underestimated.<br><br>The committee considered an analysis including confidential prices submitted to NHS supply chain by the companies. It noted that use of these prices resulted in lower ICERs but not to within the range that would be considered a cost-effective use of NHS resources by NICE.<br><br>The recommendation that the technology should therefore only be made available if a confidential price is agreed between NHS England and the manufacturers generates a huge amount of uncertainty and risk for all key stakeholders including, ICBs, patients and clinicians.<br><br>Our view is that this TA should be delayed until these prices have been agreed and the cost effectiveness robustly reconsidered. We also believe that the lack of transparency in relation to national tenders is of great concern. |
| 76 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | | This conclusion appears to be drawn on some uncertain QALY estimations which the document acknowledges. Is this in line with how other NICE Guidelines reach cost-effectiveness conclusions to ensure equity? |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 78 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | committee-discussion | Cost effectiveness for children | 3.11 | | How does the cost of QALY change if a lower HbA1c requirement for initialtion of HCL is used for modelling cost effectiveness in children? |
| 93 | University Hospitals Dorset Diabetes Service | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | | The NHSE adult pilot study appears to have an overwhelming influence on the calculated ICER. It could be argued that there appears to be the decision from the panel to pick one set of data in a subgroup (high HbA1c) from one particular study to make the case for hybrid closed-loop therapy but there is at least transparency around this in the documentation provided. |
| 199 | | information-about-hybrid-closed-loop-systems | Price | 2.9 | quality-adjusted life year gained, | Has a reduction in mental health costs been taken into account? The use of HCL, reduces the mental load of T1D therefore reduces the cost of mental health services. |
| 202 | | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | [QALY] | How accurate is this, when the increase in quality of life due to HCL is so undervalued? |
| 204 | | committee-discussion | Conclusion | 3.16 | It noted the many uncaptured benefits in terms of reduced mental burden, reduced parent and carer anxiety, and improved quality of life. These would be expected to decrease the ICER, although it was uncertain by how much. | Can this be researched? How is a QALY calculated if this isn't taken into account? |
| 243 | | committee-discussion | Uncaptured benefits | 3.9 | However, clinical experts expressed concerns that the reduced mental burden and familial or carer anxiety that HCL systems provide may not be captured adequately in the model. The | It is deeply regrettable that this key benefit of HCL is absent from the cost effectiveness model. The modest gains in TIR/HbA1c are dwarfed by the benefits to quality of life for patients, parents and carers. These are not 'potential' benefits - they are transformative and help people live (and work) with less diabetes burden. This should have been given greater weight by the committee. |

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| | | | | | committee understood that there was no quantitative evidence that could be used to estimate the value of these potential quality of life benefits. The committee agreed that there were potential quality of life benefits of HCL systems not captured in the model, including the effect on learning and education, ability to work, mental burden and fear of hypoglycaemic events. The committee concluded that these uncaptured benefits were likely to undervalue the effect of HCL systems on quality of life. | |
| 277 | | recommendations | 1 Recommendations | 1.1 | NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies | Whether the system is 'cost-effective' will also depend on the expected long-term burden on the NHS and benefits claims arising from T1-related complications. Will the 'cost-effective' calculation look at the costs likely to incurred by a T1 patient from complications over the course of their lifetime? |
| 296 | | committee-discussion | ICER per QALY gained | 3.14 | uncaptured benefits in the economic model related to reduced mental burden, and parent and carer anxiety | This should be part of the final guidelines. You also need to consider other difficulties that the patient is living with such as dyslexia. |

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| 353 | Children and Young People's North East and North Cumbria Diabetes Network | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | | It appears that modelling was done mostly on adult data. Children are exposed to longer duration of hyperglycaemia and effect expected to be magnified as is discussed later in the NICE documentation, also none of the additional costs to society related to caring for children and young people living with T1D (as mentioned in 3.1) have been taken into consideration. |
| 384 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | | It appears that modelling was done mostly on adult data. Children are exposed to longer duration of hyperglycaemia and effect expected to be magnified as is discussed later in the NICE documentation.<br>None of the additional costs to society of caring for children and young people living with T1D as mentioned in 3.1 have been taken into consideration. |
| 385 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | committee-discussion | Cost effectiveness for children | 3.11 | | The data presented shows that CYP has more benefits at a lower HbA1c than adults, making it cost-effective at a lower HbA1c threshold.<br><br>The stronger evidence base for CYP has not been taken into account:<br>CYP will have a longer time with diabetes than adults, therefore better control earlier (metabolic memory) will reduce life exposure risk and costs to NHS and society<br><br>There are fewer CYP in the data therefore the cost implication is capped. |
| 430 | | committee-discussion | Economic model and cost effectiveness | 3.6 | | You have tried to evaluate the financial cost effectiveness of these pumps but I feel that you have missed the far wider and even longer term impact that the use of this pump will have on NHS spending.<br>1) There will be less treatment/hospital admissions for hypos and DKA not only because the pump aims to keep BGL's regulated but will also eliminate many episodes, especially in young adults where they are suffering from total burn out and exhaustion from trying to deal with this terrible illness and so ultimately 'give up' trying to manage it. This will save money in all aspects of dealing with these emergency situations and ultimately free up hospital beds.<br>2) The same applies to the longer term health complications with kidneys, eyes, infections and the consequences of them, etc. all reduced by the use of CLS's.<br>3) On top of that the need for the use of mental health services, including counselling would decrease and that would be for both the type 1's and their wider families because the illness is so much easier to manage using these systems and doesn't cause such a huge mental impact.<br>4) The adverse effect of the general body health of the sufferers and their families caused by constant stress and sleep deprivation.<br>5) The savings made on the small items the use of which will not be totally eliminated but will be needed less frequently: BG testers, finger prickers, needles & strips, ketone testers, finger prickers, needles and strips, Glucogel & Glucogon and other hypo treatments as they won't need to be replaced so frequently, pens for MDI and their needles and so on. Even the cost of dental |

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| | | | | | | work required due to the sugar in hypo treatments, should be taken into account. |
| 576 | | recommendations | 1 Recommendations | 1.1 | | Para 1.1. - in considering the cost-effective price this is not simply based on the actual cost the technology. Need to complete a cost benefit calculation. This technology as shown in the trials can reduce an individual's HbA1C which in turn reduces the risk of long-term complications. This needs factoring in when considering the cost, as the technology would mean a reduction in hospital visits/time in other clinics due to long-term complications creating additional medical needs e.g. with eyes or feet. It needs to be taken into consideration that this is an auto-immune condition where the individual has not made any lifestyle choices that have resulted in them having Type One Diabetes. Therefore funding could be a higher priority for this condition. |
| 579 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | Para 3.1 - Mental Health costs have not been taken into consideration when considering cost-effectiveness. This includes the burden on both the patients and their parents/carers (if children). There is a lack of mental health support nationally even with a long-term condition and not having access to HCL would increase the requirement for both patients and their parents/carers requiring more mental health support, which in turn would increase costs to the NHS. |
| 581 | | committee-discussion | Uncaptured benefits | 3.9 | | Para 3.9 - as clinical experts have commented the model needs to be adapted to consider other factors not just cost and consider the impact on the whole healthcare system e.g.mental health, not just diabetes care/acute care. |
| 585 | | information-about-hybrid-closed-loop-systems | Price | 2.8 | The appraisal model base case used an unweighted average of the 4-year cost from various companies. This resulted in a 4-year total cost of £22,975 and an average annual cost of £5,744. | The 4 year cost model takes into account setup and training costs. A longer duration model should be used as, apart from getting a cure for T1D, the closed loop system is probably about as good as it'll get. Therefore many of the initial sunk costs of training would not be relevant in years 2 and beyond, leading to greater value and lower average costs over time. As an additional to getting companies to lower their costs, the training should be negotiated as free, with those organisations providing training to users to take the burden off the NHS. |

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| 586 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | This is crucial information that is good to see has been considered, but does not appear to have been taken into account in the cost benefit assessment. Some consideration could be included in the QALY, not just for the T1Ds but also carers and partners (my wife is never happy with disturbed sleep when my low or high BG alarm goes off) |
| 588 | | committee-discussion | Time horizon and long-term effects | 3.10 | overestimated the cost effectiveness | Given the intangibles such as improved sleep, lower stress, ability to exercise more freely without the fear of hypo, the effect on family and carers, it is unlikely that the cost effectiveness has been overestimated, but probably the opposite. |
| 702 | | recommendations | 1 Recommendations | 1.5 | cost-effective price for the systems. | The long term benefits of a whole population managing blood sugar better will far outweight the short term cost. |
| 739 | | committee-discussion | Uncaptured benefits | 3.9 | In the economic model, non-severe hypoglycaemic events and severe hypoglycaemic events were only included in a scenario analysis. The EAG said that there was high uncertainty around these annual event rates. When hypoglycaemic events were included, the ICERs were reduced and ranged from £120,679 per QALY gained to £170,193 per QALY gained, depending on the annual event rate and what source the EAG used for the hypoglycaemic event disutility values. In the EAG's exploratory modelling for children and young people, a scenario analysis included | Any investigation is only as good as the quality of its weakest point. I am alarmed that when working out the cost benefit of something which will bring huge relief and benefit to Diabetes T1 sufferers, there is an acknowledgment that there are potential quality of life benefits and evidence centered around hypoglycaemia which have not been captured. It is a sad condemnation of society that we are pre-occupied with only putting value to things that can have a number attributed to them. If it can't be measured it appears to have less value. Whilst these qualitative factors are more difficult to measure, they are no less real than the ones you can measure. This has been acknowledged by the Clinical experts and as such is a failure of the study and should be addressed especially if there is a sticking point in achieving a viable cost to benefit and implementation across the board to all Diabetes T1 sufferers. |

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| | | | | | the quality of life effects of using HCL systems. This considered the improvements reported in the hypoglycaemia fear survey. The hypoglycaemia fear survey is an 18-item questionnaire that assesses the levels of fear related to hypoglycaemia. Each item is measured on a 5-point scale from 0 (never) to 4 (almost always). Individual item scores can highlight someone's major concerns about hypoglycaemia. This reduced the ICER of the NHSE children and young people pilot scenario (which used the NHSE children and young people pilot baseline characteristics and HbA1c change). A further scenario analysis tripled the quality of life effects reported in the hypoglycaemia fear survey and applied this for 15 years to account for 2 parents having a similar quality of life improvement. This reduced the ICER further still (see section 3.11). However, clinical experts expressed concerns that the reduced mental burden and familial or carer anxiety that HCL systems | |

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| | | | | | provide may not be captured adequately in the model. The committee understood that there was no quantitative evidence that could be used to estimate the value of these potential quality of life benefits. The committee agreed that there were potential quality of life benefits of HCL systems not captured in the model, including the effect on learning and education, ability to work, mental burden and fear of hypoglycaemic events. The committee concluded that these uncaptured benefits were likely to undervalue the effect of HCL systems on quality of life. | |

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| 765 | ABHI | | | | | **3. The cost of HCL systems is disproportionately emphasised as a driver of costeffectiveness**<br><br>In arriving at the cost-effectiveness judgement, the EAG established a base-case model which included a clinical baseline taken from the relevant 2019 – 2020 National Diabetes Audit and the estimated HbA1c decrease from the RCT network meta-analysis. This yielded an incremental cost-effectiveness ratio (ICER) of £178,925 per quality adjusted life year (QALY) gained.<br><br>When the NHSE adult pilot baseline characteristics and HbA1c effect were used, the resulting ICER was £12,398 per QALY gained. Substantially lower, and deemed cost-effective by the committee.<br><br>We also note the committee's conclusion that the effect size could fall between that observed in the RCT network meta-analysis and that from the NHSE pilot. No ICER calculations are provided in the draft or committee papers based on modulating the effect size and baseline.<br><br>It is noted that the committee concluded that changes in HbA1c substantially affected the ICER, and therefore whether HCL systems could be considered cost effective.<br><br>The draft also reports that there are potential quality of life benefits, including on learning and education, ability to work, mental burden and fear of hypoglycaemic events, which are not captured in the health economic model. Importantly, that these uncaptured benefits are likely to undervalue the effect of HCL systems on quality of life. Similarly, other aspects, such as rates of hypoglycaemic events together with the disutility and cost of these, and rates of eye<br>and kidney complications, affect the ICER. |

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| 766 | ABHI | | | | | As such, there is considerable uncertainty in the assumptions used even before the committee considered pricing analysis. Yet, the committee have disproportionately focused on the cost of HCL systems in arriving at the cost-effectiveness judgement.<br><br>To remedy, we recommend that:<br>Quality-of-life benefits are taken into consideration when assessing the costeffectiveness ratio.<br>Greater weighting is afforded to the real word evidence gathered.<br>This would be in-line with NICE's Real World Evidence Framework which states:<br>"*..even if randomised evidence is available, it may not be sufficient for decision making in the NHS for several reasons including:*<br>*- the comparator does not reflect standard of care in the NHS*<br>*- relevant population groups are excluded*<br>*- there are major differences in patient behaviours, care pathways or settings that*<br>*differ from implementation in routine practice*<br>*- follow up is limited."*<br>The economic models which inform any threshold pricing analysis are shared for comment as these will undoubtedly be used for any subsequent pricing negotiations which the draft cites. |

## THEME: COSTS

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| 1 | PrescQIPP CIC | dap55-diabetes-mta-acd-final-no-acicdocx | | | | The final TA needs an accompanying resource template, broken down for each ICS.<br><br>Resources need to include details of the numerical savings that will be released, and thereby ICBs can be assured in terms of net cost to the budget. For example, the NICE TA for Dapagliflozin in CKD detailed the benefits of the intervention in terms of cost savings (drug cost £xxxx, costs offset by delays in eGFR decline: dialysis, kidney transplant, hospitalisations – net cost £yyyy).<br><br>Further information is also required in relation to the national or regional procurement frameworks for this technology as per the statement under recommendation 1.1 that HCL systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies. |
| 2 | PrescQIPP CIC | dap55-diabetes-mta-acd-final-no-acicdocx | | | | The costs of implementing the proposed guidance are significant and the size of the patient cohort is large. This is likely to be unaffordable to most systems.<br><br>Cohort size is based on the following: In UK 400,000 adults with T1DM and 29,000 children [pg5]. National Diabetes Audit shows over 65% of T1DM patients have HbA1c above 7.5% (page 10), therefore there are potentially about 200,000+ eligible patients in England. Before any, as yet unknown, discount agreement with manufacturers, there is a high cost per intervention with an average annual cost of HCL £5,744 per patient.<br><br>The guideline committee concluded (p10) that both the RCTs and the NHSE adult pilot study were not fully generalisable to the type 1 diabetes population in the NHS. Basing recommendations which will incur such a large expense on inconclusive RCT data, which suggests the technology is not cost effective, and the NHSE pilots which are not RCTs and included a narrow sampling of patients, requires the evidence to be downgraded for the limitations before an ICER is calculated. It is unclear from the consultation document if this has been undertaken. |

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| 6 | PrescQIPP CIC | recommendations | | 1 | | The recommendations need to include clear continuation criteria. The consultation document suggests a reduction of 3.1mmol/mol (0.29%) is not cost effective and a reduction of 16.2mmol/mol (1.5%) is.<br><br>Therefore, we suggest appropriate continuation criteria be added to the recommendations so that the technology is only continued where it is cost-effective to the NHS, and that a consistent approach to funding is adopted in all areas to reduce inequalities in access to treatment. |
| 124 | | | | | | By privately funding a CGMS I have had experience of 1) MDI + rtCGMS, 2) IIS + rtCGMS (none integrated), integrated rtCGMS + PLGS and HCL.<br>With the exception of PLGS (which didn't meet my expectations) I have found that each improvement in technology has significantly increased my control, reduced my HBA1C and increased my TIR while significantly reducing concerns about hypos and their impacts most of these have been converted to easily handled 'lows'.<br>So I am surprised by some aspects of the cost estimation eg. training / pump start costs. In my experience - CGMS training - 0 direct cost to NHS, upgrade from IIS to PLGS system (pump supplier swap) - training undertaken by new pump manufacturer - 0 direct cost to NHS, pump start up - undertaken by pump manufacturer with brief NHS configuration cross check - minimal direct cost to NHS, upgrade to HCL - undertaken by pump manufacturer - 0 direct cost to NHS. I appreciate that there are indirect training and support costs to the NHS but, at least for some centres this appears to be a given anyway and is not a new cost nor a new concept.<br><br>In terms of moving from an isCGM to a rtCGM I would predict the assistance required to move from Freestyle Libre 2 to Freestyle Libre 3 to be minimal. I would also expect the change from Freestyle Libre 2 to Dexcom G7 to be minimal (acknowledging that no pump has yet upgraded to Dexcom G7 although with the G7 now approved by the US FDA I believe Tandem have committed to switch to G7 within 3 months (in the US) and I would expect Insulet to be competitive here).<br><br>This document and the supporting documents are not clear about the overall solution expected by the NHS from each supplier and this may be affecting the value proposition, or that some trusts are missing out on supplier offerings? Given the focus on cost can these be documented? |

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| 125 | | | | | | I note that the document makes assumptions about the use of isCGM but lacks any input from Abbott re Freestyle Libre. FreeStyle Libre 3 is an iCGM and Tandem, CamAPS and Insulet have all stated an intention to support the FL3, as far as I can see Abbott intend the FL3 to be cost neutral compared with the FL2 in which case isCGM being cheaper then rtCGM may become an obsolete assumption and even an obsolete technology? Could Abbott provide some insight into the cost of FL2 vs FL3 and indeed the future of FL2?<br>Note: As I'm paying for a rtCGM my personal cost review(s) suggest that the CGM cost is primarily based on the sensor lifetime and not in 'is vs rt'. |
| 127 | | | | | | Other potential savings?<br>Would there be savings by using GMI derived from CGM data in place of HBA1C blood tests? |
| 146 | | | | | | If you live just a day with type 1 diabetes you would realise that money is unimportant and the ability to give people their lives back should not be a financial decision- especially if the solution is there. |
| 239 | | information-about-hybrid-closed-loop-systems | Price | 2.8 | | Does this call out the cost of the items it would replace. This isn't necessary a variance in cost for a person with diabetes nor is it a direct increase. |
| 280 | | information-about-hybrid-closed-loop-systems | Price | 2.8 | £5,744 | A T1 patient can likely expect to live to over 65 and will probably require treatment before the age of 15.<br><br>Is the total cost of managing retinopathy, amputations etc. over 50 years more or less than the expected costs for a closed loop system |
| 408 | | recommendations | 1 Recommendations | 1.1 | Hybrid closed loops systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2). | Given that certain cost reductions were not included in the cost analyses this statement may be inappropriate (see my later comments). |

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| 410 | | committee-discussion | Uncaptured benefits | 3.8 | | Differences in insulin requirement, and effect on cost of treatment were not considered although a cost for insulin was included in the cost analysis. As I understand it at least one of the available closed loop systems does not require ongoing calibration, which the current rt-CGM system does. Reduction in costs associated with reduced capillary blood glucose testing (finger-prick testing) and ketone testing are not included. These would include reduced expenditure on lancets, blood glucose test strips, and blood ketone test strips.<br><br>Long-term anxiety and worry regarding increased potential for diabetes complications with poorer control are not mentioned at all. |
| 420 | British Society For Paediatric Endocrinology and Diabetes | information-about-hybrid-closed-loop-systems | Price | 2.8 | | Was Ypsomed system with CAMAPSFX included? see comments above for children aged under 6 years |
| 441 | | information-about-hybrid-closed-loop-systems | Price | 2.8 | This resulted in a 4-year total cost of £22,975 and an average annual cost of £5,744. | How does this compare with a lifetime of NHS care for a type 1 diabetic person. With one of these systems, a lot of diabetes complications that lead to hospital admissions could be avoided. Investment in these systems could potentially save money? |
| 459 | Children & Young People's Diabetes Team, Somerset Foundation Trust | information-about-hybrid-closed-loop-systems | Price | 2.9 | | It is very unclear from the information about various cost-effectiveness models, what price point will need to be reached for this guideline to be agreed and published. This needs to be much clearer moving forwards, as we anticipate that new systems will enter the market - ICB's / other decision makers will need clarity on whether each new system will be included in prescribable options. |
| 569 | | information-about-hybrid-closed-loop-systems | Price | 2.8 | This resulted in a 4-year total cost of £22,975 and an average annual cost of £5,744. | I currently self-fund my G4 sensors and even though this is a cost I can afford after making adjustments to other areas of my life, I do feel strongly that this is something that should be funded by the NHS so as many people can benefit from the technology and not only those fortunate, like myself, to be able to afford the sensor costs. |

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| 584 | | recommendations | 1 Recommendations | 1.5 | But because there is some uncertainty in the economic model, they are only recommended if the companies and NHS England agree a cost-effective price for the systems. | Agreed that cost competitiveness needs to be considered. As an addition, it would be beneficial if T1s could pay for additional treatment but get NHS negotiated rates. As an example, my HbA1c is around 7.2% but to get there I work incredibly hard and often have disturbed sleep. I wouldn't not qualify under this draft guidance but would appreciate the quality of life if I could pay the difference for the additional technology. |
| 629 | | information-about-hybrid-closed-loop-systems | Price | 2.8 | | While this figure is undoubtedly correct, it must be remembered that many people with Type 1 diabetes are already using pumps which could be operated as a Hybrid closed loop if they were funded for the appropriate rtCGM. So the additional cost to the NHS in many cases will be significantly less in addition to current funding. |
| 648 | | information-about-hybrid-closed-loop-systems | Price | 2.7 | | Obviously, price is critical. But non-measurable costs need to also be taken into account. Poor mental health also costs the NHS, and should be factored in. |
| 752 | | information-about-hybrid-closed-loop-systems | Price | 2.9 | | How does this compare with more traditional methods/cost of treating complications and hospitalisations?<br>How are the personal costs calculated? Not necessarily financial but physical, emotional, psychological and the effects on relationships and family life |

## THEME: CHILDREN AND YOUNG PEOPLE

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| 10 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.1 | | 1.1 The proposed recommendations may disadvantage patients below the age of 7. The only technology available for this cohort of patients uses CamAPS. In general patients who have historically used this are patients with frequent hypos that despite use of standalone CGM and CSII, have been unable to gain control. We note that there was limited data in children and the EAG was unable to stratify by age (page 11). If the TA is unchanged, patients under 7 who have uncontrolled diabetes but do not have HbA1c above 8.0% will not be eligible for HCL. |
| 22 | | | | | | Those in full time education from nursery to university or in apprenticeship eligibility should be considered.<br><br>The mental health impact diabetes has on children and young adults is huge. There is already a mental health crisis and not enough staff to deal with it.<br><br>Education has a huge impact on young people without the added pressure of also being type 1 diabetic. Not only do the children and young people worry what others may think but they also need to keep on top of maintaining good hbac1 all on top of maintaining a good education like everyone else.<br><br>For a lot of young people this added pressure is too much, especially when there is equipment out there that can take this mental load away from them.<br><br>My daughter was diagnosed at 8, the pressure of having the perfect level bloods was constant...every hour, every day.... and when her bloods didn't respond 'how they should' she became anxious, angry and frustrated.<br><br>By 10, she was self harming.<br>By 12 she attempted suicide.<br><br>This is not how a young person should feel..... they should be as carefree as they possibly can!<br>Closed loop would provide a little bit of relief, with the right support and guidance their young lives would have a much better start leading into adulthood then they currently do! |

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| 28 | | recommendations | 1 Recommendations | 1.1 | | My son has had T1 diabetes for 8 years since he was 2 years old. His hba1c is on average 52 BECAUSE I micromanage him EVERY SINGLE DAY! He has full 1:1 care in school because I fought for him to have that, he has CGM because I fought for him to have that long before NICE recommended it. He is on an insulin pump because I fought for it. We have waited and waited for a tubeless closed loop system because that is what he wants rather than having a tube coming out of his stomach and literally months before it arrives in the UK we are now facing the prospect that he won't be eligible because we have FOUGHT this condition every single day to keep his hba1c down to protect his future and ensure in adulthood he is not a burden to the NHS and this is what happens? We are now basically going to be discriminated against because we have done a good job! Being a parent of a child with T1 is absolute torture we are exhausted mentally and physically and the only light we had was that a closed loop system would take some of the burden from us at some point in the future. Your recommendations are wrong they do discriminate against the people who have worked so hard to do the best for their children. It's 3.21am and I'm awake because my sons cgm alarms have gone off and I have had to get up the same as I do every single day because he needs more insulin or less insulin a closed loop system would be doing this for me but instead I do and I have done it for 8 years! I honestly would like everyone of you on the panel that makes these decisions to live for one week in our shoes and then see how you feel about whether children should get a closed loop system or not. There should not be any question about what their hba1c is all children should be treated equally. |
| 60 | | | | | | We have experienced this life changing, game changing technology as our daughter is just 2 years old. The difference it has already made to all of our lives is astounding. Others facing the daily struggle that is T1 diabetes should be able to experience this technology to alleviate some of the burden both on the individual but also on the health service longer term. |

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| 61 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | dap55-diabetes-mta-acd-final-no-acicdocx | | | | References to support recommendations<br>Rawshani A, Sattar N, Franzen S, Rawshani A, Hattersley AT, Svensson AM, et al. Excess mortality and cardiovascular disease in young adults with type 1 diabetes in relation to age at onset: a nationwide, register-based cohort study. Lancet. 2018;392(10146):477-86.<br><br>Lind M, Svensson AM, Kosiborod M, Gudbjörnsdottir S, Pivodic A, Wedel H, Dahlqvist S, Clements M, Rosengren A. Glycemic control and excess mortality in type 1 diabetes. N Engl J Med. 2014 Nov 20;371(21):1972-82. doi: 10.1056/NEJMoa1408214.<br>Steffes MW, Chavers BM, Molitch ME, et al.; Writing Team for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Sustained effect of intensive treatment of type 1 diabetes mellitus on development and progression of diabetic nephropathy: the Epidemiology of Diabetes Interventions and Complications (EDIC) study. JAMA 2003;290:2159–2167<br>Lachin JM, Bebu I, Nathan DM; DCCT/EDIC Research Group. The Beneficial Effects of Earlier Versus Later Implementation of Intensive Therapy in Type 1 Diabetes. Diabetes Care. 2021 Aug 11;44(10):2225–30. doi: 10.2337/dc21-1331. Epub ahead of print. PMID: 34380706; PMCID: PMC8929189. |
| 62 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | recommendations | 1 Recommendations | 1.1 | | This is not compatible with current NICE recommendations for pump therapy, which is only possible in children aged under 12 years, and in those aged 12 years and over with an HbA1c over 69mmol/mol.<br>In addition, we question the appropriateness of the HbA1c criteria for HCL of 64mmol/mol in paediatrics (see below) |
| 64 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | recommendations | 1 Recommendations | 1.5 | Why the committee made these recommendations | We challenge the chosen HbA1c cut off, and recommend it is lowered for children.<br>Even in individuals who achieve optimal HbA1c under 6.9% (<53mmol/mol), a 2-fold risk in death from cardiovascular disease is seen, and this is most pronounced in those diagnosed with T1D under the age of 10 years. This translates to a 16-year reduced life expectancy in individuals with T1D (Rawshani Lancet 2018, Lind NEJM 2914). Further, the EDIC study demonstrated that early glycaemic control influences future long term diabetes complications, with lower levels of glycaemia in the first years at onset saving patient and health systems burden related to diabetes complications, this has been termed ‘’metabolic memory’’ (Steffes JAMA 2003, Lachin Diab Care 2021).<br>We recommend lowering the target of HbA1c use to 53mmol/mol in children who have the highest cardiovascular risks and risks of premature death over a lifetime, directly related to glycaemic load. We also recommend that |

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| | | | | | | HbA1c criteria align (and are reduced) for insulin pump therapy where guidance should also be changed to remove age criteria. |
| 65 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | 48 mmol/mol | In order to achieve this in CYP the HbA1c criteria for HCL initiation should be lower or removed altogether |
| 74 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | committee-discussion | Evidence and generalisability | 3.3 | The committee concluded that both the RCTs and the NHSE adult pilot study were not fully generalisable to the type 1 diabetes population in the NHS | This included children as well as adults (not just adults) – children's data seems an afterthought in this discussion.<br><br>It is known that there is a higher proportion of children on pump therapy compared to adults therefore those selected for the pilot are more representative of the CYP population. |
| 77 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | committee-discussion | Uncaptured benefits | 3.9 | | We agree with these and the two-three fold benefit in children where benefits are for carers/parents also |
| 95 | University Hospitals Dorset Diabetes Service | committee-discussion | Cost effectiveness for children | 3.11 | | We believe that the majority of children with access to the HCL systems early in their life are likely to be much less prone to complications from diabetes due to improved glycaemic control, and that cost effectiveness data to reflect this will be apparent with time. |

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| 116 | | | | | | All Type 1 diabetics should be offered hybrid closed loop. My son aged 14 has used CamAPS fx for nearly two years. His Hba1c had always been excellent but it took huge amount of effort, stress and sleepless nights and had a negative affect on our son's and our mental health. Type 1's who achieve near normal blood glucose levels should not be penalised for working hard whilst a system that can take so much of the burden away is available.<br><br>Although I recognise there is an immediate cost implication the potential long term savings due to less complications later in life should also be considered.<br><br>As a parent of a child with diabetes, diagnosed over seven years ago, who has experienced the life changing benefits of closed loop I urge you to offer hybrid closed loop to all Type 1 they deserve it. It's impossible to understand the management required if you haven't lived with it. I hope you never have to |
| 144 | | | | | | My daughter has been type one since she was 2 years old she's now 11. I try my absolute best to manage her blood glucose and her hba1c is normally around 7.4. She already has an insulin pump and would benefit hugely from a closed loop system. I feel that because we are doing an ok job managing her condition we will be overlooked for this technology. I feel this is unfair because given her young age, this technology could make a massive difference to her future and could mean a future with no complications. It doesn't matter how hard I work at managing her condition, I will never get the result that I would with rhis closed loop system and I think this needs to be taken into consideration for young people with type 1 |

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| 149 | Newcastle Hospitals NHS Foundation Trust (Children and Young People and Young Adult Diabetes Teams) | | | | | We feel this guidance discriminates based on age. The consultation comments that HCL is likely to be more cost effective in Children and Young People and yet imposes the same arbitrary cut off of HbA1c 64mmol/mol.<br><br>The guidance makes only passing comment on the effect of managing T1DM in families and how HCL can support them. It makes no real reference to the significant barriers T1DM creates for young people in accessing education (at all stages), undertaking active exercise and the detrimental effect it has on parents ability to work (time off needed for appointments, manage complications, sickness at home etc). The evidence clearly demonstrates that HCL is effective in significantly reducing these burdens.<br><br>Children, Young People and Young Adults are not the same as older adults who have settled lives, jobs, often their own transport. The barriers and challenges posed by T1DM are different for them and also these barriers and challenges change on a frequent basis. For example compare the risk of a significant overnight hypoglycaemic episode of a 17 year old living at home to a 18 year old leaving home and going to the other side of the country for university with no family near, making new friends and drinking large amount of alcohol. This is the reality of risk that young people with T1DM face, that clinical teams try to manage and that HCL can be transformative in mitigating.<br><br>NPDA / NDA are clear, the outcomes for this age group during transition from CYP to Adult services get worse. They get lost to follow-up, they disengage, their HbA1c goes up, they present in DKA. HCL wont fix everything for everyone, but it will reduce the burden significantly for many. Arbitrary HbA1c cut offs at one point in time don't encapsulate the clear need, or help mitigate the risk.<br><br>The cost benefit model does not seem to include the opportunity for innovative working that HCL provides by switching from routine hospital based appointments to virtual appointments (less disruptive to education / jobs and less costly for families along with being more cost effective for hospitals).<br><br>The fundamental problem is the technology is still be separated out into rtCGM and pumps. This guidance needs to be very clear that it replaces all insulin pump guidance as pumps and HCL are no longer seperable. We now work in a context where all CYP are eligible for rtCGM first line and many young adults are eligible too. Therefore anyone currently moving on to a pump at any age will de facto get HCL. In some ways this guidance is a step back as there are currently different standards being used for (stand alone) insulin pumps with the consequence that local commissioning bodies have |

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| | | | | | | different criteria for pumps. The implication of this guidance is illogical as we would have young people in our area who are entitled to pumps (due to age <12), who are eligible for rtCGM (due to NICE guidance) but are not eligible for HCL because of this guidance as their HbA1c is too low. If their HbA1c is 58mmol/mol are we to deliberately choose an older pump system that does link to rtCGM, even though it is exactly the same cost and less effective? This is a waste of resources.<br><br>Whilst clearly well meaning I fear the consequences of this guidance have not been thought through. Many families and patients desperately want HCL technology not for some "lifestyle" reason but due to the transformative effect it will have on their lives, significantly reducing the disease burden and improving long term Quality of Life with significant longterm benefits to them and to society. Even a single day of education missed can have long term negative effects. T1DM management currently results in many days missed school and education. Even if the CYP remains in school they may not focus in lessons due to having time when hypo or hyperglycaemic. HCL has been demonstrated to improve these issues. This is a significant benefit which needs to be given much greater priority. Indeed parents in many areas have taken local authorities to court (and won) over the need for one to one teaching assistant provision (by EHCP) in order to maintain their child's blood sugars in the normal range. In my experience these CYP are all already on HCL and have HbA1cs significantly below 64mmol/mol. To say that these families are no longer eligible for HCL or indeed similar families in the future would be likely to immediate risk of judicial challenge.<br><br>The implication of this guidance is that we should put everyone on HCL at diagnosis, when their HbA1c is high (which would not be right for everyone) or to encourage families to deliberately manage their diabetes badly for 6 weeks so we can record a higher HbA1c so they become eligible for HCL. It is perverse.<br><br>Using a cut-off of 64mmol/mol is not based on evidence. The entry criteria should be when a joint decision is made between the family and clinical team that HCL is right for them at that time in their lives. However there should be an exit criteria so NHS resources are not wasted. Families should agreed to follow a "contract" or some other agreement that they use the technology effectively, continue to engage with the treating team regularly and achieve clinically relevant goals- ie HbA1c fall by a certain amount or below a certain level, not come into hospital in DKA, reduce number of hypos, increase school attendance. The exact goal would be agreed before commencing technology and the clinical team would be responsible for monitoring progress. If the agreement is not followed the technology would be withdrawn. |

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| | | | | | | We would propose the strategy would be used for anyone aged 0-25 with T1DM. The 64mmol/mol cut off could be used in those >25years age. This would give appropriate weight to the finding that HCL is more cost-effective in CYP and mitigate the potential challenge that this guidance discriminates based on age.<br><br>References<br>1)Ng SM, Katkat N, Day H, Hubbard R, Quinn M, Finnigan L. Real-world prospective observational single-centre study: Hybrid closed loop improves HbA1c, time-in-range and quality of life for children, young people and their carers. Diabet Med. 2022<br>2)Tauschmann M, Thabit H, Bally L, Allen JM, Hartnell S, Wilinska ME, Ruan Y, Sibayan J, Kollman C, Cheng P, Beck RW, Acerini CL, Evans ML, Dunger DB, Elleri D, Campbell F, Bergenstal RM, Criego A, Shah VN, Leelarathna L, Hovorka R; APCam11 Consortium. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial. Lancet. 2018 Oct 13;392(10155):1321-1329. doi: 10.1016/S0140-6736(18)31947-0. Epub 2018 Oct 3. Erratum in: Lancet. 2018 Oct 13;392(10155):1310. PMID: 30292578; PMCID: PMC6182127.<br>3)Ware J, Allen JM, Boughton CK, Wilinska ME, Hartnell S, Thankamony A, de Beaufort C, Schierloh U, Fröhlich-Reiterer E, Mader JK, Kapellen TM, Rami-Merhar B, Tauschmann M, Nagl K, Hofer SE, Campbell FM, Yong J, Hood KK, Lawton J, Roze S, Sibayan J, Bocchino LE, Kollman C, Hovorka R; KidsAP Consortium. Randomized Trial of Closed-Loop Control in Very Young Children with Type 1 Diabetes. N Engl J Med. 2022 Jan 20;386(3):209-219. doi: 10.1056/NEJMoa2111673. PMID: 35045227.<br>4)Hart RI, Kimbell B, Rankin D, Allen JM, Boughton CK, Campbell F, de Beaufort C, Fröhlich-Reiterer E, Ware J, Hofer SE, Kapellen TM, Rami-Merhar B, Thankamony A, Hovorka R, Lawton J; KidsAP Consortium. Parents' experiences of using remote monitoring technology to manage type 1 diabetes in very young children during a clinical trial: Qualitative study. Diabet Med. 2022 Jul;39(7):e14828. doi: 10.1111/dme.14828. Epub 2022 Mar 24. PMID: 35274356; PMCID: PMC9311187. |
| 155 | | | | | | My young daughter has had Type 1 for over 6 years. We have used all the methods of control over the years and she is now on a closed loop system. This has immensely improved her quality of life and her ability to take part in activities that non- diabetic children take for granted. I have had years of sleep deprivation and stress as a direct result of my daughter's condition which affects my general and mental health and massively affects every day life. The closed loop system much improves things and gives the patient more freedom as they can be monitored remotely. This system need to be available to all Type 1 diabetics without having to constantly fight for it. It provides much more consistent and lower HbA1c results which in turn |

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| | | | | | | mitigates long term conditions associated with diabetes. This in conjunction with less hospitalisations, less hypos etc saves the NHS considerable money in the long run leaving patients and their carers with better health and quality of life. |
| 157 | | | | | | My son was given a closed loop system as he slept while having hypos during the night, it meant that for several years before being given this we didn't sleep during the night. Having this system allowed him to go in school trips, do his doe award and have a near normal teenage life. We used less test strips and he has had good 3 month test results which I hope will allow a healthier adult life. My son was lucky to get it, it should be available to everyone. It changed a very dramatic medical condition into something more manageable and def. Improved all our mental heath. |
| 167 | | | | | | This is a very good document and will make a huge difference to many living with diabetes.<br><br>My only criticism is that are not separate criteria for children, with lower HbA1c thresholds, given the points about greater cost effectiveness, greater effect on quality of life for patients and families, and greater risks of complications over the course of their lives. |
| 168 | | recommendations | 1 Recommendations | 1.1 | | This is not compatible with current NICE recommendations for pump therapy, which is only possible in children aged under 12 years, and in those aged 12 years and over with an HbA1c over 69mmol/mol.<br>In addition, I would question the appropriateness of the HbA1c criteria for HCL of 64mmol/mol in paediatrics - given that children with T1D live with the condition for longer and it is well known that risk of complications and death increases with length of time of having diabetes, and the fact that good early control reduces complication risk generally ("metabolic memory"), I would advocate a lower HbA1c threshold in children under 12 eg 49 mmol/mol. |
| 170 | | committee-discussion | Children | 3.5 | | So the basis for using a cut off of 8% is based mainly on adult data? |
| 171 | | committee-discussion | Cost effectiveness for children | 3.11 | | So if HCL systems are more likely to be cost effective in children than in adults, why are there not separate criteria for children? |

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| 185 | | | | | | Please consider recommending closed loops for those with hba1cs lower than 8.<br>I am particularly concerned about children with type 1 diabetes, as persistent low blood glucose can result in a 'good' hba1c but also has the potential to be very harmful to developing brains and can result in long term permanent brain damage (as well as retinopathy, which is a complication of both high and low blood glucose).<br>Type 1 individuals with an hba1c over 48 (6.5) are also at increased risk of complications. If a child has an hba1c between 6.5 and 8 for many years, it is reasonable to assume they will have complications as an adult which will cost the NHS money as well as having a significant negative impact on the person who has likely been trying their very best to live a healthy lifestyle. |
| 186 | Type 1 Kidz, Investing in Children | recommendations | 1 Recommendations | 1.1 | | Comments from parents/carers of children with Type 1 diabetes on the overall recommendations:<br><br>1. My son has used a DIY closed loop system for 4 years and it has made not only my sons life and health better but the quality of life for me as a parent too better, mainly due to extra sleep you get as the closed loop systems can stop insulin to help prevent lows or automatically bolus to try to keep the blood glucose within range. This allows us all to sleep more and be able to fully function the following day. Not only has the time in range increased to 85% ( whilst still enjoyed normal food and puddings and treats) but the Standard variation is also much better as there is not as much swing from high to low, hba1c hasn't vastly improved (son always been below 6.5%) but that's not just down to less highs but also less time spent low which can falsely give a better hba1c.<br>Quality of life is vastly improved as the micro management is done for you with the decrease/increase in insulin every 5 minutes.<br>Not being offered to people unless hba1c is below 8% is wrong, there is so so many people who work tirelessly to keep hba1c at target or below but it takes their quality of life away or their families. Having these tools available to all will improve the lives and put less strain on the NHS resources in the long term.<br>2. This technology should be available to all - if you have good control this likely means the parent is up 2-6 times every single night. Obviously having a detrimental impact on the carers health and ability to perform at work. Also for an adult T1 a reduction in disturbed sleep would be invaluable<br>3. Would like it to be available to everyone with T1.<br>4. This should be available to all, not just those having difficultly managing their condition. It could be argued that those with a lower hba1c are putting in a lot of effort to get there. This technology talks about reducing that effort. The video also mentions the affect of stress on the conditions. Effort can often cause stress. Why not give the technology to all and allow those putting in a lot of effort the benefits too? |

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| | | | | | | 5. I don't think this should be just for people struggling to manage there condition, everyone should have the opportunity for a better quality of life.<br>6. I agree. My daughter had pump and libre before closed loop but since having closed loop her hbA1c has improved a long with my sleep patterns<br>7. Should be available to all. This encourages poor management in order to access the newer technology.<br>8. My son who is 10 switched to a closed system 8 days ago. We are already seeing a difference.<br>He is able to lead his life much more 'normally' with the pump doing a significant amount of work. Although it is early days for us abs ratios do need adjusting, over the last week he has been in range for 88% of the time.<br>His fingers are recovering well, he is sleeping better as significantly less intervention is needing to happen during the night and is overall happier.<br>The technology is unreal and we need to make sure that all children and adults have access to this technology if they wish.<br>9. I feel very uncomfortable with the proposed limiting of access based on the hba1c levels proposed.<br>As a mother of a newly diagnosed child the thought of access to a closed loop system is exciting. It is exciting because my family may get a full nights sleep. It is exciting because it will give so much peace of mind to everyone who is part of caring for her. It is exciting because it can help her reduce her hba1c levels to drastically reduce the risk of future complications. It is exciting because with more streamline management and tighter control our whole families mental health improves. It is exciting because it gives my daughter more freedom.<br>The thought that she may have access to a closed loop as a young child and then have it taken away if she works hard and has a good hba1c is already heartbreaking. I would worry that my daughter and others would intentionally try to keep their hba1c levels at a point where they could have access to this technology which would then increase chances in complications and the burden on the NHS.<br>10. It should not be limited to those with a higher HbA1c. I work 24/7 along with my full time job to try and manage my daughters levels so as to keep her HbA1c as low as possible. I will get up regularly in the night to correct. I do not feel that those who are utterly exhausted doing the best for their children should be penalised and miss out on hybrid closed loop because they don't fit the criteria. The mental and physical exhaustion of this relentless chronic disease cannot be underestimated and ANYTHING that can be done to help with the burden of this should be considered for all Type 1 diabetics, that have to deal with this everyday for the rest of their lives. |

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| 187 | Type 1 Kidz, Investing in Children | recommendations | 1 Recommendations | 1.1 | | This means that there will not be a difference for over and under 12 year olds for a Hybrid Close Loop system, as it will only be based on HbA1c. However, this difference will still be in place for accessing pumps for over 12s.<br>Insulin pumps will still be available for any child under the age of 12, regardless of HbA1c. Over the age of 12, the HbA1c requirement for a pump will be higher than for a Hybrid Closed Loop. The HbA1c requirement for a pump for over 12s is currently 69 mmol/mol or 8.5%. We aren't sure why there is a difference in the criteria.<br><br>Comments from parents/carers of children with Type 1 diabetes on this difference in criteria:<br><br>1. This is totally wrong b thinking because children will have type 1 for the ehe of their lives, denying them improving their lives and long term health is not logical. They could end up with complications, mental health issue as diabetes takes over your life, a pump never mind a closed loop system can vastly improve your quality of life and take some of the burden away. Pumps/CGM/closed loop should be available to all if they choose to.<br>2. Why do you need to deliberately mis-manage your diabetes to get access to Technology?! This does not make sense. With this kind of severe disability all options need to be available to all<br>3. Good - I just don't understand why 12 is considered a key age to shut a child or young person out of accessing life-improving tech. I also wanted to say that the age limit of 12 is especially inappropriate for kids with SEN. My kid has ASD and it has taken nearly a year to convince him to try a cgm.<br>4. These criteria are crazy and can't have been decided by anyone with any experience of type1. It's so frustrating!! I want the best for my child. This technology is the best we can get at the moment. So do we deliberately increase her hba1c in order to get access? It's counter intuitive. It's risking long term health conditions, which the NHS is likely to have to pay for. Or is that the issue here, the NHS won't exist in the long term so the decisions are being made with the short term only in mind?<br>5. Teenagers have enough to deal with, without making these things more difficult, everyone should have the option of the same care<br>6. I feel like it should be open to anybody as there is a risk that people will not look after themselves properly in order to try and get access to closed loop.<br>7. Similar to above. The technology needs to be available to all, regardless of age. It is of benefit to all with Type 1, or Type 3c<br>8. This is not a fair system. Everyone should have access to this technology. Long term, better levels and diabetic control when younger will lead to less health problems when older which will cost the health service less.<br>9. Without clear rationale on the difference in criteria I would see this as age |

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| | | | | | | discrimination.<br>10. See above. It is not right to limit this to those with a higher HbA1c. Logic says that those who work hard will simply stop doing this to fit the criteria. This is shortsighted as it will cause problems and additional costs to the NHS in the long term. |
| 188 | Type 1 Kidz, Investing in Children | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | [redacted] has shared her response to the consultation with us and she is recommending that the HbA1c requirement for Hybrid Closed Loops AND pumps for all children should be lowered to 53mmol/mol or 7%. This is because children will have a longer time with diabetes than adults, therefore better control earlier will reduce risk and costs over a longer period of time.<br><br>Comments of parents/carers on this suggestion:<br>1. Totally agree but I think that threshold should be lower due to the amount of time parents spend relentlessly trying to keep BGs in range, closed loop system reduce that burden and target ranges if 6.5% can be much more easily met. Why should families who spend vast amounts of time micro-managing this disease be penalised because they do work so hard and give uk so much to make their childrens long term health more secure.<br>2. Yes, there is definitely a cost benefit to offering hybrid closed loop to ALL children, regardless of HbA1c<br>3. Agree completely. Also as above SEN kids are especially vulnerable and less able to manage their diabetes so should have extra support options open to them.<br>4. Yes that's a good point. But I strongly believe this should be accessible to all.<br>5. This will give opportunity to a lot more children but hba1c should not be a factor<br>6. Everybody with diabetes or with a child with diabetes would obviously love hbA1c below 53 but lots of factors can play a part in sabotaging that dream. We work hard 24/7 to do our best and feel the pressure to keep it under that level would add further stress which isn't healthy<br>7. It should not just be about saving the NHS long term. It is about the way better control affects day to day life for all with a faulty pancreas why<br>8. Absolutely this. It makes sense.<br>9. Although this is a lower hba1c recommendation I do feel that everyone |

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| | | | | | | should have access to this technology regardless of hba1c results or anything else.<br>10. I agree but as I state above some parents and carers will give everything to help their child reach the lowest possible HbA1c and those parents should not have to miss out on the chance of a mental reprieve as their hard work makes their child not fit the criteria. |
| 189 | Type 1 Kidz, Investing in Children | information-about-hybrid-closed-loop-systems | The interventions | 2.6 | | It is our understanding that there are currently no Hybrid Close Loop systems licenced for use with children under 6 in the UK. We think that this unfairly discriminates against children under 6.<br><br>Comments from parents/ carers:<br>1. Absolutely, children under 6 should not miss out on advanced technology that can improve their lives, they will have to live with the effects of type 1 diabetes for a much longer time, they must be able to use these device to help secure their long term health not be penalised because of their age.<br>2. Could justly be the case that the technology cannot be validated for under 6 or for very low insulin needs. However, all should be offered when turning 6<br>3. Agree.<br>4. Totally agree. What makes the condition so different between age 5 and 6? And why happens on someone 12th birthday that's so significant their condition is approached totally differently? These decisions should be case by case, not age or hba1c related, it's unfair and discriminatory<br>5. No one should be exempt<br>6. After having a child diagnosed before the age of 6 I feel like a closed loop system would really help the parents, school caregivers and child. I feel like Primary school was the hardest time as myself and a lot of other parents have a bad time with schools not wanting to give all the support with diabetes that is needed. The closed loop system takes away some of the difficult decisions that staff may not feel comfortable making.<br>7. My little girl was diagnosed at age 3 , she is now 5. I understand why we needed to do finger pricking and injections at first to really get to grips with the condition and management. Once capable then the newest tech should be available immediately. Lillian has had Libre 2,.now has Omnipod and and Dexcom G6. If they are suitable for such young children, surely the closed loop is no different<br>8. I agree. Under 6's need this technology. The pressure on parents and carers when they have young children is immense anyway without type 1. Some parents and carets won't cope… we need to safeguard our young children even more so that young children don't get ill and social services don't end up involved. Furthermore, these young children will have type 1 for life… let's make sure we start them early with the technology that can mean |

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| | | | | | | they have good diabetic control for life and they can lead a relatively normal life. These years are vital for young children… poor control will mean they miss school and their social, emotional and educational chances are impacted because of their medical condition. This is discriminatory.<br>9. I agree that this is age discrimination.<br>10. Whilst my child is 13, I strongly feel that young children should be helped as much as possible to cope with their diagnosis, as should their parents. |

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| 191 | Type 1 Kidz, Investing in Children | committee-discussion | Children | 3.5 | | We are unclear why, given the evidence that children benefit more from access to HCLs, there are no specific recommendations in the guidance about access for children.<br><br>Parent/carer comments:<br><br>1. No response<br>2. All children should be offered hybrid closed loop when turning 6 - subsequently also being able to keep it into adulthood<br>3. Why is there no specific guidance about children?! We know that T1 typically comes on at around age 10, so children are going to be a large cohort of the newly-diagnosed who could most benefit from preventive action to safeguard their long term health.<br>4. This sounds like a huge gap. I'd the research shows the benefit, why is there no further guidance. It sounds like this needs to be addressed.<br>5. Agree<br>6. I think due to the changes in growth, hormones, more regular illnesses in children it probably is correct that they benefit children more. I think as an adult our daily lives are more structured with jobs, food etc so do think adults will be more in control with levels. However saying that adults do tend to have other people to think about partners, kids etc so the closed loop might help them as much as children as it removes the added pressure of diabetes management.<br>7. Not really sure why this would be the case. I have first hand experience of both adults and children being hypo unaware.<br>8. This is disgusting that there are no recommendations. Why would we wait until 18 and be reactive to poor or challenging diabetes management? Surely prevention is better… the closed loop would help establish excellent levels and lead to less issues as adults.<br>9. I think there should be guidance in closed loops for children which does not discriminate against age.<br>10. See above |

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| 192 | Type 1 Kidz, Investing in Children | committee-discussion | Conclusion | 3.16 | | Final comments from parents/carers:<br><br>1. No response<br>2. It is so sad to hear that so many struggle to get the necessary technology to improve their lives<br>3. Please do not ration this technology by age. Please also do not ration it for only the highest uncontrolled blood levels. Case by case decisions please. And fund the NHS properly so EVERYONE can have access to this.<br>4. No response<br>5. Everyone no matter what age or control level should have the opportunity to have the best help for a better quality of life<br>6. No response<br>7. It is sad to see that we have to justify how disadvantaged T1 makes our children or adults. Families have to fight in school to get the correct support, we fight to get the best for our children at all stages. Value people over money.<br>8. The closed loop has already had a significant positive impact on our child which we believe will only improve. This should be available to all who need it.<br>9. I think hybrid closed loop systems should be made available to everyone who lives with type 1 diabetes so everyone can see an improvement in their control, risk of future complications, mental wellbeing, social life, reduced diabetes burnout, better sleep, less daily risk and and overall improved quality of life.<br>10. See above |
| 193 | | | | | | Closed loop needs to be open to all who will benefit. My son is MDI and only has “good” control because of the amount of intervention and management I do. He wouldn’t meet criteria of having high hba1c. But as the document states, managing T1 and getting good control is a 24/7 mental burden. My son is hypo unaware and has additional needs which limit his ability to self manage - hence (even as a teenager) he is reliant on my continued involvement to achieve hba1c that should prevent long term complications. This does restrict his independence and having closed loop would benefit him hugely. If left to manage himself then he probably would meet the criteria but he shouldn’t have to be put in that position as it wouldn’t be best for his health (physical or mental). Access to closed loop would improve his quality of life from the point of view of allowing him more freedom and independence. It should really be available to all but should certainly be available to all who would benefit and not just based on a set hba1c as that misses all the input being required to achieve that - especially by parents who are having to do more to account for their child’s additional needs. |

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| 231 | | | | | | I am a parent of a 12 year old child with type 1 diabetes. I believe all children and adults with type 1 should have access to the closed loop system regardless of Hba1c.<br><br>This measure does not show the erratic highs and lows that a child might be experiencing daily. It is simply one number and does not show the full picture. Hormones, exercise, school, the weather…so many factors affect a child's blood glucose that it is a full time job to manage and both children and parents could massively benefit in terms of physical health (and future health and cost savings for the NHS) but also mental health. It would mean a huge improvement in quality of life for both my child and me if she had access to this.<br><br>Other economic factors include many parents are not working as they need to be available to help their child - this is lost productivity and taxes for the government. It's not right to just look at the cost of the closed loop in isolation.<br><br>Also, I am concerned that many will simply not manage their diabetes in order to fall within the Hba1c of 64 number. This is not something that is good for the individual health wise or the NHS as could result in more hospitalisations as a result.<br><br>Everyone with type 1 diabetes should have access to this - it will save money for the NHS long term. |
| 247 | | | | | | I have been a parent of a type 1 child for 8 years and also a granddaughter of a type 1 woman who died from type 1 complications. This technology had given us hope that whilst our sons condition is not curable his quality of life would be improved immeasurably. We work tirelessly day and night to keep our sons blood levels in range to keep his hba1c in range. Because we do this he will now be penalised and not offered the best form of care to help his condition. The closed loop system was and is light at the end of a very long tunnel for many especially those of us with children who have fought for so long to get the best level of care we can for our children. My 10 year old son is already showing signs of diabetes burnout this device should not be one that is out of reach. Many people will now let hba1c numbers increase if they now know this is the criteria. I know the NHS has difficult decisions to make but this one is short sighted. It will ultimately save the NHS millions by delivering this therapy up front. Type 1 is complex enough and to not offer this option for all u18s whos numbers are erratic at best because of hormones amongst many other things is a unacceptable. Peop work hard to achieve a good hba1c and this is will result in people allowing it to get worse creating issues for the NHS just so they can frankly get the best option for them and there loved ones. It is a woefully short sighted piece of guidance |

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| | | | | | | that is not in my opinion taking into account the long term benefits of placing people on this system. This is the same fight that we fought for CGM which is not available for all surely you must have learnt from that situation that the benefits outweighs the cost |
| 253 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | You talk about adult carers and children however young people heading off to Uni/work still need support and can struggle. Parents are still stressed about their young adult when away at Uni when the change in lifestyle will cause issue with their control, many still follow their child's bgs by setting up their own monitoring systems, surely ensuring that everyone has access to this new technology will relieve a burden from the young adults and also their parents. |
| 263 | | | | | | The effect of duration of diabetes appears to have been under accounted for. Swedish registry data shows that children diagnosed at a younger age are more likely to develop complications than those diagnosed post-puberty. As lead of a young persons service I unfortunately see 18-25 year olds with referable retinopathy all too often, and therefore think that for anyone under 25 years of age the threshold for consideration of HCL should be anyone with an HbA1c above 48. In addition, ensuring we have less young people with complications should mean that in the future they are in education and working - and therefore being more productive members of society. In effect if not amended this is discriminatory based on age - as we know hyperglycaemia is much more common in adolescents, and the negative legacy effect of this should not be under-estimated.<br><br>QoL has not been considered to the extent that it should. As part of the NHS pilot all participants were asked to complete some questionnaires - I've not seen any data on this, but from our clinic know that the most common phrase for the experience of being on HCL is "life-changing". There was also a smaller in depth qualitative study undertaken - again has this data been considered?<br><br>The effect of reduction of hypoglycaemia and the removal of the fear of significant hypoglycaemia appears to have been undervalued - some people with impaired hypoglycaemia awareness would definitely benefit from this technology. Are you assuming that they would get this therapy as meeting both NICE pump and CGM criteria? If so, please make this explicit.<br><br>I do not understand the threshold of 64 - when most of the data is for 69 and above. In the short-term some would argue that a higher threshold would be preferable so at least some can gain from this. If this were the cut-off how many people would it apply to? Would it mean that we could offer HCL sooner rather than later to those most at risk? |

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| 270 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | My son was on the trial programme and I cannot tell you the difference it has made to all our quality of life. For a young teen he was for the first time, able to go to a party and not keep doing blood tests in order to eat, which made a massive difference to him. The whole closed loop has really given him extra freedom. For example he undertook the Bronze Duke of Edinburgh expedition and did not have a single hypo. His friend, without closed loop but with Type 1, ended up being resuscitated in hospital the following day. That is the difference and as a parent it makes the worry so much less, I will be forever grateful that he has been given this chance to use the technology. We also experienced better quality of sleep and I am no longer needing to get up in the night and check his levels. He rarely struggles with blood sugar issues over night and his blood sugar is usually steady throughout the night. We have not experienced this for 11 years and it has made an immeasurable difference. |
| 271 | | committee-discussion | Children | 3.5 | | Son on the trial just had his best HbA1c of 6.2. We have never had such good control and this is at a time when we thought there would be no control because of puberty. We can see the enormous benefits of the closed loop. |
| 274 | | | | | | I have read the consultation paper on HCL systems for the management of Type 1 diabetes in detail and with interest as a 'lay person' with several family members of different ages who have the disease.<br><br>There is no doubt that HCL systems represent a potential great step forward in the management of diabetes. As such the paper and the intention by NICE to recommend the access to HCLs on the NHS is to be welcomed and celebrated.<br><br>However, on careful reading it seems that the clinical evidence as presented and the recommendations laid out in the document are not aligned with the stated goals of evidence based, non-discriminatory decision making. In particular, the recommendations seem to discriminate against children and adolescents with type 1 diabetes in comparison to pregnant women who are treated as a special group with unique 'difficulties' in managing type 1 diabetes.<br><br>The evidence presented seems to point to better clinical outcomes for children and consequent stronger cost / benefit analysis. Indeed the committee even states in the final sentence of para 3.11:<br><br>'The committee concluded that although there was some uncertainty, HCL systems are likely to be more cost effective for children than adults.'<br><br>However, despite this children and adolescents are not recommended as a one of the groups to be provided with unrestricted access to HCL systems. |

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| | | | | | | This surprising given that the paper throughout highlights the mental strain on children and their parents/ carers of managing type 1 diabetes as well as the severity of the implications for their long term physical health.<br><br>Pregnant women are correctly identified as a group who have very specific challenges in maintaining control of their blood glucose levels. Yet the same consideration is not given to children or adolescents going through hormonal changes and growth spurts. The short and long-term physical implications for the child's health of struggling to manage optimal glucose levels optimally through these periods of 'fragile type 1 diabetes' are at risk of being manifold and severe.<br><br>The developmental, emotional and mental well-being consequences should also be treated with equal consideration and seriousness - not only for the child, but the entire family and our society to which they will become key contributors over time. Section 3.9 in 'Uncaptured benefits' attempts to quantify this to a limited extent through surveying the reduction in fear of hypoglycaemic events. However, wider issues such as the increased challenges of emotional self-regulation, learning focus and the confidence & well-being usually associated with being young and fit appear not to have been considered.<br><br>I have witnessed the long-term emotional and mental health scars of a person who developed type 1 diabetes during adolescence - the self blaming and self destructive tendencies. I am witnessing the struggle of an entire family to keep an adolescent with 'fragile type 1 diabetes' on track so that they can learn, develop and become their best selves.<br><br>On the grounds of fairness (non discrimination), cost effectiveness, and long-term benefits to both the individual and society the recommendation not to include children and adolescents in the recommendation for early and unrestricted access to HCL systems needs to be revised. |

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| 275 | | | | | | I have four main comments on this consultation regarding the requirement for groups other than pregnant women needing to have an HbA1c result of around 8.0% in order to qualify for access to Hybrid Close Loop (HCL) technology:<br><br>• It discriminates against a child with type 1 diabetes when compared with an adult pregnant woman ( Equality Act, 2010 section 19 (1) (2) - protected characteristic: Age group)<br><br>• It has conflicting views of the definition of 'difficulty' in managing diabetes, which is what qualifies a patient for access to HCL. The committee papers (page 3) say 'difficulty' is 'not maintaining HbA1c levels of 6.5% or below', but the consultation only gives access to those who are having 'difficulty' and have an HbA1c of 'around 8.0% or more'<br><br>• It states that adult pregnant women should have unrestricted access to HCL because their 'blood glucose control is harder to maintain' (section 3.6) but does not cite evidence or a comparator, such as against an adolescent in a growth spurt, for example<br><br>• According to the consultation, there is more evidence of the benefit of HCL for children than for pregnant women (section 3.5/3.6), but access is unrestricted for pregnant women and limited to HbA1c over 8.0% for children, despite there being only 29,000 children in the UK with type 1 (section 2.1). |
| 302 | | recommendations | 1 Recommendations | 1.1 | difficulty managing their condition | No, I do not feel all relevant information is considered. What does this mean for children? What if a child hits the HbA1c range considered good but is continually missing class in the welfare office treating and caring for their diabetes. Managing the condition in a physical sense is too limiting for a child's life and more needs to be considered in the equation in accessing their needs. This could be even more impactful in poorer demographics where time out of class could have even greater life long implications for education. |
| 303 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | The patient experts explained that managing glucose levels is a lot of work and can affect home life, education, training or work | Again, not deep diving into the impact of children and young people - missing school days from exhaustion from highs and lows and overall struggling with illness more than a non diabetic child and the internal missing of classes (being at school but needing to go elsewhere to care for hypo or hypers from not feeling well). Lack of sleep is talked through but not the impact of parents leaving work as a child can not get through the day and the child missing their learning. |

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| 304 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | parent of a child | Why are you only focusing on the parent of the child and not the child's mental burden - especially through puberty and the stress of your body changing and constantly adapting to the changes with your diabetes. Or mentioning insulin resistance in puberty due to hormones and the impact a pump can help especially when sleeping |
| 305 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | with parents waking multipl | Again - great to focus on the parents - but why are you not discussing the child's broken sleep - the fear they feel, stress of whats happening, loss of learning the next day at school being so tired, broken sleep from running high at night and not sleeping well. |
| 306 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | mental burden | It is also a huge emotional burden for children, not just mental. The difficulty with finger pricking, pens and the needles hour on hour is painful for a child. A child's brain has not fully developed till their early 20's and having a child cope with caring and managing their diabetes is not fully reflected here. I feel that they are left out to an almost discriminatory level. |
| 307 | | committee-discussion | Uncaptured benefits | 3.9 | not captured in the model, including the effect on learning and education, ability to work, mental burden and fear of hypoglycaemic events. The committee concluded that these uncaptured benefits were likely to undervalue the effect of HCL systems on quality of life. | 100%, there are so many events that a type 1 child and student can reap benefit from in hybrid closed loop tech that has not been studied. The social aspect is also not mentioned. |

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| 308 | | committee-discussion | Uncaptured benefits | 3.9 | learning and education, | I support a 11 year old in school who is considered not eligible for a pump (again by looking primarily at Hb and BG numbers) I tracked over the last 3 weeks (19 days of school - she came out 11 days and on 5 of those days 2x) that equates to 58% of the 19 days she is leaving class to take care of her diabetes. That impact is huge on learning, socialization, self esteem etc. Even when she goes back to class she still is not cognitively 100% from the hypo or hyper. How is this impact on her education considered 'managing their diabetes'. Children need to be carved out in another point as you did with pregnant persons. Child's needs and management are not equivalent to an adult |
| 309 | | committee-discussion | Conclusion | 3.16 | t noted the many uncaptured benefits in terms of reduced mental burden, reduced parent and carer anxiety, and improved quality of life. | again, you could add a separate sentence around emotional, mental, and physical burden for children through puberty, school, sleeping, socially etc - not just the parents. It seems the focus of the NICE document is 1) adults type 1, 2)burden on parents and carers and 3 )pregnant women, as primary benefiters of hybrid closed loop . Again children need to be their own section for closed loop consideration.<br>(i.e. 1- Hb or BG control , 2) mental/ cognitive issues (e.g ASC), 3) impact on education (e.g. attendance being external or internal , 4) psychological and emotional impact (e.g. depression, low self esteem) |
| 310 | | | | | | My son, aged 8, has been on a closed loop pump for the last 3 months. It has changed his and our lives. It literally takes care of him! We can all sleep at night. I hope this technology is avaliable to support him through his teen and yearly adult hood. If not for the rest of his life. His blood sugars have the best controlled in the last few months than in the 4 years since diagonis. I feel sure this will have to help to prevent many of the later life complications of the condition. |
| 332 | | | | | | Thanks for inviting me to comment, I have two teenage daughters with type one diabetes, one is part of the closed loop system trial, my other daughter is not and their (and mine) experience of diabetes, and their health status and possible outcomes potentially vastly different partly due to one experiencing the benefits of the closed loop/algorithm system whereas the other daughter currently do not. |

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| 341 | | committee-discussion | Uncaptured benefits | 3.9 | | As mentioned previously, the experience of having one teen on they system one without is like day and night, ironically I can sleep w my younger teen (on the system whilst she is for instance on a sleep over - at camp) whereas w my older (now an adult at 19 not on the system - there are sleepness for her and me an other as she ventures out in the word and there is a delay in her moving out of the house too linked to fear of hypoglycemia (as she is trying to get the same HbA1c as her sister) and occasional calls from worried friends due to BG events on nights out and so on (despite her best efforts) which are rare but could be fatal and most importantly PREVENTED by access to the loop / algoritm - for all not just those w hba1c higher than 8 |
| 342 | | | | | | 64 is way too high to be eligible for funding. All children should be eligible for this equipment regardless of how well controlled their amazing carers work so tirelessly keep the hba1c. It appears very narrow minded to limit the role-out of this technology to persons with more unregulated hba1c. In fact, it seems outrageous to withhold access to those with exhausted carers who dedicate their life to keeping their loved ones hba1c within acceptable parameters |
| 346 | Children and Young People's North East and North Cumbria Diabetes Network | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.1 | | Children and young people have the longest duration of diabetes (highest determinant of complications) and this has not been taken into account. |
| 349 | Children and Young People's North East and North Cumbria Diabetes Network | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | With the recommendation of access if HbA1c is above 64mmol/mol, this does not take into account the evidence from people living with T1D and their families/carers on reduced burden; sleep deprivation; requirement of additional individualised support in school in the form of costly Educational Healthcare Plans; the patient and parent mental health burden and the societal impact of parents working less than full time.<br><br>It is essential and a human right that ALL children and young people should be supported to achieve their full potential in life and education, glucose control has a significant impact on this and we would recommend access to HCL for all children and young people, regardless of HbA1c. |
| 350 | Children and Young People's North East and North Cumbria Diabetes Network | committee-discussion | Evidence and generalisability | 3.3 | | This included children as well as adults (not just adults).<br><br>It is known that there is a higher proportion of children on pump therapy compared to adults. |

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| 352 | Children and Young People's North East and North Cumbria Diabetes Network | committee-discussion | Children | 3.5 | | Based on comments in point 3.1, HCL should be accessible for all children and young people. As a minimum, it should replace TA151 for young people over the age of 12, however this will discriminate on age for the less than 6 years who will be unable to access a licenced HCL with current NICE cgm guidance and under 12 years TA151 alone, if the app is not funded. |
| 354 | Children and Young People's North East and North Cumbria Diabetes Network | committee-discussion | Cost effectiveness for children | 3.11 | | The data presented shows that CYP has more benefits at a lower HbA1c than adults, making it cost-effective to have a lower HbA1c threshold.<br><br>a. The stronger evidence base for CYP has not been taken into account<br>b. CYP will have a longer time with diabetes than adults, therefore better control earlier, better metabolic memory will reduce life exposure risk and costs to society.<br>c. There are fewer CYP therefore the cost implication is capped. |
| 376 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | recommendations | 1 Recommendations | 1.5 | | We challenge the chosen HbA1c cut off, and recommend it is lowered for children. Even in individuals who achieve optimal HbA1c under 53mmol/mol in this study, a 2-fold risk in death from cardiovascular disease is seen, and this is most pronounced in those diagnosed with T1D under the age of 10 years. This translates to a 16-year reduced life expectancy in individuals with T1D (Rawshani Lancet 2018, Lind NEJM 2914). Further, the EDIC study demonstrated that early glycaemic control influences future long term diabetes complications, with lower levels of glycaemia in the first years at onset saving patient and health systems burden related to diabetes complications, this has been termed ‘’metabolic memory’’ (Steffes JAMA 2003, Lachin Diab Care 2021).<br><br>It is therefore essential that we maintain the good metabolic control from providing intensive management from diagnosis in children by facilitating access to HCL.<br>We recommend lowering the target of HbA1c use to 48 mmol/mol in children, who have the highest cardiovascular risks and risks of premature death over a lifetime, directly related to glycaemic load due to duration of diabetes. We also recommend that HbA1c cut offs align (and are reduced) for insulin pump therapy. |
| 381 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | committee-discussion | Evidence and generalisability | 3.3 | | This included children as well as adults (not just adults).<br><br>It is known that there is a higher proportion of children on pump therapy compared to adults. |

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| 383 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | committee-discussion | Children | 3.5 | | HCL should be accessible for all children and young people based on comments in 3.1<br><br>As a minimum it should replace the TA151 for >12years however this will discriminate on age for the <6yrs who will be unable to access a liscensed HCL with Nice CGM and under 12yrs TA151 alone if the app is not funded. |
| 388 | | | | | | All people with type1 diabetes should have access to hybrid closed loop. My daughter is 16, diagnosed since age 10. She has excellent hba1cs because we work really hard , looking as basal rates, calculating carbs, effects of exercise etc. why should only people with high hba1cs be eligible and not those teens who have 'good' hba1cs ? She shouldn't be denied access to latest technology just because she works hard at keeping her levels on target. It's mentally exhausting to live like this , and takes over her life . Surely having a closed loop would take some pressure off her mentally and allow her the freedom to live more like a normal teen?. It's just plain wrong to deny access to those who work hard with existing tech to keep levels 'normal'. I could use the Nightscout and looping community to create our own hybrid closed loop but why should I when the tech is out there that can be governed by NICE? |
| 407 | | | | | | Closed loop systems should be available to everyone with type 1 diabetes prioritising those struggling first. I am a parent of a child with type 1 diabetes and her HbA1c is very good. Though this paper acknowledges the struggles of people with type 1 diabetes, to not make this technology available, especially to all children, is not fair. It is especially difficult to manage type 1 diabetes in children because of the additional complications of puberty, growth, the additional pressures for teenagers, the struggles of parents to guide their children to be independent with the added complication of learning to manage their diabetes etc. A closed loop system would hugely benefit children and their families in such a difficult period. Any technology that can help everyone with type 1 diabetes and their families should be available to all. This condition is absolutely exhausting and relentless to live with and the closed loop system would transform lives beyond words. For parents it would greatly reduce the stress and worry we have for our children, and would have a profound impact on all our lives. I personally have not had a full night's sleep for over 3 years as I have to get up every night to deal with a different issue with my child's blood sugar. |

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| 414 | British Society For Paediatric Endocrinology and Diabetes | | | | | Despite acknowledging increased benefit for children, this is not reflected in the recommendations.<br><br>References to support recommendations<br>Kimbell B, Lawton J, Boughton C, Hovorka R, Rankin D. Parents' experiences of caring for a young child with type 1 diabetes: a systematic review and synthesis of qualitative evidence. BMC Pediatr. 2021 Apr 4;21(1):160. doi: 10.1186/s12887-021-02569-4. PMID: 33814007; PMCID: PMC8019496.<br>Lachin JM, Bebu I, Nathan DM; DCCT/EDIC Research Group. The Beneficial Effects of Earlier Versus Later Implementation of Intensive Therapy in Type 1 Diabetes. Diabetes Care. 2021 Aug 11;44(10):2225–30. doi: 10.2337/dc21-1331. Epub ahead of print. PMID: 34380706; PMCID: PMC8929189.<br>Lind M, Svensson AM, Kosiborod M, Gudbjörnsdottir S, Pivodic A, Wedel H, Dahlqvist S, Clements M, Rosengren A. Glycemic control and excess mortality in type 1 diabetes. N Engl J Med. 2014 Nov 20;371(21):1972-82. doi: 10.1056/NEJMoa1408214.<br>Ng SM, Wright NP, Yardley D, Campbell F, Randell T, Trevelyan N, Ghatak A, Hindmarsh PC. Real world use of hybrid-closed loop in children and young people with type 1 diabetes mellitus-a National Health Service pilot initiative in England. Diabet Med. 2023 Feb;40(2):e15015. doi: 10.1111/dme.15015. Epub 2022 Dec 4. PMID: 36424877.<br>Rawshani A, Sattar N, Franzen S, Rawshani A, Hattersley AT, Svensson AM, et al. Excess mortality and cardiovascular disease in young adults with type 1 diabetes in relation to age at onset: a nationwide, register-based cohort study. Lancet. 2018;392(10146):477-86.<br>Steffes MW, Chavers BM, Molitch ME, et al.; Writing Team for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Sustained effect of intensive treatment of type 1 diabetes mellitus on development and progression of diabetic nephropathy: the Epidemiology of Diabetes Interventions and Complications (EDIC) study. JAMA 2003;290:2159–2167 |
| 421 | British Society For Paediatric Endocrinology and Diabetes | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | Children under the age of 6-8 years consistently are not hypo aware, not all children in general |

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| 422 | British Society For Paediatric Endocrinology and Diabetes | committee-discussion | Evidence and generalisability | 3.3 | | This included children as well as adults (not just adults).<br>It is known that there is a higher proportion of children on pump therapy compared to adults. |
| 423 | British Society For Paediatric Endocrinology and Diabetes | committee-discussion | Baseline characteristics | 3.4 | | NHSE pilot – summary should also include paediatric data (Ng Diab Med 2023). Of note, the outcome of the paediatric NHSE pilot data identified a sustained improvement in glycaemic control, time in range and quality of life measures for fear, worry of hypoglycaemia and improved sleep in patients and carers after hybrid closed loop usage. |
| 424 | British Society For Paediatric Endocrinology and Diabetes | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | | It appears that modelling was done mostly on adult data. Children are exposed to longer duration of hyperglycaemia and the effect of glycaemia is expected to be magnified as is discussed later in the NICE documentation. For example, data identifying a 16-year reduced life expectancy seen in T1D, is greatest in those diagnosed under the age of 10 years (Rawshani Lancet 2018). |
| 425 | British Society For Paediatric Endocrinology and Diabetes | committee-discussion | Conclusion | 3.16 | | Despite acknowledging increased benefit for children, this is not reflected in the recommendations.<br><br>BSPED recommends in children, lowering HbA1c cut off from 64 to 48mmol/mol, as detailed above. |
| 432 | | | | | | This draft is not fair.<br>For years as parents to type1 child we don't sleep,we fight this serious condition 24/7 we can't work as no workplace offers flexibility to take time off for daily struggles<br>Thanks to our full commitment our child management is good but it's not perfect and the closed loop would be ideal with helping us all!to reduce risks in our childs life,to allow to lead somewhat normal life,to help with reducing the school absences due to diabetes,to get the weight off from the education system who does what it can to help keeping our child safe,to save the NHS millions in hospital admissions and the rest.<br>To help all families.<br>Hemoglobin is not everything.<br>It's the time in range what is important to everyone with diabetes and how it's achieved.<br>The only way of getting healthy a1c is to keep the levels from going to high or low. It's not easy on MDI,it's not easy on manual pumps it takes constant observation,djustments,corrections<br>Everything impacts the levels, hormones,food,exercise,seasonal illness,teeth growth,puberty,periods,stomach problems, thyroid problems,stress,sleep, the list goes on...it's 24/7 job adults loosing their jobs because of type 1., kids suffering because the education system does not understand and penolise or kids just can't learn like the other healthy ones because they levels aren't stable enough not mentioning the emotional |

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| | | | | | | impacts and again a vicious circle starts and everyone seeks help from NHS Type 1 Diabetes it's as serious as any other illnesses so why wouldn't you want to help people to live their lives?to help children growing to responsible adults.<br>What I've observed in our diabetes journey is that many parents deciding to home school they children because they aren't supported at schools and it's the only way of keeping their children safe and healthy.<br>This draft isn't good enough!you might see how much this might cost NHS but don't see the full benefits of how hugely this would change life's not just to keep someone alive for longer, this would help as mentioned before to lead a normal life to study to work to pay back to society. |
| 440 | | recommendations | 1 Recommendations | 1.5 | Clinical trial and real-world evidence shows that hybrid closed loop systems are more effective than standard care at maintaining blood glucose levels within a healthy range. | ...so all people with type 1 diabetes should be entitled to them. With children in particular, this will make their lives a lot easier in terms of exercise, sleep and stress levels. |

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| 443 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | A parent of a child with diabetes said that the mental burden significantly affected their quality of life. They highlighted that children are less able to recognise the symptoms of hypoglycaemia and hyperglycaemia, and this is a constant worry for parents when they are apart from their children. | Completely agree with this. It totally affects family life. I haven't been out with my husband since my daughter was diagnosed as we don't feel able to leave her with people who aren't trained to act when her alarms go off. If there was a device to help with dose adjustments, there would be a lot fewer alarms. My daughter would have more freedom and feel less unusual. It would help with things like PE lessons where she often has to eat sugar just so she can do some running around. |
| 445 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | It further concluded that automated technologies such as hybrid closed loop (HCL) systems can reduce some of the burden, and improve quality of life for people, their families and carers. | It would give my daughter more independence. She is self-conscious about her diabetes and this would help her feel as though she fits in with her friends more. |

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| 449 | | committee-discussion | Children | 3.5 | Data was not presented on age groups specified in the NICE scope for HCL in type 1 diabetes (that is, 5 years and below, 6 to 11 years and 12 to 19 years). | Why does the NICE guidance have this split? Teenagers have just as much reason to have a pump. Teenagers do not want to go out with friends and have to inject themselves all the time. Why is it easier for under-12s to get a pump? |
| 463 | Children & Young People's Diabetes Team, Somerset Foundation Trust | committee-discussion | Cost effectiveness for children | 3.11 | | HCL devices were likely more cost-effective in children than in adults despite uncertainties in the modelling and a lower initial average HbA1c in the NHSE pilot. Unclear to us therefore why the HbA1c cutoff of 64 mmol/mol has been applied to children. |
| 490 | | | | | | I welcome having a NICE guideline on these new treatment options.<br><br>However, with regards to children and young people it comes to the wrong conclusions in paragraph 1.1 despite stating significant differences between children and adults in terms of benefits and cost effectiveness under 2.<br>It should have recognised the benefits not only for the child but also for the parents and the special situation within education settings.<br>Therefore, I recommend that the HBA1c limit does not apply to children and young people under 18 years.<br><br>I agree with the paragraphs 1.2-1.5 as they help us to get patients and families to attend to mandatory training sessions.<br><br>I wish there were recommendation made to include the problem of inequality to access to these new technologies, i.e. young children would not normally have a mobile phone that can be used but parents would have to buy these devices. Therefore, children of families who are unable to buy a phone will be excluded, further increasing inequality of access to these therapies. |

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| 508 | | committee-discussion | Cost effectiveness for children | 3.11 | The committee concluded that although there was some uncertainty, HCL systems are likely to be more cost effective for children than adults. | Add something to confirm that children started on HCL should be supported to continue under adult care or we will get adult clinics taking them off after transition. Mark my words! |
| 515 | DigiBete | | | | | DigiBete employees with lived experience in Partnership with Leeds Children's Hospital are responding to the NICE Consultation on:<br>Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes<br><br>We would like to thank the NICE committee for the opportunity to respond to the NICE consultation on hybrid closed loop systems for managing blood glucose levels in type 1 diabetes. DigiBete is a not for profit (CIC) who are commissioned by the NHS. DigiBete is a community led yet clinically approved platform for children, young people and their families living with diabetes. All our work is clinically approved by the paediatric diabetes team at the Leeds Children's Hospital and they have also added some of their views to this response<br><br>A comment from the Leeds team as follows:<br>As lead children's diabetes nurse working within a large diabetes team, we aim to support children and young people with T1 diabetes and their families to manage their diabetes aiming for a target HbA1c of 48mmol/l or below. This is to help prevent long term complications associated with diabetes.<br><br>The use of Hybrid Closed Loop (HCL) technology can help to achieve this and improve quality of life. Use of HCL technology helps to reduce some of the huge amount of work needed to manage diabetes well. Therefore, HCL technology should be available as a treatment option for all children and young people with type 1 diabetes to support their care.<br><br>At DigiBete, many of us are parents to children who range in different ages and have type 1 diabetes. We are all using different systems to manage diabetes. As a result, we would like to respond to this consultation in a joint capacity and share our individual lived experiences.<br><br>The answers to each of the questions are listed below.<br>1. Has all of the relevant evidence been taken into account? |

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| | | | | | | In the consultation it states that hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1C of around 64 mmol/mol (8.0%) or more.<br><br>We strongly feel as a group that this threshold of 64 mmol/ mol is far too high and leaves out a lot of families who work tirelessly to keep numbers close to the 48 mmol/ mol range, despite the impact on their own wellbeing. What is not accounted for is the work that goes on in the background. As one of our families states they can keep the range between 48 mmol and 50 mmol over a three-month period as their daughter is on a pump and a glucose monitor. However, there are regular interventions that are needed to keep it in this range on a daily and quite often on a two hourly basis. The parents need to put on temporary basals most evenings to either reduce the insulin due to the nighttime hypoglycaemia (hypos) episodes and on other nights are having to adjust the pump to a temporary basal to increase the insulin overnight so that the hyperglycaemia (hyper) episodes come back down to a normal range. This often results in a 'yo-yo night' of balancing between high and low. No two nights are the same, so this is constantly being assessed. There are calculations and judgments to be made on basal rates for those on a pump and it is a huge mental load for parents / caregivers who need to do this on a 24-hour basis.<br><br>We feel as parents that having access to hybrid closed loop systems can take away some of this burden and help to alleviate that caregiver burnout that we have each experienced. Keeping numbers at this level is an important task for the future health of our children however it is exhausting and impacts on our daily lives and concentration at work. Many of us have had to give up and / or change our jobs due to the huge lifestyle change type 1 diabetes has on families. There is also the concern that this yo-yo effect is difficult on children and their ability to concentrate at school.<br>We would like the committee to reconsider this threshold so that more families can have access to this life changing technology and have a better quality of life. We do not want to be penalised for having good numbers by being denied access to the technology that can improve quality of life and prevent future complications including challenges with mental health for both children and their parents.<br><br>We completely agree with the following statement that is in the recommendations and understand that some input will still be required however there is a reduction in mental load and we feel that many families would benefit from this:<br>"The systems do not need as much input from the person but manual insulin |

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| | | | | | | dosing is still needed sometimes, for example, around mealtimes. So, they may reduce the mental load and improve people's quality of life."<br><br>For those with young children on the DigiBete team it is also important / imperative that the monitoring and managing of type 1 diabetes at school continues to keep in range. By having access to hybrid closed loop this reduces the burden and anxiety on caregivers who need to hand over the responsibility to teachers in the week. Some parents on the team also feel that the hybrid closed loop can give unforeseen benefits and opportunities for their child. Things such as more flexibility, less intervention from teachers constantly having to scan their child's CGM throughout lessons. As well as having slightly easier access to school trips which will hopefully give children with type 1 diabetes more confidence and a better quality of life.<br><br>Some parents on the team are already on the hybrid closed loop system and they say that using a hybrid closed loop system is invaluable as it keeps their son safe throughout the day and night.<br><br>Our son has been fortunate to have access to a hybrid closed loop system for three years full time following some previous periods on clinical trials. On hybrid closed loop his HbA1c is consistently kept in the low 40's and this will prevent future complications which would impact his quality of life and be potentially very costly to the NHS. Our Son was diagnosed as a baby aged just 20 months, and living without closed loop technology to begin with was incredibly challenging. His insulin and glucose sensitivity was so great that his blood glucose levels constantly yo-yoed up and down but despite this, we as parents, wanting so hard to keep him in good range for his future health, would stay up night and day checking every 2 hours. This resulted quickly in improvements in his HbA1c but we were exhausted. Our families struggled to see us as we were so 'obsessed by his numbers' and we struggled to access basic social situations like soft play as his blood glucose levels would go low so quickly without very close monitoring. At around 4 years old we were able to access a hybrid closed loop system full time and our lives have changed immeasurably. When he was diagnosed we were told that sadly diabetes never sleeps. It was up to us, but night checks were advisable. However, with the hybrid closed loop system this has all changed. We still monitor at night via the alarms but we are able to trust the system to cut out the Insulin when he is going low, and our night time graphs are so flat it's wonderful and is such a relief to see and be able to sleep. This also has impacted our young son's mood and readiness to learn at school too.<br><br>Before closed loop, he needed to stay back a year as he was often tired and sensitive. Now his zest for reading and learning is infectious and diabetes has become a small and manageable part of his life. If 64 mmol/mol had |

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| | | | | | | been the threshold we would still be doing all we could to keep him keep his numbers in range but might have struggled to both work and our son would have struggled more at school with potential mental health impacts in the future. Finally, in our son's class, there is another little girl with type 1 diabetes but she doesn't have a closed loop system. However she does have an HbA1c of 58 mmol/mol because her mum works so hard. School struggles with all the extra decisions they need to make and her mum has had to give up work to cope. We therefore hope that the threshold of 64 mmol/mol be reviewed for the sake of the children and their carers who work tirelessly to manage type 1 diabetes throughout the day and night.<br><br>Another view from parents whose child was diagnosed at age 10 and has had type 1 diabetes for the last 10 years is that although, through intense daily management and use of an insulin pump and cgm (which currently cannot be used for closed loop), they manage to keep HbA1c within the recommended targets, there is still a negative impact in quality of life right now due to the burden of the constant management and decision making. The negative impact of high and low blood glucose levels on concentration and motivation and general wellbeing is always there.<br><br>Our daughter is almost 20 and is at university, a difficult transition time for lots of young people, learning to become independent, learning life skills, perhaps embarking on personal relationships, getting used to living away from home, seeing a new diabetes team (which in itself can cause them to fall through the gaps due to everything else that they have going on).<br><br>It doesn't seem fair to work so hard every day at managing type 1 diabetes and all the decisions that go with it, on everything they do, and be denied access to this life changing technology that would likely reduce the burden (the right now impact on quality of life) of living and managing type 1 diabetes.<br>We therefore feel the daily burden of managing Type 1 and the impact on mental health needs to be considered as important as the HbA1c threshold.<br><br>2. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?<br>[no comment]<br><br>3. Are the recommendations sound and a suitable basis for guidance to the NHS?<br>[no comment]<br><br>4. Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group |

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| | | | | | | of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?<br><br>Inequalities and access to technology - One of the parents on our team commented that when their young child was diagnosed at 2 years old in 2018 access to technology was difficult. They are unsure if this was due to the location of where they were diagnosed, however CGM's weren't funded so they had to self-fund a CGM in the initial days. The funding has now changed, and the family have access to a pump and CGM however they think it's very important for families across the country, particularly with young children, to have access to the latest technology from the start of diagnosis regardless of numbers as injections are not refined enough for very young children and to get access to hybrid closed loop straight away is key. The waiting and applying for tech can be very frustrating and overwhelming particularly when you are first diagnosed so having instant access to tech and training of this tech should be a high priority that can save a lot of mental health issues for the family in the long run and it can give the child and family a good start on their type 1 diabetes journey which is imperative to avoid long term health conditions in the future that could also impact the NHS.<br><br>In conclusion we would like to reiterate that we hope that the threshold of 64 mmol/mol be reviewed for the sake of the children and their carers who work tirelessly to manage type 1 diabetes throughout the day and night.<br><br>Yours Sincerely,<br><br>[redacted] |

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| 525 | | recommendations | 1 Recommendations | 1.2 | | Providing HCL to adult pregnant women with no restrictions on HbA1c but not providing the same to children, despite the evidence cited by the Committee papers for the HbA1c improvement in children and the acknowledged 'lack of evidence' for the improvements in adult pregnant women (see 3.6 of the Consultation), is a potential contravention of s. 19 (1) and (2) of the Equality Act 2010.<br><br>Age is a protected characteristic under the Act. Section 19 effectively says that a clinician would be discriminating against a child if he/she would carry out the practice of providing HCL for an adult but not for a child and that child is disadvantaged as a result, if the clinician cannot show that depriving the child of HCL access is proportionate.<br><br>Given the lack of evidence acknowledged in the Committee papers relating to the benefits of HCL for adult pregnant women, it is difficult to justify that it is proportionate to provide them with HCL regardless of their HbA1c figure and deprive those who are under 18, for whom there is significant evidence of benefit in the Committee papers. |
| 526 | | committee-discussion | Children | 3.5 | | See comments in Recommendation section 1.2 above re Equality Act 2010. |
| 527 | | committee-discussion | Pregnancy | 3.6 | | See comments in Recommendations section 1.2 above re Equality Act 2010 and children.<br><br>In this section, adult pregnant women are stated to be given access to HCL because "blood glucose control is harder to maintain" and yet no evidence is cited for how this is "harder" to maintain than, for example, an adolescent going through a growth spurt or puberty.<br><br>The paragraph implies that there is the least evidence of the effectiveness of HCL systems in pregnancy of any cohort, yet they are the only group not to have the HbA1c 8.0% criterion.<br><br>On this basis the 8.0% should be removed for other groups (or at least for children on the basis of the age group protected characteristic) and the standard of 6.5% set out in the Committee papers (page 3) as the standard for 'difficulty' in managing diabetes should be adopted for all groups. |
| 530 | | committee-discussion | Cost effectiveness for children | 3.11 | | Given the statement that HCL systems are likely to be more cost effective for children than for adults and it is stated in the Consultation that only '29,000' of the '400,000' people with type 1 in the UK are children, and given the Equality Act point stated in relation to section 1.2 above, the 8.0% restriction for children does not seem proportionate. |

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| 536 | | | | | | I feel deeply disappointed that it is felt appropriate that people with a level of 64 or above should be considered for a closed loop pump. It should be available for all type 1 people and if a choice had to be made my view is ALL type 1 children should be the priority. It is hard for adults to deal with type 1 should it occur, however they are adults and in the majority can be responsible and look after themselves. Children on the other hand cannot, they rely on a multitude of adults for help in their care, from parents, grandparents, teachers, one to ones at school, respite carers and the list continues- surely the cost of the closed loop should be considered against the cost of additional support required for a child as this would no longer be required and the child will become independent. My grandson was diagnosed at 2, he is now 10. The past 8 years his parents have worked tirelessly to keep his levels as close to 48 as they can, this includes taking alternative nights to check him every 2 hours and deal with the hypo or hyper relentlessy. The days are monitored closely by themselves and his one to one when at school. They are exhausted and the knock on effect for all the family is immense. This is one family of thousands living this nightmare, the closed loop is the closest thing to a replacement pancreas that we may ever see. I urge you to revisit the recommendation and either amend the criteria or abolish the paper completely. |
| 540 | | | | | | section 3.1 - it cannot be underestimated how much a diagnosis affects the family. With young children you worry about 'dead in bed' and nightly checks are common for many parents. With teens, nighttime is also the greatest worry, as they may conceal food, have exam stress and puberty affects levels enormously. Huge concerns that sick bolus's remain on after sickness leading to overdoses. Very hard to balance safety/control over growing independence. This closed loop system is the unintrusive guardian angel. |
| 562 | | | | | | I am disgusted that all children are not eligible! Children are impacted massively from a mental health perspective when they have type 1 diabetes! You know this! Their stress levels and anxiety is by far higher that that if a child without type 1! And their parents they never stop stressing! Never! So when there is a light at the end of the tunnel that gets blocked it is just cruel! Clearly this decision is based on cost over quality of life! That disgusts me! Too much money is wasted on non value add people! We need fair access to treatments that improve quality of life, more nurses in general but specialist nurses and we need our NHS working to do what it set out to do! That was to make sure everyone had fair access to medical support and help. This decision does not fit that description does it! |

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| 580 | | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | | Para 3.7 - this does not consider the length of life left to live increasing the potential of long term complications e.g. a young child will have longer time with T1D which would increase the risk of long-term complication. Therefore age should also be a factor. Reducing risk of long-term complications will be of benefit to all parties including NHS. |
| 612 | | dap55-diabetes-mta-acd-final-no-acicdocx | | | | This is a collated response from the leads of the CYP diabetes team at University College London Hospital. We are one of the largest diabetes teams in the country.<br>We do not feel there has been appropriate analysis of paediatric data to support this document. We understand that our concerns about paed data are not limited to this guideline but reflect the tools that NICE use for measuring QALY gain across paediatric data.<br>There needs to be evaluation of the gains of HCL systems specifically within a paediatric population, taking into consideration the economic impact in terms of parent's ability to work; duration of diabetes will be greater if diagnosed in childhood; diabetes burden to the whole family; impact on education and education attainment.<br>We would like to see this guideline reflect previous TA151 recommendations, namely that all CYP under the age of 12years should be offered HCL systems given the additional unique difficulties in managing diabetes in this age group.<br>Using HbA1c alone as a decision-making tool, discriminates against those achieving a lower HbA1c with high diabetes burden. |
| 619 | | information-about-hybrid-closed-loop-systems | The interventions | 2.6 | | An important criteria for children using these devices is real time transmitting of blood glucose and insulin pump values to a parent. The anxiety of parents of T1D children is often overlooked. |
| 623 | | | | | | It has become clear as I have read these consultation documents on HCL technology that insufficient weight is being given to specific groups, other than pregnant women, and their needs for early access to this new technology. In particular, children and adolescents, who should be given the earliest possible unrestricted access to HCL technology to help support them and their families as they cope with the terrible ups and downs of this chronic, life threatening and life shortening disease. Pregnant women no doubt need the earliest access possible, but so do children and adolescents. There are four areas where I think the case being made by the consultation document should consider children and adolescents as much as pregnant women:<br><br>1. The consultation document seems to make the cost-benefit analysis clear |

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| | | | | | | that there is more evidence of children/adolescents gaining a greater benefit from HCL than any other group, and therefore in terms of gaining the greatest impact for the early investment in technology, HCL technology should be made available to children/adolescents and their families as soon as possible on an unrestricted basis. Furthermore, given that there are only 29,000 young people in this group (i.e. children and adolescents with type 1), rolling this technology out to them would transform the prospects of a relatively small, but very needy subset of the overall type 1 population.<br><br>2. The document maintains that offering unrestricted access to HCL for pregnant women is justified by the claim that control of blood glucose levels is harder to maintain. But the question remains as to 'harder' than what? Is it really harder than maintaining those levels in a sensitive adolescent in the middle of a puberty fuelled growth spurt, for example? The document does not really offer any control group comparisons here to justify this claim and thereby excludes children and adolescents at this stage and on this basis without making the case.<br><br>3. The legal problem raised by the Equality Act (2010) is also inadequately addressed, if at all. Section 19 (1) (2) creates protected characteristics of which age groups are one. To exclude children/adolescents from early access to HCL technology amounts to a form of age group discrimination in comparison to the unrestricted access being given to pregnant women. This is not to say that pregnant women should not be given unrestricted access, but they are not the only group who should, particularly if the evidence that it is harder for them to maintain blood glucose levels is not proven, and the cost benefit analysis favours children/adolescents even more.<br><br>4. Finally, the documentation seems to be inconsistent in defining difficulty in the management of type 1 diabetes and this is important because this is the basic gateway qualification for a patient to access HCL. The papers on page 3 describe difficulty in terms of not being able to consistently maintain HbA1c levels below 6.5%, as opposed to the consultation only giving access to those who are having difficulty and have an HbA1c of 8% or more. This anomaly needs to be clarified and/or removed as any basis on which children/adolescents are excluded from early and unrestricted access to HCL. |
| 633 | | recommendations | 1 Recommendations | 1.1 | | Consider HCL as first line for young children especially from diagnosis. Small incremental doses/erratic eating patterns etc make MDI impractical for this age group. |

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| 635 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | What can be recommended for those CYP who are over 12yrs, not achieving target Hba1c levels nor have a HbA1c <64mmol? This group is vulnerable to further deterioration and account for a large proportion of our caseload. Are we again needing them to have a deteriorating Hba1c, with the psychological/physical implications this brings, to be eligible for pump therapy? |
| 646 | | recommendations | 1 Recommendations | 1.5 | | This is reassuring to hear. As a mother of a teen with T1D, who is suffering burnout after 10 years of trying to manage this condition, the risk of having his pump and CGM withdrawn would be very cruel and add to his already fragile mental health. |
| 680 | | recommendations | 1 Recommendations | 1.1 | who are having difficulty managing their condition | I am a parent of a child who was accepted on the closed loop trial in the first 24 hours of my son's T1 diagnosis in 2017. He was two weeks away from his 13th birthday. He was randomised but ended up on the pump. We cannot speak highly enough of this system and we know we are one of the lucky ones. This system must be given to all children with T1.<br><br>It has reduced the mental strain of managing my son's condition, for both him and us as parents. we can't even begin to describe the impact including reducing the strain of managing a condition at the time of his GCSE and A level exams. He is now 18 and at university.<br><br>It has kept him healthy and particularly the background insulin in the evening and at night time is an absolute godsend to him and us. Our sleep patterns are rarely disrupted as a family.<br><br>The recommendation that the system is adopted for those with poor control seems to reward bad control, although bad control of blood sugar isn't necessarily in the power of the individual for example those with learning disabilities.<br><br>By creating universal access this system will encourage positive behaviours from an earlier age and reduce the amount of complications which will be more costly on the NHS budget which can range from multiple conditions including eyes, circulation, renal problems.<br><br>There should be universal access for children diagnosed with T1 as this will encourage lifelong behaviour change and reduce later life costs on the NHS and on the UK economy in terms of lost adult working effectiveness. There is a duty to reduce health inequalities and in those communities suffering from multiple deprivation, lack of education, awareness or understanding will contribute to poor type1 diabetes management. |

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| | | | | | | The mental strain of managing type1 diabetes at the same time as there are corresponding shortfalls in mental health provision for young people means that almost seamless type1 management through the closed loop system means there will be a corresponding reduction in the mental strain both on users and their families and carers.<br><br>'Only to be used where there are multidisciplinary teams available' - this will see an increase in the number of patients, service managers in diabetes teams should ensure that training includes pumps. At Nottingham University Hospitals, there is one pump nurse for adult services who works two days as week and covers 30 patients. Even though that Trust has at least a dozen children on the closed loop trial, possibly more, though the paediatric team, but that one adult nurse professed to 'know nothing' about the system.<br><br>The number of patients with pumps will substantially increase. NHS diabetes teams need to be trained and given the resources to manage this number of patients. This is just one localised example which will be replicated across England.<br><br>From previous work in the NHS the last figure I saw was that one person in the most expensive part of the system (acute, including ED) will cost the taxpayer £2,500 per day. The costs of this system will pay for itself back to the UK taxpayer though reduced A&E attendance and acute admission. And it is not simply the economic impact on the individual, I had a member of staff who's daughter suffered from 'denial' who was constantly being admitted to A&E through bad control, which resulted in my member of staff losing day and days of work. |

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| 683 | | | | | | I am the mother of a 17 year old with T1D, my son was diagnosed in October 2020 at the age of 15 years old when he was rushed to hospital in severe DKA. Fortunately due to an amazing medical team at our local hospital he made a full recover. This is where our T1D journey began. I had no idea of the mental and physical exhaustion that a type 1 diagnosis would bring, the condition requires 24/7/365 micromanagement and is simply relentless. So when I found out about hybrid closed loop I hoped this would bring some respite for my son and myself, we might actually get a good night's sleep and not have to think about T1D every minute of the day and night.<br><br>After reading the document I assessed that in its current form my son would not qualify for hybrid closed loop as we have done "too good" a job at managing his condition and so he would be penalised by the current criteria in the draft recommendations of January 2023.<br><br>My son's HbA1c is currently below 48mmol but this has only been achieved by micromanaging his blood glucose levels 24 hours a day, 7 days a week and 365 days a year. We manually respond to alarms and trends from his Dexcom G6 CGM to maximise his time in range of the NICE recommended levels which are a glucose range of (3.9 to 10 mmol/litre). In short we are manually doing what a hybrid closed loop would do automatically. For instance, to counteract high blood sugars overnight last night I corrected him with this Omnipod pump 4 times, so as you can imagine I feel exhausted today, this is not unusual. Can you imagine being woken up almost every night to an alarm and having to respond to it? Knowing you rarely get a full night's uninterrupted sleep is soul destroying. Hybrid closed loop would greatly reduce this happening.<br><br>My son will to take over this burden when he goes to university next September and I know he will not be able to manage this in the same way, I am currently handing over the management of his diabetes and he is already showing signs of diabetic burnout, the sheer exhaustion both physically and mentally is overwhelming and he will not be able to achieve the same HbA1c number he has at home.<br><br>As a young man at the start of his life this greatly concerns me, he will have T1D for his entire life, knowing he has this disease forever is simply overwhelming and knowing that he needs to constantly maintain good control 24/7/365 to stay healthy is difficult to comprehend.<br>I find it almost impossible to put into words the mental and physical burden that a T1D diagnosis has on an individual and their family, until you have walked in those shoes you would not understand. I implore you to reconsider the criteria of these guidelines to include all those diagnosed with T1D. |

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| | | | | | | The cost of treating patients who have been unable to keep good control is significant, the mental health cost of those who do achieve good control is also significant and I feel this has been overlooked in these recommendations and they should be reconsidered and all T1D patients should have access to hybrid closed loop if they want it.<br><br>Thank you for taking the time to read our story, I hope you will reconsider the criteria for hybrid closed loop. |
| 689 | UK Association of Children's Diabetes Clinicians (ACDC) | | | | | Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes<br>NICE guideline consultation- feedback template<br>Name: [redacted] Association of Children's Diabetes Clinicians (ACDC)<br>Unit: UK Association of Children's Diabetes Clinicians<br><br>Document section Your comments<br>1. Recommendations<br>1.1 HbA1c cut off above 8.0%, and who have tried pump therapy This is not compatible with current NICE recommendations for pump therapy or CGM NG18, ACDC feels very strongly that there should be no criteria set and that HbA1c should not be a criteria in which to offer closed loops in 0-18yos<br>1.2<br>1.3<br>1.4<br>1.5<br>Why the committee made these recommendations In individuals who achieve optimal HbA1c under 6.9% (<53mmol/mol), a 2-fold risk in death from cardiovascular disease is seen, and this is most pronounced in those diagnosed with T1D under the age of 10 years. This translates to a 16-year reduced life expectancy in individuals with T1D (Rawshani Lancet 2018, Lind NEJM 2914). Further, the EDIC study demonstrated that early glycaemic control influences future long term diabetes complications, with lower levels of glycaemia in the first years at onset saving patient and health systems burden related to diabetes complications, this has been termed ''metabolic |

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| | | | | | | memory'' (Steffes JAMA 2003, Lachin Diab Care 2021).<br>We recommend all 0-18yo be offered closed loop based on clear evidence frm the NHSE close loop trial data<br>2. Information about Hybrid Closed Loop Systems<br>2.1 "If type 1 diabetes is not well controlled…"<br>2.2<br>2.3<br>2.4<br>2.5<br>2.<br>2.7<br>2.8<br>2.9<br>3. Committee discussion<br>3.1 age of hypoglycaemia awareness Children under the age of <8 years are consistently are not hypo aware, not all children in general<br>3.2<br>3.3 NHSE pilot This included children as well as adults (not just adults). Please separate the results of the chidlren's NHSE closed loop trial outcomes<br>It is known that there is a higher proportion of children on pump therapy compared to adults.<br>3.4 NHSE pilot – summary should be specific that the outcomes for the paediatric data shows improvemeents in HBA1c, reductions in hypoglaycamei, improvemenet in QOL sucha s fear of hypos and sleep, and also for carers<br>3.5<br>3.6<br>3.7 the model The modelling was done on adult data. Children are exposed to longer duration of hyperglycaemia and effect expected to be magnified as is discussed later in the NICE documentation.<br>3.8<br>3.9<br>3.10<br>3.11<br>3.12<br>3.13<br>3.14<br>3.15<br>3.16 recommendations for use Despite acknowledging increased benefit for children, this is not reflected in the recommendations. ACDC feels extremely strongly that closed loops should be recommended for children 0-18 years and there should not be any HBA1c criteria set<br>4. Implementation |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| | | | | | | 4.1<br>4.2<br>4.3<br>5. Committee members & NICE project team<br>Comments on document as a whole:<br>Comments on any of the supporting documents (please say which)<br><br>References to support recommendations<br>Rawshani A, Sattar N, Franzen S, Rawshani A, Hattersley AT, Svensson AM, et al. Excess mortality and cardiovascular disease in young adults with type 1 diabetes in relation to age at onset: a nationwide, register-based cohort study. Lancet. 2018;392(10146):477-86.<br><br>Lind M, Svensson AM, Kosiborod M, Gudbjörnsdottir S, Pivodic A, Wedel H, Dahlqvist S, Clements M, Rosengren A. Glycemic control and excess mortality in type 1 diabetes. N Engl J Med. 2014 Nov 20;371(21):1972-82. doi: 10.1056/NEJMoa1408214.<br>Steffes MW, Chavers BM, Molitch ME, et al.; Writing Team for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Sustained effect of intensive treatment of type 1 diabetes mellitus on development and progression of diabetic nephropathy: the Epidemiology of Diabetes Interventions and Complications (EDIC) study. JAMA 2003;290:2159–2167<br>Lachin JM, Bebu I, Nathan DM; DCCT/EDIC Research Group. The Beneficial Effects of Earlier Versus Later Implementation of Intensive Therapy in Type 1 Diabetes. Diabetes Care. 2021 Aug 11;44(10):2225–30. doi: 10.2337/dc21-1331. Epub ahead of print. PMID: 34380706; PMCID: PMC8929189. |
| 690 | | | | | | The recommendation only takes into account those with higher than recommended blood sugars. My son is a little below the threshold for the following reasons<br>- 24 hour a day micro management by parents and specialist nurses<br>- he has a lot of lows despite above micromanagement - including on average 3 a night, requiring a minimum 20 minutes care each time<br>The impact of this level of care and sleep deprivation affects so much:<br>- his school performance and attendance - he feels dreadful many times a day<br>- his ability to participate in sports, social activities and lessons<br>- his parents performance at work and mental health (I'm relying strongly on a private psychologist)<br>- the amount of time parents have to pay attention/care for the other 3 kids<br><br>The closed loop would have an incredible affect on the whole family and we are heartbroken to think that no help is coming. |

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| 691 | | | | | | The recommendation only takes into account those with higher than recommended blood sugars. My son is a little below the threshold for the following reasons<br>- 24 hour a day micro management by parents and specialist nurses<br>- he has a lot of lows despite above micromanagement - including on average 3 a night, requiring a minimum 20 minutes care each time<br>The impact of this level of care and sleep deprivation affects so much:<br>- his school performance and attendance - he feels dreadful many times a day<br>- his ability to participate in sports, social activities and lessons<br>- his parents performance at work and mental health (I'm relying strongly on a private psychologist)<br>- the amount of time parents have to pay attention/care for the other 3 kids<br><br>The closed loop would have an incredible affect on the whole family and we are heartbroken to think that no help is coming. |
| 694 | | information-about-hybrid-closed-loop-systems | The interventions | 2.6 | | My daughter 8s against having a tubed pump and she is waiting for omnipod 5, I just hope that in time she would also be funded the dexcom so it can be integrated. She has been waiting for this for years, asmany others have. It is a far cry from forcing her to inject especially her long acting insulin. It would be nice to have a mother daughter relationship back. Rather than her getting frustrated at ne asking if she's scanner her libre. That was the beauty of dexcom, it gave me the numbers so I could do what I needed to do without bothering her too much all the time. |
| 704 | | recommendations | 1 Recommendations | 1.1 | | I would like to see this widened to all children and adolescents with type 1 diabetes.<br><br>An area of evidence that I haven't seen within the committee papers is that which discusses the effect of lower Hba1C values in children having longer term benefits in reducing complications. Two such papers are included below. Giving young people access to hybrid closed loop would enable lower long term glucose levels and benefit the NHS in terms of longer term complications.<br><br>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4662600/<br><br>https://pubmed.ncbi.nlm.nih.gov/30932298/<br><br>Finally, as this paper outlines, children and young people struggle with meeting NICE guidelines for target glucose levels with existing therapies, so providing access for all to hybrid closed loop therapy would be a step in the right direction.<br><br>https://diabetesonthenet.com/wp-content/uploads/jdn20-6-213-7-1.pdf |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 708 | | committee-discussion | Evidence and generalisability | 3.3 | A clinical expert said that most people using CSII in their clinics were adults. | It's unclear why this has been highlighted in the text, given that across the NHS in general, access to CSII is much more difficult for adults than for children, and National Diabetes Pump Audit data (last done in 2017/2018) suggests that a significantly greater proportion of children use pumps compared to adults. https://www.diabetes.org.uk/resources-s3/2019-09/Insulin_%20Summary_2019_v3.pdf |
| 712 | | | | | | I have four main comments on this consultation regarding the requirement for groups other than pregnant women needing to have an HbA1c result of around 8.0% in order to qualify for access to Hybrid Closed Loop (HCL) technology:<br>• It discriminates against a child with type 1 diabetes when compared with an adult pregnant woman (Equality Act, 2010 section 19 (1) (2) - protected characteristic: Age group)<br>• It has conflicting views of the definition of 'difficulty' in managing diabetes, which is what qualifies a patient for access to HCL. The committee papers (page 3) say 'difficulty' is 'not maintaining HbA1c levels of 6.5% or below', but the consultation only gives access to those who are having 'difficulty' and have an HbA1c of 'around 8.0% or more'<br>• It states that adult pregnant women should have unrestricted access to HCL because their 'blood glucose control is harder to maintain' (section 3.6) but does not cite evidence or a comparator, such as against an adolescent in a growth spurt, for example<br>• According to the consultation, there is more evidence of the benefit of HCL for children than for pregnant women (section 3.5/3.6), but access is unrestricted for pregnant women and limited to HbA1c over 8.0% for children, despite there being only 29,000 children in the UK with type 1 (section 2.1). |
| 714 | | | | | | Type 1 children and their parents work tirelessly night and day, we are up in the night often because diabetes has a mind of its own, no 2 days are the same, most of us are exhausted and struggle to function daily. The closed loop system will do a small part of our job for us which will have a huge impact on the children with type 1 and their carers. We were so looking forward to getting the omni pod 5 it would be life changing. My sons HbA1c was 43 at his last appt so way off being entitled but this is through dammed hard work from him, being so disciplined, missing out and being so different to his mates. Please please re consider these type 1 kids deserve it, they are exhausted, they work so hard, this would truly be a blessing.<br>I think what will happen is that many will put them selves at risk by not keeping themselves in range, HbA1c rises and they think they'll get get it |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 723 | | | | | | I am a parent of a child with type 1. My partner and I both now work part time and now home Ed to try and manage his diabetes. We would not yet qualify for this yet we work so hard and mentally it is very distressing and tiring trying to keep him in range. We feel penalised for giving more than 100 percent effort to keep him well. Our own lives are on hold. We don't get a full night sleep. We feel for his health and for ours, that everyone with type 1 should be allowed this. |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 738 | | committee-discussion | Children | 3.5 | The EAG's subgroup analyses showed that in the RCT children and young adults (under 18 years) subgroup, the change in HbA1c for HCL systems was greater (-0.31 percentage points, 95% CI -0.43 to -0.20) than the adult subgroup (-0.24 percentage points, 95% CI -0.32 to -0.15). The NHSE children and young people pilot had a lower baseline HbA1c of around 62 mmol/mol (7.9%) compared with the adult pilot study. The decrease in HbA1c after using HCL systems was also lower than the adult pilot, at 7 mmol/mol (-0.7 percentage points) after using HCL systems for 6 months. Data was not presented on age groups specified in the NICE scope for HCL in type 1 diabetes (that is, 5 years and below, 6 to 11 years and 12 to 19 years). A clinical expert explained that in the NHSE children and young people pilot, child age subgroups were not reported because of the low numbers of children in certain age groups that were using devices. | Why weren't more children offered these HCL devices in the study group so we could see the benefits which could guide the cost benefit analysis for children. This is especially pertinent given the reported increase in Diabetes T1 in children and the difficulty most parents have in getting their children to recognise and respond to hyper/hypo glycaemia events. |

## THEME: EDITORIAL

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
|---|---|---|---|---|---|---|
| 66 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.1 | If type 1 diabetes is not well controlled, | This needs defining as to 'not well controlled'; even with optimal control (under 6.9%) there is a 2-fold higher cardiovascular risk, as discussed above. |
| 67 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | 3 | should read over preceding 8-12 weeks |
| 75 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | committee-discussion | Pregnancy | 3.6 | overall population | This should read “general adult population” – evidence shows HCL more effective in paeds than adults |
| 220 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.1 | | Should also include Chronic Kidney Disease (CKD) and Stress |
| 221 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | | Clarification required: -<br>Multiple Daily Injection (MDI)<br>continuous subcutaneous insulin infusion (CSII) - Pump Therapy<br>(capillary blood testing) - Finger Prick Testing<br><br>It should be emphasised that TIR is associated with CGM systems only. |
| 223 | | information-about-hybrid-closed-loop-systems | The interventions | 2.5 | | Need to explain Interstitial Fluid Glucose and Blood Glucose and highlight differences |
| 224 | | information-about-hybrid-closed-loop-systems | The comparators | 2.7 | | Repeat meanings of Acronyms ?<br><br>Needs a statement that both CGM types can be used in free standing / manual mode with most CSII (Pump) systems |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 347 | Children and Young People's North East and North Cumbria Diabetes Network | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | multiple daily insulin injections | Should read - multiple daily injections or insulin pump therapy |
| 351 | Children and Young People's North East and North Cumbria Diabetes Network | committee-discussion | Baseline characteristics | 3.4 | | NHSE pilot – summary should also include paediatric data |
| 378 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | multiple daily insulin injections | should read Should read “multiple daily injections or insulin pump therapy” |
| 382 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | committee-discussion | Baseline characteristics | 3.4 | | NHSE pilot – summary should also include paediatric data |
| 417 | British Society For Paediatric Endocrinology and Diabetes | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.1 | | This statement needs altering; even with optimal control (under 6.9%) there is a 2-fold higher cardiovascular risk, as discussed above. |
| 418 | British Society For Paediatric Endocrinology and Diabetes | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | | Should read “multiple daily injections or insulin pump therapy”<br>This is incorrect and should read over preceding 8-12 weeks |
| 500 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | is | not is<br>suggest instead the word<br>reflects |
| 599 | Diabetes Technology Network -UK | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.2 | | It would be valuable here to define "healthy ranges" as Time in range [ 3.9-10mmol/l] or HbA1c of < 7% without disabling hypoglycaemia |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 600 | Diabetes Technology Network -UK | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | | "lifestyle adjustments - as T1D is not a condition related to lifestyle - we do not think this should be here - core philosophy of managing T1D is to fit the therapy into their lifestyle - so encouraging healthy lifestyle would be a better term but it comes after regular measurements and appropriate dosing of insulin |
| 601 | Diabetes Technology Network -UK | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | This is incorrect: targets in pregnancy are lower - 70% time between 3.5 - 7.8 mmol/l and aiming for A1c < 6% also - we should say target A1c < 6.5% without disabling hypoglycaemia [ with < 4% time below range] |
| 675 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.2 | supplemental i | Apologies for nit-picking, but should this be exogenous insulin? People with type 1 diabetes need insulin, not as a supplement but as essential therapy. |

## THEME: EVIDENCE

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 126 | | | | | | In general there is concern expressed in the background briefing that the evidence around HCL is unclear. Given that pump clinics are already supporting HCLs has consideration been given to analysing their data / surveying existing HCL users? While not scientifically ideal this would provide insight into the degree of support needed for a HCL, end user experience of HCL systems within the NHS context and any reduction in hypos / severe hypos / NHS support costs and hospital admissions while using HCLs? |
| 507 | | committee-discussion | Uncaptured benefits | 3.9 | The committee agreed that there were potential quality of life benefits of HCL systems not captured in the model, including the effect on learning and education, ability to work, mental burden and fear of hypoglycaemic events. The committee concluded that these uncaptured benefits were likely to undervalue the effect of HCL systems on quality of life. | Can the final guidance be reviewed again within a very specific period of 4 years to see if more evidence has been generated on this point? I do not want to see a repeat of NICE TA 151 which has basically not been revisited since 2008 |
| 529 | | committee-discussion | Uncaptured benefits | 3.9 | | "The committee understood that there was no quantitative evidence that could be used to estimate the value of these potential quality of life estimates". Why was robust qualitative evidence not considered, particularly given the drive for patient inclusivity and the reality of the value of patient experience being mostly contained in qualitative research evidence? |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 587 | | committee-discussion | Baseline characteristics and HbA1c effects | 3.6 | | It would be useful to have some citizen science used in this study. Many T1Ds have been closed looping for year using DIY kit. There should be data for when they started and how this progressed out there which would provide support for this business case. |
| 603 | Diabetes Technology Network -UK | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | | The EAG did not consider a large RCT with a relevant population, the ADAPT study (Choudhary et al; Lancet Diab Endo 2022 OCt 10(10):720-731) that randomised 82 participants using isCGM with HbA1c > 8% ( mean HbA1c 9.0%) to continued care or HCL and demonstrated a -1.42% difference - this is exactly the population that the current recommendation is considering |
| 707 | | recommendations | 1 Recommendations | 1.5 | Continuously managing blood glucose levels is a substantial mental load for people with type 1 diabetes (and their families or carers). Hybrid closed loop systems automatically deliver insulin using a calculation based on continuous glucose measurements. The systems do not need as much input from the person but manual insulin dosing is still needed sometimes, for example, around mealtimes. So, they may reduce the mental load and improve people's quality of life. | Whilst I appreciate that many pieces of feedback have been collected, and the specifics of closed loop therapy have been investigated, there are many sources of data relating to the issues raised that appear not to have been presented in the committee papers. In terms of impact on carers, for example, there are studies showing the effects on sleep of T1D that don't seem to have been considered: https://pubmed.ncbi.nlm.nih.gov/30465480/<br><br>Additionally, the OPEN project within the EU has provided specific research looking at the benefits of using open source AID systems for young people and caregivers that suggests that more should be available within NICE guidance for commercial options: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9335170/ |

## THEME: GENERAL

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 39 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | | | | | From NG17 section on CGM:<br><br>“1.6.10 Offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash'), based on their individual preferences, needs, characteristics, and the functionality of the devices available. See box 1 for examples of factors to consider as part of this discussion. [2022]<br><br>Box 1 Factors to consider when choosing a continuous glucose monitoring device<br><br>The person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function)”<br><br>The above NICE recommendation is already well placed to offer guidance relating to the closed loop aspect, so where is the new guidance aiming to sit? |
| 222 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | Very important that this reference and target is included |
| 225 | | committee-discussion | Evidence and generalisability | 3.3 | | Need to make new acronyms and Pilot Study names stand out: -<br><br>EAR<br>RCT<br>CSII<br><br>NHSE Adult Pilot Study<br>NHSE Children and Young Adult Pilot Study |
| 226 | | committee-discussion | Baseline characteristics | 3.4 | | Presentation of data is confusing |
| 227 | | committee-discussion | Children | 3.5 | | Presentation of data is confusing |
| 228 | | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | | Presentation of data is confusing |
| 229 | | committee-discussion | Innovation | 3.15 | | Acronym ? |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| | | | | | | ICER ?<br>QALY ? |
| 299 | | committee-members-and-nice-project-team | NICE project team | 5 | NICE project team | I would love to know how many of the project team have diabetes or have a child with diabetes. You cannot possibly understand the implications of this dreadful disease unless you live with it day in, day out. |
| 364 | | recommendations | 1 Recommendations | 1.5 | Evidence suggests that the systems appear to be more effective for people with higher long-term average blood glucose (HbA1c) levels. | ALL treatments are bound to be more effective when they are needed more. |
| 365 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | Time below range (less than 3.9 mmol/litre) is associated with increased risk of severe hypoglycaemia | this lower limit is set too low. Judgement is impaired at any level below 5.0 mmol/l, one should not drive a car for example, and self medication by insulin pump is a high-risk activity, which could result in death if mistakes are made. |
| 368 | | committee-discussion | Baseline characteristics | 3.4 | The network meta-analysis showed that HCL systems were associated with a decrease in HbA1c of 3.1 mmol/mol (-0.29 percentage points) compared with CSII plus CGM. But the NHSE adult pilot study reported a decrease in HbA1c of 16.2 mmol/mol (-1.5 percentage points). | It is a mistake to work on the basis that a reduction in HBA1C is always a good thing. If everyone's BG level was around 3.9 mmol/l, we would have a very sick population. Much better would be to look for a reduction in standard deviation (over time and across the population) from the normal BG level of say 5.5 mmol/l . CGM is well capable of producing this information. |
| 370 | Association of British HealthTech Industries | dap55-diabetes-mta-acd-final-no-acicdocx | | | | ABHI welcomes the National Institute for Health and Care Excellence (NICE)'s draft appraisal of hybrid closed loop systems (HCL) for managing blood glucose levels in type 1 diabetes |

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| | | | | | | (T1D). HCL systems represent an important opportunity to make a step change in the management of this condition so that people with T1D can improve their health and quality of life.<br><br>We recognise the important work lead by NHS England (NHSE) to collect evidence of the utilisation of HCL systems in a real-world setting. That process engaged clinicians, people with diabetes, support groups, and industry (in the UK and internationally), amongst others, to work together with the intention of widening access to innovative diabetes management technology.<br><br>It is imperative that these recommendations focus on continuing that work to expand access. Though the draft appraisal is a strong stride forward, ABHI members have several concerns which we highlight below. |
| 396 | Families With Diabetes National Network | recommendations | | 1 | | We are responding as Families With Diabetes National Network who are a group of parent representatives who work alongside the CYPDN, to gather the views of families nationally on issues regarding diabetes care for CYP & accessibility of good care to all CYP. We have canvassed for views on this document on social media  support groups. |
| 402 | Families With Diabetes National Network | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | In the latest available NPDA for 2020/21 only 11.8% of CYP achieved a HbA1c <48 mmol/mol<br>Only 37.8% achieved <58mmol/mol |
| 450 | | committee-discussion | ICER per QALY gained | 3.14 | NICE's guide to the methods of technology appraisal 2013 notes that above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of a technology as an effective use of NHS resources will take into account the degree of certainty around the ICER. | There is a lot of jargon in this - I'm afraid I don't understand! |

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| 487 | | | | | | This is a test please ignore |
| 617 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.1 | | Out of interest, of the 400,000 people, some 25,000 have been living with the condition 40 years or more and some 9,000 have been living with the condition 50 years or more. Don't you think these people have endured enough and deserve a rest from diabetes? It might be worth re-thinking the criteria: when you get a Nabarro Medal you also finally get the tech to treat your diabetes! |
| 644 | | | | | | Thank you for asking for feedback on this document. HCL are a great step forward for PWD. |
| 761 | ABHI | | | | | About ABHI<br>ABHI is the UK's leading industry association for health technology (HealthTech).<br><br>ABHI supports the HealthTech community to save and enhance lives. Members, including both multinationals and small and medium sized enterprises (SMEs), supply products from syringes and wound dressings to surgical robots and digitally enhanced technologies. We represent the industry to stakeholders, such as the government, NHS and regulators. HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth. HealthTech is the largest employer in the broader Life Sciences sector, employing 145,700 people in 4,300 companies, with a combined turnover of £30bn. The industry has enjoyed growth of around 5% in recent years. ABHI's 330 members account<br>for approximately 80% of the sector by value. |

## THEME: HYPOGLYCAEMIA

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 8 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.1 | | The scope for this TA is stated as follows:<br>https://www.nice.org.uk/guidance/gid-ta10845/documents/final-scope-2<br><br>Decision question: Does the use of hybrid closed loop systems for managing glucose levels in type 1 diabetes represent a clinically and cost-effective use of NHS resources?<br><br>The population included: People with type 1 diabetes who are having difficulty managing their condition despite prior use of at least one of the following technologies: continuous subcutaneous insulin infusion or real time continuous glucose monitoring or intermittently scanned glucose monitoring. These difficulties may include:<br>• not maintaining HbA1c levels of 6.5% or below or<br>• not maintaining at least 70% time in range of 3.9 -10 mmol/l or<br>• ongoing disabling hypoglycaemia<br><br>No recommendations on the use of HCL systems in patients with ongoing disabling hypoglycaemia have been made in the draft TA.<br><br>Was the evidence for clinical and cost effectiveness in this group of patients considered?<br>If yes, there should be a statement on whether use is recommended or not.<br>If not, there should be an explanation of why the final TA differed from the scope.<br><br>The draft NICE TA implies that patients who continue to experience ongoing disabling hypoglycaemia despite optimal therapy including CSII and rtCGM or isCGM, whose HbA1c is less than 8.0% are NOT eligible for treatment with HCL systems, therefore preventing access to this technology for this group of patients. |
| 29 | | recommendations | 1 Recommendations | 1.1 | | Yes, the solution should be offered to those with higher HbA1c levels, but also to type 1 diabetics who have frequent episodes of hypoglycaemia, which can be potentially extremely dangerous. This stipulation should be added to the recommendation. |
| 32 | | committee-discussion | Uncaptured benefits | 3.9 | | There must be quantitative data available of people needed hospital interventions from hypoglycaemic events. There is an alarming number of type 1 diabetics that are hypo-unaware, especially children, with potentially serious consequences. |
| 33 | | committee-discussion | Conclusion | 3.16 | | People with frequent hypos should be added to this list. |

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| 72 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | Should include hypoglycaemia unawareness in other groups such as sports people<br>Children under the age of 6-8 years consistently are not hypo aware, not all children in general |
| 117 | | | | | | Could you publish what data you have used on which to base your recommendations? Users of Omnipod 5 in the US are overwhelmingly of the opinion that it is more helpful for those who suffer from frequent episodes of low blood glucose. The long term effects of frequent hypos on the brain are just as significant and will cause just as much expense to the NHS as the damage caused my high glucose readings. I urge you to include those who are particularly sensitive to insulin and suffer frequent hypos to be included in your recommendations and to also consider the money that will be saved by ensuring that all Type 1 diabetics have access to the best technology to enable them to manage their diabetes and keep their blood glucose levels within normal range. |
| 173 | | recommendations | 1 Recommendations | 1.1 | | What about the mental load for those type 1 diabetes (T1Ds) who have a lower HbA1c? Some T1Ds find that they have a lower HbA1c due to excessive hypoglycaemia, which would be much better supported by the hybrid closed loop system than current treatments. |
| 359 | | | | | | Hi, this is very welcoming news for T1D. Understand that's it's currently for hba1c >8%. Has any consideration been given to those with much lower % purely because of the number of hypos in any given time? This is also very important for potential complications. Although closed loop won't entirely stop hypos from happening the likelihood of complications & stress is much reduced. I would ask that this is taken into account, possibly on an individual basis.<br>Thank you. |
| 372 | Association of British HealthTech Industries | recommendations | 1 Recommendations | 1.2 | | The risks and burden of hypoglycaemia need to be an indicator for the utilisation of HCL systems<br>The fear of hypoglycaemia and its negative quality of life impact on people with T1D is highlighted in the Committee papers . Clinical studies have shown that more tightly managed diabetes can make it more likely that hypoglycaemia might occur and that its burden among patients with T1D is significant and associated with mortality and morbidity .<br><br>NICE guidance 21 highlighted that: "People with type 1 diabetes may experience 'disabling hypoglycaemia', which is when hypoglycaemic episodes occur frequently or without warning so that the person is constantly anxious about having more episodes."<br><br>NICE guidance TA151 makes clear that insulin pump therapy is recommended as a treatment option for adults and children 12 years and |

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| | | | | | | older with T1D who experience disabling hypoglycaemia.<br><br>It is therefore vital that people with T1D at risk of hypoglycaemia is added to the HCL guidance as an outright indicator. |
| 465 | | | | | | As someone living with type 1 diabetes it is promising to see NICE developing guidance for closed loop - a huge step forward in care for us.<br><br>I am lucky enough to be using the Medtronic 780G with Guardian 4 sensors as a hybrid closed loop.<br><br>I have 2 small children age 3 and 1, work full time and suffer with hypoglycaemic episodes almost everyday. The nature of my caring responsibilities and need to work full time means that every day is different and very difficult to keep scanning my Libre and prevent hypos in time. I am hugely grateful to my diabetes team who recognised this and the ICB for funding my G4 sensors so I can now take the weight out of my diabetes management.<br><br>I was experiencing 8% hypoglycaemia and this has reduced to 1%. I also experienced huge fluctuations and I am now only 10-15% out of range. I completely understand this evidence could not be considered in full as part of NICE's rigorous process but I am sure I'm not the only one sharing these experiences.<br><br>From a review of Facebook groups I am part of where people discuss the Medtronic 780g HCL system the consensus is the benefits to hypoglycaemia. Not to hyperglycaemia.<br><br>This is why I am surprised and concerned to see no mention of management of hypoglycaemia within the recommendations. Particularly when there is such an imminent threat to life (in some cases not just your own but your dependents).<br><br>I strongly urge NICE to include a recommendation that ensures those facing regular hypoglycaemic episodes are considered, alongside other decisions. |

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| | | | | | | Many thanks for your consideration. |
| 499 | | recommendations | 1 Recommendations | 1.5 | The aim of treatment is to decrease blood glucose levels and keep them within a healthy range. | This is broadly true but misses a point when it comes to minimising the frequenct and impact of hypoglycaemia. How many people with elevated HbA1cs run their glucose levels a bit high or correct conservatively to avoid hypos? Many. |

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| 504 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | They highlighted that children are less able to recognise the symptoms of hypoglycaemia and hyperglycaemia, and this is a constant worry for parents when they are apart from their children. | Hypoglycaemia unawareness has major effects on many adults with type 1 diabetes too. HCLs can give confidence in aiming for tighter control because the algorithm can help reduce the risk of hypoglycaemia |
| 590 | | recommendations | 1 Recommendations | 1.1 | who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more | The recommendations seem to disregard hypoglycaemia, despite being seen as an uncaptured benefit. HbA1c can be artificially reduced with increased "hypos" meaning a patient could benefit from an HCL system without meeting the elevated HbA1c |
| 597 | Diabetes Technology Network -UK | recommendations | 1 Recommendations | 1.1 | | This primary recommendation should also include people who have "disabling Hypoglycaemia " as defined in NICE TA 151 despite optimal management with at least 1 of the following treatments<br>Disabling hypoglycaemia was defined as repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life.<br>We believe this can be made more specific by specifying<br>- persistent impaired awareness of hypoglycaemia [ Gold score > 4] and inability to detect events < 3 mmol/l despite use of isCGM or rt-CGM<br>- > 1 severe hypoglycaemia in the previous year [ associated with cognitive impairment severe enough to require external assistance]<br>- persistent time < 3.0 mmol/l > 3% despite use of isCGM or rt-CGM and high level of care [ based on Lin et al; Endo Pract. 2019 June; 25(6):517-525] |

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| 604 | Diabetes Technology Network -UK | committee-discussion | Uncaptured benefits | 3.9 | | We are surprised that the committee did not consider results of the SMILE study ( Bosi et al; Lancet Diabetes Endo, 2019, Jun; 7(6):462-472) that randomised 153 people with high risk of hypoglycaemia despite CSII to use predictive low suspend - and demonstrated an 87% reduction in risk of Severe hypoglycaemia. As HCL is a further advance on predictive suspend, it is reasonable to expect at least similar - if not greater reductions in severe hypoglycaemia with HCL. The time below range seen in Real world and RCT data from HCL is similar to that seen in this SMILE study. These data could have been used to model the benefits in reduction of severe hypoglycaemia in a hypoglycaemia prone population. |
| 632 | | recommendations | 1 Recommendations | 1.1 | | Can consideration be given to people who have difficulty managing their diabetes due to disabling hypos that impact on their quality of life/ability to work etc. This group are often achieving a HbA1c below these targets due to the number of hypos they are experiencing and would hugely benefit from HCL |

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| 673 | | recommendations | 1 Recommendations | 1.1 | | I would ask NICE to consider adding people who are having difficulty managing their condition because of problematic or disabling hypoglycaemia to the list of people for whom hybrid closed loop should be considered, irrespective of HbA1c.<br><br>NICE guidance has recommended CGM for people with type 1 diabetes with problematic hypoglycaemia since 2015 (1.10.7) and has recommended CSII for people with type 1 diabetes for “disabling hypoglycaemia, defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life” since 2008 (TA151). Facilitating addition of the algorithms of hybrid closed loop is important, especially if, as stated in the papers supporting the present document, CSII plus CGM with LGS/PLGS, a vital component for the effectiveness of automated delivery systems to reduce hypoglycaemia risk, will “no longer available for purchase in the UK”. This means that people continuing to experience hypoglycaemia on CGM with MDI or CSII, who will often have HbA1c below 8%, need to be included here to allow them access to hybrid closed loop, in addition to other measures.<br><br>I accept that the data for hybrid closed loop in people at particular risk for severe hypoglycaemia are still limited, and that time below 3 mmol/l and severe hypoglycaemia are not always reduced. However, including hypoglycaemia in cost-effectiveness analyses show reduced ICERs and the committee papers show that one of the presented network meta-analysis on the small amount of data available shows a reduction in time below 3.9 mmol/l from LGS/PLGS comparable to that achieved by LGS/PLGS vs unlinked CSII and CGM, in people not all at enhanced risk for hypoglycaemia. A recent report from the US type 1 diabetes exchange registry data, 8.7% of people on HCL report recurrent severe hypoglycaemia vs 11.8% on CGM with pump (https://diabetesjournals.org/diabetes/article/71/Supplement_1/92-OR/145095/92-OR-Persistence-of-Impaired-Awareness-of).<br>Notably, the Benhamou study attributed severe events on closed loop to “hardware malfunctions or human error”, and severe hypoglycaemia occurred at least once when the participant had temporarily come out of closed loop. These data suggest that technology alone will not resolve severe hypoglycaemia risk in everyone. But the quoted 2019 Andersen study in people at high risk of hypoglycaemia showed HCL reduced time spent below target range more than did SAP and the Bosi study (doi: 10.1016/S2213-8587(19)30150-0) in people at increased risk of severe hypoglycaemia through impaired awareness of hypoglycaemia or recent severe events showed less severe hypoglycaemia on closed loop vs pump and self-monitoring. A recently published Garg study showed no severe hypoglycaemia compared to 6 events per 100 patient years in |

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| | | | | | | people not at high risk (Garg S et al., Adult and Pediatric MiniMed™ HCL Outcomes 6-month RCT: HCL versus CSII Control Study Group. Improved Glycemia with Hybrid Closed-Loop Versus Continuous Subcutaneous Insulin Infusion Therapy: Results from a Randomized Controlled Trial. Diabetes Technol Ther. 2023 Jan;25(1):1-12. doi: 10.1089/dia.2022.0421. Epub 2022 Dec 20. PMID: 36472543) and another recent study showed reduced time below range, when converting to HCL from CSII and flash glucose monitoring (Gros Herguido et al Effectiveness and Safety of an Advanced Hybrid Closed-Loop System in Adolescents and Adults with Type 1 Diabetes Previously Treated with Continuous Subcutaneous Insulin Infusion and Flash Glucose Monitoring. Diabetes Technol Ther. 2022 Nov 23. doi: 10.1089/dia.2022.0287. Epub ahead of print. PMID: 36108305).<br>While more data are clearly required for the high risk population, and adjunctive solutions to technology are still required, I would like to suggest that NICE consider facilitating introduction of HCL for people with type 1 diabetes who continue to experience disabling hypoglycaemia while using CGM. These people are already eligible for pumps and CGM and should be able to access conversion to an interactive CGM-pump system. Failure to list this group will actively exclude people with problematic hypoglycaemia and an HbA1c of less than 8%. |
| 716 | | | | | | The majority of patients with T1D are hypo unaware at night. Closed loop systems keep patients safe via alarm notifications and suspension of insulin. This is particularly important for patients who live on their own and have no live in support. The student population of under 25s are within this category. The 19-25 age group typically are more likely to have DKA or severe hypoglycaemia resulting in hospital stays. |

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| 744 | King's College Hospital NHS Foundation Trust | recommendations | 1 Recommendations | 1.1 | difficulty managing their condition | TA151 referred to the following as an indication of insulin pump therapy "attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. For the purpose of this guidance, disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life".<br><br>Disabling hypoglycaemia is not mentioned explicitly as an indication for hybrid closed loop therapy. So if patients with HbA1c below 8.0% are experiencing disabling hypoglycaemia, they would not meet the proposed recommendations for hybrid closed loop, but would meet the criteria for insulin pump therapy from TA151, if this is to continue, and will have access to continuous glucose monitoring following the update to NG17 last year. Please clarify, as we have anecdotes of patients in this situation arguing that they are being penalised for having "too good" glucose control to be able to access diabetes technology, some of whom will allow their HbA1c to rise above the previous threshold of 8.5% for pump therapy recommended in TA151 in order to be able to access this. |
| 764 | ABHI | | | | | **2. The risks and burden of hypoglycaemia need to be an indicator for the utilisation of HCL systems**<br><br>The fear of hypoglycaemia and its negative quality of life impact on people with T1D is highlighted in the Committee papers[2]. Clinical studies have shown that more tightly managed diabetes can make it more likely that hypoglycaemia might occur[3] and that its burden among patients with T1D is significant and associated with mortality and morbidity[4]<br><br>NICE guidance 21 highlighted that: *"People with type 1 diabetes may experience 'disabling hypoglycaemia', which is when hypoglycaemic episodes occur frequently or without warning so that the person is constantly anxious about having more episodes."*<br><br>NICE guidance TA151 makes clear that insulin pump therapy is recommended as a treatment option for adults and children 12 years and older with T1D who experience disabling hypoglycaemia.<br><br>It is therefore vital that people with T1D at risk of hypoglycaemia is added to the HCL guidance as an outright indicator.<br><br>References:<br>2 Section 2.1.3, Committee Papers.<br>3 Gerstein HC, Miller ME, Byington RP, et al. Action to Control Cardiovascular Risk in Diabetes Study Group. Effects of intensive glucose lowering in type 2 diabetes. New England journal of medicine. |

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| | | | | | | 2008 Jun 12;358(24):2545-59<br>4 McCoy RG, Van Houten HK, Ziegenfuss JY, Shah ND, Wermers RA, Smith SA. Increased mortality of patients with diabetes reporting severe hypoglycemia. Diabetes care. 2012 Sep 1;35(9):1897-901. |

## THEME: IMPLEMENTATION

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| 14 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.3 | | Agree that this should be managed by specialist diabetes teams. However, it is likely that existing capacity issues and increased demand could lead to delays in access treatment leading to inequalities. Have the increased costs in relation to demand activity been factored into the resource impact assessment?<br><br>See further comment and discussion in relation to point 4: implementation. The high degree of publicity associated with the publication of this consultation and then the final guidance will result in high demand for this technology from type 1 diabetes patients, some of who may not be eligible for treatment. It needs to be acknowledged that specialist diabetes teams may not have the capacity to start all eligible patients on treatment as soon as the guidance is published, and the NHSE framework deals are finalised. ICBs will require additional support to manage patient demand and enquiries from patients. |
| 16 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.4 | | Review and stopping criteria need to be included in this guidance e.g. in line with those set out NICE TA151<br><br>i.e. Following initiation in adults and children 12 years and older, HCL systems, therapy should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, [or a sustained decrease in the rate of hypoglycaemic episodes]. Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer. |
| 17 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.5 | | 1.5 What are NICE proposing should happen to those patients who have a non HCL pump in place with warranty remaining, but qualify under the recommendations for hybrid closed loop technology? Upgrading patients early would create capacity issues for the specialist teams and again create large extra costs and waste.<br>Have these costs been taken into account when assessing the overall costs to the system? |

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| 18 | PrescQIPP CIC | implementation | 4 Implementation | 4.1 | | The draft NICE TA appears un-implementable. Full implementation of the guidance is likely to be impossible for the majority of ICBs without significant investment.<br>75% of people with diabetes nationally are not on insulin pumps (pg 14). To initiate and provide the necessary support for an insulin pump (pre-pump work up) with CGM and follow up appointments is a significant undertaking. Most diabetes services are already over stretched. The proposal as currently written would need the diabetes services to manage approximately twice the number of patients (currently on average 25% of patients may be on a pump). The cohort size as detailed in previous comments suggests this number will double.<br>We suggest that resources to support safe implementation of the recommendations should be included in the costings. There is one payer for all these resources (ICB), and it is unrealistic to assume that the additional work could be absorbed by the current workforce at no additional cost. NICE TAs should consider holistic costs including cost of the service to deliver the intervention. |
| 19 | PrescQIPP CIC | implementation | 4 Implementation | 4.1 | | Many ICBs are currently implementing recent NICE guidance on the use of rtCGM and isCGM (NG17 and NG18) in a phased manner due to its high budget impact. This NICE TA will be mandatory. The net impact will be that the HCL recommendations may be implemented before the full recommendations on the use of rtCGM and isGCM in NG17 and NG18 are implemented. Patients who would otherwise have benefitted from access to these technologies earlier, may be disadvantaged by the recommendations in the HCL TA.<br><br>The fragmented approach to issuing guidance with different legal implementation requirements which relates to the same patient pathway, may therefore have unintended consequences and lead to further inequalities in treatment access, both locally and nationally. |
| 43 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | recommendations | 1 Recommendations | 1.3 | Only use hybrid closed loop systems with the support of a trained multidisciplinary team experienced in continuous | Is there any evidence on the amount of extra clinician (consultant, DSN, dietitian) and administration team resources needed based on this hybrid closed loop guidance?<br><br>Clinical team feels strongly that guidance implementation will place extra burden on specialist diabetes services, who may require extra resources to enable this service. |

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| | | | | | subcutaneous insulin infusion and continuous glucose monitoring in type 1 diabetes. | We are already inundated with Libre and CGMs. We need to have a better central support system to provide online/tel support service to this high risk group – ideally 24/7. |
| 80 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | implementation | 4 Implementation | 4.1 | | In order to achieve this these Guidelines will need to be supported by extra funding as is provided for the provision of CGM during pregnancy and to provide appropriately staffed and skilled specialist diabetes teams to support patients using HCL systems |
| 97 | University Hospitals Dorset Diabetes Service | implementation | 4 Implementation | 4.1 | | Achieving funding from local fund holders for this proposed guidance will be the key step in its implementation. The benefits for people with type 1 diabetes are likely to be substantial in the longer term. |
| 130 | | | | | | In general the shape of this discussion feels misaligned with the wider reality as it appears to treat HCLs as a new product category. In practice I would say that support for HCLs is driven by competition in the IIS market – as such most pumps (from major suppliers) will be HCL capable going forward and will be steadily advanced with better algorithms and better auto-tuning as pump manufacturers compete for sales advantages. Is this tendering process saying that any supplier who 'fails' will no longer be able to supply pumps to the NHS (given that in most cases it will be the same pump simply with HCL disabled)?<br>In general the additional cost of HCL enabling these systems is largely down to adding a rtCGM from (in most cases) a 3rd party supplier which means pricing may not be within the pump manufacturers direct control, nor is it necessarily the best approach for the NHS. Does this tender allow the NHS to negotiate directly for rtCGM with Dexcom (and Abbott in future) across the board? (Caveat – care needs to be taken with support here – CGM suppliers don't tend to allow for the fact that a 'wonky' CGM can have a big impact on an HCL system that is adjusting insulin based on the rtCGM data…..).<br>Further this aligns poorly with the recent NICE recommendation that all type 1s be offered CGM systems which also states that any pump user should be provided with a pump compatible rtCGM – these 2 recommendations appear to be out of step with each other? |

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| 138 | Primary Care Diabetes Society | information-about-hybrid-closed-loop-systems | Price | 2.9 | | NICE recommendations, if this technology appraisal is approved, should include a recommendation to NHSE and the other bodies in devolved nations, to consider funding resources for these devices. Many ICS already operate with funding challenges. Even if considered cost-effective, may systems may consider that such devices are not affordable without funding to support implementation . Without new funding stream, this may impact other service provision and/or other service users. |
| 142 | Primary Care Diabetes Society | implementation | 4 Implementation | 4.3 | | NHSE should be advised of the need to offer the new finance required to support implementation |
| 230 | | | | | | The mental burden still exists for well controlled T1s and they shouldnt be penalised from accessing this life changing technology. This group already has the skills to carb count and should be rewarded for their efforts by being the first (along with children and pregnant women) to be given closed loop.<br>For adults closed loop should be offered in stages - carb counting /CGM, Pump then closed loop. As a user of closed loop I would suggest a minimum of 3 months using a pump before accessing closed loop because users need a good understanding of all elements for times when technology fails. Why not consider using existing T1 users of closed loop who are willing to 'buddy up' with new diabetics locally or those with higher hb1acs to answer questions to prospective users to reduce the financial burden on the NHS? |
| 241 | | committee-discussion | Access to technology and care | 3.2 | They said that improvements to the availability of and access to patient training were needed. | We were the first family to start on CamAPS FX in our NHS Trust, following our pressure for this to be introduced. Whilst some of the clinical team have been really keen, we have seen a degree of clinical interia from others who seem uninterested in learning how to harness the benefits of this technology to improve QoL alongside glycaemic control. Clinical teams need more support. |
| 269 | | information-about-hybrid-closed-loop-systems | The interventions | 2.6 | | Whilst the Medtronic pump and closed loop system is excellent, Medtronic need to work on their logistics if they are going to roll this out to more people. My son was part of the trial and we have had endless problems actually acquiring the items needed. We also had the reverse problem of being sent four new pumps. This is relevant as we were aware the NHS was being charged for all these incorrect items. As cost is an issue, Medtronic need to get this aspect of their delivery right. |

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| 286 | | implementation | 4 Implementation | 4.3 | if a patient has type 1 diabetes and the doctor responsible for their care thinks that a hybrid closed loop system is the right treatment | Doctors continue to complain that T1 patients order too much insulin or need too many flash glucose monitoring sensors. This decision should be left to endocrinologists in response to patient commitment, not GPs or CCGs |
| 339 | | committee-discussion | Access to technology and care | 3.2 | | Access to regular trainings in different formats by tech rep and dsns |
| 399 | Families With Diabetes National Network | recommendations | 1 Recommendations | 1.3 | | Yes , it is really important that there is support from a trained MDT. In our CGM survey 2016 we asked about training in CGM use & 76% were self taught. Important that all eligible for HCL have easy access to trained MDTto avoid discrimination. |
| 438 | | recommendations | 1 Recommendations | 1.3 | rained multidisciplinary team experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring in type 1 diabetes. | There needs to be more trained staff. My daughter is on a waiting list for a year before she can get a pump. |
| 455 | Children & Young People's Diabetes Team, Somerset Foundation Trust | recommendations | 1 Recommendations | 1.1 | | We wondered if some advice about an initial step-wise approach to priortisation of eligible patients would be useful. For example, initially prioritising patients with HbA1c > 80 mmol/mol, possibly recurrent DKA, and those with severe hypoglycaemia; then working through the rest of the eligible cohort. |
| 458 | Children & Young People's Diabetes Team, Somerset Foundation Trust | recommendations | 1 Recommendations | 1.5 | | Needs to be more explicit on whether NHS will take over funding of those who are currently self-funding these systems, and whether that depends on them meeting eligibility criteria. If raised HbA1c is the recommended criteria, self-funders who have achieved target HbA1c by using & paying for the technology are excluded from expansion in funding, which is punitive. |

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| 462 | Children & Young People's Diabetes Team, Somerset Foundation Trust | committee-discussion | Evidence and generalisability | 3.3 | | Data from the NHSE pilot is very promising. However we are conscious that the frequency of specialist nurse follow up provided by many teams in the pilot may not be achievable if rolled out rapidly on a much larger scale. This raises questions about applicability and possibly safety. This would be addressed better if there were more in the guidance about requirements for training, staffing models and key elements of education which must be delivered. |
| 464 | Children & Young People's Diabetes Team, Somerset Foundation Trust | implementation | 4 Implementation | 4.1 | | A duration of 3 months to implement may be realistic for funding the devices, but if workforce (including both recruitment and training) needs to be increased to enable safe education for this therapy, that will clearly require longer. |
| 498 | | recommendations | 1 Recommendations | 1.5 | These recommendations are not intended to affect use of hybrid closed loop systems that was started in the NHS before this guidance was published. People using hybrid closed loop systems outside these recommendations may continue until they and their NHS clinician consider it appropriate to stop. | What about people who have been self-funding their use of HCL because prior to using HCL they would have met the criteria of high HbA1C and using at least one of the technologies? Is there a transitional arrangement for them to access funding for the CGM supplies and/or algorithm (if they pay for it) if they are in receipt of NHS pump funding? |
| 543 | | information-about-hybrid-closed-loop-systems | The interventions | 2.5 | | Should be joint decision on device between clinician and person with diabetes at present pressure from ICB to choose cheapest |

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| 567 | | | | | | I have been using CamAPS for two years, privately funded until January 2023 when my Secondary care team's committee approved funding. I have been on NHS funded pump therapy since mid 2007 (Insulin allergy post pancreatectomy for PC). I use the NHS funded Dexcom G6 sensor.<br>My Hba1c using CamAPS was last measured at 41! Superb.<br><br>One issue NICE should insist on if this moves forward to implementation is that providers such as CamDiab MUST have 24/7 support. Currently they only provide M-F 9-5 support. They seem proud of this fact. Any organisation providing a health critical solution such as this needs to provide out of hours support. CamDiab rely on users calling the physical device support teams if issues arise (Dexcom, Dana, etc) out of their support hours. This can inevitably lead to "it's not our device problem..." responses.<br>The APS solution provider must provide 24hr cover. I have already raised this requirement with CamDiab but received no response. |
| 577 | | recommendations | 1 Recommendations | 1.5 | | Para 1.5 - what about individuals who are nearly on a hybrid closed loop e.g. using dexcom G6 and Omnipod Dash - Omnipod 5 due this year which would replace the dash and create a hybrid closed loop for the individual |
| 596 | | information-about-hybrid-closed-loop-systems | Price | 2.7 | | This should be a national agreement so centres cannot form a commercial relationship with a sole supplier thereby limiting patient choice plus providing the best system for a persons needs. |
| 631 | | | | | | Given the challenges we have had implementing the NICE guidance re: CGMS - will this be a TAG allowing us more leverage for the ICB's to implement it? |
| 659 | Novo Nordisk UK | recommendations | 1 Recommendations | 1.3 | | We have noted that it is recommended that hybrid closed loop systems should only be used with the support of a trained multidisciplinary team experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring in type 1 diabetes.<br><br>We support the recommendation for the need to ensure that patients using a hybrid closed loop system are supported by appropriately trained clinical staff, with the necessary knowledge to provide this. However, we note the committee’s discussion regarding concerns raised by clinicians and patients about a 'postcode lottery' in access |

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| | | | | | | to diabetes technology, with one clinical expert highlighting that many diabetes centres lack enough trained staff within their clinical teams to support people with type 1 diabetes in being trained to use these innovations (section 3.2).<br><br>Given current pressures on NHS workforce resources, including the diabetes clinical workforce, we believe that the definition of what constitutes a multidisciplinary team should not be a prescriptive requirement, or a barrier to patients being able to access technology where it is deemed that they would benefit from this. Local diabetes teams should have the autonomy to determine which of their clinical staff have the necessary training and knowledge to support people with type 1 diabetes in the use of hybrid closed loop systems and to meet all their needs, based on their local workforce models and availability of qualified staff. It would be helpful if the wording could be further clarified to reflect this and to actively encourage local health systems to ensure they have established clinical teams, with the necessary skills and knowledge, to support people with type 1 diabetes in regards to the use of hybrid closed loop and other technology. |
| 668 | NHS England | recommendations | 1 Recommendations | 1.3 | | People living with Type 1 Diabetes cannot be easily transitioned to Hybrid Closed Loop and it takes time. This is particularly pertinent to people who are not already accessing Pumps. In this scenario, people living with Type 1 Diabetes would need to be transitioned to a Pump first. It would be helpful for NICE to confirm if people living with Type 1 Diabetes are anticipated to be transitioned to a pump first before starting Hybrid Closed Loop, and to consider the impact on workforce.<br><br>The proposed NICE recommendation for Hybrid Closed Loop will lead to significant demand and clinical workload constraints. Should the NICE proposal be adopted in its current format – with wide eligibility criteria and no phased implementation - it will have a significant impact on the diabetes workforce, who will be expected to adhere to the MTA. It takes additional clinical time to transition people living with Type 1 Diabetes and support them in the use of this new technology. |

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| 720 | | recommendations | 1 Recommendations | 1.5 | So, to ensure wider access, hybrid closed loop systems are recommended for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition, and have an HbA1c level of around 64 mmol/mol (8.0%) or more. And because blood glucose levels are harder to manage in pregnancy, they are also recommended for people with type 1 diabetes who are pregnant or planning a pregnancy. But because there is some uncertainty in the economic model, they are only recommended if the companies and NHS England agree a cost-effective price for the systems. | Whole population data from England & Wales (the National Diabetes Audit) suggests that in respect of short term gains (reduced DKA) and long term benefit (reduced complications) the target population should initially be people with Type 1 diabetes aged less than 30yr as well as pregnant women with type 1 diabetes. HbA1c starts rising at 9yr, peaks at 19yr and drops slowly to age 30. DKA rises steadily from age 10, peaks at 18yr and then falls gradually. |

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| 722 | | implementation | 4 Implementation | 4.3 | When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has type 1 diabetes and the doctor responsible for their care thinks that a hybrid closed loop system is the right treatment, it should be available for use, in line with NICE's recommendations. | This is as it should be. But evidence of effectiveness and cost-effectiveness is presently weak and small scale. I would recommend that rigorous monitoring of implementation and its effectiveness should be built in. This could be done at essentially zero cost if the HCL consumables were made prescription items whereupon patient level data could immediately be incorporated into the NDA and added to the tech parameters presently reported at national, regional, ICB, PCN and specialist service levels. |
| 727 | | information-about-hybrid-closed-loop-systems | Price | 2.9 | the companies will need to agree a discount with NHS England, | When will this take place in relation to the timing of the guidance? |
| 759 | CVD, Respiratory and Diabetes Clinical Networks, NHS England - South West | | | | | Although not directly relevant to the actual NICE HCL TA (i.e we understand they will make the recommendations and then we are expected to manage the logistics) we worry about implementation.<br>• Should this be agreed, it is likely to be very difficult to fulfil this within the time period agreed–<br>o Eligible patients - likely to need some way of assessing/ updating where are at within structured education and updating parts needed<br>o more HCPs will need education in pump and CGMS as well as HCL starts to allow safe uptake of patients on this at a larger scale than currently possible<br>o much more time will be needed not only for patient education, pump start, CGM start, HCL start but also for ongoing data interpretation and follow up (than in usual diabetes clinic time)<br>o it would be helpful to provide guidance on how these guidelines should be implemented, to ensure that health inequalities are addressed rather than widened as could easily happen<br>• Increased time set aside for this will mean that already stretched diabetes teams will have less time to support other patients with diabetes who are not on HCL systems |

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| | | | | | | • Patient expectations of timing for this need to be managed<br>• We would suggest a phased implementation to allow for this |

## THEME: INNOVATION

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| 101 | | committee-discussion | Innovation | 3.15 | | As a current user of a D.I.Y. Open Loop (which could be made into a HCL), I would have to disagree with the paper on this point. If you consider what has been available in the past up until the present day, the last 10-15 years alone has seen major innovative leaps forward (which bearing in mind is a quarter of the 60 year time horizon this paper seems to set on). You only need look at D.I.Y. and start up innitiatives that have sprung from that to see just how much has changed and developed in recent years. The very idea of a HCL was not even in the majority of the diabetic community's general consciousness between five and eight years ago but if you look at the uptake in interest in diabetes technologies in recent years, there is clearly innovation going on and still to come. It might not be like AppleMac or Microsoft but considering where their tech started out from and where they are now, some health tech is just going to take more time to get to the super small, super fast, super clever iphone and tablet stage. Whilst Mac and Microsoft can run ahead at whatever speed they wish, health tech has more at stake, people's lives and health (which can bring the speed down but the aim to reach optimal efficiency upwards). Innovation is definately on the cards, it is just about keeping the last 100 years in perpective. |
| 284 | | committee-discussion | Innovation | 3.15 | The committee concluded that although HCL systems provide an alternative treatment option for people with type 1 diabetes, the level of innovation is not sufficient to justify consideration of a higher ICER (over £20,000 per QALY gained). | This is fairly unbelievable. The principle of a closed loop system has been considered for decades to be the 'holy grail' of diabetes treatment short of a cure. To declare such a treatment option as 'not sufficiently innovative' is astonishing. |

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| 532 | | committee-discussion | Innovation | 3.15 | | Characterising attributes of innovation of technologies for healthcare: a systematic review by Syeed et al (2022) https://doi.org/10.1080/13696998.2022.2140591.<br><br>This recent systematic review includes eight criteria to determine innovation attributes.<br><br>The algorithm used to integrate rtGCM data with CSII would fall within these criteria which would justify consideration of a higher ICER, namely, 'novelty, step-change, an improvement over existing technologies, substantial benefits, an improvement over existing technologies, convenience and/or adherence, added value, acceptable cost, and uncounted benefits'.<br><br>This systematic review also highlighted the need for patients' and caregivers' perspectives on healthcare innovation. The changes that HCL make to HbA1c coupled with QoL improvements are truly innovative from a patient/caregiver perspective - this Consultation does not consider the full evidence for this, because it has not included qualitative research studies. |

## THEME: MENTAL BURDEN

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| 25 | | recommendations | 1 Recommendations | 1.1 | | In the rationale for why you have made these recommendations you have acknowledged that the "substantial mental load" of continuously managing diabetes yet you are only recommending a hybrid closed loop system for those with a HbA1c of 64 mmol/mol. You are no acknowledging those who are struggling mentally but still manage to keep their HbA1c in range, often because their levels are so erratic they fluctuate from hyperglycemia to hypoglycemia.<br><br>To give you some background I'm going to tell you about myself and where i am coming from as i feel you need to hear directly from a diabetic. I am Type 1 diabetic for 25 year, been on insulin pump therapy for 10 years and on Libre flash glucose monitoring for 4 years.<br><br>My HbA1c is 52 mmol/mol, which i appreciate is within range, but i spend my whole life, 24/7 working non-stop to achieve this. Throughout the day and night I am continuously monitoring what is happening. I wake up regularly in the night (naturally - no alarm!!) to check my levels as they are so erratic. I can never forget about my diabetes or ignore it.<br><br>This is a condition that requires CONSTANT monitoring, awareness and cautiousness (of what we eat, insulin dose, activities we do etc). it isn't just a mental load, it's mentally exhausting and debilitating.<br><br>I am in regular contact with my diabetes specialist team, phone and email to seek advice about my glucose levels. Every time i speak, and see them (DSNs and the endocrinologist) i can't stop crying because of how knackered and fed up i am with my diabetes. I work very very hard to try and achieve great levels but it doesn't happen and I have been crying like this for at least 10 years.<br><br>i am receiving CBT because of how depressed and anxious i am from my diabetes. As much as i try my hardest and do everything I'm supposed to do sugar levels still are erratic. It's a condition i wish i could forget about but i can't. It's not like some chronic conditions which you can take a pill and forget about it, it is 24/7 with no breaks.<br><br>As i mentioned just because someone's HbA1c is in a good range, it doesn't mean they automatically have control. To give you an example; for the past 90 days my average blood glucose is 8.4 mmo/l. In the past week alone 2 out of 7 days my average glucose has been above 10 mmol/l and I've gone from hypos of 3.1 to hypers of 17.6. averages are not always a true reflection.<br>Over 90 days my time in range consists of: 9% above 13.3, 20% between 10.1-13.3, 67% of the time has been in range (3.9-10) and 3% below 3.9.<br><br>The hybrid system would allow me to sleep throughout a night, to stop my body naturally waking me up 4+ times a night to check my glucose. the stress and anxiety i feel about my |

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| | | | | | | diabetes can cause high glucose readings and the hybrid technology would help reduce those rises and all the associated risk. It would allow diabetics to aim towards living a more 'normal' life and give us some quality of life back which has been missing since diagnosis.<br><br>Please consider expanding your recommendations to other diabetics. |
| 30 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | I agree with the mental load. (I'm an adult type 1 diabetic, living with diabetes for 11 years.) The closed-loop system is life-changing for us and significantly reduces the mental load of living with type 1. I read somewhere that a person with type 1 needs to make 100 decisions a day around their diabetes; this solution would significantly decrease that. Not to mention the improvement to the quality of life of children! There are immeasurable benefits to this system. |
| 35 | | committee-discussion | Conclusion | 3.15 | | You have absolutely hit the nail on the head with regards to the mental load of living with T1D.<br><br>Why therefore is not everyone who is capable of using a closed loop effectively not being offered one?<br><br>The stress of T1D and managing Glucose levels is playing a part in increasing depression leading to more suicide attempts. let along the added burden for anyone living with additional chronic conditions. A closed loop system would dramatically improve QoL, reduce depression in patients who are struggling and provide better sleep, reduced complications, productivity and reduced visits to NHS services saving money and resources in the long term<br><br>Closed loop should really be offered to ALL with T1D with capability or a much more fluid eligibility based on individual patients circumstances. Personalised Care!! Not continuing for just a select few.<br><br>PCT, CCGs etc need to be given strict time frames to get this rolling. They are far too slow in making decisions and actually providing what NICE recommends |

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| 44 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | recommendations | 1 Recommendations | 1.4 | | Patients would be considered for this technology based on the same current considerations made for CSII and CGM with assessment appointments and following the DAFNE course (or an appropriate method of training tailored to the individual).<br><br>The recommendations have NOT considered the overall diabetes burden (especially mental health) and effect on quality of life despite these being highlighted in the listed evidence (see below):<br><br>“Continuously managing blood glucose levels is a substantial mental load for people with type 1 diabetes (and their families or carers). Hybrid closed loop systems automatically deliver insulin using a calculation based on continuous glucose measurements. The systems do not need as much input from the person but manual insulin dosing is still needed sometimes, for example, around mealtimes. So, they may reduce the mental load and improve people’s quality of life.” |
| 48 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | committee-discussion | People with type 1 diabetes, families and carers | 3 | | The closed loop pumps also have numerous alarms and one of the reasons for people handing them back was that the alarms were going off all night. |
| 54 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | Patient experts explained that the mental load of living with diabetes is significant. This is because people with diabetes (and their parents or carers) look at a lot of data and have to make a lot of calculations and decisions about their insulin dose every day. This can be exhausting, affect people's mood and frequently leads to burn out. People with diabetes and their families can also be woken by continuous | I fully agree with this statement. Additionally, one does not have a single day off from diabetes, it is relentless and particularly hard to live with when brittle. I feel a loop would benefit me greatly, particularly as I exercise daily to try and keep as fit as possible to be in as good health as possible |

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| | | | | | glucose monitor (CGM) alarms, causing sleep disruption. The patient experts explained that managing glucose levels is a lot of work and can affect home life, education, training or work. Although a CGM and continuous subcutaneous insulin infusion (CSII) can help maintain blood glucose control, if they are not integrated then this still involves substantial user input, which can be a mental burden. A parent of a child with diabetes said that the mental burden significantly affected their quality of life. They highlighted that children are less able to recognise the symptoms of hypoglycaemia and hyperglycaemia, and this is a constant worry for parents when they are apart from their children. They also explained that disrupted sleep was a significant problem, with parents waking multiple times a night to monitor their child's blood sugar and | |

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| | | | | | administer glucose or insulin. The committee concluded that managing type 1 diabetes is a substantial mental burden on people with diabetes and their families. It further concluded that automated technologies such as hybrid closed loop (HCL) systems can reduce some of the burden, and improve quality of life for people, their families and carers. | |
| 82 | | | | | | 3.1<br>Touching on the subject mentioned I can personally add that I suffer with lack of sleep due to CGM alarm waking me due to hypos through the night , and through the day, and I am constantly recalculating insulin doses trying to solve hypos, and it has caused very low mood, exhaustion, and anxiety, that is why people with type 1 diabetes should have an integrated system. So a hybrid loop would most defiantly reduce the burden for adults and children alike. And improve their quality of life. |
| 108 | | | | | | The NHS Constitution's opening paragraph includes the words mental wellbeing and work to the limits of science, as below.<br><br>' It is there to improve our health and wellbeing, supporting us to keep mentally and physically well, ... It works at the limits of science... '<br><br>This document does not appear to consider the benefits of the mental wellbeing of those with a long term condition, as required by the NHS Constitution.<br><br>Indeed the benefits of mental wellbeing will outweigh the documented benefits of Hba1c, in that poor mental wellbeing is all pervasive on life and employment including the commitment and ability to deliver Hba1c.<br><br>The foundations of mental wellbeing must be present and delivered, across the full TID population. Agreement to implement HCL across the full population will satisfy the NHS Constitution in both terms of mental wellbeing and working to the limits if science. |

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| 118 | | | | | | 1.1 Although there is clearly a need for prioritisation of access, the mental burden mentioned can sometimes be the same or even higher in people with diabetes who are working hard to keep their HbA1c in recommended levels. Mental health should also play a part in how people are assessed for eligibility. |
| 132 | | recommendations | 1 Recommendations | 1.1 | | As a parent of a 13year old with type 1, who is struggling with his mental health due to his life long condition. I would ask you to also consider mental health in your allocation of closed loop therapy. It should be closed loop for all surely better control means less cost and pressure to the NHS in the long term? Also this could lower the cost of the looping systems in terms of buying power. |
| 134 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | I totally agree with this section, as a mother of a type 1 teen, we are currently in a very dark place, sleepless nights, exam stress, hormonal insulin resistance. The mental strain is a huge part of our lives, its a constant battle, 24 hours a day. A closed loop would improve my child life, but also the quality of life for the whole family. |
| 179 | | committee-discussion | Baseline characteristics | 3.4 | | Although studies prefer solid numbers for effect, I wonder if the study asked the participants what the reduction of mental load was like, and how that affected quality of life. A good measure of this would be reduction in stress, or how many times the patient or carer had to get up in the night for diabetes. |
| 200 | | committee-discussion | People with type 1 diabetes, families and carers | 3 | | This is an accurate description of how relentless the day-to-day management of T1D is, for all who have T1D, not just those with HbA1C over 64mmol/mol. HCL can make a big difference for all, not just to their numbers, but to quality of life, which is sorely needed. |
| 208 | | recommendations | 1 Recommendations | 1.1 | | Consider discussing & offer to Type 1 Diabetics who are suffering or have suffered from burn out and discuss mental load due to the continuous and substantial management of blood glucose levels. |
| 213 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | As a patient with T1D, the mental load and burden described here is so very accurate and the section resonates with me. |
| 234 | | recommendations | 1 Recommendations | 1.5 | substantial mental load | The recommendations do not appear to recognise the mental health burden and are only related to an HbA1c value. It is telling that in response to the Diabetes UK comment no 4 on page 63 of the supporting document that the reply was 'Any QoL gain purely from increased convenience of HCL compared to CSII+CGM is not included in the economic analysis'. An admission that QoL and reduction of mental burden has not been included in the assessment. |

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| 252 | | recommendations | 1 Recommendations | 1.5 | | You acknowledge that looking after or being a person with t1 carries a huge mental load and yet only want to relieve this burden from some people, why? |
| 260 | | recommendations | 1 Recommendations | 1.1 | | Consider removing such a restriction which fails to take in to account anything more than a random snapshot of an individuals control. One of the key benefits of a closed loop system is in regards to the burden of management, which is significant, and often leads to burnout and emotional/mental distress. The focus here is on a figure which doesn't provide the whole story of a patient and the burden placed upon them to achieve it. It also fails to consider those patients who have satisfactory hba1c numbers achieved through constant large swings back and forth from high to low glucose levels. From my experience as a type 1 of 16 years is that the numbers are meaningless without considering the challenges behind achieving it. |
| 265 | | committee-discussion | | 3 | | I also note that none of the clinical experts were Diabetes Specialist Psychologists. This is a significant oversight and suggests that there is no parity of esteem between the mental and physical in NICEs approach to Diabetes. This is highly concerning considering repeated calls from patient communities for recognition of the psychological burden of Type 1 Diabetes, also I notice that the recommendations acknowledge 'Psychological Difficulties' without the relevant input from Specialist psychologists. |
| 272 | | committee-discussion | Uncaptured benefits | 3.9 | | All I can say is that I worry all the time. The closed loop has considerably reduced my anxiety and enabled me to allow my son more freedom to meet friends etc in a normal way, without me worrying about his levels, because I now trust the closed loop will do its job. I still worry of course, but that is reduced. |
| 281 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | The committee concluded that managing type 1 diabetes is a substantial mental burden on people with diabetes and their families. | The committee is correct, and it should be recognised that the load is NOT diminished for those with well-controlled T1. T1 patients who are able to achieve better-than-average A1Cs have to really work at doing so, and quite possibly in many cases may well have significantly higher mental burdens than those with higher A1Cs, as their better control may well be because they spend more mental time managing their diabetes. |

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| 288 | | recommendations | | 1.5 | Continuously managing blood glucose levels is a substantial mental load for people with type 1 diabetes (and their families or carers). Hybrid closed loop systems automatically deliver insulin using a calculation based on continuous glucose measurements. The systems do not need as much input from the person but manual insulin dosing is still needed sometimes, for example, around mealtimes. So, they may reduce the mental load and improve people's quality of life. | Continually managing glucose levels is a huge mental strain on families. It is particularly difficult when a child reaches 18 and suddenly wants to drink alcohol and experience the same freedoms that their peers have. I believe that you should offer the same level of support to young adults as you do to 'children'. I am terrified of my daughter being out with friends and going low in her sleep due to alcohol (even though I know that she is sensible). I get no sleep if she is out with friends and staying somewhere else over night and this is not healthy for me or her. The closed loop system would improve the quality of life for our whole family, not just my daughter. |
| 293 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | Patient experts explained that the mental load of living with diabetes is significant. | This is absolutely true and should not be underestimated. I have not had a full night's sleep since my daughter was diagnosed in 2016. |

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| 301 | | recommendations | 1 Recommendations | 1.1 | | It is inequitable for the NHS to restrict availability of a hybrid closed loop system to those people who are are perceived to be having difficulty managing their condition. Type 1 diabetes is difficult for everyone to manage. Some of these difficulties are observed as relatively high HbA1c measurements but some of these difficulties do not show up in measurements and are often kept hidden by the individual so as not to cause extra burden to the carer and the family. These are the difficulties of worry, anxiety and depression and they may prove to be a great expense for the NHS. A person with Type 1 diabetes may be vary proficient at keeping their HbA1C measurement within the recommended range but the personal burden of constant vigilance to achieve these results can have a huge impact on quality of life. If the hybrid closed loop system works effectively, as it has been shown to do, then it should not be subject to any discriminatory application process. |
| 314 | | recommendations | 1 Recommendations | 1.1 | | Quality of life has been ignored in these recommendations. Constantly monitoring blood sugar levels, injecting 5+ times a day, monitoring food intake versus exercise and calculating doses is mentally exhausting, particularly when you have been doing it for 50 years. Patients in this situation should be eligible to try a HCL to determine whether it improves their quality of life and lessen the mental pressure. |
| 357 | | | | | | I am commenting as a type 1 diabetic of 4 years. The current guidance for the provision of most technology and solutions that make living with diabetes easier are understandably offered to those struggling to manage their condition. However, these recommendations only define good management by an average HbA1c of under 64, when in reality there are many other metrics that contribute to living well with diabetes. In particular, I feel the guidance for this, and so many technological solutions, fail to recognise the mental impact that long term management can have on a patient. A diabetic might have excellent "control", but to the detriment of their mental health. To some extent, it feels like these guidelines unfairly punish those who have prioritised their physical health, no matter the cost. It would be nice to see guidance that can also reward those who are striving for optimum control. We need to be moving towards a type of care that gives everyone equal opportunity to access life changing technology, and prevents future health complications, rather than one that only intervenes when the most basic treatment fails. |
| 389 | | | | | | Please consider the mental burden of managing type 1 and the additional factors such as menstrual cycles that require additional management as a separate factor from hba1c. Mental burdens cannot be measured and having a good hba1c as a result high levels of management should not prevent access to this technology |

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| 431 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | Patient experts explained that the mental load of living with diabetes is significant. | On a personal level, this is very important. People who work very hard to keep their levels in range (if on a CGM) do get exhausted. I understand the need to roll this out to Children, Pregnant Women and people with high levels but please open this up to others when it is possible. | | |
| 442 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | The patient experts explained that managing glucose levels is a lot of work and can affect home life, education, training or work. | Completely agree with this. Having devices to take off some of the mental load should be an option for EVERYONE with type 1, not just those with poor levels. Those who take good care of their diabetes are potentially more stressed and sleep deprived than those to don't (and consequently have worse hba1c). | | |
| 460 | Children & Young People's Diabetes Team, Somerset Foundation Trust | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | This is a highly important factor in our opinion. It is concerning to our team that this does not form any part of the actual eligibility recommendations for this therapy. | | |
| 467 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | Poor sleep also may lead to increased risk of dementia (https://www.health.harvard.edu/blog/sleep-well-and-reduce-your-risk-of-dementia-and-death-2021050322508) | | |

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| 471 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | Completely agree with the significant mental load that comes with type 1 diabetes. It is a constant, chronic, life long, life altering disability. Any technology which eases this burden should be offered to as many people as possible to improve mental health and wellbeing of many diabetics. |
| 483 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | I strongly agree with this paragraph as a parent of a T1 diabetic and completely relate to it. |
| 484 | | | | | | I have had type 1 diabetes since the age of 7 (27 years in total). Since technology has been made vastly available across the past few years (insulin pumps and flash/cgm), my control of the disease and indeed my mental health has VASTLY and SIGNIFICANTLY improved. My hba1c has improved drastically and my day to day control of hypos and high blood sugars is so much easier to manage. I do a lot of training and exercise and the ability to manipulate insulin rates by the hour has enabled me to train more effectively and be more healthy. One thing I do want to discuss is the stress and anxieties caused by constantly managing 'background' insulin (basal). Regardless of the technology, many type 1 diabetics are micro managing day by day to get blood sugar levels perfect. This has a profound impact on the stress and anxiety AND mental health of diabetic people. The closed loop system would eradicate a whole lot of this anxiety and mental health and ultimately provide better control and better quality of life. I wholeheartedly believe that the UK is one of the greatest countries to be a diabetic in. The technology available on the NHS has transformed people's lives to the point that they feel ever so much more 'normal'. The closed loop system would be the final stepping stone to the UK leading the way in healthcare provision for type 1 diabetes and would save many lives. Let's lead the way on this and make the closed looping system available to all type 1 diabetics who want it, and improve the standards of our lives with this wonderful and incredible piece of technology. |
| 491 | | | | | | My son has been using closed loop for 2 years after having type 1 diabetes for 16 years . He has autism and anxiety, his mental health was affected by the stress of managing his diabetes. The relief of having good control of his diabetes has helped him so much. He is now able to sleep and has Hba1c is around 50 instead of 60 plus as it had been for so long<br>However, we have been unable to be prescribed the sensor required. We hope this changes |

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| 513 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | As a 45 year long, Type-1 juvenile onset diabetic I can attest to the findings justifying clinical need for close loop systems. As a 68 years old, I find that the burdens of good diabetic management are equivalent or similar in difficulty to the challenges I faced as a young person, not least being the mental and emotional strain Type-1 imposes. While the circumstances are different in detail, overall I would say they are equivalent. For the record my A1c hovers around 55mmol/mol using a pump. A closed loop system could greatly improve that (not too bad) result, which I would welcome. |
| 514 | | | | | | As a parent of a young adult who has suffered from Type 1 for 15 years I welcome this report and its conclusions. However, when considering the value/cost of closed loop, I strongly believe that significant weight should be given to the enhanced quality of life that comes from relieving much of the minute to minute decision-making that type 1 entails. In my daughter's case, before we privately funded looping, the stress and burnout from type 1 had a significant impact on her mental health, which itself resulted in large costs to the NHS via CAMHS and for a lengthy in-patient stay in hospital. Even without such direct costs that might be reduced/eliminated by better treatments such as closed loops, the general improvement in mental health should be ascribed a real value in any assessment. |
| 516 | | | | | | I fully understand that there are many calls on NHS budgets, and that the amount allocated to this would need to be reasonable and appropriate in comparison to other pressing issues.<br><br>However as a parent and advocate for my soon-to-be teenager daughter, I know that the impact on her life of the new technology would be hugely positive. Type 1 places massive demands on her physically and emotionally, and is very damaging to her stress levels and mental health, and ability to live a normal life.<br><br>I await the outcome of the consultation with fervent hope for a favourable outcome.<br><br>Thank you<br>[redacted] |

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| 523 | | committee-discussion | Uncaptured benefits | | 3.9 | However, clinical experts expressed concerns that the reduced mental burden and familial or carer anxiety that HCL systems provide may not be captured adequately in the model. The committee understood that there was no quantitative evidence that could be used to estimate the value of these potential quality of life benefits. The committee agreed that there were potential quality of life benefits of HCL systems not captured in the model, including the effect on learning and education, ability to work, mental burden and fear of hypoglycaemic events. The committee concluded that these uncaptured benefits were likely to undervalue the effect of HCL systems on quality of life. | This is a significant omission from the model, particularly as it will only operate to increase cost effectiveness.<br><br>In addition, patient expert evidence in this consultation speaks almost entirely towards this impact. Patient experts are not concerned about their HbA1c, or time in range, as a numerical value. They are concerned about the quality of their lives, or the lives of the people they care for. |

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| 533 | | committee-discussion | Conclusion | 3.16 | | The uncaptured benefits need to be considered to be 'in scope'. The Committee did not look at how HCL systems can maintain HbA1c levels which are below 8.0% without the concomitant risk of burnout. Why did the Committee only focus on HbA1c change? The cost to the NHS mental health services from people with Type 1 and their families/carers suffering diabetes distress or burnout from maintaining lower HbA1c is a relevant one in deciding who should get access to HCL. |
| 547 | | committee-discussion | Uncaptured benefits | 3.9 | | It is difficult to quantify the massive emotional burden of managing T1 diabetes but these systems are a massive help in reducing some of the complex and continuous treatment decisions |
| 565 | | | | | | The benefit to diabetes burden and quality of life is mentioned, however assumed to be greater with patients who have higher HbA1c. Patients with lower HbA1c (less than 64) may be working incredibly hard to achieve optimal control to the detriment of sleep, anxiety and other mental health issues.<br><br>Diabetes care is negatively reinforcing: The patients who invest less in looking after their diabetes are offered the better technologies to reduce burden. These are less likely to maintain good use of diabetes technologies over time however. Patients working hardest to look after their diabetes are not offered any benefit of better technologies to reduce diabetes burden.<br><br>Introduction of technologies has been shown to both reduce some burden but increase other burdens regarding diabetes management. Patients working hard to self manage diabetes without HCL and who are keen to use this, are more likely to experience a reduction of burden and so long term compliance with HCL systems. |
| 566 | | | | | | The benefits of HCL for patients who do a lot of physical exercise should also be considered. The benefits of physical exercise on patient health and therefore NHS long term budgets, is well documented. There is a huge burden of diabetes management for patients who do lots of physical exercise for their own health and well being. This can have a negative impact upon mental health and sleep (dealing with hypos following extensive exercise) as a consequence.<br><br>People with Type 1 diabetes make around 180 additional health-related decisions each day (Tack et al 2018). With people doing increased physical exercise, this number will be far greater. |

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| 570 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | frequently leads to burn out | | I have had to leave jobs I cared about due to diabetes burn out and distress, the impact that functioning as your own pancreas has on your daily life cannot be understated. |
| 591 | | dap55-diabetes-mta-acd-final-no-acicdocx | | | | | | It is disappointing that, altho mentioned throughout the document, the psychological burden of managing type one on adults as well as carers & children plus QOL is not included in the recommendations.<br>Mental & physical health go hand in hand so both need to be given the same importance. |
| 618 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | | | This section assumes that some people magically achieve <48 and does not recognise the huge effort that some people have to put into their management. It does not recognise that there are some people who's jobs do not allow them to monitor their blood glucose frequently enough, or do the corrections, to achieve these values. It is VERY important that the burden of diabetes is used as the most important criteria |
| 620 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | | | The burden of diabetes on the individual should be a criteria for hybrid systems. If the system relieves the amount of effort the individual puts into their diabetes management - regardless of what their HbA1c is - then they should be eligible. Similarly for the burden on their family and if the patient says they cannot do their work with the amount of effort T1D management imposes on them. |
| 630 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | | | I am extremely pleased that the committee took into account the mental load of living with diabetes. Even for someone with very good control, that is often achieved by even more monitoring and decision making and adjustments to pump settings or ratios for calculations. Without a hybrid closed loop I would suggest that those with the best control and therefore a HbA1c below the average are in fact taking more mental load trying to keep their control so toght. |
| 634 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | | | | Can the psychological/ emotional/ time factors be considered in managing type 1? |

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| 636 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | 100% agree with the explanations of the patient experts - think this needs to be emphasised in the document and be considered when thinking about HbA1c criteria as this mental load cannot be underestimated esp in the paediatric population. It is impacting both the child/young person and the wider family members |
| 662 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | As a parent of two young children with type 1 diabetes of different age groups, I would say that the impact on the family as a whole is huge, both physically and mentally draining, not just on either carer/parent or child. More studies need to be completed on showing the overall picture of the significant changes to a whole family unit that having type 1 diabetes has, and then the impact of having access to HCL. |
| 686 | | | | | | This innovation will make a huge difference to patients mental well-being. I was diagnosed with type 1, 12 months ago and have found the management of this condition exhausting and I have to do it all again for the rest of my life. Taking some of the stress out of This management with an automated system will have huge life benefits. |
| 698 | | recommendations | 1 Recommendations | 1.5 | Continuously managing blood glucose levels is a substantial mental load for people with type 1 diabetes (and their families or carers). | Even people with better management have the mental load, let them have this technology as well. |
| 703 | | | | | | NICE needs to consider other challenging factors to add to the criteria rather than pregnant or higher than average Hb1ac. T1D is a constant struggle which impacts on the lives of the whole family. The mental strain and anxiety of that constant struggle should be considered. |
| 728 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | Patient experts explained that the mental load of living with | Can this also be considered for a patient who has a Hba1c below 64 mmol/mol as a factor to consider closed loop? |

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| | | | | | | | diabetes is significant. | |
| 737 | | committee-discussion | People with type 1 diabetes, families and carers | | 3.1 | Patient experts explained that the mental load of living with diabetes is significant. This is because people with diabetes (and their parents or carers) look at a lot of data and have to make a lot of calculations and decisions about their insulin dose every day. This can be exhausting, affect people's mood and frequently leads to burn out. People with diabetes and their families can also be woken by continuous glucose monitor (CGM) alarms, causing sleep disruption. The patient experts explained that managing glucose levels is a lot of work and can affect home life, education, training or work. Although a CGM and continuous subcutaneous insulin infusion (CSII) can help maintain blood | The mental burden is still as great for parents of children with HbA1c below the HCL qualifying threshold of 64mmol/mol. It could be argued that this burden is greater because of the effort involved in getting below that threshold. |

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| | | | | | | glucose control, if they are not integrated then this still involves substantial user input, which can be a mental burden. A parent of a child with diabetes said that the mental burden significantly affected their quality of life. They highlighted that children are less able to recognise the symptoms of hypoglycaemia and hyperglycaemia, and this is a constant worry for parents when they are apart from their children. They also explained that disrupted sleep was a significant problem, with parents waking multiple times a night to monitor their child's blood sugar and administer glucose or insulin. The committee concluded that managing type 1 diabetes is a substantial mental burden on people with diabetes and their families. It further concluded that automated technologies such as hybrid closed loop | |

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| | | | | | | (HCL) systems can reduce some of the burden, and improve quality of life for people, their families and carers. | |

## THEME: MULTIPLE THEMES

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| 34 | | | | | | As a person with Type 1 diabetes and a parent of a child with Type 1 diabetes I am speaking from personal experience of using the TSlim and Dexcom in combination, as a hybrid closed loop system.<br><br>My son was diagnosed, aged 16, following double open heart surgery. He spent six months using injections and was then kindly offered a TSlim pump. At 17 he started working shifts as a HCA in a care home in preparation for applying to university to study medicine. Despite good control after several shifts where he suffered bad hypos we decided to self fund the Dexcom for him. We had applied for funding twice and despite both his diabetic and cardiac consultants supporting the application he was turned down. As parents we knew his dream was to be a doctor and wanted to support him in any way we could and have therefore been funding the Dexcom ever since. He is not from a background of wealth, we work hard running our own small business and we fund this over many other things. He went through state education and is now at Oxford studying medicine but as a future junior doctor he will need this technical intervention to help him cope. To look at him on paper under the current recommendations he still wouldn't qualify. Why? Because the technology is already doing the job and because as a future medic he works so hard to manage his control. People like my son should also be supported.<br><br>Secondly, I have now been using the same technology for a week. Again we have made the decision to self fund. I am in my late 40's and going through the perimenopause. It is a period of adjustment for any women but whilst coping with Type 1 diabetes it makes things even harder. My levels have been increasingly difficult to control and yet, again on paper, they look fine and would not qualify for the funding technologies. This is because I spend hours working on tight control and dealing with the times when control does not happen for the reasons only known to hormones! The difference in my physical and mental health having been close looping for just a week is just incredible.<br><br>I appreciate my ramblings may not be scientific but they are based on real living cases, battling through different stages of our lives. There should never be a one size fits all argument, we are all different and we should all have the same opportunities for funding, we have fought hard to fight the post code lottery situation we are currently in, with no luck and yet I'm telling you. The technology is saving the NHS money in future issues as we take matters into our own hands. We know we cannot fund this ourselves indefinitely, so are hopeful NICE see the long term benefits. It is life changing. |

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| 50 | | | | | | Are the recommendations sound, and a suitable basis for guidance to the NHS<br><br>I do not believe that the criteria for offering closed loop is correct. I have had type 1 for 40 yrs and as such have around 10 type 1 friends, real friends not virtual. Amongst them those that would put the work in that is still needed to get the full benefit of closed loop would most likely not reach the 64/8% mark, those that would are the ones who really dont want to be bothered to put the work in! I have been lucky enough to get funding for closed loop due to the impact my control was having on both mine and my husband's sleep, I would scan 3-4 times a night as some nights I would go high and need a correction and some nights hypo and need glucose, I had to turn the libre alarms off as they woke my husband before me. My hba1c was around 7 because I work hard at it, I had 4 separate basals I got through every month. In 5 weeks of closed loop my hba1c has dropped to 6.5 but it has still taken a lot of work. The closed loop systems are still a long way from easy, for example my active insulin time is just 1 hr and my pump is set to 5 hrs which cant be changed meaning if the correction hasn't worked in 1.5hrs the pump wont correct again for 3.5 hrs. I tweak this by telling it im eating carbs to get the relevant amount of insulin to give another correction. The other major issue is it only delivers 60% of your calculated corrections, why? I dont know!! So this combined with the 5hrs actually makes this part of the pump useless. I have worked my way around this by programming the pump to believe my ratio is 1-3.5rather than 1-6. The less worrying problem is that despite thinking insulin works over 5 hrs it will stop your insulin when low for maybe half hr plus and what a suprise 1 hr later your sugars are high, again there is a way around this, I eat a sugar cube or 2 and as soon as 5 or above tell the pump ive had some carbs to match the missed bolus!<br>Despite these teething problems I really love my closed loop, my time in range has gone from 70% to 80-90% most days. It is so nice to go to sleep in range, have a full night's sleep knowing the pump can keep me there. It does work brilliantly at keeping you in range when you are there, 100% brilliant then, it can't deal with highs very well or exercise, not without user help. If the pumps are handed out to the people with high hba1c who are there because they dont want to try then the NHS is going to waste a huge amount of money! If the criteria was more along the lines of the nurses checking how often the flash systems are used and how active the patient is in changing and trying different basals you might just fund the people who will make the most of the system. I am fully aware some with hba1c above 8% would be in that category but the proof would be in the effort. Mixing in my life with other type 1s I can assure you using the hba1c as a guild to who gets funding will definitely mean a lot of people worthy of it missing out and the NHS wasting millions on people who will believe it will do all the work for them, sadly closed loop isnt there.. yet! |

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| | | | | | | Blood glucose levels are harder to manage in pregnancy.<br>Whilst I agree this is true having had my daughter 15 yrs ago, ending up in hospital with preeclampsia at 30 weeks pregnant and having an emergency c section at 33 weeks I know exactly what type 1 and pregnancy entails. That said controlling my blood sugars during pregnancy was a walk in the park compared to controlling my blood sugars during peri menopause! As previously mentioned I use 4 different basals over the course of a month, each of these need tweaking every month as the times of day I become insulin resistant vary every month as do the times each month I need to change my basals. If you are going to consider the hormonal effects of pregnancy on blood sugar control then you really should also be considering the hormonal effects of menopause on blood sugar control. Menopause effects every woman not just those choosing to become a mother! |
| 79 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | committee-discussion | Conclusion | 3.16 | people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0% | We recommend clarifying and expanding this statement.<br><br>How do you define “difficulty”?<br>“Difficulty” does not always result in high HbA1c – there may be disabling or frequent hypoglycaemia (which in CYP affects brain development), eating disorders (restricted eating due to not wanting to inject), mental health issues, sports people struggling to achieve performance due to BG levels)<br><br>Despite acknowledging increased benefit for use of HCL in children compared to adults, this is not reflected in the recommendations. We recommend in children, lowering HbA1c cut off from 64 to 53mmol/mol or removing it as a criteria completely. |

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| 100 | | committee-discussion | Uncaptured benefits | 3.9 | | There is a gross undervaluing of the mental and physical load on persons with type 1 diabetes and their loved ones. And lest we forget, the greater added costs to the NHS when type 1 diabetes goes very, very wrong (as touched on in section 2.1).<br>Quality of life is linked to our economy - the stats do not lie. And with patient's mental and physical efforts going almost entirely into just taking care of their type 1 diabetes and little else, we as a society (and economically) lose out on a wealth of potential. For too long society has been lacking the manpower that the type 1 diabetic community has the potential to provide if only the patients had means of relieving the burden of caring for their condition. Being zapped all the time from caring for this chronic condition means we as a society are missing out on the expertise, creativity, resourcefulness and ability of thousands of gifted individuals whose only fault is that they must care for a chronic condition that may kill them or at least degrade their health faster than their peers. Better quality of life brings greater success across the piece |
| 102 | | | | | | 1.1 - Stipulating a HbA1c of 64mmol/mol (8.0%) is very short sighted in my opinion. One of the biggest burdens of T1D is the strain on the patients mental health with the constant management of the disease regardless of the patients numbers or results. Arguably the toll on the persons mind and the effect it has on their day to day life could be construed as a heavier burden for those with good control below 8.0%. To omit these patients from having access to this life changing technology is bordering on discrimination. I myself have a HbA1c of less than 8% and the mental strain and sacrifices I make to keep these figures is very often unbearable and too much to handle. The affect on my life since diagnosis is immeasurable. Please reconsider this recommendation for the sake of myself and thousands of others like me. I would move heaven and earth to have access to this type of technology and if it was financially plausible would self fund this in a heartbeat.<br><br>3.16 - Cost effectiveness is here being measured once again by a persons HbA1c levels (as is most of the document) and a conclusion is given that is above 8.0% is most cost effective as you will see the greatest results by which you can measure in the easiest way. I refer to your section 3.1 where you have almost perfectly showed your understanding of the burden and toll on a persons mental health and overall quality of life, this I would like to point out is regardless of the patients HbA1c level and in my opinion in many cases the burden can be more for a well controlled patient. A persons mental health and quality of life is, I agree, is hard to measure, certainly the costs for the NHS is, but it is measurable and it is real and it does cost the NHS (reported at £117.9 billion annually). I repeat ignoring this as a recommendation and taking the easy route of measuring HbA1c levels that are easily recorded from captured data is bordering on lazy, negligent and discriminatory. |

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| 103 | | | | | | 1.1 - Stipulating a HbA1c of 64mmol/mol (8.0%) is very short sighted in my opinion. One of the biggest burdens of T1D is the strain on the patients mental health with the constant management of the disease regardless of the patients numbers or results. Arguably the toll on the persons mind and the effect it has on their day to day life could be construed as a heavier burden for those with good control below 8.0%. To omit these patients from having access to this life changing technology is bordering on discrimination. I myself have a HbA1c of less than 8% and the mental strain and sacrifices I make to keep these figures is very often unbearable and too much to handle. The affect on my life since diagnosis is immeasurable. Please reconsider this recommendation for the sake of myself and thousands of others like me. I would move heaven and earth to have access to this type of technology and if it was financially plausible would self fund this in a heartbeat.<br><br>3.16 - Cost effectiveness is here being measured once again by a persons HbA1c levels (as is most of the document) and a conclusion is given that is above 8.0% is most cost effective as you will see the greatest results by which you can measure in the easiest way. I refer to your section 3.1 where you have almost perfectly showed your understanding of the burden and toll on a persons mental health and overall quality of life, this I would like to point out is regardless of the patients HbA1c level and in my opinion in many cases the burden can be more for a well controlled patient. A persons mental health and quality of life is, I agree, is hard to measure, certainly the costs for the NHS is, but it is measurable and it is real and it does cost the NHS (reported at £117.9 billion annually). I repeat ignoring this as a recommendation and taking the easy route of measuring HbA1c levels that are easily recorded from captured data is bordering on lazy, negligent and discriminatory.<br><br>My conclusion and fear is there will be a percentage of patients that currently have good control that will make a horrendous decision to let there HbA1c drift above 8% just to be considered for approval. This is wrong on so many levels for everyone involved including the patient and the NHS. This is a real conclusion that needs consideration. I know this because it is a decision that I would have to consider myself if these recommendations come into force, it goes against everything I believe in and stand for and to feel I am pushed into purposely and seriously sacrificing my health to meet criteria for specific treatment seems absolutely crazy. |

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| 111 | | | | | | Restricting access to those with HbA1c's at 8% and above is wrong. Its not just wrong, its borderline criminal. What justification is there for excluding all population groups except those with incredibly poor control and pregnant women? Where is the access for children and young people? This is all purely driven by money and not in the best interests of patients or their care givers. Why did you ignore the target of 6.5% and choose to target 8% and above? It feels like a backwards step from the already narrow criteria for a pump. It should be access for all, without ridiculous loops to jump through. My son is a teenager, diagnosed at 13, he is coming into the age group which has the highest number of DKA's and unexpected deaths. All children and young people should be offered closed loop as standard. All older people who want to use technolgy should be offered closed loop. Use of technology means fewer hospital visits and a lower requirement on the staff within the NHS. The staffing issue in the NHS will only get worse and worse, you should be pushing technology to accomodate for the shortall in access to qualified staff. Allow all T1D's to use the technology that is available so that they can manage their condition as successfully and independently as possible. My son has a HbA1c of 5.6% for the past 2 years and in the past 2 years of our relentless management he has not had to see the GP once, we have not had to place one call to his DSN, he has not needed to go to hospital, his endo appointments are quick- beyond his prescriptions his condition costs the NHS nothing. But at what cost is that fantastic number - it means I as his parent am going to work at least 3 times a week on less than 2 hours sleep, it is a constant demand for him to monitor his numbers, it means him having to miss out on activities because he may go low, it means food restrictions, it means constantly having to adjust his basal and bolus, it means he has not stayed out overnight on his own, it costs him is independence. It is a psychologically exhausting existence, that if left unchecked will eventually cost the NHS alot more than your £5744 per year in mental health costs and hospital intervention, because burn out will come, managing like this in not sustainable. For now, I as his parent carry much of the load in terms of making insulin adjustments, which are constant due to hormones. He is in his GCSE year, and should be free to focus on studies and his future, not having to spend so much time thinking about adjusting insulin. As a parent I have had a break down from lack of sleep, I lost 2 stone that I could not afford to lose. He as the T1D, has missed a lot of school when we get basal adjustments wrong and he has a night of lows or highs. We have been hanging on, knowing that technology was on its way and now to read that its here, but not for you! You who have tried too hard, you who have worked too hard to take the best care of yourself possible. No, lets only give it to those who have not engaged with their condition, who have not dedicated the time to manage! What a message this sends. Shame on you! The NHS is in an awful shape, here is a chance for England to be world leading in the care of T1D's and they choose not to take it. When I read the draft, I cried, not with relief that at he |

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| | | | | | | could access the technology available to give him some of his life back, but bitter tears of disappointment that yet once again he will be punished. This technology should be for every type one, not just for those who are managing their condition poorly. So what is the answer for my son? Well he has already said, I will make myself sick, I will stop managing so that I can get a closed loop. Every DKA episode damages his health and costs the NHS £1000's in care. He is not the only T1D who will do this, if you want to restrict rewards to poor behaviour I do hope you have the NHS staff ready to look after the influx of patients that will be the end result of this policy. If you insist on arbitary numbers to allow closed loop, it should be anyone not achieving 6.5% (which is the actual target), access should be the same at a minimum, as the existing pump criteria, the pump criteria should be expanded to all children and young people, and also to include anyone who is suffering with burnout or mental anguish. These decisions should be made by people who live with the condition, not by people who just see pounds and then say "we hear there is a mental load attached to managing"- you don't see, you have no idea of how difficult type one diabetes is to manage. You have no idea of how it robs you of your sleep, your security, your confidence. You have no idea of what it is like as a parent to go to sleep and worry your child will die in the night. Young people (under 25 years) should be considered a priority group, they are just starting life, they are not known for excellent decision making and should be allowed the opportunity to have some of the mental load removed. The reality is not every type one will want to access technology, but every single one who does, should be entitled to. |
| 131 | | | | | | Hi, I have been using Medtronic 780G with G4 sensor for about 6 mths and it has been a revolution in terms of anxiety reduction, improved time in range (averaging 78% over last 3 mths)and improved sleep. It is unclear from the document how many patient experts there were and the degree of experience each had. Also I self fund the G4 sensors which costs about £1900p.a. The cost comparisons should look at the cost for the additional functionality of the sensors in isolation rather than giving a "lump sum" cost for pump with sensors. |
| 147 | | | | | | The major problem with the conclusion reached by the committee is that although it acknowledges the many uncaptured benefits - particularly the reduction of the mental load on the patient and carers and the improved quality of life - it appears to dismiss these as too difficult to quantify and therefore makes recommendations based purely on a fairly arbitrary HbA1c level of 64mmol/mol.<br><br>I am the carer of a recently diagnosed 11 year old type 1 diabetic (diagnosed May 2022), and the last 8 months have been some of the hardest I have had |

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| | | | | | | to deal with. It is a constant, round the clock battle, to even try and manage my son's diabetes. Myself and my wife haven't had a full night's sleep since he came home from the hospital. We are either worrying about him going low and having a hypo, or running too high all night, with the associated short and long term health implications that that has.<br><br>As a result of some fairly serious hypos my son has suffered he is now scared to let his blood glucose levels drop into a 'normal' range of between 4-7mmol/l and we are struggling watching him run high all day while at school to try and avoid the possibility of having a hypo.<br><br>It has a massive impact on the quality of my son's life as he has constant headaches and can become irritable when his blood glucose is high. He simply doesn't have the confidence to treat these highs during the school day for fear of possibly having a hypo. It is affecting his education and his mental health.<br><br>The mental burden of monitoring his blood glucose constantly and either worrying as we see it sitting at high levels, or getting up multiple times during the night to administer glucose or insulin is huge.<br><br>Despite all of this, his HbA1c is currently 'only' 54mmol/mol - albeit is rising since his previous consultant appointment - and with the proposed recommendations he would not meet the criteria for HCL.<br><br>The proposed recommendation of HCL for people who have an HbA1c of around 64 mmol/mol is a massive blow for all individuals and families who work incredibly hard to manage their type 1 diabetes and would benefit hugely from HCL. This is not to say that people with HbA1cs of 64 and above are not working hard - far from it - but it is simply to make the point that the committee has not adequately considered the massive benefits that HCL could offer to reduce the mental load and improve the quality of life for people with HbA1cs below 64 mmol/mol. This is even more so for children, where, typically, the impact of managing the diabetes is shared by parents and the child. The benefits are therefore extended to the parents in addition to the child.<br><br>It is submitted that there has been an over-reliance on numerical data obtained from relatively small scale trials, rather than considering a more holistic approach to the possible impact that HCL can offer. |

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| 48 | | | | | | While it seems sensible to limit the access to the technology initially as was seen with the Flash glucose sensors, there should be consideration for future wider scope for getting access to all T1 diabetics who want to use the technology (regardless of control level) especially as some centres tend to be slow to adapt to NICE guidelines.<br>It's right to allow access to those struggling to control their condition and during pregnancy first, however there should be consideration for other scenarios where a loop system could be beneficial to someone with T1 diabetes outside of these guidelines, with the aim of eventually offering it to anyone with T1 who wants it once cost effective.<br>I think that a better way to go (on top of what is already here), is to offer the loop systems automatically to all paediatric T1 diabetics (including the option to keep the technology once an adult if they want it). This would reduce the mental burden of anxiety on young patients and parents from the very start, and gradually create a system where anyone with T1 has access to the technology from diagnosis onwards rather than having to wait with all the uncertainty around access. If the loop systems create better outcomes, as proposed here, then that would reduce the burden on NHS services in turn from diagnosis in a lifetime commitment (after an initial outlay and training on current patients/parents) straight away rather than getting a range of outcomes from those who can and cannot access the technology. |

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| 182 | Wolfson Diabetes and Endocrine Clinic, CUHFT | | | | | Congratulations to all involved in pulling together this much anticipated document. Closed loop systems have been transformative for those who have already had access to them and a policy for increasing this is extremely welcome.<br><br>Comments from our clinicians<br>1) We are concerned that this is focused on HbA1c lowering (and as an aside, the document uses wording that is increasingly regarded by some as pejorative - “improve control” etc rather than lower average glucose- language matters!) and that the committee were unable to find sufficient evidence to support hypoglycaemia management. There is a major EU funded study currently examining the value/ disutility of non -severe hypoglycaemia (HypoRESOLVE with the embedded clinical study HypoMETRICS) but this will report too late for this appraisal. There is also a US NIH funded study including 2 UK centres about to start specifically examining hybrid closed loop technology in problematic hypoglycaemia but again will be some time before this study reports. Nevertheless, we would urge the committee to consider again whether there is a pragmatic case to be made for including some wording about problematic hypoglycaemia as a potential indication, especially given the clinical experience which is that HCL can be an epiphany for those with no recognition of hypos and recurrent severe hypoglycaemia. We already have TA151 which allows access to pump technology for problematic hypoglycaemia and the NICE NG17 revision from March of 2022 (1.10.9 and 1.10.10) recommends options including access to CGM and then referral to a specialist centre for impaired awareness/ severe hypoglycaemia. This means that the incremental cost for switching from pump and CGM as already covered by NHS is the cost of automation which is complex but can effectively be free (example is Ypsopump MyLoop). The costs of CGM are also falling fast and the committee will be aware for example that Libre 3 can be used in an approved HCL system in one European country. We note the wording about dialogue between NICE/ NHSE and companies around costs and would ask the committee to consider again adding hypoglycaemia into indications (e.g. consider use by specialist centres where referred for impaired awareness/ severe hypoglycaemia).<br><br>2) We also agree with highlighting the problem of inequities into access to diabetes technology. Would the committee consider recommending further research into this?<br>This also raises the question of those who have self funded sensors, and used off license HCL - but now want to come back into the 'licensed' world, now that it has caught up. The HbA1c cut offs would discriminate against them now, having now achieved optimal control.<br><br>3) The disparity in HbA1c cut off of 8% for HCL and 8.5% for pump use in |

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| | | | | | | TA151 needs some thought as this will confuse.<br><br>4) the guidelines around pregnancy are vague, what timeline constitutes planning for pregnancy, is their a HbA1c cut off associated with this recommendation? Post pregnancy, can they continue on the HCL?<br>If so - does this become discriminatory to men, who cannot claim to be planning a pregnancy.<br><br>5) Structured education programme - the word validated has been dropped - so what constitutes an education programme?<br><br>The following are comments from our Patient Group<br>Individual 1<br>I (would of course) think the inclusion criteria is too narrow - but it looks like the horse has bolted on this, it appears to read only the trialled criteria can be considered and that was a restricted group. If this is the case is there a way of NICE dictating a next step in terms of trials and protocols<br>• elderly people who are unable to administer their own insulin safely should be a priority group for such technology, the actual cost of community nurses going out to administer insulin and the quality of life issues of twice daily mixed insulin must be considerable & risks high<br>• pregnant women, do the commercial systems allow low enough targets - the DIY community seems to think not<br>• those already on pumps with CGM etc, the incremental costs must be relatively low and this group have the experience and the will to use the new technology well and so benefit from it, it could be rolled out quicker as this group would need little or no training and would be able to set up and use quickly with probably minimal online training<br>• those fully insulin dependant but not Type 1 with multiple health issues and currently generally not meeting pump criteria, could benefit massively from this technology - this is a group of people who may have regular hospital admissions and a greater burden on the health service<br>• (again a personal angle) menopausal women, if they can't be considered for many drug trails & phycological research because of it, perhaps this is an area that should take into account the issues that arise. On the same vein pre menopausal women with particular hormonal problems may also benefit more than others too<br><br>It is unclear how the closed loop technology will interface with existing pump and CGM criteria. Will people not currently on a pump be offered closed loop or will stand alone pumps still be issued. Will those not being offered a closed loop pump only be offered some lower price less technically sophisticated pump or will they get a pump capable of closed loop but not given that functionality? Relative pump cost information does not seem to be disclosed |

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| | | | | | | but if the more sophisticated pumps cost more but the functionality is not used is there a waste of resources?<br><br>Should those who currently have pumps be upgraded if they now qualify for a closed loop? If NICE doesn't include this sort of guidance then the postcode lottery will continue<br><br>What is the experience of sustained use of pumps in terms of demographics ie those that stick with it, for example amongst my circle I am aware the vast majority of teenagers have been given a pump but they don't use it. What are the reasons for this? I would hate to think the closed loop roll out "fails" because the group who are being prioritised are a group who are perhaps most likely not to stick with it and so generate the improvement statistics required to open up further access<br><br>The paper mentions phycological issue but doesn't really quantify them or suggest how they are measured or figure in the allocation of closed loop, obviously measures are difficult but this area needs to be expanded. Again from a personal prospective, I wouldn't say I am in anyway depressed or otherwise physiologically challenged but boy does achieving the level of control I have take a toll on me and my family and inhibits some of the things I would want to do or the time I can do them. I certainly lost all my career based drive and aspirations when I was diagnosed (feeling I personally could no longer sustain the pace of my career) and it was a major factor in my giving up on my career many years before I believe I otherwise would have<br><br>There is some limited mention of adverse events, there appear to be few and no details but trial populations are small. Is there a danger of over reliance on technology in some cases? Again from social groups I am in parents of children whose CGM or pump fail are distraught and appear to have no idea what to do and are willing to beg, borrow or steal kit, take advice from anyone and everyone on social media without any filter. We need to be carefully what wider education goes along with the technology<br><br>The emphasis is on people who have difficulty achieving a good level of control despite having access to (and presumably using) at least one piece of technology, maybe we are setting ourselves up to fail? My understanding is that the current pumps still need one to carb count and to remember to enter the carbs into the pump to get the best from it? If this is true it maybe that the people who are "failing" will need more education and supervision / mentoring on an ongoing basis until we have true fully automated closed loop. I appreciate keeping everyone safe and avoiding serious hypo's is essential and that the closed loop pumps are good at this |

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| | | | | | | The current trail statistics do not seem to have achieved an HBa1c of participants at anything like the level suggested to be required to avoid complications - whilst all improvements are to be welcomed and any help with quality of life for the individual and lower costs for the health care system dealing with complications should be grasped - shouldn't we be aiming higher and including those that are engaged in achieving the target<br><br>There is little in the cost analysis I can understand (and finance is my profession) but one statistic is that the additional cost over and above existing cost of pump + sensor is around £1560 pa, this is such a drop in the ocean compared to health costs associated with poor diabetes control (lost work days, direct health costs etc), rapid rollout should be considered as a priority<br><br>Will there be any other criteria where the medical profession can recommend closed loop for adults over and above the very restricted, Hba1c criteria & pregnancy and if not how and when will this be tackled? Sadly the NICE criteria and local health organisation interpretation of criteria seems to constantly work against people who put in a lot of effort to stay well, many of whom will have very successfully implemented technology to achieve what they have. If pure statistics are used in an under analysed way the aim will always be at the low hanging fruit and so development and the greater good hampered. We are where we are largely because of the highly motivated DIY community why should they have to stay DIY? The criteria are required to avoid discrimination, whilst not a "legal" discrimination, there is inbuilt discrimination against engaged individuals who have achieved success in getting good control. This discrimination started by excluding such individuals from trials and then developing criteria based on those trials. Maybe there should be at least some "compliance" element to the criteria, to avoid poor results from some individuals distorting the overall good that this technology will achieve.<br><br>Despite all of the above I am so pleased to see that hopefully the UK will soon have better technology available to many more people.<br><br>Individual 2<br>Firstly I fully endorse X's comments. I haven't read the document in the detail she clearly has but I wholeheartedly support all the comments in her response. I would like to add one point and expand on a second.<br><br>With the caveat that I've read this in haste (so hope I've not missed it) it appears that people with diabetes are not included in the Stakeholder list. In an era of inclusion this would appear to be a significant omission and (I imagine) hard to justify. |

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| | | | | | | I would like to expand on X's comments about the psychological impact. NICE has already created a QUALI - a unit to measure impact on quality of life. The impact of closed loop technology on quality of life, which includes wellbeing, could be assessed using the QUALI framework and the data included in the overall consideration.<br><br>In addition, I'm convinced some psychological impacts can be measured in terms of cost. There are so many anecdotes about people with T1 having to either leave work prematurely (me and Caroline for a start) or take a sideways promotion (nurses having to leave emergency care and take on administrative roles) or risk assessed as no longer able to drive, or work with heavy machinery or on their own. This means both individuals and employers can identify their costs in terms of shortened employment or reasonable adjustments or re recruitment or additional training.<br><br>The significance is that these costs are not felt by the NHS but the wider economy. As the culture of budgets is increasingly to diminish/blur/share boundaries between them (Social Care and NHS) is the perfect example, I think it is justified that consultations like this take a similar approach and look at global cost implications rather than only their own.<br><br>Caroline mentions the impact of her diabetic management extending to her family and I echo that. Whilst I am not someone assessed as needing a live in Carer, collectively the adjustments made by my family (child care, type of recreation, point of retirement, food costs, transport) amounts to me being cared for to enable the level of bg control that I have. If using closed loop technology meant someone with T1 could dispense with the services of a paid for Carer it would be measured and taken into account. In this context to not consider the extent to which caring family members would benefit in time, money and QUALIS appears an omission.<br><br>I think including QUALIS and assessing costs would shift consideration of the significance of psychological impacts from a 'feel good factor' to the empirical and add to the rigour of assessment.<br><br>Individual 3<br>• As a user of closed loop I have been able to increase my working hours back to 3 days a week having dropped to 2 days a week prior to the invention of Libre1. I feel these could be further increased as I have so much more energy and less anxiety.<br>• I currently have a TIR of 90% during th last 2 weeks with only 1% being low. Proper hypos are a thing of the past for me and many other closed loop users. Its now unusual for me to drop below 3 unless I have a faulty sensor. |

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| | | | | | | • My blood stick requirements have gone down to 1 canister every 2-3 months now compared to 10 canisters a month prior to flash and CGM |
| 190 | Type 1 Kidz, Investing in Children | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | We suggest that clinical staff should be able to recommend a Hybrid Closed Loop system where there would be a psychosocial benefit to a person with T1 diabetes, or their carers. We think this is especially important for people that have mental health needs or a learning disability.<br><br>Parent/carer comments on this:<br>1. No response<br>2. Absolutely YES. However I believe all should have access to this technology. Include disrupted sleep in the mental needs and then that will apply to all<br>3. Agree completely. We struggle so much as a family to keep our kid stable (still very erratic over a year in) and diabetes dominates our lives in many ways. I am constantly worried and dread thinking about the future. My kid's grandmother is the same. Inevitably this passes on to my child though I try not to let him see how anxious we all are. I also agree that the stress can be extra difficult for SEN children and their families. There are so many sensory issues for ASD kids and needles and adhesives can be so hard to cope with. Understanding why this has to be done to them can also be really hard to |

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| | | | | | | explain.<br>4. Yes absolutely. There is so much involved in managing type 1, the diagnosis itself can be traumatic, then there's so much to learn. It can have an enormous emotional and mental impact.<br>5. Agree<br>6. 100% agree with this.<br>7. Why should we wait until there is a mental health issue? We need to recognise the huge impact of the condition of the person and their family. o<br>8. We are in a mental health crisis. In my own local authority, Cumbria, referrals to CAMHS now have a three year waiting list. Our special needs schools are full and new places are snapped up. The pressures within schools, due to budgets and staffing crisis, are immense. All children are suffering currently and those with mental health or a learning disability, even more so…. Health professionals know the children, can see the issues, they speak to the children and families. They should absolutely be able to recommend the closed loop where they think it will have benefit for emotional impact.<br>9. I full agree with this. Even though Type 1 has only been in our family for 2 and a half months the toll it has played on our mental wellbeing and social life is astronomical. It is a completely life changing illness for everyone involved.<br>10. Totally agree. It is such a relentless mentally exhausting disease and anything that can help with the mental burden of dealing with this should be provided. It is impossible to ever have a 'day off' from diabetes and knowing it is a chronic lifelong disease can be overwhelming. |
| 195 | | recommendations | 1 Recommendations | 1.1 | | Great news for those with HbA1c over 64mmol/mol. How will this help those whose HbA1c is under 64mmol/mol but whose quality of life is poor because they spend so much time, both in duration and frequency, day and night, diligently managing their glucose levels with the equipment they have, but long to have an HCL so that they can sleep at night most nights and not have to deal with as much of the relentless nature of T1d during the day? DIY closed loop is an option for some in this situation, but out of the reach of many. Some will suffer burnout and no longer be able to manage their glucose levels and will end up meeting the criteria but by this time their mental health will have suffered also. Why wait 'til this stage? HCL should be available for all those with T1D who are willing and able to use them, unless there are exceptional circumstances. The positive impact of HCL on quality of life is as valuable as the increased time in range and decreased HbA1c and is vastly underappreciated.<br><br>Second comment on this: Why use HbA1c rather than time in range, or both in this recommendation? We know that two people with the same HbA1c can have very different time-in-range figures and this can give a much fuller picture to show how they are managing their T1D. |

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| 257 | | | | | | I believe there are benefits from using a closed loop system that are not captured by the data used to create the inclusion criteria. I was diagnosed with T1 diabetes in 2017 at the age of 54. The subsequent affect on my ability to engage with normal activities was severely impaired. I was working for a local authority but found that I was making mistakes, having severe hypoglycaemic events in an open plan office, injecting in a small toilet, reprimanded for needing to take time during the work day to speak to my diabetes team, having to wait 45 minutes following a hypoglycaemic event before I could drive home, crying at my desk and generally feeling unsafe, unsupported, misunderstood, terrified and depressed. I handed my notice in after a few weeks and haven't worked since. I developed a severe fear of hypoglycaemia, especially at night time which triggered a previous PTSD episode of my life. I developed insomnia, which I still have. My marriage suffered. I organised several weeks of counselling via iTalk which helped me to understand that fear of hypoglycaemia was triggering my PTSD. I developed additional health issues, menopause symptoms following a hysterectomy, hypothyroidism which often goes with T1, mild asthma, then later breast cancer. Older people are often managing multiple health problems and medications that impact on blood sugar levels. At times I felt hopeless and even suicidal. I decided to try and get back some control over my T1. I fought for a CGM by breaking down in front of my Diabetes Specialist Nurse. I fought for a pump. I found out about DIY looping which changed things round for me, allowing me to get more sleep and stop the yo-yo blood sugars - it made me feel safe and probably saved my life. I don't want to be DIY looping. I don't want to feel like I'm doing something wrong and hiding things from my healthcare professionals. I want to be supported and safe. My hba1c was 115 at diagnosis, then quite quickly was in the sixties. Achieving this occupied all my time and was a massive burden. More recently my hba1c was in the low fifties, which is wonderful. Closed loop has done this for me. The mental burden of T1 and fear of hypoglycaemia has at times been almost unbearable for me but I've found a way to walk a careful path that looks after both my physical body and my mental health. I don't believe the current inclusion criteria for closed loop systems takes account of those faced with the fear of hypoglycaemia and the other health issues that can arise from it. Thanks for reading. |

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| 259 | | | | | | The wording "around 64mmol/mol" is not specific. The figure may be seized on by CCGs and used to refuse closed loop.<br><br>I would suggest "have an average HbA1c over 59mmol/mol despite..." or something similar.<br><br>Alternatively it would be appropriate to add a line whereby a closed loop can be provided where the clinical team consider that the patient will benefit.<br><br>Finally, I note that under the committee discussion, there is some consideration of price. Given that CCGs are already providing patch pumps and flash glucose readers to children, I think it would be wise to consider that if the cost of closed loop is within say 10% of the cost of a normal flash reader / pump combination, the benefits of closed loop far outweigh the small additional cost. It makes no sense to pay for someone to be on a dumb system if the costs is broadly similar to the closed loop.<br><br>I note that this consultation has been going on since 2018. We need these recommendations to be made available more quickly. Technology is improving year on year and we need to keep pace. |
| 312 | | | | | | Hospitals need to take into account the mental load of having diabetes and not just Hb1ac and all patients in mental distress need to be offered the hybrid closed loop system.<br>Needing a HB1ac of 8 or over before being offered the system seems to encourage poor control. The mental health of the patient also needs to be considered.<br>also parents looking after young children needs to be considered. Children are prioritised and yet the parents with type 1, who look after children are not prioritised in the same way and I feel they should, in order to be fit and well to look after them.<br><br>At present the offer of CGM seems to be a post code lottery placing stress on the patient to fund sensors.<br><br>I feel the guidelines for who is eligible should be widened to include mental health, hypo awareness if this is impaired the closed loop can help by stopping insulin delivery. |
| 333 | | dap55-diabetes-mta-acd-final-no-acicdocx | | | | With regards to the questions: sorry left this to last so running out of time before submission but in brief<br>1)Has all of the relevant evidence been taken into account? hypos effect Hba1c, teenagers w diabetes<br>2)Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? short term gain? long term loss?<br>3)Are the recommendations sound and suitable basis for guidance... |

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| | | | | | | personally do not agree w HbA1c 8% (as can be many reasons for this no which may not necc be best first approached using a looped system - instead of HbA1c - an individualised approach, right timing and also access for all will give hope motivation for optimal management<br>4) Are there any aspects of the recommendations that need particular consideration to ensure... learning difficulities and other silent invisible disabilities and especially in terms of understanding and access to education<br>4) (sorry any typos in this comment box but was running out of time)<br>5) |
| 343 | Children and Young People's North East and North Cumbria Diabetes Network | | | | | 1. Area of Discrimination (Age) As per the NICE recommendation that the first choice for all CYP is rt CGM, all CYP over age of 6yrs will be able to access a HCL if they wish as some of the available pump options have integrated algorithms. However, under the current guidance there will be a gap in funding the algorithm app for those under 6 years as the only licensed closed loops currently for this require separate funding for the app.<br><br>2. Area of Discrimination (DISABILITY) Diabetes is a disability under the disability discrimination act<br>For young children unable to self-manage not facilitating access to a HCL would need additional supervision under an EHCP at significant cost to manage their diabetes/ glucose levels. It is essential and a human right that CYP should be able to fully integrate into school life and achieve their full potential.<br><br>3. Area of Discrimination (PSYCHOSICIAL) for those with mental health and learning disabilities and psychosocial needs where a HCL will have significant positive benefits but having to fail (show deterioration in glucose control) to be able to access a HCL has adverse effects on mental health and psychosocial well-being and educational achievement. These people were less likely to have been included in the HCL RCT and NHSE trial due to their personal circumstances.<br><br>4. NHS Core 20 plus 5 suggests we should positively discriminate to support those with mental health problems and the plus groups from paediatrics include those with learning disability and psychosocial needs. |

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| 344 | Children and Young People's North East and North Cumbria Diabetes Network | recommendations | 1 Recommendations | 1.1 | | 1. This is not compatible with current NICE recommendations for pump therapy, which is only possible in children aged under 12 years, and in those aged 12 years and over with an HbA1c over 69mmol/mol.<br><br>2. We do not agree with having a defined hba1c level as cut off for recommending HCL system – why penalise patients with good control – time in range and glucose variability is more important than actual hba1c. Quality of life important in all patients not just those with a HbA1c above 64mmol/mol. Patients with good control may decide to run their HbA1c above 64mmol/mol to qualify for HCL. Prevention of hypoglycaemia also important and the glucose suspend feature of HCL important safety feature for children. Very difficult to achieve the target hba1c <48mmol/mol without a HCL system<br><br>3. The evidence and interpretation of evidence are sound but recommendation 1.1 is still vague and could potentially lead to inequitable access to technology from varied interpretation.<br><br>4. The median HbA1c prior to closed loop was 61.5 mmol/mol in the real world study, comparable to the median for the general paediatric population. The median on hybrid closed loop was 54 mmol/mol. A reduction in HbA1c of 7 mmol/mol. That would be a big step towards achieving the NICE target of 48 mmol/mol. Why offer HCL technology to those over 64 mmol/mol if there is the potential to move the population median from 61 mmol/mol to 54 mmol/mol! Surely anyone above 48mmol/mol could be deemed to be struggling in that they are not meeting the target!<br><br>5. The biggest predictor of complications is duration of diabetes (strong evidence for retinopathy) Children will have diabetes for the longest and so cost effectiveness of HCL to NHS is greater, this hasn't been considered. |
| 355 | Children and Young People's North East and North Cumbria Diabetes Network | committee-discussion | Conclusion | 3.16 | | 1. Despite acknowledging increased benefit for children, this is not reflected in the recommendations<br><br>2. If more cost-effective for children then HCL should be available if clinicians judge it to be an appropriate treatment for CYP regardless of Hba1c<br><br>3. Area of Discrimination (DISABILITY) Diabetes is a disability under the disability discrimination act<br>For young children unable to self-manage not facilitating access to a HCL would need additional supervision under an EHCP at significant cost to manage their diabetes/ glucose levels. It is essential and a human right that CYP should be able to fully integrate into school life and achieve their full potential.<br><br>4. Area of Discrimination (PSYCHOSICIAL) for those with mental health and |

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| | | | | | | learning disabilities and psychosocial needs where a HCL will have significant positive benefits but having to fail (show deterioration in glucose control) to be able to access a HCL has adverse effects on mental health and psychosocial well-being and educational achievement. These people were less likely to have been included in the HCL RCT and NHSE trial due to their personal circumstances.<br><br>5. NHS Core 20 plus 5 suggests we should positively discriminate to support those with mental health problems and the plus groups from paediatrics include those with learning disability and psychosocial needs. |
| 361 | | | | | | I am adult type 1 diagnosed in 40s, and parent of type 1 diagnosed aged 7.<br>I am concerned that quantitative data models strongly underestimate the mental and emotional burdens of living with type 1 diabetes (and trying to mitigate it's long-term health effects by having to manage it 24/7, plus avoiding severe hypos). This daily stress is magnified hugely when looking after small children with the condition.<br>If technology can be offered that reduces this burden across ALL groups, NICE should have a goal to roll it out for anyone who can benefit from it, as soon as possible after the initial qualifying group.<br>Including only children or pregnant women may prevent better treatment for those who are now adults but have lived with Type 1 since childhood, whose glucose control has been fluctuating for years (eg as teenagers).<br>Focusing entirely on children and pregnant women in the long term could prevent other groups of diabetics from accessing the technology which would reduce stress (a major cause of disease in itself). for example, menopausal & post-menopausal women - there is very little clinical attention given to the difficulty of managing blood glucose in this group.<br>The developments discussed in this consultation are good news - but there is much work still to do for all those of us living with type 1. Having a good HbA1c level in the long-term is the aim. But the cost involved in achieving this can be very hard to bear. If a closed-loop system can help, it should be available for all who want to try it. |
| 362 | Insulin Pump Awareness Group Scotland (IPAG-Scotland) | | | | | We believe that the draft guidelines, which limit funding for HCL pump therapy to pregnancy and those with HbA1c of over 8% are predicated on a highly limited consideration of the evidence. In particular, the committee has placed an undue reliance on improvements in HbA1c, ignoring the extensive data on Time-in-Range (TIR). The substantial survey evidence of improvements in Quality-of-Life (QoL) whilst acknowledged in the report also appears to have been discounted. Our reasoning is set out below.<br><br>Improvements in Control with HCL pump therapy: The committee considered |

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| | | | | | | the very extensive published data from a large number of RCT trials and also the results from the NHSE trials. In analyzing the outcomes of these studies, the report appears to have focussed almost exclusively on improvements in HbA1c. Whilst this is an accepted and reliable measure of average blood glucose levels (BGL) weighted over a 3-month period it also gives an incomplete indicator of control because it does not account for variability in BGL nor does it provide evidence on frequency of hypo- hyper-glycaemic episodes. For this reason, TIR, conventionally defined as the percentage of time spent between 3.9 and 10 mmol/L and easily calculated from CGM data, is a more comprehensive measure of BGL management and is now becoming the accepted gold standard. All the published RCT trials provide extensive evidence of significant improvements in percentage TIR and importantly reduced frequency of hypoglycaemia, evidence that has not been captured in the draft report because HbA1c has been used as the proxy for glucose control. HbA1c is a function of average BGL; therefore those with lower HbA1c will be more at risk from disabling (as defined by NICE TA151) hypoglycaemia. By focussing almost exclusively on this, benefits to this group resulting from lower variability and reduced frequency of hypoglycaemia have not been captured or considered.<br><br>Improvements in QoL with HCL pump therapy: The report acknowledges the extensive body of evidence, from RCT trials or based on surveys of users, that HCL systems provide a considerable improvement In QoL. In particular, users report substantial improvements in sleep because the systems very effectively minimize the danger of overnight hypoglycaemic events (parents of children using closed loops report that for the first time they can sleep for a full night). Survey results also report significant reductions in the time and attention devoted to managing their diabetes (in some surveys reductions of an hour or more per day or more). Although improvements in QoL are difficult to measure quantitatively and therefore more difficult to fit into the economic analysis, they nevertheless should form part of the NICE criteria for judging the effectiveness of a treatment. NICE explicitly recognised this when considerations of disabling hypoglycaemia were included in the criteria for funding insulin pump therapy (TA151). It seems illogical to disregard such criteria when considering funding for HCL pump therapy.<br><br>Insulin pump provision – conventional vs HCL systems: By the end of 2023, all insulin pump models provided by the NHS to new users and to existing users as warranty replacements will be HCL-compliant, requiring only the appropriate rtCGM systems to access the capability. A substantial proportion of these users will have qualified for pump-funding on the grounds such as disabling hypoglycaemia and QoL. Excluding these people from accessing the full design capability of their pumps seems illogical. The Scottish Health Technology Group (SHTG) recently carried out an assessment based on a |

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| | | | | | | similar body of evidence for funding for HCL systems in Scotland. They estimated that although the full costs of providing funding at ~£40k per QALY were greater than the cut-off value, the additional costs of upgrading from isCGM to the rtCGM needed for allow existing or new pump users to access the HCL capabilities of their pumps, were less than £20k per QALY. SHTG have therefore recommended users of HCL-compatible pumps should be funded for the rtCGM to allow them to access the full capabilities of their pumps. NICE should consider a similar approach. |

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| 371 | Association of British HealthTech Industries | recommendations | 1 Recommendations | 1.1 | | The HbA1c baseline threshold at which HCL systems are recommended is too restrictive<br>The draft appraisal recommends HCL as an option for people with T1D who have difficulty managing their condition and have an average HbA1c of 8%.<br><br>The 12 randomised control studies assessed by the EAG identified a mean HbA1c baseline of 7.4% to 8.3% , with the median HbA1c baseline of nine studies at 7.6%.<br><br>The threshold needs to be lowered for the appraisal to be aligned with the clinical evidence and not unduly limit access to a technology for individuals for whom it has been shown to be effective.<br><br>The cost of HCL systems is disproportionately emphasised as a driver of cost-effectiveness<br>In arriving at the cost-effectiveness judgement, the EAG established a base-case model which included a clinical baseline taken from the relevant 2019 – 2020 National Diabetes Audit and the estimated HbA1c decrease from the RCT network meta-analysis. This yielded an incremental cost-effectiveness ratio (ICER) of £178,925 per quality adjusted life year (QALY) gained.<br><br>When the NHSE adult pilot baseline characteristics and HbA1c effect were used, the resulting ICER was £12,398 per QALY gained. Substantially lower, and deemed cost-effective by the committee.<br><br>We also note the committee's conclusion that the effect size could fall between that observed in the RCT network meta-analysis and that from the NHSE pilot. No ICER calculations are provided in the draft or committee papers based on modulating the effect size and baseline.<br><br>It is noted that the committee concluded that changes in HbA1c substantially affected the ICER, and therefore whether HCL systems could be considered cost effective.<br><br>The draft also reports that there are potential quality of life benefits, including on learning and education, ability to work, mental burden and fear of hypoglycaemic events, which are not captured in the health economic model. Importantly, that these uncaptured benefits are likely to undervalue the effect of HCL systems on quality of life. Similarly, other aspects, such as rates of hypoglycaemic events together with the disutility and cost of these, and rates of eye and kidney complications, affect the ICER.<br><br>As such, there is considerable uncertainty in the assumptions used even |

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| | | | | | | before the committee considered pricing analysis. Yet, the committee have disproportionately focused on the cost of HCL systems in arriving at the cost-effectiveness judgement.<br><br>To remedy, we recommend that:<br>> Quality-of-life benefits are taken into consideration when assessing the cost-effectiveness ratio.<br>> Greater weighting is afforded to the real word evidence gathered.<br>This would be in-line with NICE's Real World Evidence Framework which states:<br>"..even if randomised evidence is available, it may not be sufficient for decision making in the NHS for several reasons including:<br>- the comparator does not reflect standard of care in the NHS<br>- relevant population groups are excluded<br>- there are major differences in patient behaviours, care pathways or settings that differ from implementation in routine practice<br>- follow up is limited."<br>> The economic models which inform any threshold pricing analysis are shared for comment as these will undoubtedly be used for any subsequent pricing negotiations which the draft cites. |

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| 374 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | | | | | Area of Discrimination (Age): As per the NICE recommendation that the first choice for all CYP is rt CGM, all CYP over age of 6yrs will be able to access a HCL if they wish as some of the available pump options have integrated algorithms. However, under the current guidance there will be a gap in funding the algorithm app for those under 6 years as the only licensed closed loops currently for this require separate funding for the app.<br><br>Area of Discrimination (DISABILITY) Diabetes is a disability under the disability discrimination act:<br>For young children unable to self-manage not facilitating access to a HCL would need additional supervision under an EHCP at significant cost to manage their diabetes/ glucose levels. It is essential and a human right that CYP should be able to fully integrate into school life and achieve their full potential.<br><br>Area of Discrimination (PSYCHOSICIAL): for those with mental health and learning disabilities and psychosocial needs where a HCL will have significant positive benefits but having to fail (show deterioration in glucose control) to be able to access a HCL has adverse effects on mental health and psychosocial well-being and educational achievement. These people were less likely to have been included in the HCL RCT and NHSE trial due to their personal circumstances.<br><br>NHS Core 20 plus 5 suggests we should positively discriminate to support those with mental health problems and the plus groups from paediatrics include those with learning disability and psychosocial needs. |

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| 375 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | recommendations | 1 Recommendations | 1.1 | | 1. This is not compatible with current NICE recommendations for pump therapy, which is only possible in children aged under 12 years, and in those aged 12 years and over with an HbA1c over 69mmol/mol.<br>2. We do not agree with having a defined HbA1c level as cut off for recommending HCL system – why penalise patients with good control – time in range and glucose variability is more important than actual HbA1c. Quality of life is important in all patients not just those with an HbA1c above 64mmol/mol. Patients with good control may decide to run their HbA1c above 64mmol/mol to qualify for HCL. Prevention of hypoglycaemia also important and the glucose suspend feature of HCL important safety feature for children. Very difficult to achieve the target HbA1c <48mmol/mol without a HCL system.<br>3.The evidence and interpretation of evidence are sound but recommendation 1.1 is still vague and could potentially lead to inequitable access to technology from varied interpretation<br>4.The median HbA1c prior to closed loop was 61.5 mmol/mol in the real world study, comparable to the median for the general paediatric population. The median on hybrid closed loop was 54 mmol/mol. A reduction in HbA1c of 7 mmol/mol. That would be a big step towards achieving the NICE target of 48 mmol/mol. Why offer HCL technology to those over 64 mmol/mol if there is the potential to move the population median from 61 mmol/mol to 54 mmol/mol! Therefore anyone above 48mmol/mol could be deemed to be struggling in that they are not meeting the NICE recommended target!<br>5. The biggest predictor of complications is duration of diabetes (strong evidence for retinopathy) Children will have diabetes for the longest and so cost effectiveness of HCL to NHS is greater, this hasn't been considered. |
| 377 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.1 | | This statement needs altering; even with optimal control (under 53mmol/mol) there is a 2-fold higher cardiovascular risk, as discussed in 1.5.<br>Long duration of diabetes in children and young people being the highest determinant above HbA1C of complications has not been accounted for. |
| 380 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | With the current recommendation of access if HbA1C above 64mmol/mol this does not take into account all the evidence from people living with T1D and their families and carers on reduced burden; sleep deprivation; requirement of additional individualised support in school in the form of costly EHCP (educational health care plans); the patient and parent mental health burden and the societal impact of parents working less than full time. It is essential and a human right that all children and young people should be suported to acheive their full potential in life and educationally. Glucose control has a significant impact on this and we would recommend access to HCL for all children and young people regardless of HbA1C. |

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| 386 | Gateshead Health NHS Foundation Trust Paediatric Diabetes Service | committee-discussion | Conclusion | 3.16 | | Despite acknowledging increased benefit for children, this is not reflected in the recommendations.<br>If more cost-effective for children then surely they should be available if clinicians judge it to be an appropriate treatment for CYP regardless of Hba1c<br><br>Area of Discrimination (DISABILITY) Diabetes is a disability under the disability discrimination act:<br>For young children unable to self-manage not facilitating access to a HCL would need additional supervision under an EHCP at significant cost to manage their diabetes/ glucose levels. It is essential and a human right that CYP should be able to fully integrate into school life and achieve their full potential.<br><br>Area of Discrimination (PSYCHOSICIAL) for those with mental health and learning disabilities and psychosocial needs where a HCL will have significant positive benefits but having to fail (show deterioration in glucose control) to be able to access a HCL has adverse effects on mental health and psychosocial well-being and educational achievement. These people were less likely to have been included in the HCL RCT and NHSE trial due to their personal circumstances.<br><br>NHS Core 20 plus 5 suggests we should positively discriminate to support those with mental health problems and the plus groups from paediatrics include those with learning disability and psychosocial needs. |
| 391 | | | | | | Has the impact of the constant strain of managing blood glucose levels been considered. There is more to consider rather than just a simple criteria of HB1ac of more than 65, (or pregnant). What about consideration for debilitating hypoglycaemia episodes, post hypo debilitating headaches, and if course the fear of those hypoglycaemic episodes. There can be other impacts on the quality of life when you live with this condition, particularly when you strive to try to meet the target of a HB1ac of 48 to avoid the physical impact of this condition. The constant strain and other areas must be taken into account. Otherwise it seems that the newest technology is rewarded to those with poor control. Trying to achieve good levels is at like having to do another 24 hour job on top of everything else, work school and home commitments. |

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| 395 | Families With Diabetes National Network | dap55-diabetes-mta-acd-final-no-acicdocx | | | | We believe that not all evidence has been taken into account because the recommendation is only based on HbA1c & not on Time In Range. There's data that shows you can have a good HbA1c but have a poor TIR due to large swings of highs & lows, (that give a better average of BG/HbA1c). Less TIR can increase the risk of complications , such as microvascular complications.<br>We also believe that not enough evidence has been taken into account for children as a subgroup, as the demands of managing T1 in children can be huge. The benefits of managing T1 well needs to be taken into account for their education/cognitive ability. Also there is no mention with children with T1 & other special additional needs , such as autism.<br>Re cost effectiveness - we don't think it has been taken into account the extra costs that can be associated with the burden of managing T1 - mental burden & associated mental health problems, emergency beds for DKA , especially in the teen rebellion period.<br>Has the fact that many CYP are already funded for CGM & CSII & that to upgrade to a HCL may not incur a large increase in costs?<br><br>We believe that children & young people should be regarded as a sub group for this HCL recommendation , with potentially different criteria , which we will discuss further under the recommendations section.<br><br>We believe the current recommendation is discriminating against those CYP with a HbA1c lower than 64 & does not take into account the hard work & burden 24/7 that goes into achieving the lower HbA1c |

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| 397 | Families With Diabetes National Network | recommendations | 1 Recommendations | 1.1 | | Many people with type 1 have difficulty managing their condition. Those that have a lower HbA1c will have often worked very hard to achieve this , including night time monitoring of CGM & making adjustments throughout the day & night to treat hyperglycemia & treating hypoglycemia.<br>Restricting HCL access to those with a HbA1c of 64 is being seen by many as a punishment for the intensive work required to achieve a lower HbA1c. It also runs the risk of people neglecting their diabetes care to have a higher HbA1c to then qualify for HCL.<br>It has been noted that diabetes is harder to manage in all pregnancies but the difficulties of managing diabetes in children has not been recognized .<br>Children often have poor hypo awareness, have unpredictable activity & meals, disturbance to learning due to hypos in school, hormonal changes & growth especially in puberty.<br>We are pleased that quality of life has to some extent been recognized as a factor to consider, however we feel that this has not been recognized in the actual recommendation.<br>HCL has the potential to increase quality of life for both CYP & their families with the following -<br>-increased sleep for CYP & also carers<br>-decreased mental burden<br>-increased independence for CYP<br>-increased independence for YP moving away from home<br>- increase independence to allow them to experience the same as their peers, including school residential, sleepovers etc<br>-decreased hospital admissions<br>-CYP able to feel 'normal'<br>-decreased stigma<br>-decreased anxiety over hypoglycemia , including 'dead in bed'<br>-decreased anxiety over hyperglycemia & complications<br>- decreased complications especially as some CYP will have had diabetes for many years if diagnosed very young<br>-decreased risk of burn out for both CYP & carers ( many parents give up work to look after CYP with T1)<br>-allow all CYP to access sports with less fear<br>- help high level sports people to manage their T1D & the risk of hypos at night following sports<br><br>Our Outcomes Survey from 2014 showed that the biggest worry for CYP & their carers was severe hypoglycemia & hypoglycemia at night.<br><br>NICE recommends the target HbA1c to be 48mmol/mol to reduce risk of complications & future NHS costs. Since that recommendation families have worked hard to aim for that target. By limiting HCL access to 64mmol/mol they are denying many a better quality of life & health outcomes. The 20/21 NPDA |

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| | | | | | | report shows that only 11.8% of CYP are achieving < 48.<br>29.8% have a HbA1c of >69 so this gives an indication of how many would not be able to access HCL.<br>There is a huge variation in HbA1c related to ethnicity & socio-economic deprivation & also a huge variation depending on which PDU attended - average achieving <58 mol 37.9 % but depending on PDU 17.8% to 67.7%.<br><br>We believe the recommendation for HbA1c of 64 is too high & that this should be reviewed for CYP especially. We believe HCL should be available to all CYP who can understand & use the system effectively.<br>All patients should be informed about the benefits of HCL to ensure equity of access across the country.<br>Barriers to using HCL need to be looked , eg access to tech eg mobile phone , language to ensure equitable access.<br><br>It is important that there is a clear pathway to funding of HCL & this is transparent to all families & HCPs. |

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| 403 | | | | | | 1. On a simple level, those with the poorest control potentially have the most to gain from a closed loop system. However, those with good control are more likely to suffer from diabetes burn out (as they will have been working very hard to keep their levels as low as possible). This is a real condition and affects a great many people with Type 1 resulting in increased lost work days, medication, GP time and hospital referrals. The cost of these needs to be estimated and considered.<br>2.There are also significant costs when people with Type 1 get ill in other ways. Maintaining blood glucose levels when suffering from an infection is extremely difficult as you are both ill (and so not up to the mental skill needed to work out insulin requirements) and the illness affects your blood glucose levels in an extreme way. Type 1 diabetes patients are often admitted to hospital on these occasions because of these issues. Is the cost of these potentially avoidable admissions take into account?<br>3.Type 1 patients have to become experts in their own condition as they are regularly self administering a potentially lethal drug. There are many times in people's lives where outside stresses will cause them to neglect this task and having an automated system would help. My experience is that GPs and many hospital nurses/doctors are not up to date with diabetes management (which is understandable as they have so much to know) and can potentially cause harm because of this. If the patient has a closed loop system the opportunity for these errors is diminished. Errors, in my experience, have lead to increased hospital time and the development of further costly complications.<br>4. There are a number of professions where checking your blood glucose and adjusting your insulin on a regular basis is just not possible - e.g. teachers (especially primary school teachers), nurses, doctors, police. Not being able to do this can lead to more sickness and time away from work. Although this does not necessarily have a direct cost to the NHS (although it can lead to hospital admissions) it does represent a cost to society. Has any work been done to quantify the number of days working people with Type 1 have had to take off work due to their condition? Or how many hospital admissions related to Type 1 diabetes patients have had?<br>5.Has the evidence considered the toll on parents/carers? Has there been any quantifying of GP visits, hospital admissions, medication and loss of working days type 1 diabetes patients parents/carers have had?<br>6. Conclusion- the evidence has looked a narrow range of costs related to the management of Type 1 diabetes. In order to give a true picture of the savings to the NHS (and wider society) of a wide spread roll out of closed loop technology evidence beyond time in range with HbA1c should be taken into account. There are many other ways that the NHS will save if any Type 1 patient who wants it can have the red . This, of course, relies on having suitable training and the continued commitment of the patient. |

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| 404 | Locala CIC | | | | | 1.1 Why no reference to people with hypoglycaemia? The RCTs were more directed at people with raised HbA1c but there was a reduction in hypoglycaemic events.<br>The evidences shows more effective in children and young people why not offer it to all of them as they are more at risk of the long term complications of diabetes due to length of having diabetes.<br>In terms of 3.1 with the burden of diabetes why are you limiting the use of HCL to people with HbA1c of 64 or above?<br>This is especially in children and young people with Type1 diabetes. A parent will have sleepless nights with a child with an HbA1c below 64mmol/l.<br><br>3.5 why when the RCT shows the change in HbA1c was greater in children and young people who actually started with a lower HbA1c would you not offer HCL to all children and young people with Type 1 diabetes?<br>3.9 The burden of care of Type 1 Diabetes is massive especially when you are diagnosed from a small age.<br>3.11 Why if it is agreed that HCL is likely to more cost effective in children and young people do you not open it to all children and young people? |
| 413 | | | | | | I very much welcome the recommendation to make HCL available for T1Ds. It will greatly help BG control, as evidenced by the trial data, but also have a huge impact on quality of life. While I appreciate that there are economic considerations, I urge the recommendation to be expanded to include all T1Ds who would like to move to HCL.<br><br>It is not fair to discriminate against those who - through hard work and dedication - manage to achieve a better HbA1c than 64 (I fall into this group) by not offering HCL also to them.<br><br>While the percentage improvement in HbA1c of course will be smaller among better controlled T1Ds than in groups with higher HbA1c, the improvements to quality of life and reduction is stress linked to the condition that HCL can result in is just as relevant to the better controlled T1Ds.<br><br>The mental distress of dealing with the condition is also costing the health system. Thus HCL should be offered to all those who want it.<br><br>I have myself gone through a period where I have really struggled to manage my diabetes - partly due to work stress and burnout (cortisol levels are impossible to predict and counter) and possibly also due to perimenoause. From one month to the next I had to reduce my daily insulin intake by 20-25%. Then the following month I've had to increase it to a level that is higher than the month before I reduced it. These massive fluctuations in insulin needs require constant adjustments to my pump settings (I have first generation omnipod + Freestyle Libre). And despite being very clued up on carb counting |

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| | | | | | | and the effects various factors have on my BG, I cannot get levels right. HCL would be of great help to me and would take a lot of stress away. I gave gone from having two weeks of being woken up by low blood sugar alarm every night two months ago to now being woken up by high blood sugar alarm two out of three nights. Such sleep interruption really takes a toll. And HCL could provide invaluable help.<br><br>Thank you for the opportunity to comment. I look forward to following the project - and to move to HCL in the future. |
| 427 | | | | | | These closed loop systems should be made available to all that want to make use of this amazing advance in diabetes care technology, it is indeed an absolute game changer for both the user and their families.<br>The impact on the quality of life for those with type 1 and their wider families/carers is immeasurable.<br>I am a mother of a daughter aged 23 with type 1. She was diagnosed aged 10. She has had the T-Slim/Dexcom combo since November and the benefit of using this system became immediately apparent.<br>She (and as a result of this the whole family) have had the first nights of unbroken sleep since her diagnosis. The control IQ technology has taken away so much of the fear and effect of night time hypos/hypers. The adverse impact of type 1 on her working and social life has been greatly reduced. She is able to lead a much more 'normal' life, not totally dictated by the restrictions of trying to manage the illness with MDI or a normal insulin pump (even if these are combined with the unlooped use of a CGM) or the frustration of having to stop whatever she is doing to deal with hypos, which is a particular issue when she is working, or not being able to drive for an hour because of a hypo. She is also able to partake in exercise without the constant worry that she will hypo.<br>All of the above has had such a positive impact on both her physical and mental wellbeing and also that of our family as a whole.<br>Having diabetes and trying to regulate it manually is an horrific trial on a daily basis as its affected by hormones, stress, hot weather, cold weather, exercise, stress, excitement and many other factors. Obviously the ability of this system to keep the users BGL in range for more of the time by automatically adjusting the insulin doses giving them a better HbA1c will have an immense impact on the longer term effects of type 1 and the health complications associated.<br>In the document you have tried to evaluate the financial cost effectiveness of these pumps but I feel that you have missed the far wider and even longer term impact that the use of this pump will have on NHS spending.<br>1) There will be less treatment/hospital admissions for hypos and DKA not |

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| | | | | | | only because the pump aims to keep BGL's regulated but will also eliminate many episodes, especially in young adults where they are suffering from total burn out and exhaustion from trying to deal with this terrible illness and so ultimately 'give up' trying to manage it. This will save money in all aspects of dealing with these emergency situations and ultimately free up hospital beds.<br>2) The same applies to the longer term health complications with kidneys, eyes, infections and the consequences of them, etc. all reduced by the use of CLS's.<br>3) On top of that the need for the use of mental health services, including counselling would decrease and that would be for both the type 1's and their wider families because the illness is so much easier to manage using these systems and doesn't cause such a huge mental impact.<br>4) The adverse effect of the general body health of the sufferers and their families caused by constant stress and sleep deprivation.<br>5) The savings made on the small items the use of which will not be totally eliminated but will be needed less frequently: BG testers, finger prickers, needles & strips, ketone testers, finger prickers, needles and strips, Glucogel & Glucogon and other hypo treatments as they won't need to be replaced so frequently, pens for MDI and their needles and so on. Even the cost of dental work required due to the sugar in hypo treatments, should be taken into account.<br>Im sure there are many other savings that I've missed!<br>The clinical trials showed an improvement to the daily lives, physical health and mental health of almost all of the participants with minimal adverse effects, also people who have already been issued with these systems via the NHS provide confirmation of these results, so they should be made available to anyone with type 1 rather than limiting its issue to just pregnant women and those with bad control.<br>The diabetic community and their friends and families donate a huge amount towards research for the advancement of such technologies to improve the quality of life of ALL type 1 diabetics, as well as towards finding the ultimate cure. What is the point if these amazing advancements are then not made available to anyone who wants to take advantage of them? |

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| 433 | | | | | | I believe that an individual's duration of diabetes over age needs to be considered for closed-loop technology. I see children accessing the technology within months of diagnosis, but I had to wait 40 years to get access, and that was due to increased sensitivity to insulin, and my very small basal requirements. When I was pregnant with my son in 2003-4 there was no technology available to me. In the 70s, 80s, and 90s doctors rationed testing and I believe the patients that were diagnosed in those decades had very little time in range compared to now, so I believe complications might be reduced if they were offered the closed-loop technology NICE is considering. Quality of life is most important, and I believe that better education programmes for ALL diabetics need to accompany the offer of closed-loop technology, because despite coming up to nearly 50 years as a Type 1 I have never done DAFNE, and I have had to educate myself. I think the technology will be difficult for disabled patients: I have hand problems that make changing cartridges a struggle. The Tandem pump has a very small nipple into which the insulin gets injected into the reservoir and for anyone with sight issues, it is very tricky indeed. For people with mental disabilities, the use of closed-loop technology could be a burden because it requires a high degree of technical expertise and problem-solving. I would also like to comment on the pump providers in the NICE document. Having used Animas, Medtronic and Tandem I believe the suppliers of the Tandem pump have poor customer service, poor technical advisors, and their ordering service has failed me before now. It took Air Liquide 9 days to respond to my question!! In the meantime, I posted my question on Facebook and got an answer in minutes! Air Liquide does not have the capability of dealing with thousands more customers at present, but Medtronic definitely do have the expertise and capability. There needs to be an audit of all patients using pumps to ascertain if key performance indicators are being met because Air Liquide will not meet them. I recently had a pump replaced because it was overheating. Medtronic would have sent a courier the same day, but it took 4 days for Air Liquide to get it delivered after I posted I was still waiting on Twitter. The update process of Tandem pumps meant Air Liquide called all their customers by phone to give them an access code! This should not be happening and should have been an automated process of notification.<br>One thing I would like to say is that having lived in Australia between 2009 and 2014 I discovered that Australia moved all type 1s onto pumps back then to improve quality of life and time in range, as well as reduce complications, and the UK is too late and too slow in comparison.<br>One bit of vital consideration that needs to be addressed is the stress of technical burnout. I suffered from this having moved onto the Medtronic 640G & Guardian 3 CGM. The CGM refused to pair with the pump, the readings were often out, the calibration drove me mad, and the alarms were unbearable. The CGM sensor turned out to be faulty, but I lost hypo awareness due to that, which in turn made me lose my driving licence and |

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| | | | | | | consider suicide. I also got basal cell carcinoma on my stomach from the stress this put me through, and have had 2 lesions surgically removed from my lower abdomen.<br>Choice of pumps is very important to the user, and I believe NICE should allow patients to try a loaner pump BEFORE making a decision. Canulla choice needs addressing too because one might work considerably better than others. I had 2 cases of DKA from 3 bent silicon cannulas in a row within 3 weeks. I changed to a steel one following this.<br>I believe there is discrimination going on in clinics when pumps are offered. My training was with a barrister who was having hypos in court, so he got a better pump to cope with that. I do not agree with the condition of an HBA1C of 8% because in reality, health care professionals need to look at frequency of hypos, insulin sensitivity, time in range history as well as sleep, retinopathy history, and the patient's skin. I believe all children need to learn the basics about injecting before they can move onto a pump because they need to understand what to do if their pump fails them.<br>In my own case, the closed-loop technology has meant that I finally reduced my HBA1C to 6.4% after 49 years with diabetes hovering above 7%, living with up to 7 hypos per day. This was not sustainable and I think if it is made available a lot of people with diabetes might benefit from a better quality of life with this investment in closed-loop technology, BUT, without adequate training, it will fail. |
| 435 | | | | | | I agree with much of this document, however I don't feel the restriction of closed loop to only those with a Hba1c of 8.0 and above is fair. Considering this document rightly highlights the mental load that type one diabetes presents to patients and their carers, doesn't it make sense to role this technology to all type one diabetics? Having a lower Hba1c does not mean there are no worries or issues with diabetes, indeed a lot of work and stress can go into achieving that Hba1c, including many sleepless nights. To then be excluded from accessing this technology because of this is extremely frustrating. As a parent of a child with a lower Hba1c, I can assure you that things are not that easy. Quality of life is impacted greatly, as diabetes is both worrying and unpredictable. It is always there, 24 hours a day, highs and lows, consequently resulting in a lot of disruption day and night. To those who work so hard to achieve a low Hba1c, this guidance feels like a punishment. In some cases, I think it could encourage people to stop looking after their diabetes so well in order to meet the target of 8.0%. I understand there are issues around cost, but considering it's more cost effective in children, surely all children should be eligible for this. A child with diabetes has a lot on their shoulders, even if people don't really see it. For them feeling normal like their peers is probably their biggest wish, this technology goes a long way towards making life normal again for them. The benefits are a happier, healthier, longer life. There shouldn't be any barriers to that. |

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| 436 | | | | | | Section 1.<br>1.1.<br>- Recommend a pathway that includes trial of pump not in loop first so that person knows how to use the pump if the loop fails or needed in scenarios such as 'sick day'.<br>- Criteria should include recognition of burden. Patients may be achieving HbA1c below the threshold but unable to sustain this without significant burden on their wellbeing. We shouldn't insist they deteriorate before using tech. Can there be a statement that allows recognition of this or MDT leeway if benefit is perceived?<br>1.2 If a patient meets the criteria, do we need to state pregnancy. As stated above (and as per 1.5), patients need to understand how to manage a pump independently and pregnancy is not an ideal time to be learning this.<br>1.5 Structured diabetes education should ideally happen before, not during pump set up. |
| 453 | | | | | | I have been a type 1 diabetic for 45 years. This document is fantastic for those that meet the criteria but I feel it does not take a few things into account.<br><br>1. Anxiety re management of diabetes ie severe anxiety re management of hypos so the patient runs there glucose levels higher. A closed loop system could help some point patients address this<br>2. This document does not address some issues for patients like myself who have been diabetic for many years and had good control but have still developed complications. Tighter control through a closed loop system can prevent complications getting worse. |
| 456 | Children & Young People's Diabetes Team, Somerset Foundation Trust | recommendations | 1 Recommendations | 1.3 | | This is a workforce demand both in terms of staff numbers and level of staff training that may be challenging to roll out rapidly.<br>We feel this will be an issue across the whole system.<br>There may be disparity for specific trusts / regions where rtCGM funding has been behind E&W averages, or there are particular issues with deprivation / ethnicity inequalities where there have been greater barriers to accessing / adopting these technologies. In these teams, there are likely to be greater training needs of both staff, and a bigger group of patients needing education in use of technologies, particularly pump therapy. |

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| 478 | National Children and Young People's Diabetes Network | | | | | Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes<br>NICE guideline consultation- feedback template<br>Name: [redacted] Children and Young Peoples Diabetes Network including the Families with Diabetes National Network<br>Unit: National Children and Young Peoples Diabetes Network<br><br>Document section Your comments<br>1. Recommendations<br>1.1 HbA1c cut off above 8.0%, and who have tried pump therapy My comments are made on behalf of the members across the National Children and Young Peoples Diabetes Network and the Families with Diabetes Network in England. It is with a unanimous voice that the members of both these Networks, feel that the threshold that has been suggested for gaining access to HCL technology is excessively high especially for the group of Children and Young People aged 0-18 years. A threshold of 64mmol/mol is inappropriate when the current NICE Guidelines for Children and Young People with Diabetes states a target of 48 mmol/mol is one that individuals should achieve to minimise the risk of developing the long-term complications of this disease. It is felt that there should be NO threshold of HbA1c value below which access to the HCL should be restricted for this group of patients and that we should be offering them every assistance we can to achieve the best outcomes as early in the disease process as possible. Children and Young People live longest with this condition and therefore stand to be most at risk from the devastating effects of both chronic hyperglycaemia and short-term hypoglycaemia, with the children under 5 years being the most susceptible group to suffer brain damage and compromised brain development.<br>1.2<br>1.3<br>1.4<br>1.5<br>Why the committee made these recommendations As stated above, we challenge the HbA1c cut off being above 8% in those who have tried pump therapy. We recommend that there is NO threshold for accessing this vital technology for Children and Young People living with diabetes aged 0-18 years.<br>There is a 16-year reduced life expectancy in individuals with T1D ( Rawshani, Lancet 2018). Even in individuals who achieve optimal HbA1c under 6.9% (<52mmol/mol), a 2-fold increased risk in death from cardiovascular disease is seen (Lind NEJM 2914). Further, the EDIC study demonstrated that early glycaemic control influences future long term diabetes complications, with lower levels of glycaemia in the first years at onset, saving patient and health systems the burden related to diabetes complications, a |

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| | | | | | | phenomenon termed ‘‘metabolic memory’’ (Steffes JAMA 2003, Lachin Diab Care 2021).<br>In addition to the influence of glycaemia on long term health and mortality, there is inadequate mention of the impact of T1D on parenting and family stress, quality of life for the child and parents, school attendance, educational attainment, the effect on parental employment, and mental health, which needs to be considered (Kimbell BMC Pediatrics 2021).<br><br>2. Information about Hybrid Closed Loop Systems<br>2.1 “If type 1 diabetes is not well controlled…” This statement needs altering; even with relatively good control (under HbA1c < 6.9%) there is a 2-fold higher cardiovascular risk, as discussed above.<br>2.2<br>2.3 multiple daily injections<br>HbA1c as a measure of glycaemia over 3 months This statement should read “multiple daily injections or insulin pump therapy”<br>This is an inaccurate statement and should read over preceding 8-12 weeks<br>2.4<br>2.5<br>2.6 HCL systems The CAMAPS FX system should also include compatibility with the Ypsomed pump<br>The Omnipod 5 is currently not available in the UK<br><br>CAMAPSFX is currently the only HCL system licensed for children aged under 6 years<br>2.7<br>2.8 Cost Was Ypsomed system with CAMAPSFX included? see comments above for children aged under 6 years<br>2.9<br>3. Committee discussion<br>3.1 age of hypoglycaemia awareness Children under the age of 6-8 years are consistently unreliable when reporting hypoglycaemia and very often completely hypoglycaemia unaware.<br>3.2<br>3.3 NHSE pilot Whilst the Warwick evidence review does refer to the "real world study" in both adults and Children and Young People it is not clear what weight was given to it as much of the NICE evidence review is redacted. The median HbA1c prior to the children using hybrid closed loop technology was 61.5 mmol/mol in the NHSE pilot real world study. This is very comparable to the median for the general paediatric population. The median whilst using hybrid closed loop was reduced to 54 mmol/mol. This is a reduction in HbA1c of 7 mmol/mol. As a community of practice, the Children and Young Peoples Network professional members are struggling to help families to support young people to achieve the NICE HbA1c target of 48 mmol/mol. Using hybrid |

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| | | | | | | closed loop would greatly assist us to achieve this goal. It seems illogical for NICE to set a target of 48 mmol/mol but then only offer HCL technology to those over 64 mmol/mol if there is the potential to move the population median from 61 mmol/mol to 54 mmol/mol.<br><br>I<br>3.4 More reference should have been made to the NHSE Pilot having been performed in Children and Young People as well as in adults. The summary should also include paediatric data (Ng Diab Med 2023). Of note, the outcome of the paediatric NHSE pilot data identified a sustained improvement in glycaemic control, time in range and quality of life measures for fear, worry of hypoglycaemia and improved sleep in patients and carers after hybrid closed loop usage.<br>3.5<br>3.6<br>3.7 the model 1. The economic modelling does suggest that the IQVIA Diabetes model that was used may not be appropriate or applicable to children. We feel strongly that Children and Young People should be considered as separate group because<br>a. they are the group most likely to develop complications simply due to the duration of diabetes<br>b. economic models such as IQVIA may not be reliable in modelling the cost per QALY in paediatric populations and alternative or more pragmatic methods should be used<br>c. the impact on mental health as well as physical health needs to be carefully considered in both the young person and their family. Hybrid closed loop use has been found to significantly reduce both the patients and their family's anxiety and worry. It also significantly improves sleep patterns. Anxiety and poor sleep are well known to affect educational attainment as well as mental health<br>d. In CYP the impact on their parents, their parents QOL and their parent's ability to engage in economic activity also need to be addressed. The real-world study showed improvements in parental well-being with Hybrid Closed Loop therapy<br>e. the impact and costs of the other carer's e.g. school & nursery also need to be considered. HCL reduces the need for support in these environments<br><br>3.8<br>3.9<br>3.10<br>3.11<br>3.12<br>3.13<br>3.14 |

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| | | | | | | 3.15<br>3.16 recommendations for use Despite acknowledging the increased benefit for children, this is not reflected in the recommendations. We would very much like to see Children and Young People 0-18 yrs should be considered as a separate group with no HbA1c threshold applied for HCL access. The decision to use HCL with Children and Young People with diabetes should be a decision taken by their responsible physician in conjunction with the family, in the same way that other clinical decisions to benefit patients are made in the NHS today<br>4. Implementation<br>4.1<br>4.2<br>4.3<br>5. Committee members & NICE project team<br>Comments on document as a whole: The National Children and Young Peoples Diabetes Network were very disappointed with the recommendations in relation to Children and Young People 0-18 years and for young adults/adults too. Despite acknowledging that hybrid closed loops potentially offer increased benefits for children, this is NOT reflected in the recommendations. It appears the stance taken is one that rewards individuals who may be making less effort to look after their disease condition and doesn't take into account the immense effort that goes into the care of someone attaining an HbA1c approaching and exceeding the NICE target of 48 mmol/mol in order to try their best to achieve good outcomes and avoid costly complications of living with this disease<br>Comments on any of the supporting documents (please say which)<br><br>References to support recommendations<br>Kimbell B, Lawton J, Boughton C, Hovorka R, Rankin D. Parents' experiences of caring for a young child with type 1 diabetes: a systematic review and synthesis of qualitative evidence. BMC Pediatr. 2021 Apr 4;21(1):160. doi: 10.1186/s12887-021-02569-4. PMID: 33814007; PMCID: PMC8019496.<br>Lachin JM, Bebu I, Nathan DM; DCCT/EDIC Research Group. The Beneficial Effects of Earlier Versus Later Implementation of Intensive Therapy in Type 1 Diabetes. Diabetes Care. 2021 Aug 11;44(10):2225–30. doi: 10.2337/dc21-1331. Epub ahead of print. PMID: 34380706; PMCID: PMC8929189.<br>Lind M, Svensson AM, Kosiborod M, Gudbjörnsdottir S, Pivodic A, Wedel H, Dahlqvist S, Clements M, Rosengren A. Glycemic control and excess mortality in type 1 diabetes. N Engl J Med. 2014 Nov 20;371(21):1972-82. doi: 10.1056/NEJMoa1408214.<br>Ng SM, Wright NP, Yardley D, Campbell F, Randell T, Trevelyan N, Ghatak A, Hindmarsh PC. Real world use of hybrid-closed loop in children and young people with type 1 diabetes mellitus-a National Health Service pilot initiative in England. Diabet Med. 2023 Feb;40(2):e15015. doi: 10.1111/dme.15015. Epub |

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| | | | | | | 2022 Dec 4. PMID: 36424877.<br>Rawshani A, Sattar N, Franzen S, Rawshani A, Hattersley AT, Svensson AM, et al. Excess mortality and cardiovascular disease in young adults with type 1 diabetes in relation to age at onset: a nationwide, register-based cohort study. Lancet. 2018;392(10146):477-86.<br>Steffes MW, Chavers BM, Molitch ME, et al.; Writing Team for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Sustained effect of intensive treatment of type 1 diabetes mellitus on development and progression of diabetic nephropathy: the Epidemiology of Diabetes Interventions and Complications (EDIC) study. JAMA 2003;290:2159–2167 |

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| 479 | | recommendations | 1 Recommendations | 1.1 | | Hybrid closed loop should be available to any type 1 diabetic who is supported by their clinical team and can prove that they are working hard to manage their diabetes irrespective of HbA1c outcomes and that they would benefit from this system to improve the quality of their life and reduce the stress and mental load associated with managing this condition on a day to day basis. It feels like some T1 diabetics will be penalised for having above average control of their condition based on a 6 - 8 week statistic. An average or good HbA1c outcome does not always correlate to good overall control or good management on a day to day basis eg there could be a high level of hypos within the period that prevents the individual from having a good quality of life but this is shown as having above average control in the HbA1c reading. Time in range should also be considered. The fear of hypos and hypers can have a significant affect on the mental and physical health of an individual and their carer / family and the hybrid closed loop system would remove some of that anxiety. |
| 492 | | | | | | Section 1: A criteria relating to HBA1C is limiting and will not help those in most need.<br><br>Firstly, one may have a low HBA1C because they yo-yo between hypos and hypers, thus could benefit from HCL.<br><br>Secondly, this criteria does not consider mental health.<br>Setting a high HBA1C as the criteria misses the fact that diabetes isn't just a disease with long-term physical implications, but also mental ones.<br><br>With a HBA1C of 42, I wouldn't meet this criteria. Yet I only have that A1C because I work so hard. I exhaust myself and give up my mental health to maintain my physical one out of fear for the future.<br><br>I am up at all hours of the night, every night, adjusting my basal, bumping and nudging to stay in range. I do the same all day. In fact, I am now on the dexcom 1 but when I had the libre I would scan it more than 80 times a day. I also eat low carb. I exercise strategically. I look online and in support groups for new tips and tricks. It takes over my life. I have no freedom, but this could give me that.<br><br>In contrast, I've seen people in support groups not even know what basal testing is, get lazy with carb counting, eat a poor diet and never use their CGM alarms. These are the people your criteria help.<br><br>Would it be easier to let myself go, turn off my high alarm at night and eat what I want? Yes. But I work hard. I get burnt out. It's a significant burden on my mental health to the point where the NHS pay for me to speak to a therapist. This could really help me, yet I wouldn't qualify. |

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| | | | | | | I actually also think this criteria would make people like me purposely let go just to get access to this quality of life improving technology. Which surely costs the NHS more in the long run. How much does it cost to treat an episode of DKA, for example? That's what we're at risk of if we "let go".<br><br>Please, please add something in here for those with mental health issues.<br><br>Or those who get up in the night to correct regularly despite a tailored basal programme. We deserve to sleep too.<br><br>I also respect that you've got a note for pregnant women. However, what about other hormonal challenges? Each month my period affects my insulin needs by around 40%, making it really hard to manage. Something I just have to get on with. But imagine how it is for someone with PCOS or similar. Another way a closed loop would help. How about menopause too?<br><br>Another comment is on training. I know many trusts have now limited their training. I may be wrong but I believe Wiltshire, where I live, now only offer their Freedom For Life course to people who have only had diabetes for a certain amount of time. How then, would old timers access this tech? |
| 510 | | committee-discussion | Access to technology and care | 3.2 | | There is a postcode lottery to access to this life saving, life enhancing tech. Unless you have type 1 diabetes you have no idea what this tech means to life. Making life possible, bearable. Especially for those of us who micro manage every minuscule detail of carb counting every gram we consume for precision, micro managing our blood sugars using this tech to prolong our lives without being a burden to the NHS, by spending hours checking the data and making micro adjustments. It needs to be made available to all, not just a select few, with an hba1c barrier. |
| 534 | | | | | | I am the parent of a child with Type 1 Diabetes.<br><br>— INADEQUATE CONSIDERATION GIVEN TO AGE AT DIAGNOSIS —<br>The data that you are considering shows the greatest impact on HbA1c in those that are poorly controlled at baseline. You then appear to extrapolate the HbA1c at baseline, and the impact in the reduction thereof, over the longevity of the condition. However there is plenty of evidence that show multiple other factors that impact outcomes in T1D over time. I appreciate that the RCT & pilot studies are not powered to look at these segments, but if you are going to extrapolate HbA1c at baseline throughout the longevity of the disease, I would also expect you to consider other factors that have been shown to impact long-term outcomes, in particular age at time of diagnosis.<br><br>Age at time of diagnosis, both as a discrete factor and as a proxy for length of time with T1D, lowers the average HbA1c that is needed over time to avoid |

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| | | | | | | adverse outcomes. Age < 10 at age of diagnosis is also specifically associated with worse outcomes. I propose that age at time of diagnosis should also be considered in the cost effectiveness model, especially if the guidance is going to extrapolate a point-in-time HbA1c over the course of the condition.<br><br>— INADEQUATE CONSIDERATION GIVEN TO IMAPCT OF T1D ON CHILDREN —<br>I appreciate that NICE acknowledges that there may be uncaptured benefits in its modelling. However evidence suggests that there is a greater likelihood of these uncaptured benefits occurring in children. Children with T1D miss more schools days than their peers, and are susceptible to additional mental health burdens during puberty and their teenage years. This impact on education may have long-term effects, as yet unmodelled. T1D is also disruptive in the classroom, with repeated isCGM checking impacting both the child and the wider class. The impact of overnight checking for hypos is also considerable on parents, both on their health and ability to work. The guidance should at least, emphasise that there is greater potential for uncaptured benefits in children.<br><br>— INCENTIVISING OF GOOD CONTROL —<br>With a lifelong chronic disease, part of the role of health systems should be to encourage behaviour by the individual to bring their diseases under control. T1D is a condition where many continuously strive to improve their “numbers”, as they know of the long term benefits of doing so. I would be wary that this guidance could disincentivize this positive behaviour, whereby the HCL criteria could encourage a temporary weakening of control, in order to meet the threshold for pump use.<br><br>The guidance, as drafted, rightly flags the inequality factors which are associated with poor T1D outcomes and access to technology. But it does not once mention the drive by many to get good control, including by the DIY loopers who have done so much to advance this entire area of technology. It would be encouraging to see NICE also factoring in the potential “reward” of HCL to drive positive behaviour and the overall benefit that this might bring to the individual and the overall health system. |

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| 537 | | | | | | Diabetes control is paramount to the long term health of an individual with type 1. The new closed loop systems offer those with type 1 the opportunity to have a life which not only reinforces this but also gives them a freedom which is denied with this condition. Parents of children with type 1 fight hard for excellent control but this comes at a great cost to them and the child. Diabetes burnout often creating significant mental health episodes for all. To prescribe this option based upon an HBA1C is short sighted and counterintuitive. This therapy will ultimately save the NHS millions with hospital stays reduced long term complications minimised and overall patient well being improved. The community have waited years for this treatment and now through a short sighted view will have it taken away unless they allow themselves to have poor control. The physical and emotional impacts of this condition are profound and to deny people this therapy will have far reaching consequences on the NHS for years to come. This battle was had with CGM and NICE guidelines changed due to the benefits this is exactly the same situation again. Treatment for a chronic condition should be the best on offer. Type 1 is unpredictable and erratic and this provides the NHS with the opportunity to create better long term outcomes for all with this condition. Those under the age of 18 suffer erratic numbers and control as hormones and insulin struggle to cope with the demands each expects of the body. This is only managed with sheer hard work from parents to keep their children safe and in range. Closed loop therapy should not be seen as a possibility it should be seen as a necessity particularly for those under 18s who live with this chronic limiting condition. |

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| 553 | | | | | | I believe the committe has appraised the relevant RCTS and studies and have identified the difficulties with the evidence accurately. There are some areas in which I would like to voice my concern:<br>1. "difficult to manage type 1 diabetes" refers to all type 1 diabetes and can't really be defined by an HbA1c number. I know the committee members are all well aware of this. That HbA1c number also does not not necessarily define the benefits of HCL. In qualitative reports users have reported giving up roughly 80% less headspace to diabetes and its management when using HCL. Parents go out and leave kids at home with babysitters and people sleep at night. concern about hte future and complications is significantly diminished. These benefits are huge and apply across al achieved HbA1c ranges. Those obtaining an HbA1c of 53 (still above target for NICE) or time in range of 70% may well be achieving this at rather more impact on QOL and their mental health than those with higher HbA1c numbers and I think that we really need to get at this aspect in more detail very soon-in some ways the HbA1c threshold suggested of 64 (based largely on those more easily measured hard clincal endpoints) will discriminate against those who are spending many more hours of their life thinking about and managing their condition and who deserve no less support and are no less deserving of the support that an HCL offers and the potential benefits to longer term mental health. I appreciate evidence of the long term potential benefits I infer is not available right now but I suspect you will find i thard to find a diabetes nurse specilaist or consultant who does not belive these benefits to be truly realisable and even if this first version of hte guidance uses an HbA1c threshold (for which some will jsut slacken control to hit potnetially putting htem briefly at increased risk) then ther should be provisions to review this soon and with research strategies supported to gain the evidence required<br><br>2. Costing. Whilst I agree that there is a deal to be done with industry I am not sure that using an average cost for HCL systems was appropriate as there are huge differences in cost between using the different systems as things stand. This is made even more diofficult by thte fact that industry representatives make different deals with different services so some access the technologies and very differnet rates but the cost of the Dana I and RS systems with CamAPS is significantly lower than the cost of the other systems for our service in Plymouth.<br>3. Costings CGM: the discrepancy in costs between HCL and pump + CGM for us locally relates to the difference in cost between isCGM or lower cost cGM options and the cost of the guardian or dexcom G6 sensors since the hardware would cost the same otherwise and the HCL element otherwise adds no cost-there is clearly a huge opportunity here for the companies to offer CGM with integrative compatibility at much lower cost given the predicted far higher volume of sale which should be exploited (Dexcom one and G7 are the same hardware units at hugley different costs I belive with the |

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| | | | | | | cost sttributed to teh support and software integration and upkeep, but doing that software upkeep for one device works for all devices so these costs are limited for the companies and I htink the committee should be willing to conisder limiting approval to systems which work to come in on budget (I am sure this is waht is intended, similar arguments pertain to most of the pumps too)<br>4. I do think that at some point there has to be recognition that not all CGM is the same and there need to be clear quality standards and standards of proof of accuracy in target populations provided fofr any device approved as stand alone or integrated CGM. this definitely does not apply to tand alone CGM at the moment with poor quality and badly evidenced devices getting CE mnarked for use in the UK |

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| 574 | University Hospital Southampton | | | | | As a Multidisciplinary Specialist Insulin Pump team, we of course applaud the effort of making Hybrid closed loop system technology more widely available for the right patient, under the right circumstances.<br><br>That said, we feel the recommendation criteria for who is entitled to a trial of Hybrid closed loop system technology is slightly lacking and out of step with other existing insulin pump related NICE guidance, both CSII [TA151} and Type 1 Diabetes NG17). In addition, fairly critically, there is no mention of experiencing significant, disabling hypoglycaemia (with/without symptomatic awareness/needing third party assistance/high Gold score etc?) as a criteria for eligibility of the Hybrid closed loop system, which could significantly help individuals in this situation.<br><br>Our view would be to advocate for better alignment of the HbA1c thresholds across the 3 guideline documents, with additional recommendations for use of technology based more specifically on clinical factors (e.g pregnancy) and/or entrusting the clinical specialist team to make the most appropriate recommendation on which particular technology is likely to support their patient best (based of course on clinical appropriateness, with cost issues also considered). On the issue of cost, what would the position be if companies could not agree a cost-effective price with NHS England?<br><br>Thankyou<br><br>The University Hospital Southampton Adult Insulin Pump team |
| 592 | | recommendations | | 1 | | Missing categories which feel need to be included:<br>- adults without the capacity to manage their own treatment. In particular elderly people or others who may not have the dexterity or mental capacity who may be relient on carers without an indepth knowledge of T1<br>- the substantial mental burden of T1 can lead to diabetes distress & burn out. There are no recommendations which take the psychological burden of T1 into account. PWD are more than just an hba1c result.<br>- recurrent hypos. HCL can significantly reduce these & therefore reduce the cost of treatment/support needed as well as improve QOL. |
| 607 | | | | | | 1.1 Establishing an average hba1c threshold for access to hybrid closed loop systems could penalise those who are intensively managing their type one diabetes at great personal (or carer) burden. E.g. parents or individuals will frequently wake several times each night to manage glucose levels and therefore attain a hba1c which is lower than 64 mmol/mol but the personal cost is unsustainable.<br><br>1.2 life stages like pregnancy present huge challenges for diabetes management but so do other life stages such as puberty and menopause |

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| | | | | | | 1.4 concerned that the need to be "attending" (currently??) a structured education programme may be a barrier. With regard to paediatrics, DAFNE is not available and many clinics only provide ad hoc (in appointment) education programmes. Surely the issue is covered off in the previous point "understands and is able to use them" and this should be the only criterion here?<br><br>3.1 Good to see the point about mental load and burn out referenced here. Surely this should be incorporated into eligibility criteria. Additional point, support for children with type one diabetes in schools is very very variable. Hybrid closed loop systems could allow children to have better attendance, less need to miss lessons to deal with hypo and hyperglycaemia, less school staff involvement and better impact of family's ability to return to employment for example. With regard to adults, hybrid loop systems could increase productivity at work and employment prospects. |
| 611 | | | | | | I would urge the NICE committee to reconsider the conditions for accessing hybrid closed loop technology. Currently these guidelines prevent those using a pump and cgm to effectively mange their glucose levels from upgrading to a hybrid closed loop, when they have demonstrated how much they can benefit from technology in thier track record of pump use. It feels, as a patient, as if we are being punished for doing the exhausting job of acting as a functioning pancreas successfully. Some, like me, were put on pumps as children and have been waiting for the promised closed loop technology that will take the burden of micromanagement off our shoulders for 15+ years.<br>Furthermore, these guidelines do not take into account the mental load and distress caused by making hundreds of decisions per day, or loosing sleep to adjust for lows and highs, and of micromanaging a very intense condition. This technology could be particularly beneficial to those suffering from mental ill health as a result of their diabetes. |
| 614 | | recommendations | 1 Recommendations | 1.1 | | There is a danger of moral hazard here, it is "rewarding" poor diabetes management, whereas those people who put in a lot of effort (20+ scans a day, 5+ insulin corrections a day) are excluded because they are "too good". The criteria should actually be about lifestyle: the hybrid system is able to significantly reduce the burden of diabetes. For people who have HbA1c >64 without much effort managing their condition means that a hybrid system will not improve their life much, but someone who does a lot of corrections means a hybrid system will improve their life a lot, regardless of their HbA1c "score". The commentary at the bottom of the page says "Continuously managing blood glucose levels is a substantial mental load for people with type 1 diabetes (and their families or carers)" and yet the criteria given for eligibility for hybrid systems does not take this into account. |

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| 625 | | | | | | I am a 51 year old late onset type1 - currently using Medtronic 780g with Guardian 4 sensors (self funding sensors and upgrade of pump from 640g). Based on my experience as an educated and motivated user of the technology (HbA1C about 46 and TIR 70-80%) I would comment:<br><br>HCL systems are revolutionary for the lives and carers of T1D patients and I wholeheartedly support widening access to the technology for patients, especially those who will benefit most (children, those otherwise struggling to maintain good control for various reasons). The un-quantified benefits noted in the consultation are huge (mental health, etc.) and just because a monetary value cannot at this time be placed on them the NHS should recognise this value and ensure all T1D patients are offered choices, including HCL.<br><br>Exercise also become much more manageable which is not considered in detail in the study, but many diabetics do not move enough as they naturally worry about the impact on BG levels. Being able to set temporary targets during exercise, and after if needed, substantially eases stress and enhances wellbeing from exercise.<br><br>I recognise resources are not limitless but targeting of resources, whilst maintaining opportunity to choose, could be enhanced by introducing co-funding models for those that can afford it - I was happy to pay for access to the technology but had to wait over 2 years to get support from the care team and jump through lots of hoops to get there. This would allow for funding to be allocated to those do not have the resources to support themselves.<br><br>I therefore would suggest that all patients are offered access to HCL, not limiting to those with a particular HbA1C. Wider access and use would enable the tech companies to access economies of scale and reduce pricing in time, increasing cost effectiveness for the NHS. The long term effect of reduced cost for treatment of diabetic complications would be substantial.<br><br>Many thanks<br><br>[redacted] |
| 627 | | | | | | 1. The requirement for Hba1c of 8.0 or above will mean that Type 1 diabetics with lower Hba1c due to frequent hypoglycaemic events will not have access to improved glucose control. I note that it is difficult/not possible to calculate the cost benefit of reducing hypoglycaemic events but the negative impact across a lifetime is significant.<br>2. Experts by experience may not need to complete a formal education programme. This should be determined by the lead clinician on a case by case basis. This may reduce unnecessary expenditure on education programmes a little. |

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| 639 | | | | | | Firstly I am so pleased about the possible update to the NICE guidelines, as a parent of a daughter with Type 1 I feel this is the biggest step forward for a long time in treating and living with this chronic condition.<br><br>My daughter is 19 years old and was diagnosed at age 10 so we have vast lived experience and know what a toll the daily management of type 1 diabetes can take on the individual living with it and also the family supporting the individual.<br><br>In commenting on this document I wish to acknowledge the work that has gone into getting this far, the clinical trials and data that support this and the time and dedication of everyone involved.<br><br>That said the daily burden of living and managing type 1 is huge and I believe that by disregarding people who work tirelessly with no days off at managing the condition, and who manage to maintain a HbA1c of 63 or below is not acceptable.<br><br>There are a few reasons for this;<br><br>Firstly, my daughter has recently transitioned from children's to young adults team for her care, this happened last year in July, and since then we have not managed (despite our efforts of asking for it and going to get bloods done) to receive a HbA1c result and we do not know when she will actually get one. Luckily she also uses a cgm so we have access to knowledge of her time in range which gives us peace of mind, but if we don't even know what her HbA1c is, where does that leave her in relation to being considered eligible for access to HCL?<br><br>Also, the impact on mental wellbeing is important to mention, during the almost 10 years of living with Type 1 my daughter and myself, as a carer trying to take away the daily burden, have suffered and continue to suffer on a regular basis with coping mentally. I am sure you will realise it can be a rollercoaster of a condition to manage with no two days being the same. So to be told that although you have been managing this condition well for 10 years you still cannot have access to life changing tech that will undoubtedly make a huge difference to the daily grind of managing it, is like a kick in the teeth.<br><br>What measure do you put on mental wellbeing in this consultation for eligibility?<br><br>My daughter is now at university and unlike some her age, she not only has to adapt to being independent and living away from home, studying (which is |

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| | | | | | | also impacted by the daily high and low BG levels) but she also has to now manage her condition more than ever, managing appointments, prescriptions, managing drinking alcohol, as many students do, with the worry of going hypo in her sleep.<br>The addition of managing type 1 alongside everything else that is happening at this age is a heavy burden and the HCL technology would take away a lot of that burden.<br>I feel you should give special consideration to the age group that are eligible for HCL.<br>Thank you for reading these comments. |
| 641 | | | | | | Diabetes control is paramount to the long term health of an individual with type 1. The new closed loop systems offer those with type 1 the opportunity to have a life which not only reinforces this but also gives them a freedom which is denied with this condition. Parents of children with type 1 fight hard for excellent control but this comes at a great cost to them and the child. Diabetes burnout often creating significant mental health episodes for all. To prescribe this option based upon an HBA1C is short sighted and counterintuitive. This therapy will ultimately save the NHS millions with hospital stays reduced long term complications minimised and overall patient well being improved. The community have waited years for this treatment and now through a short sighted view will have it taken away unless they allow themselves to have poor control. The physical and emotional impacts of this condition are profound and to deny people this therapy will have far reaching consequences on the NHS for years to come. This battle was had with CGM and NICE guidelines changed due to the benefits this is exactly the same situation again. Treatment for a chronic condition should be the best on offer. Type 1 is unpredictable and erratic and this provides the NHS with the opportunity to create better long term outcomes for all iTunes this condition. Those under the age of 18 suffer erratic numbers and control as hormones and insulin struggle to cope with the demands each expects of the body. This |

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| | | | | | | is only managed with sheer hard work from parents to keep their children safe and in range. Closed loop therapy should not be seen as a possibility it should be seen as a necessity particularly for those under 18s who live with this chronic limiting condition |
| 642 | | | | | | I have been a type 1 diabetic for 40 years now and frequently suffer from burnout and anxiety due to my condition. I put a lot of mental effort into controlling my levels. I also invest finances self funding my dexcom. I do this for my own benefit and peace of mind as it helps me mentally relax a bit more. I find it extremely unfair that due to my constant efforts to control my levels I seem to always miss out on qualifying for the best technology. When I found out about this pump and it's capabilities, having been told by a diabetes nurse to look at pumps as a possibility, I cried tears of joy and relief knowing that this life changing technology was coming! You can imagine how I then felt to learn that not only was this unavailable in my postcode area but that I also did not qualify for a pump as my HBA1C was too good. I feel repeatedly punished for bothering to spend time and energy chasing my levels. This is my life and it could be changed so, so much by access to this. I really feel this should be available to all type 1 diabetics that have the capability to use it. Imagine how many less incidences of secondary complications we would see and how much more time in range there would be, not to mention the luxury of peaceful nights sleep. |

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| 654 | | | | | | As a sufferer of Type 1 Diabetes for over 20 years, with 9 years on an insulin pump and just 3 months on the closed loop system, I can not emphasise enough what the technology does to quality of life, even additional to the insulin pump. It relieves the mental burden (you do have to be an engaged user and understand your condition but the burden is significantly reduced) and that physical 'fog' of having permanently elevated blood sugar levels is so hugely reduced it almost reminds me of a time when I did not have the disease. I was able to manage a successful pregnancy on the libre sensors and an insulin pump, but the addition of the closed loop and access via my smartphone, just takes away a lot of that mental strain and worry as I look to expand my family, now with a toddler (plus a 9-5 job). Even a sufferer like myself with a relatively 'good' HbA1c generally between 7-8%, just getting it down to around 6% is 1-2% on paper but it is more than that in terms of long term health and quality of life. The discussion of cost and value to taxpayers is understandable but frustrating. The upfront cost of this technology is nothing in comparison to how much a type 1 diabetic who is poorly controlled and/or a long term sufferer would cost and burden the NHS over a life time- daily drugs, extended hospital stays, surgery, mental health support, checkups, phsyiotherapy, podiatrists, specialists, ambulance use, their unborn children, I could go on. Just under £6,000/annum this costs- I know people who spend this on commuting to work or a holiday! Is this a burden our NHS needs to battle? £millions+ caring for people who don't have to be in that poor state of health if only they had had access to appropriate healthcare initially. I haven't calculated the payback but I am sure it calculable and would payback within years, not decades. With so many causes and conditions wanting a slice of NHS money, as a taxpayer myself, my vote goes to those technologies that allow people to live as normal and as happy a life as possible; keep them out of our hospitals, around for their families and contributing to the economy/society. |

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| 655 | | | | | | The recommendations do not take into account severe fear of hypos as well as loss of hypo unawareness. This is a major impact for people living with type 1 diabetes.<br><br>It is also recommended for women trying to conceive, and for those who are pregnant - what happens to these women once the baby is born? Will they lose access to insulin pumps?<br><br>I feel it should also take into account women suffer severe impact on their type 1 diabetes when they go through the menopause. This stage in a woman's life can severely affect their blood glucose control.<br><br>Hormones affect type 1 diabetes a lot<br><br>What happens to people who have access to close loop and then they gain control of their diabetes (which should be the ultimate aim of diabetes technology). Will they lose access when their control is nood and they have an optimal hb1ac?<br><br>The issue with the hb1ac recommendation is that it does not take into account people who work super hard to control their diabetes. People who set alarms in the middle of the night to take insulin; people who take 10 or more injections a day to get optimal control. These people are suffering, and having their lives impacted so that they can have good control (on paper), and not suffer complications - this is not an easy life to live, and these people are doing their best.<br><br>These recommendations seem like they reward those who have poor control and don't care. I fear these will encourage type 1 diabetics to give us control for a while in order to meet the hb1ac criteria.<br><br>These recommendations really haven't been thought through, and take into account how type 1 diabetes affects people's daily lives. |

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| 665 | NHS England | | | | | The NHS England Diabetes Programme asks NICE to consider the following clinical feedback in response to the Appraisal Consultation Document:<br><br>1. The proposed HbA1c inclusion threshold is now lower for Hybrid Closed Loop than the threshold set out in NICE TA151 requiring pump prescribing for people living with Type 1 Diabetes. HbA1c threshold needs to be aligned across TA151 and Hybrid Closed Loop MTA. TA151 also recommends access to Pumps for people with Disabling Hypoglycemia and consideration should be given for alignment with this aspect as well.<br><br>2. In the consultation documentation structured education for people living with Type 1 Diabetes is recommended as being mandatory, but NICE may wish to reconsider this. The experience from the implementation of Pumps is that it creates problems regarding access and especially barriers to those living in economically deprived communities and people with other protected characteristics. NICE might therefore consider that structure education should be routinely recommended and offered, but not necessarily mandated prior to access to the technology, in order to address these potential health inequalities. Of course, patient education in the use of the technology itself is essential.<br><br>3. NICE are asked to provide a summary of evidence to support the recommendation of Hybrid Closed Loop as an option for managing blood glucose levels in Type 1 Diabetes for people who are pregnant or planning a pregnancy. NICE are also asked to bear in mind the potential dilemma patients and clinicians face when people are asked to return their technologies after their pregnancy – this is already causing difficulties with regard continuous glucose monitoring in pregnancy.<br><br>4. People living with Type 1 Diabetes cannot be easily transitioned to Hybrid Closed Loop and it takes time. This is particularly pertinent to people who are not already accessing Pumps. In this scenario, people living with Type 1 Diabetes would need to be transitioned to a Pump first. It would be helpful for NICE to confirm if people living with Type 1 Diabetes are anticipated to be transitioned to a pump first before starting Hybrid Closed Loop, and to consider the impact on workforce.<br><br>5. The proposed NICE recommendation for Hybrid Closed Loop will lead to significant demand and clinical workload constraints. Should the NICE proposal be adopted in its current format – with wide eligibility criteria and no phased implementation - it will have a significant impact on the diabetes workforce, who will be expected to adhere to the MTA. It takes additional clinical time to transition people living with Type 1 Diabetes and support them in the use of this new technology. |

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| 670 | | | | | | 1) As a Type 1 diabetic of 30 years on an insulin pump and CGM, who strives and toils on a daily basis on a mental and emotional level, to keep my blood sugar below the 64 number you mention - and I manage to - I find this number too high. I cannot comment on the reasons for others being above 64, but for me, I work really hard, constantly day and night (every time I wake, I scan and correct insulin levels if needed which affects my sleep patterns) to keep it below this number. I scan over 20 times a day, add insulin, suspend insulin etc and do what this system would do, but it is exhausting. I don't believe that a number should be added here, as it penalises people for striving hard to keep within range. Most of my decisions are made around what my blood sugar is doing and I watch and manually correct it regularly throughout the day. That is tiring when life is normal, but the minute there are extreme stresses - like recent flooding in my home for example - having to manage the ups and downs of blood sugar on top of other life stresses becomes overwhelming and one can feel at cracking point - and in some cases then the diabetes suffers. Please reconsider having any number here at all. And have the consultants and specialist nurses decide based on need, ability to handle the technology, effort put in etc. The mental load is immense and continual. Sometimes that keeps my Hba1c at a good number and sometimes it doesn't. But the effort and strain is there regardless. And this strain may well impact our future NHS needs, with blood pressure impact, impact of bad sleep etc. The physical aspect of managing diabetes is only one part of it. The majority is mental.<br><br>2) I'm aware of the cost impacts of these hybrid systems. For those already on CGM and insulin pump, can there be some leeway to negotiate with the supplier companies, as the gap is surely less than if not on a pump already. Or to look at the gap and give people the option to self fund the difference if it were not immense and the only other option were to stay on the current solution.<br><br>3) I do agree that ability to manage the technology is important. However, having conditions to go on a diabetes course in order to have this - particularly for those with for example 30 years experience with it - seems unnecessary and an extra cost to the NHS. I see the need to watch a virtual video on the technology, but I have managed using a pump for over 5 years now and am very adept at stopping insulin, watching blood sugars, knowing when there are issues etc. It's part of managing and living with diabetes. I think ability to use the tech, understand diabetes and again, the consultants and specialist nurses will know who is able to cope and who is less likely to - as they speak to us regularly. But I do not feel a diabtes course or even going on a technology course is necessary. Watching a video, being on virtual webinars, yes. But not the rest - particularly for existing pump users. Those of us on pumps are used to the technology, the concepts and we manage it minute by |

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| | | | | | | minute 365 days a year. No technology supplier, consultant or nurse - unless type 1 diabetic has that level of experience. Please give discretion to consultants and nurses who know the abilities of their different patients. |

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| 682 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | The committee concluded that managing type 1 diabetes is a substantial mental burden on people with diabetes and their families. It further concluded that automated technologies such as hybrid closed loop (HCL) systems can reduce some of the burden, and improve quality of life for people, their families and carers. | My son has type 1 and now lives away from home in a flat. He uses a pump but is on his own and hypos in the night are a constant worry to him and us. Also, he has to move locations now and then for his job so it is important there is no postcode lottery in provision, either of pumps or of the new hybrid systems. |

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| 687 | | | | | | Not enough consideration has been given to the relevance of HbA1c levels, both high and lower. Even people with a lower HbA1c should benefit from a closed loop and I speak from personal experience. I was using Freestyle Libre (initially self funded for 3 years) and an Omnipod insulin pump as I had quite profound Dawn Phenomenon each night waking with levels in excess of 25. This was extremely debilitating as I was working full-time. I was approved for funding by Vale of York CCG on this basis to control this problem which it did and my average HbA1c was reduced from 55+ down to 42. But this did not stop repeated hypos as it is very difficult for some diabetics to keep BG lower without the added complication of more hypos despite very careful monitoring. It does not take much to tip someone into a hypo when you are trying to keep your levels lower to avoid complications in the future. However, around 18 months ago, and despite going to bed with a BG of around 9, I suffered an extremely severe, life threatening hypo during my sleep. Looking back on my Libre data, my levels kept plummeting for no reason during the night until when I eventually woke I was so low I had lost all cognitive ability not even being aware enough to wake my husband. The result was that I came out of the bedroom (no recollection of this) and fell the entire length of the stairs hitting my head on the square post at the bottom. I was clearly unconscious for quite some time before I came to (I had drank a small amount of lucozade in my bedside drawer thankfully prior to my fall). When I screamed to wake my husband who is hard of hearing he found me with a huge amount of blood loss all around me on the floor and I was fading in and out of consciousness. The result was that I had torn a full thickness flap of skin from my scalp (around 20cm in total) down to the bone and cut a branch of the superficial temporal artery which explained the horrendous blood loss. I was rushed into the Resus area at my local hospital where my haemoglobin was 89 and I needed a blood transfusion. They estimated I had lost the equivalent of 3 pints of blood. I also had a subdural haematoma but thankfully I did not need an operation. I am so very lucky to be alive but this had a dramatic effect on my mental state of mind and hypos and significant mental strain on my husband and family as they feared a repeat. On the day of my admission my team at York immediately arranged for me to go onto a closed loop system (Tandem Tslim and Dexcom G6) and I have never looked back. My current HbA1c is 39. I have been a Type 1 diabetic for the last 46 years and I have never been hospitalised for my diabetes. However, this particularly episode was life threatening and I think not enough emphasis is placed on the risks of our condition on diabetics not just from highs, but lows too. It is not just about those with high HbA1c's who frequently do not look after themselves (and are now going to be rewarded for this lack of care) but even those with excellent BG levels are at severe risk. I also have two Type 1 diabetic adult sons and my experience has been extremely frightening for them too. Diabetes has a huge psychological impact on us on a day to day basis and a closed loop is not only safer but also helps to relieve some of |

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| | | | | | | mental burden which is always forgotten by those who make the decisions and who don't live with this condition. The amount of time lost in the workplace from Type 1s who have experienced hypos during the night and wake feeling 'not great' cannot be underestimated and the time to recover from hypos at any time of the day and the impact of this at work also. I owe my life to this technology and I cannot emphasise enough how important it is that this technology is available to all Type 1s and not just those who do not care for themselves in the beginning. People need a degree of dedication to use a closed loop so for those who are not dedicated to start with that will be a huge ask and potentially will end in failure but those who do look after themselves will be much keener to use a closed loop if it is offered. It just feels like NICE are rewarding bad behaviour, similar to the original guidelines around using Flash Glucose Monitoring until it was hitting the powers that be in the face that this technology was improving everyone's HbA1c. Using a closed loop has demonstrated how much better control can be and has virtually eliminated any hypos and I have had absolutely none during my sleep. I would implore NICE to think about the wider Type 1 community and not just those who will not help themselves. |
| 692 | | | | | | I do think if people are struggling to deal with their T1, it's not always caused by t1, but how they are treated by people, friends, teachers. Then it's going to have an impact on mental health and how they deal with their t1. She has seen everyone around her I different areas being funded dexcom, now 1 from our hospital, but she is told she isn't eligible. I understand her frustration and maybe it was my fault for funding the dexcom fir her so she sees the difference in management. I hope this is the end of the postcode lottery. |

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| 693 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | My daughter was diagnosed at 8 years old. For the past 4 years I have mostly been looking after her T1 with her input. She has started to take over. Since she has taken over control she has become withdrawn. She has been out of school for almost a year due to bullying. She is on the omnipod pump and libre 2. She is afraid of drawing attention to herself or teachers telling her off for having her phone out to scan her libre. She has been seeing the team psychologist for a year, to build her back up and is starting a new school next week. Before covid I self funded the dexcom and it changed her life. Although wasn't integrated with pump, it helped me as a parent to step in before things got bad. It was still a lot of work but it was worth it to see her doing the things she loved. Unfortunately can no longer afford the dexcom, she is now on libre 2. She still struggles with the mental load. I am a single parent with the only support i have of T1 has been in the online community. I have lost friends as they treated my daughter differently and just didn't grasp an understanding. My patience for other people has diminished from what it use to be like. Her diabetes management has gone downhill since coming off dexcom (but she is a teenager, so we are in new terrortory). Closed Loop would lower hers and my mental load and just give us back some mental space. She also has coeliac and is scared of eating out in case she gets glutened, as thid has a severe reaction on her diabetes. She will be sick and bloods will be low for hours and it will take a couple of weeks to go back to normal. This is just another aspect of her life that sometimes gets affected. Even if my daughter wouldn't be eligible I will still be pleased that this will be offered to some T1's as I know it will be life changing. I'm hoping she settles into her new school, then eventually I can go back to work, if all goes well. She has needed a lot of support in school and out. She struggles to sleep due to anxiety and has a fear of hypos. I just want to say thank you for reading and giving us the opportunity to have a say. |

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| 695 | Young Diabetologist and Endocrinologists' Forum (YDEF) | | | | | We are pleased that the committee are broadly in support of the option of HCL for people with type 1 diabetes and that they have recognised the benefits they offer in terms of clinical outcomes and quality of life. We recognise that this is a first step in improving the provision of HCL and that in future more consideration may be given to broader access or for indications around quality of life.<br><br>However, we have two primary concerns that the committee did not take into consideration. Firstly, the positive impact that NHS provision of HCL will have in reducing health inequalities.<br><br>There is strong evidence that people with type 1 diabetes from socioeconomically deprived and ethnic minority groups have higher HbA1c and poorer health outcomes (1, 2). Such inequalities appear to be widening (3). The reasons are complex, but likely to be related to lower health literacy and barriers to the take-up of structured education (4).<br><br>The committee will not have considered recent evidence which shows that even without precise carbohydrate-counting, people with type 1 diabetes were able to achieve treatment targets using HCL technology (5). HCL therefore has the potential to transform the landscape of type 1 diabetes care in a way that has not been seen before, by giving those from underprivileged groups who struggle with their self-management (due to poor literacy or numeracy, for example) the option of an effective therapeutic intervention. These are in fact the same groups who are likely to derive the greatest benefit from HCL, as the evidence from trials and the NHSE pilot shows that the higher the HbA1c at baseline, the greater the improvement . Conversely, failure to support wider adoption of HCL is likely to accelerate health inequalities, with only the most affluent and articulate of PWD accessing these systems.<br><br>The committee does not consider that the relative cost of these devices (as with many developing technologies) is likely to decrease with time. For example, the latest version of the Dexcom continuous glucose monitor, the G7, is not only smaller and faster but cheaper than the previous iteration, the G6. When seeking to model the cost impact of HCL, failure to take the falling relative cost of technology into account risks the guidance becoming rapidly outdated.<br><br>Our second concern is in regards to the absence of severe hypoglycaemia as an indication for closed-loop insulin therapy. Many people already access real-time CGM through existing NICE guidelines for this indication. This cohort are particularly high risk of hospitalisation and death due to hypoglycaemia. Excluding them from the TA for HCL will invariably lead to differential implementation of NICE guidelines, a post-code lottery and widening divide. |

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| | | | | | | HCL is often the last therapeutic option for individuals with severe hypoglycaemia to improve quality of life and prevent imminent harm. After this, the options on the table are pancreatic transplnation (whether solid pancreas or islet cell) which are associated with significant cost and risk of complication from both the procedure itself and from life long immunosuppression – it seems clear that the cost savings from utilising HCL as a means, for many, of obviating the need to transplantation should be taken into account.<br><br>1. Lindner LME, Rathmann W, Rosenbauer J. Inequalities in glycaemic control, hypoglycaemia and diabetic ketoacidosis according to socio-economic status and area-level deprivation in Type 1 diabetes mellitus: a systematic review. Diabet Med. 2018;35(1):12-32.<br>2. Khanolkar AR, Amin R, Taylor-Robinson D, Viner RM, Warner JT, Stephenson T. Young people with Type 1 diabetes of non-white ethnicity and lower socio-economic status have poorer glycaemic control in England and Wales. Diabet Med. 2016;33(11):1508-15.<br>3. Ng SM, Evans ML. Widening health inequalities related to type 1 diabetes care in children and young people in the UK: A time to act now. Diabetic Medicine. 2021;38(11):e14620.<br>4. Harris SM, Shah P, Mulnier H, Healey A, Thomas SM, Amiel SA, et al. Factors influencing attendance at structured education for Type 1 diabetes in south London. Diabetic Medicine. 2017;34(6):828-33.<br>5. Petrovski G, Campbell J, Pasha M, Day E, Hussain K, Khalifa A, et al. Simplified Meal Announcement Versus Precise Carbohydrate Counting in Adolescents With Type 1 Diabetes Using the MiniMed 780G Advanced Hybrid Closed Loop System: A Randomized Controlled Trial Comparing Glucose Control. Diabetes Care. 2023:dc221692. |
| 10 | | | | | | What an incredibly short-sighted and pointless set of guidelines.<br><br>When taxpayers' money for diabetes funding is entirely going on complications rather than preventative systems like HCL & RTCGM with full feature sets, you should be offering these systems to anyone who wants one.<br><br>I have used open source closed loop systems and have massively improved my control and mental health. Going from 5% in range every day, to 90% in range.<br><br>With your guidelines, I wouldn't even be considered to get an HCL on the NHS, even though I have evidence of the systems working.<br><br>So now I am stuck using open-source technology because the NHS is only thinking about money. I understand this approach, it needs to be funded, but |

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| | | | | | | it's very clear this approach has failed diabetics.<br><br>Your guidance has failed Diabetics when we are now considering getting pregnant<br><br>https://ibb.co/0Q7V950<br><br>or considering worsening their control to get above the 8% threshold to be granted funding for a HCL<br><br>https://ibb.co/ScLgGXq<br><br>Or when a teenager has been given access to a HCL, your guidance basically shows that once this teenager improves their control below the 8% threshold, they won't ever be funded for a HCL as an adult when they transition from child to adult diabetes teams. How awful for young diabetics. This is going to be detrimental to teenagers' mental health.<br><br>What a backwards way to prescribe life-saving technology. Stop thinking about money and think about the mental burden diabetes has on us.<br><br>The diabetes facebook groups are angry and I don't see this getting any better. We are stuck with antique systems, given access to CGM's from Dexcom which has all its main features removed, and only given a closed loop when they neglect their control or get pregnant. I am very unhappy with NICE and the NHS' attitude towards diabetics. |
| 711 | | recommendations | 1 Recommendations | 1.1 | | What an incredibly short-sighted and pointless set of guidelines.<br><br>When taxpayers' money for diabetes funding is entirely going on complications rather than preventative systems like HCL & RTCGM with full feature sets, you should be offering these systems to anyone who wants one.<br><br>I have used open source closed loop systems and have massively improved my control and mental health. Going from 5% in range every day, to 90% in range.<br><br>With your guidelines, I wouldn't even be considered to get an HCL on the NHS, even though I have evidence of the systems working.<br><br>So now I am stuck using open-source technology because the NHS is only thinking about money. I understand this approach, it needs to be funded, but it's very clear this approach has failed diabetics.<br><br>Your guidance has failed Diabetics when we are now considering getting |

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| | | | | | | pregnant<br><br>https://ibb.co/0Q7V950<br><br>or considering worsening their control to get above the 8% threshold to be granted funding for a HCL<br><br>https://ibb.co/ScLgGXq<br><br>Or when a teenager has been given access to a HCL, your guidance basically shows that once this teenager improves their control below the 8% threshold, they won't ever be funded for a HCL as an adult when they transition from child to adult diabetes teams. How awful for young diabetics. This is going to be detrimental to teenagers' mental health.<br><br>What a backwards way to prescribe life-saving technology. Stop thinking about money and think about the mental burden diabetes has on us.<br><br>The diabetes facebook groups are angry and I don't see this getting any better. We are stuck with antique systems, given access to CGM's from Dexcom which has all its main features removed, and only given a closed loop when they neglect their control or get pregnant. I am very unhappy with NICE and the NHS' attitude towards diabetics. |
| 733 | | | | | | I am the parent of two children aged 14 and 8 with T1. They are both fortunate enough to have HCL one uses CamAPS and the other T-Slim. The HCL undoubtedly reduces the mental load both for us as parents and them in their day to day lives. To think that the decision to make HCL available to those with high HbA1c levels whilst understandable from a financial point of view does not make sense from the patient perspective. If patients/parents are working incredibly hard to achieve a good HbA1c using MDI on non-looping pumps they will be excluded from qualifying for a HCL system which is not fair. It may even remove motivation to control BMs in order to meet criteria for HCL which is not in best interest of the patient. Encouraging good BM control at all ages is crucial as is enabling all those with T1 to engage fully in all aspects of life. A HCL system undoubtedly makes this easier. With this chronic condition where there is an excellent management option available it must be widely available and not discriminate against those who put huge amounts of effort into controlling BMs through other methods. Good control early will surely reduce costs later as the effects of poor glucose control will be reduced. Many thanks for your work on this but as someone for whom T1 is a very central part of life despite not having the condition myself, the guidance does not go far enough |

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| 741 | | | | | | This is a step in the right direction, I however feel slightly deflated by this, I have been type 1 diabetic for 17 years now and have funding approved for a pump (back in May 2022) but am yet to be seen due to NHS waiting lists, during this time my control has worsened significantly yet I still don't get anywhere near the hba1c figures that would be approved. It feels like another reason for individuals to lessen their control in order to access this.<br><br>I would also be interested to see some research done on the cost implications of upgrading the cgm of pump users, perhaps those with a Tandem T Slim pump using Libre 2 or Dexcom one being enabled to get a Dexcom G6, surely they advance in control and care would far outweigh the difference in cost between the Libre 2/Dexcom One and the Dexcom G6. |
| 758 | CVD, Respiratory and Diabetes Clinical Networks, NHS England - South West | | | | | • We are concerned that there is no analysis/ mention of patients who have severe hypoglycaemia and hypoglycaemia unawareness within this assessment. There are a number of studies (summarised in the Endocrine Society consensus recommendations for Use of Automated Insulin Delivery technologies in Clinical Practice (Endocrine Reviews 2022, 00, 1-27) commenting that “AID use can be particularly useful in persons at moderate to high risk for frequent and/or severe hypoglycaemia and hypoglycaemia unawareness. Small studies have reported improvement in hypoglycaemia unawareness with the use of AID systems”. In our limited experience people who have gone onto HCL systems because of hypoglycaemia unawareness have improved control and quality of life.<br>• We are concerned about those who have HbA1c below 64mmol/mol and work very hard to achieve good diabetes control – this is likely to incentivise them to worsen their diabetes control in order to fit the criteria.<br>• There is no mention of learning disabilities and the impact and challenges that has directly on the individual with diabetes, the family and wider community<br>• The economic model is based on the benefit of the HbA1c lasting for 60 years. I think this is totally unrealistic – there are no therapies that have a consistent improvement over a prolonged period of time and in diabetes all our current therapy benefits wane with time<br>• Will the current insulin pump guidelines remain in place or will they be withdrawn – this is particularly pertinent to the use of pump therapy in children, many of whom (and their families) will benefit from HCL<br>• Within one ICB in our region, around 1,500 patients will be eligible under the current guideline if a TA is attached – the population is very large to manage. The clinical teams will not have capacity to deal with these numbers and may not be cost effective unless the acquisition cost falls<br>• The guidelines are vague – using terms such as ‘difficult to manage’ – open to significant differences in interpretation<br>• I am fully supportive of the new guidelines. They are a good start. It will take a significant amount of effort for the clinical teams and I appreciate there will |

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| | | | | | | be a financial consideration but the outcomes in the short term are quite remarkable and the translation to long term costs will be dramatic<br>• I think that patient expectation will need to be managed very carefully and support for that at a local and national level will be very important |
| 760 | Norfolk & Norwich University Hospitals NHS Trust | | | | | • HbA1c of 64 mmol/mol [8.0%])- This does not capture or reflect hypoglycaemia burden. Problematic Hypoglycaemia should be included in the eligibility criteria.<br>• Structured education – should be much broader ( not just limited to NICE) . Our young people transitioned from paediatrics services on CSII have not received any structured education. So the criteria should be considered to include this factor.<br>• Ypso pump with CAMAPS is very common HCL – this is not included in the current consultation. Could this be included in the existing systems please?<br>• Quality of Life etc should be considered as an eligibility criteria for HCL |

## THEME: OTHER MEASUREMENT CRITERIA

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| 151 | | | | | | Surely time in range should also be taken into consideration, as this is a much better measure than largely basing decisions on Hab1c. Also the number of hypos a person has. If you're having a lot of hypos it will lower you Hab1c, which is still poor control but in the opposite direction. Far too simplistic in this day and age. |
| 152 | | recommendations | 1 Recommendations | 1.1 | | Consider the following groups for inclusion:<br>(a) Patients experiencing frequent hypoglycaemic episodes in-spite of real-time monitoring<br>(b) Patients who have already, or it is felt are close to, diabetic burn out trying to maintain tighter control<br>(c) Patients with consecutive sub-50% 90-day TIR readings when monitored with a realtime CGM.*<br><br>Since proper use of closed loop technologies still relies on a patient being significantly 'invested' in their own treatment, an assessment as to potential risk/reward would seem appropriate over a naked evaluation of the HbA1c metric.<br><br>* HbA1c can be a misleading metric, and at the very least there is now evidence to suggest TIR is a more important and revealing metric [1,2]. Two patients may have identical HbA1c results, but very different TIR. The evidence is clear that the patient with lower TIR is at higher risk of complications.<br><br>[1] Beck RW, Bergenstal RM, Riddlesworth TD et al (2018) Validation of time in range as an outcome measure for diabetes clinical trials. Diabetes Care 42(3):400–405. https://doi.org/10.2337/dc18-1444<br>[2] Mohr DC, Zhang L, Prentice JC, et al Association of hemoglobin A1c time in range with risk for diabetes complications BMJ Open Diabetes Research and Care 2022;10:e002738. doi: 10.1136/bmjdrc-2021-002738 |
| 158 | | recommendations | 1 Recommendations | 1.1 | | Frequent/ severe hypoglycaemia and excessive glucose variability should also be considerations Should also be available to those struggling with the psychological burden of diabetes ( as eloquently documented in the reccs ) |
| 159 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | unsure why frequent/ severe hypoglycaemia and psychosocial criteria ( struggling with the psychological burden of diabetes) are not considered to be inclusion criteria for HCL especially as the discussion in this section eloquently makes the point that these are key areas that would show benefit for HCL users and their families |

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| 217 | | recommendations | | 1 | | I hope that this is the appropriate place to make these comments: -<br><br>In general, the qualification criteria laid out below are based on limited, and primarily historic, data obtained from laboratory blood tests, namely HbA1c data.<br><br>Both rtCGM and isCGM systems have been in wide use for some time and have highlighted that HbA1c data alone provides an insuficient picture of good control diabetes.<br><br>Time in Range (TIR) and Coefficient of Variation (%CoV) data, available from these CGM systems, provide a more complete picture of diabetic control.<br><br>HCL Systems have the ability to impact both TIR and %CoV. Thresholds for these parameters should therefore be used as criteria for their recommendation.<br><br>This document also needs a list of Acronyms: -<br><br>HCL<br>CSII<br>HbA1c<br>rtCGM<br>isCGM<br>TIR<br>%CoV<br>RCT<br>EAG<br>NHSE<br>ICER<br>CALY |
| 218 | | recommendations | 1 Recommendations | 1.1 | | I am concerned that this is based solely HbA1c greater than or equal to 64 despite either: -<br>A pump<br>Continuous Glucose Monitoring<br>Flash Glucose Monitoring<br>being use.<br><br>I believe that it should also have criteria: -<br>Time in Range (TIR) e.g. Target >70%<br>Coefficient of Variation (%CoV) e.g. Target <35%.<br><br>Comorbidities e.g. Chronic Kidney Disease and Stress should also be considered |

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| 290 | | recommendations | 1 Recommendations | 1.1 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following: | HBA1C is not the only factor that needs to be taken into consideration. Time in range is probably even more critical as a 'good' HBA1C can be achieved by having many highs and lows which are arguably even more dangerous than a steady state HBA1C of over 8.<br><br>You should also consider mental health/anxiety, fear of hypoglycaemia, needle phobia, and any other conditions that the patient lives with such as dyslexia. |
| 291 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.3 | Time in range is a measure of blood glucose control that shows the percentage of time a person spends within a target glucose range (3.9 to 10 mmol/litre). | Time in range should be a factor in this decision making - not just HBA1C |
| 298 | | committee-discussion | Conclusion | 3.16 | people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0%) | This should also take into account time in range, not just HBA1C. |

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| 313 | | recommendations | 1 Recommendations | 1.1 | | I feel setting a HbA1c eligibility criteria of 64 mmol/mol is discriminatory and demoralising for those who have had diabetes for decades and have worked very hard to keep their blood sugars as good as possible with the tools they had in the past, and currently have to use. I have been married to a type 1 diabetes patient for over 40 years, he was diagnosed over 50 years ago. We have seen many changes in care and equipment during that time: glass syringes to disposable syringes then pens, and if you are really lucky a pump. Urine testing with test tubes and tablets to urine tests with strips, but having to cut strips in half and only use 2 per day, then finger prick blood tests. In the last couple of years he has had libre sensor and that has been a game changer for both of us. Invariably when something new becomes available it is those with high HbA1c who get it first, even if they are not making an effort with their care. Those who have had diabetes for a longer time but are "doing OK" are often overlooked until the the device becomes "normal" care. I feel it would be fairer to have another inclusion criteria, e.g patients who have had diabetes for X years (possibly 10+) who have a lower HbA1c. They have proved they will use technology to optimise their health and therefore be less of a burden to the NHS and society. Those patients deserve to have help to lessen the mental load of constantly monitoring glucose and mental calculations. More recently my husband has converted to libre 2 which alerts several times a night, he does not hear it because he takes his hearing aids out, so I am being woken every night. As I understand it the HCL will reduce the incidence of night time blood glucose fluctuations, which should be good for my husband and I will get some undisturbed sleep. Therefore I would like to see this as be an eligibility criteria? |
| 593 | | recommendations | 1 Recommendations | 1.1 | | Time in Range should also be a considered as gives a fuller picture of management in combination with hba1c.<br>Someone may have a "good" hba1c but actually be experiencing large swings in glucose levels which a HCL could help with & improve outcomes, levels & QOL. |
| 718 | | | | | | Studies have shown that earlier intervention with CL technology (Horvoka et al) fosters better engagement and outcomes long term. While these should absolutely be available for those finding management difficult, as reflected by a higher HbA1C or low time in range, pregnant women, and children and young persons who are still growing and where hormones affect their levels; it should also be available to those that rely on CL technology to stay within target. Time in range is increasingly used over HbA1C by clinicians to reflect management effectiveness. This is also the case in RCTs where time in range is the measured outcome. |
| 725 | | recommendations | 1 Recommendations | 1.5 | 64 mmol/mol (8.0%) or more. | Could "time in range" be also used as a qualifier here? What about those just below 64mmol/mol who work really hard to achieve this but would not qualify for closed loop because they are just below. |

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| 726 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | 48 mmol/mol (6.5%) | If you cannot access closed loop if Hba1c is below 64 mmol/mol - how do you get to 48 mmol/mol without it? Is there a target for Time in Range? |
| 729 | | committee-discussion | Conclusion | 3.16 | people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0%) | Can/should Time in Range also be considered as and and/or against the 64mmol/mol? Also what about patients that have been managing Type 1 diabetes for many years and may be experiencing burn out? what happens when the HbA1c is lowered? Does the device need to be returned and back to MDI? |
| 749 | | | | | | I believe it is a mistake to look purely at a reduction in hba1c to decide the criteria for technology related to diabetes as this rewards people for not putting as much effort into looking after their diabetes. It's fairly easy to not bother to bolus for carbs and increase your hba1c. There is so much more that goes into the management of type 1 diabetes including impact on mental health (and mental health of the parents in the case of children with diabetes) my daughter has never had an hba1c as high as 64 but closed loop had changed our lives and improved her time in range immensely including a huge reduction in the % of time she spends suffering from hypoglycemia which was a large contributing factor in her previously low hba1c. Time in range is a much better indicator of diabetes control that hba1c. Since she had used hybrid closed loop all her retinopathy screening tests have been clear when every single one she had before that showed background retinopathy which we were unable to do anything about. I am hopeful that the closed loop had reduced the risk of other diabetes related complications. We can both sleep through virtually every night when before closed loop I was awake every night dealing with hypoglycemia and hyperglycaemia as she needs very different amounts of insulin from one night to the next. This lack of sleep impacts on both of our lives and costs the NHS money due to the health impacts of sleep deprivation. |

## THEME: OTHER SUBGROUPS

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| 38 | | | | | I would like to point out that although I do currently manage to control my Type 1 Diabetes with an hbA1c below 8.0 this is only achieved through regular assessment up to 20 times a day. This has led to me suffering with diabetes burn out in the past. Being diagnosed with intrusive GAD and OCD.<br>I therefore request that you consider individuals with Mental Health conditions should be included for this method of treatment. Without some relief from 24/7 monitoring I do feel it could result in an adverse affect upon my Mental Health; and with the current deficiencies in Mental Health Care this is not a path I would like to follow. Mental Heath and Mental Wellbeing are equally as important as Physical Health with long term health conditions. I have used my own experience as example but know as a Life Member of Diabetes UK I am not alone with this concern. In the longer term technology for all will reduce the burden and cost to the NHS.<br>Thank you for for giving me the opportunity to comment. |
| 47 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | 1 Recommendations | 1.5 | | Is there any evidence of hybrid closed loop use in highly unstable Type 1s who can't manage their own diabetes (eg Type 1 diabetes mellitus in a care home), or recurrent DKA in whom it maybe able to provide some stability? |

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| 113 | | | | | Discriminating against menopausal women with hot flushes and disrupted cognitive function struggling to differentiate between hypos and menopausal symptoms are not considered.<br><br>Discrimination against those with mental health conditions not just burnout but control for other mental health conditions e.g. longterm depression and mental toll for OCD sufferers.<br><br>Discrimination against those with several chronic health conditions on multiple treatments trying to cope with them all, where a HCl would relieve some of burden are not included in the criteria for funding.<br><br>Quality of Life mentioned but not considered important in the criteria for NHS funding.<br><br>Discrimination to people with depression. Encouraging diabetics to worsen control for access to tech especially those with mental health disorders.<br><br>Discrimination for people with OCD that micromanage and obsess over blood sugars to exhaustion to gain reasonable control and penalised because that control rules them out of hcl funding criteria.<br><br>For those with mental health conditions that neglect eating at regular times and sleep in bed frequently due to bouts of depression whose emotions create erratic control not always apparent by HbA1C. HCL would help remove some of the guilt of neglecting self-care and should be mentioned in the criteria for funding.<br><br>Why has such a high HbA1C been set? Type 1 diabetics need some relief of the burden of micromanaging this chronic illness not punished because they have worked so hard by being refused NHS funding for HCL. The criteria is quite frankly being cruel to the well controlled for their hard work. |
| 114 | | | | | The inclusion criteria is too narrow - but it looks like the horse has bolted on this, it appears to read only the trialled criteria can be considered and that was a restricted group. If this is the case is there a way of NICE dictating a next step in terms of trials and protocols<br>• elderly people who are unable to administer their own insulin safely should be a priority group for such technology, the actual cost of community nurses going out to administer insulin and the quality of life issues of twice daily mixed insulin must be considerable & risks high<br>• pregnant women, do the commercial systems allow low enough targets - the DIY community seems to think not |

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| | | | | | • those already on pumps with CGM etc, the incremental costs must be relatively low and this group have the experience and the will to use the new technology well and so benefit from it, it could be rolled out quicker as this group would need little or no training and would be able to set up and use quickly with probably minimal online training<br>• those fully insulin dependent but not Type 1 with multiple health issues and currently generally not meeting pump criteria, could benefit massively from this technology - this is a group of people who may have regular hospital admissions and a greater burden on the health service<br>• menopausal women, if they can't be considered for many drug trails & phycological research because of it, perhaps this is an area that should take into account the issues that arise. On the same vein pre menopausal women with particular hormonal problems may also benefit more than others too<br>It is unclear how the closed loop technology will interface with existing pump and CGM criteria. Will people not currently on a pump be offered closed loop or will stand alone pumps still be issued. Will those not being offered a closed loop pump only be offered some lower price less technically sophisticated pump or will they get a pump capable of closed loop but not given that functionality? Relative pump cost information does not seem to be disclosed but if the more sophisticated pumps cost more but the functionality is not used is there a waste of resources?<br><br>Should those who currently have pumps be upgraded if they now qualify for a closed loop? If NICE doesn't include this sort of guidance then the postcode lottery will continue<br><br>What is the experience of sustained use of pumps in terms of demographics ie those that stick with it, for example amongst my circle I am aware the vast majority of teenagers have been given a pump but they don't use it. What are the reasons for this? I would hate to think the closed loop roll out "fails" because the group who are being prioritised are a group who are perhaps most likely not to stick with it and so generate the improvement statistics required to open up further access<br><br>The paper mentions phycological issue but doesn't really quantify them or suggest how they are measured or figure in the allocation of closed loop, obviously measures are difficult but this area needs to be expanded. From a personal prospective, I wouldn't say I am in anyway depressed or otherwise physiologically challenged but boy does achieving the level of control I have take a toll on me and my family and inhibits some of the things I would want to do or the time I can do them. I certainly lost all my career based drive and aspirations when I was |

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| | | | | | diagnosed (feeling I personally could no longer sustain the pace of my career) and it was a major factor in my giving up on my career many years before I believe I otherwise would have<br><br>There is some limited mention of adverse events, there appear to be few and no details but trial populations are small. Is there a danger of over reliance on technology in some cases? Again from social groups I am in parents of children whose CGM or pump fail are distraught and appear to have no idea what to do and are willing to beg, borrow or steal kit, take advice from anyone and everyone on social media without any filter. We need to be carefully what wider education goes along with the technology<br><br>The emphasis is on people who have difficulty achieving a good level of control despite having access to (and presumably using) at least one piece of technology, maybe we are setting ourselves up to fail? My understanding is that the current pumps still need one to carb count and to remember to enter the carbs into the pump to get the best from it? If this is true it maybe that the people who are "failing" will need more education and supervision / mentoring on an ongoing basis until we have true fully automated closed loop. I appreciate keeping everyone safe and avoiding serious hypo's is essential and that the closed loop pumps are good at this<br><br>The current trail statistics do not seem to have achieved an HBa1c of participants at anything like the level suggested to be required to avoid complications - whilst all improvements are to be welcomed and any help with quality of life for the individual and lower costs for the health care system dealing with complications should be grasped - shouldn't we be aiming higher and including those that are engaged in achieving the target<br><br>There is little in the cost analysis I can understand (and finance is my profession) but one statistic is that the additional cost over and above existing cost of pump + sensor is around £1560 pa, this is such a drop in the ocean compared to health costs associated with poor diabetes control (lost work days, direct health costs etc), rapid rollout should be considered as a priority<br><br>Will there be any other criteria where the medical profession can recommend closed loop for adults over and above the very restricted, Hba1c criteria & pregnancy and if not how and when will this be tackled? Sadly the NICE criteria and local health organisation interpretation of criteria seems to constantly work against people who put in a lot of effort |

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| | | | | | to stay well, many of whom will have very successfully implemented technology to achieve what they have. If pure statistics are used in an under analysed way the aim will always be at the low hanging fruit and so development and the greater good hampered. We are where we are largely because of the highly motivated DIY community why should they have to stay DIY? The criteria are required to avoid discrimination, whilst not a "legal" discrimination, there is inbuilt discrimination against engaged individuals who have achieved success in getting good control. This discrimination started by excluding such individuals from trials and then developing criteria based on those trials. Maybe there should be at least some "compliance" element to the criteria, to avoid poor results from some individuals distorting the overall good that this technology will achieve.<br><br>Despite all of the above I am so pleased to see that hopefully the UK will soon have better technology available to many more people. |
| 115 | | | | | Hello<br>I have decided to put all my comments in one place - here!<br>I am approaching my 57th 'diaversary' (T1 parlance) having been diagnosed when I was 4. I took early retirement at 58 ending one successful career ... but my other career - managing my T1 diabetes - continues, for ever, and ever ... until I pop my clogs. It is tiring, demanding, like a naughty child, always nagging at you, pestering you for attention. The only difference is it doesn't sleep! I would so love to be able to only think about my T1 a couple of times a day but your guidance for who should get a closed loop system will exclude me. I feel like I am being punished for working too hard! Please reconsider those of us who have had this unrelenting condition for 50 years or more. There are quite a few of us around now. We would like a bit of a rest, a break from our unwanted norm, a reward if you like for keeping going. I have spent nearly 57 years terrified that I might go blind, lose a foot or have kidney failure. If a closed loop system can help stop me thinking like that, what a blessing that would be.<br>Many thanks |
| 123 | | | | | Whilst welcoming discussion on HCL systems, I have to express my disappointment that the published document makes no mention of applicability to type 3c diabetes 0 once again we are left out in the cold! My diabetes is the result of a congenital abnormality, exacerbated by subsequent illness and means that I have to go through the same process of multiple daily injections, albeit recently benefiting from the availability of CGM. Can I please ask that you consider the applicability to Type 3c alongside Type 1 varieties of the condition |

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| 150 | | | | | The focus of the trial is Type 1. I am defined as a Type 2 diabetic but following pancreatic cancer and a Whipple procedure, I have no real pancreatic function. The surgeon said the remaining pancreas was shrivelled and probably highly non-functional.<br><br>After my op, the consultant diabetitian told me to think of myself as Type 1 and manage my condition accordingly.<br><br>I have to continuously monitor and use bolus and basal insulin to manage. This is problematic. My Hb1ac is well over 64: currently 80-95 and I am out of range for over 70% of the time.<br><br>I would argue that I more than meet the conditions for a closed loop system but the crude label of Type 1 would probably automatically exclude me from benefitting from this highly beneficial protocol. Rather than a crude label, I would suggest eligibility is based on a set of measurable criteria.<br><br>Dave Jay |
| 209 | | | | | I don't understand why diabetes type 3c are not included. I had a whipple operation in 2010 for a mass on my pancreas.in 2013 I started with pancreatitis I don't drink or smoke and they can't find a cause I have now had at least 70 bouts of pancreatitis over the last 2 years I have had 30 plus hospital admissions and acute/on chronic pancreatitis. I 'm type 3c but pancreas still working and not diabetic but the only option to me is the removal of the pancreas and I won't take that option at present but with the artificial pancreas this could be a game changer for people my position so why would this not be offered to people with no pancreas. |
| 160 | | | | | I have read through this policy document and consider that the provision of HCLs for people with Type 1 diabetes to be a huge step forward in treatment for people with this auto immune condition.<br>Given that maintaining a good HBA1c will lower the risk of developing complications - and thereby lower the costs of NHS medical care if this occurred - this is surely money well spent.<br>My adult daughter has T1 and recently required chemotherapy. This, unsurprisingly, resulted in nausea and sickness yet she was not able to persuade her diabetes clinician to provide the technology which would have allowed her to better manage her diabetes during these difficult months.<br>I feel that provision of HCLs during chemo would be an extremely useful addition to the limited provision included in this proposal. This could be treated in a similar manner to those requiring this technology during pregnancy ie 'on loan' and returnable after treatment has ceased. |

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| 172 | | | | | The guidance does not cover scenarios where HbA1c is an inadequate assessment of glucose control in patients for example those with Haemoglobin variants or those with rapid red cell turnover. I wonder if there is evidence on the use glucose, fructoseamine or glycated albumin in these patients and if we can have specific recommendations for them. |
| 180 | | Children | 3.5 | | There is an enormous mental load for T1D during puberty, especially in those assigned female at birth (AFAB). |
| 232 | | | 1.1 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following: | Consider offering to those with learning difficulties, impaired cognitive function due to age, mental health or brain injury where an automated system will improve diabetes management.<br>Considering offering to those with diabetes burnout or evidence of requiring excessive (greater than 8) injections of MDI to achieve adequate diabetes management to reduce the mental health burden. |
| 246 | Kushy | | | | You haven't taken into consideration that some type 1 diabetics have an extreme needle phobia and therefore cannot take their insulin and have to have a partner or family member administer it, if one of these patients was offered a loop service it could give them their life back and improve their quality of life greatly.<br><br>I think the criteria for being able to be eligible for this should also be based on pre-existing mental health conditions in the T1 patient (especially for those diagnosed in their 20s&30s) and how this is effecting their day to day life living with diabetes. I also feel if you suffer from needle phobia this should be in the criteria to get it because this comes hand in hand with mental health.<br><br>If someone with needle phobia wasn't having to do injections 4-8 times a day then this could potentially give them their life back.<br><br>This is something that I strongly believe should be added to the criteria of who gets one. |
| 267 | | 1 Recommendations | 1.1 | | There seems to be a group missed out of this category. Teens and pre-teens who will struggle with control due to puberty. They are also the group most likely to have real mental health issues if diagnosed at this time. It seems that this age group should be considered as a priority, so that they do not lose control of their blood sugar at such a crucial time. |

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| 289 | | 1 Recommendations | 1.2 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy. Hybrid closed loops systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2). | Agree. However, this needs to go further. it is very difficult for many women to manage their glucose levels when pre-menstrual or taking the birth control pill because of female hormones. |
| 295 | | Cost effectiveness for children | 3.11 | The committee concluded that although there was some uncertainty, HCL systems are likely to be more cost effective for children than adults. | This needs to be looked at more closely. My daughter's control was much better under the age of 18 because she was living at home and I was able to help her more. In my opinion, age 18-25 is a dangerous age because they are going out into the world on their own at a time when their brain development has not matured enough to understand the risks involved with diabetes. |
| 297 | | Conclusion | 3.16 | The committee also said that HCL systems are likely to be more cost effective for children than adults. | I do not agree with this - my daughter had better control under the age of 18 (because me and her dad had an influence) than she does now at the age of 18. 18-25 is a critical age in my opinion. |
| 311 | | | | | Please will consideration be made to people like myself who are currently self-funding closed loop. Looking at the criteria I would not qualify due to my diabetes being well managed due to already being on a closed-loop system. I work for the NHS and work extra hours to find the money to purchase dexcom sensors. Would I need to stop my closed loop system, my diabetes HC1A to rise to then qualify? I self-fund to ensure I don't cause underlying issues which would cost the NHS more having to treat the underlying conditions. Please, please could self-funded patients which hospitals would know due to having pumps which are closed-loop enabled be the first to qualify for sensors such as dexcom g6. |
| 363 | | 1 Recommendations | 1.3 | | This is a fundamental error. The whole point of using AI to control diabetes is to supplement the intelligence of the input of the user. So the less capable the user, the more valuable the AI. In my case, I have managed my T1DM for over 50 years, but my mental ability is diminishing, and a working AI system would be welcome. |
| 369 | | 3 Committee discussion | 3.16 | HCL systems should be recommended for: people with type 1 diabetes who are having difficulty managing their | Concerned that this is far too prescriptive and feel that the inclusion criteria needs to allow some extra exceptional circumstances within the recommendation.<br><br>I have been type 1DM for over 42 years & have moved to omnipod and |

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| | | | | condition and who have an HbA1c of around 64 mmol/mol (8.0%) people who are pregnant or planning a pregnancy. | freestyle libre within the past 5 years from a MD insulin regime with 20+ BMs per day.<br><br>My HbA1c currently ranges from 6.0 to 6.5% yet especially overnight can suffer prolonged lows around 3mmols without alarms triggering on the libre 2.<br><br>I work shift work, remain very active and for the past 2-3 years have receive regular chemo/immunotherapy for a hopefully controlled malignancy & all these factors play havoc on my DM control with me fiddling continually with my PDM night an day.....<br><br>I would love the opportunity to use and assess whether this new closed loop system enables me to avoid nocturnal lows and gain safer control with some automated insulin delivery adaptions. I note that if this new system didn't offer me any benefit when assessed by my diabetic team , then I would not continue to use and would continue to set alarms 2-3 hourly at night to check my levels.<br><br>I strongly feel the risks of lows is a risk that hasn't gained true evidence basis re complications such as increased risk of dementia etc..however with QUALYs and financial reviews re cost, I believe other circumstances should be made with individual diabetic teams assessing the evidence on a more personal and objective individual level and not on such a prescriptive patient basis. |
| 393 | | | | | I would like to say that people with complications of diabetes should be considered for closed loop. I've been living with diabetes for 43 years and I have a complication of gastroparesis which I've had for over 20 years. I'm also going through the menapause due to a hysterectomy. I struggle on a daily basis to get my control right as I don't know which way or how slow my digestive system is working. I give my insulin through a pump and either hypo or hyper. It's so hard and frustrating. I don't drink or smoke, I exercise and eat well and it's a daily struggle. If I can have something to make my life easier it would be amazing and life changing. Not to have to worry about fluctuations so much would be life changing. Thank you |

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| 494 | | | | | Section 2.3<br>Of course there was less evidence of a lowered a1c in those already with good control.<br>This study was clearly limiting if that's your measure of success.<br>Did those people have less hypos?<br>Did they feel better in themselves?<br>Did they sleep better?<br>Can they concentrate better on day to day tasks?<br>Do they have a more positive view of their life now?<br>Do they think of diabetes less?<br><br>Not every T1 will want a closed loop but for some of us, it's all that's keeping us going. I get that you can't currently give them to everyone but you NEED to add the below:<br>- People suffering considerably with their mental health<br>- Hormonal challenges (e.g menopause or conditions like PCOS) |
| 609 | | | | | Please include breastfeeding, post natal, pre menopausal and menopausal type 1 diabetic women in the eligibility criteria for closed loop systems. Please also include men and women or young adults suffering from “long Covid” in the eligibility criteria for closed loop systems. Thank you. |
| 743 | King's College Hospital NHS Foundation Trust | 1 Recommendations | 1.1 | type 1 diabetes | Cystic fibrosis related diabetes is mentioned in the committee papers in the equality considerations section (page 51). Does this mean that hybrid closed loop therapy is recommended for patients with cystic fibrosis related diabetes? If so, should this also be open to patients who have had pancreatectomies, or other forms of Type 3c diabetes? |
| 754 | | Access to technology and care | 3.2 | | Consideration of those attempting to manage diabetes and mental conditions, those taking medications known to disrupt blood glucose control, those battling the effects of peri menopause and menopause on good control. |
| 755 | | | | | I am disappointed to learn that it is only considered for those who are trying to become pregnant or who are pregnant, what about those who struggle with control due to being peri-menopausal?<br><br>Can those who have achieved outstanding control with a DIY loop (or self funded) be considered? It does appear that you discriminate against those who strive for and achieve a hba1c of below 48 by their own means. |
| 358 | | | | | Please consider perimenopausal women. I have fairly well controlled diabetes, mainly because I have 40yrs experience. However, since becoming perimenopausal I often have uncontrolable highs and lows whilst I sleep at night. This, added to the other well know sleep disturbances experienced by women in this group make life even more tiring than usual. |

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| | | | | | Secondly, are patients jobs planned to be a consideration? As a trainee art psychotherapist, the knowledge unexpected highs or lows are far less likely to interupt a clients' session would be fantastic. Though I appreciate this is no a physical stressor it is certainly a psychological one, and quality of life influence (for therapist and client). |
| 360 | | | | | I have Type 1 Diabetes and I have been coping with this incredibly stressful, all consuming, 24/7 condition for the last 40 years.<br>For me personally, it is like having a second job that you never ever get a day off from.<br>I have almost died from hypoglycemia on many occasions over the years and having to live with this fear of dying on a nightly basis is something that only Type 1's (and care givers) will understand.<br>During the last 6 years my HBA1C has been fantastic and more importantly my daily blood sugars. They have been on a more even keel, rather than a continual rollercoaster.<br>However, I am now at the stage in my life where I am now going through the perimenopause which brings about it's own difficulties. My blood sugars have become more unbalanced due to the oestrogen, progesterone fluctuations. So trying to carbohydrate count and manage my blood sugars is proving incredibly difficult and therefore more stressful.<br><br>I am always worrying about the complications due to high blood sugars and this is therefore not helping my mental health when I am struggling to keep my blood sugar levels balanced.<br>Also, no-one in the Diabetic medical profession prepares you for this stage of your life and they are unable to provide advice. My Diabetic consultant simply told me 'Oh yes, if you're going through the perimenopause or menopause it will have a dramatic effect on your blood sugars.'<br>I believe that women who are going through the perimenopause/menopause should be considered when deciding on who should be given this closed loop system. |
| 434 | | | | | Please would you consider adding peri-menopausal and menopausal women into the list of those eligible for closed loop systems. As a peri-menopausal woman with Type 1 diabetes it has been a nightmare trying to manage my sugar levels with frequent fluctuations due to hormonal changes that are beyond our control. I've experienced 3 hr low sugars and days of extremely high sugars. These were a nightmare to manage on MDI and only slightly easier to manage with a pump. During peri-menopause your cycle changes without warning as you are probably aware but the effects on your blood sugars is awful and because your cycle becomes so erratic this makes your sugars erratic too and something that you cannot preempt with your basal/bolus. |

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| 685 | | | | | Yet again this is another tool to improve the lives of Type 1 Diabetics in this Country, which discriminates, and is therefore withheld, from people who seemingly have 'good control'.<br>I say 'seemingly', as again, one of the main criteria is hba1c. Anyone living with Type 1 Diabetes knows that hba1c never tells the whole story of daily life as a diabetic.<br>Pregnant women are (correctly) being highlighted - BUT - why are women with perimenopause being excluded and discriminated against?<br>A woman with perimenopause is just as likely (if not more) to suffer from extreme / daily highs and lows through hormone changes, as a pregnant woman.<br>A woman with perimenopause can have a seemingly good hba1c, but a very poor quality of life. Surely this should be taken into consideration? |
| 610 | | | | | Could the committee please consider including people with significant complications as a result of their type 1 diabetes? I am constantly fighting Dawn phenomenon which cannot be controlled using MDI & now am suffering with neuropathy in my legs & feet & microvascular cranial nerve palsy. I try so hard & think I deserve a pump based on these conditions. |
| 163 | | | | | I would question if the scope of this initiative is too narrow. T1 & T2 seem to be easily defined, however the greatest 'at risk' group are those with a T2 diagnosis who are actually LADA/MODY. This could be the case for up to 10% of those with a T2 diagnosis. Early intervention with insulin is recommended in such cases. In my opinion, this initiative should not be limited to T1 - and greater focus should be applied to achieving accurate diagnosis for T2. |
| 27 | | | | | Please consider widening access to closed loop and add additional categories to the 64mmol/mol group.<br>Given the mental load of managing T1 there will be a group of people who will have strong psychological reasons to access closed loop including some of those who are micro managing their type 1.<br>There will also be people in certain occupations who will benefit from closed loop in that it would allow them to stay in work or extend their work.<br>There may also be other medical conditions e.g. some gastro issues which cause difficult to manage sugars which vary considerably and these patients would also benefit .<br>Thank you for your consideration |
| 112 | | | 1 | | Given the feedback (including those in the supporting documents) it seems obvious that hybrid closed loop systems can have significant benefits to mental health as well as to HbA1c.<br>The advice in Scotland seems to be to also recommend offering hybrid closed loop systems to some people experiencing diabetes-related |

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| | | | | | distress, and I feel these recommendations would be improved by some such category. |
| 162 | | 1 Recommendations | 1.1 | | Only recommending closed loop systems to those "people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following:<br><br>continuous subcutaneous insulin infusion<br><br>real-time continuous glucose monitoring<br><br>intermittently scanned continuous glucose monitoring"<br><br>leaves out anyone with Type 1 diabetes who has difficulty managing their blood glucose levels, but whose HbA1c is lower than 64 m/mol. We may only be getting that lower HbA1c because we have no other choice but to use unlicensed DIY looping systems which have to be self funded because we may be in contract with another pump or system which isn't working well for us. By it's very nature, Type 1 diabetes is difficult to manage so this applies to everyone with the condition. It will mean people who should rightly qualify to get an NHS funded closed loop system won't meet the criteria and are being discriminated against because they are using their own resources and money to self fund supplies and consumables for a DIY looping system, which is the only reason why their HbA1c is lower than the qualifying number. It perpetuates their need to use an unlicensed, self-funded system. |

## THEME: PREGNANCY

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| 11 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.2 | | This statement suggests that all patients who are planning a pregnancy or are pregnant would be able to access closed loop technology despite their current HbA1c, and would again bypass the recommendations and criteria for insulin pump therapy set out in TA151.<br><br>A clear definition of what constitutes planning a pregnancy is needed e.g. treatment must be provided as part of a recognised pre-pregnancy pathway. Without a definition, the risk is that all women of childbearing age are eligible for ongoing treatment resulting in a large use of resources for potentially no clinical improvement, particularly for patients who already have good control, and raises issues of inequitable access to treatment. |
| 12 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.2 | | Guidance is needed on when treatment with hybrid closed loop system should be discontinued e.g. 3 months after end of pregnancy?<br><br>The guidance needs to be clear that funding for consumables for insulin pump/CGM will cease at a specified time post-partum. Continuing to fund HCL systems for patients who would not otherwise qualify for treatment due to poor glucose control would be inequitable.<br><br>Pumps have a 4 year warranty. What will happen to the insulin pumps supplied to patients as part of pre-pregnancy/pregnancy treatment?<br><br>Duration of treatment may influence the choice of HCL system – for example systems may prefer to use Omnipod 5 + Dexcom - because unlike the tethered pumps (Medtronic/Tandem/Dana) Omnipod does not have a 4 year sunk cost for the warranty. |
| 13 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.2 | | The committee noted there was only 1 small study on HCL systems' effectiveness in pregnancy. The EAG said that it was difficult to draw firm conclusions in this population, however HCL in |

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| | | | | | | pregnancy for patients with T1DM but has been proposed. There is evidence for increased TIR and reduced TAR for pregnant people with T2DM using rtCGM, but this group of patients have not been included in these recommendations. Could this be considered as being inequitable? |
| 31 | | committee-discussion | Pregnancy | 3.6 | | I have been through 2 pregnancies with Type 1 diabetes and it is extremely difficult. I would wholeheartedly agree that this solution would benefit pregnant people. |
| 42 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | recommendations | 1 Recommendations | 1.2 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy. | Considerations about:<br><br>o How would we define “planning a pregnancy”? In a pre-conception clinic? Down to the clinicians discretion?<br><br>o None of the current closed loop systems are licensed in pregnancy, the target glucose cannot be changed (factory setting) and therefore doesn’t fit with our current pregnancy guidelines<br><br>o Additional workforce resources would be required to fulfill this, for both initiating the technology but also clinic time for reviewing patients<br><br>o How do we withdraw this system once the patient has delivered? Could be costly if paying out for the pump for only a short period of use. |
| 96 | University Hospitals Dorset Diabetes Service | committee-discussion | Cost effectiveness in pregnancy | 3.12 | | Agree that overall cost effectiveness of HCL systems in pregnancy would likely be greater than in the overall population. |
| 120 | | | | | | 1.2 Pleased to see pregnant women and those looking to become pregnant are a priority group. |
| 141 | Primary Care Diabetes Society | committee-discussion | Conclusion | 3.16 | | I welcome the inclusion of women planning pregnancy, as this offers potential to support good preparation for pregnancy and improved pregnancy-related outcomes. |
| 174 | | recommendations | 1 Recommendations | 1.2 | | What happens if the person planning pregnancy has infertility? Does their hybrid closed loop get taken away if they do not fall pregnant in a certain time scale? |

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| 181 | | committee-discussion | Pregnancy | 3.6 | | The Artificial Pancreas Trial by Roman Hovorka has a lot of data from pregnancy and HCL control. The data is there.<br>Addenbrookes Hospital also recommends that whilst pregnant people use a HCL system as best practice, due to the enormous changes in hormones and insulin requirements throughout the pregnancy |
| 196 | | recommendations | 1 Recommendations | 1.2 | | Will they be allowed to keep the HCL after giving birth? I can see the benefit of having an HCL before / during pregnancy but what a wrench to have to go back to previous methods. |
| 255 | National Pregnancy in Diabetes (NPID) | | | | | On behalf of the National Pregnancy in Diabetes (NPID) audit we strongly support the hybrid closed-loop (HCL) recommendation for women with type 1 diabetes who are pregnant or planning a pregnancy. We also agree that blood glucose levels are harder to manage during pregnancy, because of tighter targets and gestational changes in insulin sensitivity and pharmacokinetics.<br><br>One in two babies are admitted to neonatal care unit, separating mothers and babies and associated with substantial NHS costs. National pregnancy audit data confirm that rates of obstetric & neonatal complications requiring neonatal unit admission are lowest in women with HbA1c <=43mmol/mol after 24 weeks gestation. Currently, this unachievable for most women using existing CGM and insulin pump therapy. HCL is the technology which is most likely to support pregnant women to safely achieve their pregnancy glucose targets and improve neonatal health outcomes.<br><br>We know from the CONCEPTT RCT data (Fig DS Lancet 2017) that improvements in maternal glucose are both clinically and cost effective, largely due to fewer and shorter neonatal inpatient days. Therefore, we agree that the cost effectiveness of HCL systems in pregnancy would likely be greater than in the overall population. |

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| | | | | | | Available evidence regarding HCL use in type 1 diabetes pregnancy suggests that it can be safely used by women on intensive insulin regimens, multiple daily injections of insulin pumps with glycaemic benefits including increased time spent in target glucose range and reduced frequency and severity of hypoglycaemia. HCL can also be used during maternal hospital admissions for example following antenatal corticosteroids for fetal lung maturation as well as during labour/birth and the post-natal period with JBDS guidance supporting pregnant women and HCPs to safely use HCL.<br><br>Only 12% of women with type 1 diabetes are well prepared for pregnancy, therefore we strongly support the HCL recommendation for women with type 1 diabetes who are planning pregnancy. National pregnancy audit data confirm that serious adverse outcomes (congenital anomaly and perinatal death) are lowest in women with early pregnancy HbA1c <=48mmol/mol, hence any improvement in maternal glucose before pregnancy is likely to reduce congenital anomaly, stillbirth and neonatal death rates.<br><br>We totally agree that the choice of components or HCL system should be based on a person's preference. However, since pregnancy glucose targets are tighter than outside of pregnancy, women with type 1 diabetes who are pregnant or planning a pregnancy should be informed that systems with lower glucose targets may be more applicable for use during pregnancy. Currently, the CamAPS FX is the only HCL system which is CE marked/licensed for use in pregnancy. It has specific features including a lower glucose target which can be customised for day/night and early/late pregnancy as well as automated increased or decreases in basal insulin delivery which may help users to optimally manage gestational changes in insulin sensitivity and pharmacokinetics. However, all HCL systems are likely to offer maternal wellbeing, clinical and cost |

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| | | | | | | effectiveness benefits before, during and after pregnancy. |
| 278 | | recommendations | 1 Recommendations | 1.2 | people who are pregnant or planning a pregnancy. | This recommendation effectively makes closed loop systems 'emergency' treatment for a maximum of 9 months at a time, plus will lead to assertions that NICE is gender-biased, or biased against women who are childless either by choice or biology.<br><br>It also risks women claiming to be trying for a baby in order to access the system. Plus, how will a clinician justify placing a patient back on conventional treatment post-pregnancy? They would be actively ordering the patient to have worse control. |
| 283 | | committee-discussion | Pregnancy | 3.6 | It further concluded that the effectiveness of HCL systems in pregnancy would likely be greater than in the overall population. | How? Pregnancy lasts 9 months. There are thousands of people with T1 who will struggle with poor control for far longer. |
| 398 | Families With Diabetes National Network | recommendations | 1 Recommendations | 1.2 | | We agree that HCL should be used for those pregnant or planning to become pregnant. |
| 480 | | recommendations | 1 Recommendations | 1.2 | | I agree with this recommendation. T1 diabetes is more difficult to manage during pregnancy and the hybrid closed loop system would support the individual , helping them to stay in range at a time |

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| | | | | | | when hormones are fluctuating due to the pregnancy. This will support the health of both the mother and the unborn child and reduce some mental load at this time. |
| 496 | | recommendations | 1 Recommendations | 1.2 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy | Not all HCLs are indicated for use during pregnancy and it would be a huge shame if a woman got onto one of those pre-conception and then had to discontinue use of the HCL during pregnancy because it wasn't indicated for use. There must be provision for switching HCL to one that is indicated in pregnancy or else this whole point is moot! Also, women of childbearing age and their care teams should not lose out in having a choice regarding which HCL to get. It's not fair to say that all women who could potentially get pregnant must be on the a make of HCL that's indicated in pregnancy 'just in case.' |
| 501 | | information-about-hybrid-closed-loop-systems | The interventions | 2.5 | The choice of components or system is based on a person's preference | This is not necessarily true in pregnancy, where the algorithm needs to be sufficiently aggressive to target the tighter range for glucose control. As in my other comment, provision needs to be made for someone using HCL prior to pregnancy to access an appropriate system during pregnancy, rather than tell them because they chose one that isn't indicated before they got pregnant, they must not use the HCL during pregnancy (which is the current standard practice) |
| 531 | | committee-discussion | Cost effectiveness in pregnancy | 3.12 | | There is no evidence for your statement that "HCL systems would likely be cost effective when used in pregnancy and for people planning a pregnancy". So there is no evidential justification for the removal of the 8.0% HbA1c threshold for pregnant women at the expense of other groups. |

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| 558 | | recommendations | 1 Recommendations | 1.5 | And because blood glucose levels are harder to manage in pregnancy, they are also recommended for people with type 1 diabetes who are pregnant or planning a pregnancy. But because there is some uncertainty in the economic model, they are only recommended if the compa | As previously commented - preganancy and economic viability appear to be two seperate statements. |
| 605 | Diabetes Technology Network -UK | committee-discussion | Cost effectiveness in pregnancy | 3.12 | | We agree |
| 667 | NHS England | recommendations | 1 Recommendations | 1.2 | | NICE are asked to provide a summary of evidence to support the recommendation of Hybrid Closed Loop as an option for managing blood glucose levels in Type 1 Diabetes for people who are pregnant or planning a pregnancy. NICE are also asked to bear in mind the potential dilemma patients and clinicians face when people are asked to return their technologies after their pregnancy – this is already causing difficulties with regard continuous glucose monitoring in pregnancy. |
| 676 | | committee-discussion | Pregnancy | 3.6 | | Might be worth adding that the hybrid closed loop offered should be able to have the targets advised for pregnancy, or at least targets that are closer to the recommendations for pregnancy than the user is able to achieve otherwise? |
| 746 | King's College Hospital NHS Foundation Trust | recommendations | 1 Recommendations | 1.2 | pregnant or planning a pregnancy | For women who are considering pregnancy or fall pregnant using an "in-warranty" insulin pump that is not compatible with continuous glucose monitoring to deliver hybrid closed therapy, or using hybrid closed loop technology that is not licenced for use in pregnancy, what is there a recommendation? |
| 747 | King's College Hospital NHS Foundation Trust | recommendations | 1 Recommendations | 1.2 | pregnant | What is recommended after pregnancy? Continue or discontinue hybrid closed loop? |

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| 92 | University Hospitals Dorset Diabetes Service | committee-discussion | Pregnancy | 3.6 | | This conclusion is a shame, although I understand that evidence was lacking in the population of type 1 diabetes who are pregnant. Hybrid closed-loop systems could substantially improve glycaemic control during pregnancy at a vital time in patients who find achieving good glycaemic control challenging. A greater short-term cost effectiveness argument made in this group if complications from pregnancy were to be reduced by introduction of a hybrid closed-loop system for this group. This would need to be balanced against the need for a multidisciplinary team capable of providing education and support at short notice on the systems in patients who become pregnant. We are glad to see the final conclusion in the guidance that hybrid closed-loop system should be considered for patients pregnant / contemplating pregnancy. |

## THEME: QUALITY OF LIFE

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| 56 | | committee-discussion | Conclusion | 3.16 | people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0%) | I feel that this system would benefit someone like me with brittle diabetes and unable to control it, it would also in the long term save money for the NHS as previously explained. It would also greatly improve someone with brittle diabetes' quality of life and mental wellness. Personally, I imagine that having one of these would also make me less worried about my diabetes control and long term complications. |
| 145 | | | | | | Providing closed loop systems to allow better glucose management is a must.<br>I have had such a system for the last 5 years or so following issues with sudden hypoglycaemic incidents with no warning - leading to collapses, blackouts, hospitalisation, temporary paralysis, seizures. It was horrible and dramatically affected not only my physical health but the mental health of my partner and daughters. They were frightened whenever I left the house that I wouldn't return.<br>The closed loop system has completely changed my life. It has allowed me to carry on working in my job as an NHS nurse, a job I have 20 years experience in but was struggling to manage. It has reduced my time in hospital as inpatient and outpatient, allowed me to continue to contribute to society as professional care giver and as a tax payer rather than being a recipient of benefits and care. It has improved my glucose level management and no doubt prevented or delayed significantly the more damaging effects of Diabetes. It has allowed my partner to carry on working full time and helped reduce the anxiety levels of my daughters who are now both in tertiary education. All this for £6000 a year is a fantastic investment which will pay for itself many times over. I cannot recommend it highly enough. I work in the NHS so am acutely aware of lack of financial investment in preventing illness which ends up costing much much more further down the line. DON'T MAKE THE SAME MISTAKE AGAIN. |

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| 197 | | recommendations | 1 Recommendations | 1.5 | So, they may reduce the mental load and improve people's quality of life. | The improvement in quality of life as a result of using HCL is not recognised enough. |
| 203 | | committee-discussion | Conclusion | 3.16 | HCL systems are likely to improve blood glucose control in type 1 diabetes. | and quality of life. |
| 292 | | information-about-hybrid-closed-loop-systems | Price | 2.9 | | It's not just about life years gained - it's about all of the support someone needs if they get complications or if they are struggling mentally with the daily grind of diabetes. |
| 392 | | | | | | My son, 26, was diagnosed as type 1 at 19, in his first year at university. This condition has adversely affected every aspect of his life. He completed his degree, has run a marathon and achieved a Duke of Edinburgh Gold Award. He is a scout leader and currently a post graduate student and trainee teacher. He has so much potential and so much to offer the world, but type 1 affects not only his health but also his mental and emotional wellbeing. He has suffered from burnout, has night hypos and bouts of despair and total exhaustion. He had developed background retinopathy. He has used MDI and pumps - both are 'adequate' but flawed and require constant monitoring and adjustment.<br>A closed loop system, the closest thing to a working pancreas, would give him, and his family, peace of mind and hope for the future without fear of future complications and reduced life expectancy. The ripple effect of all the young people he could influence and mentor would be enormous.<br>Thank you for your consideration. |

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| 405 | | | | | | As the parent of a child lucky enough to have had a closed loop/'artificial pancreas' system for over a year I can confirm what a huge difference it has made to our lives. My son's HBAC and time in range are excellent. He can manage his bolus delivery quickly and discreetly. It was a bit strange at first, entrusting such an incredibly important thing to technology but for us it has more than paid off.<br>For five-plus years I probably only had a handful of full nights' sleep. Now I can go to bed relatively secure that the system is working to keep his levels steady and in range, and I can go to sleep in the knowledge I'll be alerted if there is a problem.<br>I hesitate to say life-changing because it sounds melodramatic but it really is. And all of this contributes to a better chance of good health long-term for my son, including reduced stress. It seems to me that in the long-term it will be mutually beneficial for as many diabetic people as possible to be on the closed loop system. |
| 411 | | committee-discussion | ICER per QALY gained | 3.13 | | I do not believe the quality adjusted life year figure used in the analyses takes full consideration of the benefits gained from better sleep with no CGM alarms for both patient and partner, improved quality of family life without having to deal with both severe and non-severe hypos, reduced worry about diabetes complications, reduction/exclusion of hypoglycaemic episodes interrupting daily life e.g. The DVLA specifies that one must wait 45minutes before driving after blood glucose has returned to normal following a hypo. This could delay a journey for more than one hour in total which impacts on working and home life considerably. |

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| 429 | | committee-discussion | Clinical need | 3 | | These closed loop systems should be made available to all that want to make use of this amazing advance in diabetes care technology, it is indeed an absolute game changer for both the user and their families.<br>The impact on the quality of life for those with type 1 and their wider families/carers is immeasurable.<br>I am a mother of a daughter aged 23 with type 1. She was diagnosed aged 10. She has had the T-Slim/Dexcom combo since November and the benefit of using this system became immediately apparent. She (and as a result of this the whole family) have had the first nights of unbroken sleep since her diagnosis. The control IQ technology has taken away so much of the fear and effect of night time hypos/hypers. The adverse impact of type 1 on her working and social life has been greatly reduced. She is able to lead a much more 'normal' life, not totally dictated by the restrictions of trying to manage the illness with MDI or a normal insulin pump (even if these are combined with the unlooped use of a CGM) or the frustration of having to stop whatever she is doing to deal with hypos, which is a particular issue when she is working, or not being able to drive for an hour because of a hypo. She is also able to partake in exercise without the constant worry that she will hypo.<br>All of the above has had such a positive impact on both her physical and mental wellbeing and also that of our family as a whole. In fact, she has just been on her first holiday since using this system and the first thing she said when she got home was that it has totally changed her life.<br>Having diabetes and trying to regulate it manually is an horrific trial on a daily basis as its affected by hormones, stress, hot weather, cold weather, exercise, stress, excitement and many other factors. Obviously the ability of this system to keep the users BGL in range for more of the time by automatically adjusting the insulin doses giving them a better HbA1c will have an immense impact on the longer term effects of type 1 and the health complications associated. |

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| 444 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | They also explained that disrupted sleep was a significant problem, with parents waking multiple times a night to monitor their child's blood sugar and administer glucose or insulin. | ...so why should those parents whose children have good hba1cs continue to suffer with sleep deprivation? |
| 452 | | | | | | This closed loop system is critical for type 1 diabetics to enable them to take much better control of their condition. To help minimise human error in over or under dosing of insulin, to help prevent debilitating and potentially dangerous hypoglycaemic events and to 'normalise' their day to day lives as much as possible. |
| 511 | | committee-discussion | Conclusion | 3.15 | | Please make this available to all with type 1 diabetes. Not just available to a select few - who potentially are not the people who will benefit from access to it. Or putting a restriction hba1c figure as the determining qualifier. This is 2023.<br><br>This doesn't factor in the benefit and massive improvements in quality of life access to this tech would bring for those with type 1 diabetes. The amount of time I spend, daily, is hours and hours of micro managing blood sugars, weighing every gram of food that i consume, micro managing insulin, keeping the best control possible so i'm not a burden to the NHS now or in the future. There's no respite from it, no mental respite from it. There's the financial implication to me on top of trying to live a normal life, which is mentally and physically exhausting. And this criteria for access to this tech is demoralising. It penalises those of us who have done everything we can to have the best possible control at huge financial cost, which I for one can only afford by spending almost nothing on anything else apart from food, fuel and housing. |

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| 544 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | Having used the system I can confirm that the system is frequently described as life changing - people sleep better and say they just feel so much better and anxiety reduced |
| 549 | | | | | | Hybrid closed loop treatment options are revolutionary and would massively benefit patient livelihood and quality of life. With HCL, not only are sugars monitored and responded to when they start to rise, the low alarms, alongside responses when sleeping, would allow T1D patients new levels of freedom and the ability to live a more fulfilling, less stressful life. |
| 550 | | | | | | As a type 1 diabetic, I highly commend these efforts to expand access to hybrid closed loop systems. I would strongly advocate that these systems are made available to all type 1 diabetics. The impacts on quality of life, health and well-being would be truly transformative. Even for those that do not fall under a high risk category, the day-to-day burden of managing the disease are immeasurable. |
| 563 | | | | | | I have been a Type 1 Diabetic for 45 years and this would be Such a blessing if it becomes available to ALL. I hope that you would see what a difference this would make to all type 1 diabetics. |
| 568 | | recommendations | 1 Recommendations | 1.5 | But they are also effective for people with average HbA1c levels (the UK average HbA1c for people using a pump is around 64 mmol/mol [8.0%]). | The technology has been incredibly helpful for me. My average HbA1c is now (48.9 mmol/mol [6.6mmol/mol]) and auto-corrections and Smartguard are a massive reason why I worry less about my blood sugars now and feel much happier and healthier with a life long condition. |

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| 571 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | They also explained that disrupted sleep was a significant problem, | Distrupted sleep is also a key issue for adults with and partners of those with T1D. Having a HCL system has meant that I worry less about my blood sugar and can sleep through the night. I am now sleeping better than I have in the last 22 years since diagnosis. Being able to wake up in range and not wait for hours for my blood sugar to come in range means I can finally eat when I am hungry at breakfast. The effect the system has on overnight blood sugars is, without a doubt, life changing and I am hitting a minimum of 80% TIR consistently. |
| 649 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | Thank you for recognising this. My son's quality of life has been poorer for having T1D. and the impact on his education has been significant. He is 16 now, and still worries about hypos and dying in his sleep. We are exhausted by this condition which impacts the whole family. |
| 713 | | | | | | I've been T1D for 45 years, having been diagnosed at aged 10.<br><br>Having gone through relatively recent periods of "burn out", my experience of DIY and then hybrid closed loop has been an overwhelmingly positive one.<br><br>I started Dexcom G6 / Tandem T-Slim X2 back in October and my time-in-range has gone from 65/70% up to 80% plus. My estimated Hba1C has dropped from 6.6 down to 6.4.<br><br>Apart from the obvious physical/control improvements, more important for me is the enhanced quality of life and my emotional/mental wellbeing. Whereas before, there was massive anxiety about the control of my diabetes, I'm now no longer suffering as much from periods of doubt about hypos and complications etc.<br><br>For me, the Dex/TSlim hybrid closed loop system has been a total game changer and should, in my opinion, be widely available for those that need/want greater control of their condition. |

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| 717 | | | | | | On a personal note, my child has has 3 severe hypo attacks at night, all requiring 3rd party intervention. This was pre CGM technology. CGM is a game changer in diabetes care in terms of management, mental load, and learning how food and activity affects them as each patient is different. Closed loop further brings in safety mechanisms by suspension of insulin and correcting hyperglycaemia, improving management and quality of life. As a long term condition requiring intensive daily management, T1D is as much a mental condition as it is a physical one. |

## THEME: RECOMMENDATIONS

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 5 | PrescQIPP CIC | recommendations | | 1 | | Clarity is needed on which patient groups the recommendations apply to e.g. does 'people' refer to adults and children of all ages? |
| 45 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | recommendations | 1 Recommendations | 1.4 | | Not sure about some of the clinical experts reasons for giving a closed loop. |
| 137 | Primary Care Diabetes Society | recommendations | 1 Recommendations | 1.2 | | needs clarity here as to whether this applies to all women with diabetes who are pregnant, or only those with type 1 diabetes |
| 219 | | recommendations | 1 Recommendations | 1.5 | | Needs clarification - what are these schemes ? |
| 266 | | recommendations | 1 Recommendations | 1.1 | | Why only people who are struggling to maintain their levels? I would have thought most people with Type 1 have difficulties at some points. |
| 409 | | recommendations | 1 Recommendations | 1.1 | having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, | Given the acknowledged uncertainty about the effect on HbA1c later in the document, and that it is quite possible to have a reasonable HbA1c whilst having highly uncontrolled Type 1 diabetes (high - low swings, excessive hypoglycaemic episodes) it seems inappropriate to recommend the technology only if both factors are met. Please consider changing this to "or". |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 520 | | recommendations | | 1.1 | despite optimal management with at least 1 of the following:continuous subcutaneous insulin infusionreal-time continuous glucose monitoring intermittently scanned continuous glucose monitoring. | Including the phrase "optimal management" seems conflicting and unnecessary here.<br><br>If someone is having difficulty managing their condition, or has an HbA1c above the NICE guideline of 6.5% let alone above the suggested threshold of 8.0%, then their management cannot be "optimal" by definition.<br><br>What would optimal management look like that would still result in difficult management or an HbA1c >8.0, and why should those people be ineligible? |
| 555 | | recommendations | 1 Recommendations | 1.2 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy. Hybrid closed loops systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2) | This appears to be two unrelated statements in the same paragraph. |
| 622 | | committee-discussion | Conclusion | 3.16 | | Agree fully with the wording of the pregnancy criteria.<br><br>I have issues with the first criteria since "having difficulty" is too easy for commissioners to (deliberately) misinterpret. This should be a measure of the burden of diabetes, for example, how often the patient checks their glucose during the day, how often do they check their glucose during the night (when they should be sleeping), how many corrections (insulin or glucose) do they make every day, do they restrict their diet solely to achieve their HbA1c value.<br><br>If you do not include a measure of the burden of diabetes then you will be rewarding bad behaviour with hybrid systems.<br><br>The HbA1c value should be a separate criteria,. |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 658 | Novo Nordisk UK | recommendations | 1 Recommendations | 1.1 | | Section 1.1 summarises the recommendation that hybrid closed loop systems are recommended for people with type 1 diabetes who are having difficulty managing their condition.<br><br>To provide additional clarity for the NHS and clinicians and to support access for everyone with type 1 diabetes who would meet the criteria outlined in the recommendations, and who could benefit from the use of a hybrid closed loop system, we recommend that this section makes clear that these recommendations apply to both adults with type 1 diabetes and to children and young people with type 1 diabetes. We would recommend that the wording in this section is amended to clarify this and to say:<br><br>“Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for adults and children and young people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following:<br>• continuous subcutaneous insulin infusion<br>• real-time continuous glucose monitoring<br>• intermittently scanned continuous glucose monitoring.”<br><br>The subsequent section 1.2 specifically highlights that use of hybrid closed loop systems to manage type 1 diabetes should be an option for women with type 1 diabetes who are pregnant, or who are planning a pregnancy. The additional reference to children and young people as a particular group who the recommendations will also apply to is important, to ensure this is clear for clinicians working to subsequently implement the recommendations and so that children and young people who would benefit from use of a hybrid closed loop system do not experience any difficulty with |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| | | | | | | access. We note that the diagnostics advisory committee specifically references children and young people in its conclusion to the technology appraisal, stating that: “HCL systems are likely to be more cost effective for children than adults”. We feel that the reference to the recommendations applying to children and young people, as well as adults with type 1 diabetes, should therefore be made explicit in the recommendations section.<br><br>This also reflects the reported results of NHS research into the use of hybrid closed loops in children and young people with diabetes, which it was concluded showed improvements in glycaemic control, time in range (TIR), frequency of hypoglycaemia, hypoglycaemia fear and quality of sleep for children and young people, when using a hybrid closed loop for 6 months. It was reported that the study also showed hypoglycaemia fear and quality of sleep were also improved for their parents and carers at 6 months (source Ng SM et al. Real world use of hybrid-closed loop in children and young people with type 1 diabetes mellitus-a National Health Service pilot initiative in England. Diabetic Medicine. November 2022. Available at: https://doi.org/10.1111/dme.15015). |
| 679 | | | | | | All people with type 1 diabetes struggle to manage their condition. The management of the condition changes from day to day, hour to hour; and what works one day may not work the next day. The results of a blood test which estimates blood glucose levels over a 12 week period does not and cannot translate to a sliding scale of how difficult people with t1d are finding the management of their condition. If the person with diabetes shows a commitment to seeing their consultant, and both the consultant and the person with t1d believe the use of a HCLS will enable them to struggle less with their control, and that they have the skills, confidence and education to be able to use the technology |

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| | | | | | | properly, then this should be the only criteria applied to them accessing the treatment. |
| 705 | | recommendations | 1 Recommendations | 1.3 | | This is too strict a requirement and based on historic TAs relating to pumps, will cause significant restriction to uptake in many places due to a lack of trained personnel. Individual users may not need the full team to use a system, and this should be reflected in the recommendations.<br><br>I suggest:<br><br>Use hybrid closed loop systems with the support of a trained multidisciplinary team experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring in type 1 diabetes only where required by an individual. |
| 721 | | recommendations | | 1.1 | despite optimal management with at least 1 of the following:continuous subcutaneous insulin infusionreal-time continuous glucose monitoring intermittently scanned continuous glucose monitoring. | suggest change to<br>despite completing structured education and attempted improvement with at least 1 of the following... |
| 730 | | recommendations | 1 Recommendations | 1.1 | | It is unfortunate that the system relies on a failure model. Whilst the cost of new technology has to be considered and use of it to be proven to be cost-effective, it can slow down the achievement of better care and outcomes, and create inequality. Use of CGMs highlights this; originally only available to those who could |

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| | | | | | | afford it, then on the NHS for those with poor control. Now all people with type 1 DM can benefit from using CGMs, both in reducing long term complications and the burden on the NHS. |
| 742 | King's College Hospital NHS Foundation Trust | recommendations | 1 Recommendations | 1.4 | carer | This guidance is for both paediatric and adult patients, so "carer" may mean different things for the different patient populations. One potential interpretation is that adult patients requiring care from healthcare professionals e.g. patients dependent on others for activities of daily living in a care-home, should be able to access hybrid closed loop technology, when this might not be practical or safe in this setting. Is it expected that the requirement that all carers in this setting would need to attend a type 1 diabetes structured education programme, mitigate this? |
| 745 | King's College Hospital NHS Foundation Trust | recommendations | 1 Recommendations | 1.1 | optimal management | How is "Optimal management" defined? In TA151, "Specialist teams should provide structured education programmes and advice on diet, lifestyle and exercise appropriate for people using CSII". Should this not be mentioned in this guidance? |
| 750 | | recommendations | 1 Recommendations | 1.1 | | Surely this would be an ideal method for avoiding reaching this state and avoiding the onset of associated complications. Thus saving time and money within the NHS.<br>Would it be worth considering people who have lived with the condition for many years, who would benefit both medically from having a more stable blood glucose level and emotionally from having some of the daily burdens lifted. |

## THEME: STRUCTURED EDUCATION

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 15 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.4 | | In addition to people or their carers being able to understand and be able to use HCL systems, there needs to be an agreement that they will use the technology as advised by their specialist diabetes team and take appropriate actions required to manage the pump effectively.<br><br>This recommendation suggests all patients must be attending a structured education programme. We would consider this to be part of optimal care that would be provided prior to considering CSII or HCL systems. Patients may also have attended a structured education programme in the last 12 months – would they need to repeat this? What about patients who cannot attend such as those with learning difficulties or dementia? |
| 46 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | recommendations | 1 Recommendations | 1.4 | is also attending a type 1 diabetes structured education programme. | It's good to have recommended patients attend a structured education course, but how do we decide whether they understand? - currently we have only really put people who have already been using a pump onto a closed loop type pump. I know of one patient that we put onto closed loop from MDI and he handed it back. |
| 63 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | recommendations | 1 Recommendations | 1.4 | | In order to provide this appropriate funding will need to be provided to upskill diabetes teams to enable patients and/or parents and carers to understand them and to deliver the structured education programme.<br><br>In addition teams will need to increase capacity to provide additional and ongoing monitoring to reduce the risk of using these devices including retinopathy if overall BG levels fall too rapidly |

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 73 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | committee-discussion | Access to technology and care | 3.2 | They said that improvements to the availability of and access to patient training were needed. They noted that many centres were limited because they do not have enough trained staff in their clinical teams to provide this | We agree<br>How will this be funded? |
| 87 | University Hospitals Dorset Diabetes Service | recommendations | 1 Recommendations | 1.4 | | Education is understandably important in adults with type 1 diabetes. However, should the need to attend structured education be an absolute necessity to have access to hybrid closed-loop system?This could potentially result in increased difficulty accessing the technology in patients of a lower socio-economic status who might find it difficult to attend education, or in other groups that might benefit from access to hybrid closed-loop technology, such as patient's with memory difficulties who require input from care systems, and were hybrid closed-loop technology could be of benefit in improving your glycaemic control. |
| 119 | | | | | | 1.4 It would be helpful to define what is meant by a 'structured education programme' - could this be online? Any programme that requires a large amount of time or physical attendance could be a significant barrier to access. |
| 128 | | | | | | There are repeated statements that HCL would only be viable if discounts can be agreed - however it has been stated in the past that pump availability on the NHS is limited by the pump clinics ability to support patients. Discounts are typically linked to either volume or cost reduction (eg. if the NHS did pump education this would reduce supplier support costs) if NHS resource is the bottleneck then the scope for discounts may be limited. I would also note that many clinics have a preferred supplier effectively giving that supplier a ‘post code monopoly’ which |

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| | | | | | | may look good in the short term but in the longer term reduces competitive pressure…. |
| 175 | | recommendations | 1 Recommendations | 1.4 | | What about those T1Ds who were diagnosed as children and therefore did not attend a structured education programme as they were taught by their parents or diabetes team? What if the education programme is inaccessible to the person? Do they not get access to the hybrid closed loop system? |
| 176 | | recommendations | 1 Recommendations | 1.4 | | What about those T1Ds who were diagnosed as children and therefore did not attend a structured education programme as they were taught by their parents or diabetes team? What if the education programme is inaccessible to the person? Do they not get access to the hybrid closed loop system? |
| 233 | | recommendations | 1 Recommendations | 1.4 | is also attending a type 1 diabetes structured education programme. | Is the tense correct - this seems to mean the technology can only be offered during the actual duration of education? Suggest this should be attended a suitable structured education programme within the previous 2 years (and should include online self guided learning)/ |
| 235 | | committee-discussion | Access to technology and care | 3.2 | They noted that many centres were limited because they do not have enough trained staff in their clinical teams to provide this. | The lack of local trained staff to deliver training for structured education and for use of devices. There appears to be significant waste in each area developing their own training / systems - should this not be leveraged at a national level particularly for online training? |

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| 236 | | committee-discussion | Access to technology and care | 3.2 | Clinical experts said that the automation offered by HCL systems could help reduce some of the inequalities for people who find it difficult to maintain healthy blood glucose levels because of a language barrier, a lower level of education or a learning disability, for example. | In order to reduce inequality given the recommendations include the requirement to attend structured education the committee need to consider how this would be delivered to those with learning difficulties, language barriers or cognitive impairment. |
| 251 | | recommendations | 1 Recommendations | 1.4 | | What the structured diabetes education programme? Teens/young adults won't have completed dafne will have been constantly taught/learnt how to manage the condition whilst growing up. Maybe those who are newly diagnosed need to have attended/completed a course but anyone currently on a pump with cgm will have been trained in its use, will be aware of carb counting, sick days rules etc |
| 256 | | | | | | Access to closed loop shouldn't be dependent on whether someone has attended structured education - evidence shows that the poorer a person is with more socio-economic disadvantage, the less likely they are to have completed structured education - requiring patients to have completed structured education bakes in health inequality |
| 287 | | recommendations | | 1.4 | Only use hybrid closed loop systems if the person or their carer:understands and is able to use them is also attending a type 1 diabetes structured | Agree |

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| | | | | | education programme. | |
| 335 | | recommendations | 1 Recommendations | 1.4 | | There will be a vast difference here between peoples level of understanding, readiness to change and take the new technology on board, psycho social issue will play a part. Timing of intervention and access to support most important. |
| 337 | | recommendations | 1 Recommendations | 1.4 | | At this point in type access to type 1 diabetes structured education is sparse and highly varied.<br><br>Also the person readiness to learn and take in what is learnt in the education is highly varied depending on where they are on their "diabetes" journey and they may have to repeat the course or for the training to be delivered in a different way. Again in the absence of clarity around this an individualised approach (w system being available for all w the right support a better "bottom-up" approach. |
| 373 | Association of British HealthTech Industries | recommendations | 1 Recommendations | 1.4 | | A flexible approach to education and training is needed to support adoption of the guidance<br>ABHI members recognise that high quality, appropriate training is essential for optimal and safe use of HCL systems. Currently such training is well supported by several education programmes provided by the NHS, industry, patient support organisations and others. Funding for some 'structured' education programmes is not always in place or a specialist clinical team will want to use their own. These factors may pose a hurdle to access.<br><br>We propose the current recommendation is broadened to allow for clinical discretion in the education programmes which can be utilised. This would support the equity goals of the NHS and |

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| | | | | | | provide choice for people with T1D.<br><br>We suggest the existing recommendation is amended to read, "…also attends an education programme approved by their specialist care team." |
| 400 | Families With Diabetes National Network | recommendations | 1 Recommendations | 1.4 | | Ensure structured education programme is easily accessed as above to avoid discrimination if your hospital can't provide<br>It is really important to be well trained in use of a HCL system to gain the maximum benefit |
| 457 | Children & Young People's Diabetes Team, Somerset Foundation Trust | recommendations | 1 Recommendations | 1.4 | | Need greater definition on what counts as type 1 diabetes structured education programme.<br><br>Surely also this should really read 'has attended structured education, and can show competency in key diabetes related knowledge. 'is attending' is present tense & implies even if already an expert patient, have to be booked in again. Think should read 'is attending or has attended and has been assessed as competent' |
| 470 | | recommendations | 1 Recommendations | 1.4 | | Education should not be a barrier to accessing technology. How is it intended for healthcare specialists to assess if someone understands management options for their own condition? This is subjective and could have negative outcomes, for example, denying access to technology based on the perception of lack of education/understanding. |
| 497 | | recommendations | 1 Recommendations | 1.4 | is also attending a type 1 diabetes structured education programme. | This requirement needs more explanation. There are no 'official' structured education programmes for HCL use at this point. Some of the things taught in DAFNE are likely to undermine the effectiveness of HCL, for example always treating a hypo with 15g carbs. If the algorithm proactively reduced someone's insulin delivery prior to the system generating a low glucose alarm, the person will need fewer carbs to treat the hypo or they will end up in rebound hyperglycaemia. Consider advising that diabetes teams personalise education that they provide to people on HCLs rather than refer them to |

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| | | | | | | an existing programme that might actually not meet their needs |
| 505 | | committee-discussion | Access to technology and care | 3.2 | They said that improvements to the availability of and access to patient training were needed. They noted that many centres were limited because they do not have enough trained staff in their clinical teams to provide this. | Well put - but also teams can combine resources to be able to offer education to more patients, something they are currently not often encouraged to do |
| 506 | | committee-discussion | Access to technology and care | 3.2 | Clinical experts said that the automation offered by HCL systems could help reduce some of the inequalities for people who find it difficult to maintain healthy blood glucose levels because of a language barrier, a lower level of education or a learning disability, for example | If this is true, where will these people get the structured education they are supposed to have in order to access an HCL in the first place? This comment seems like well intentioned virtue signalling |
| 542 | | recommendations | 1 Recommendations | 1.4 | | Is that has attended or is attending a course? |
| 548 | | committee-discussion | Costs in the economic model | 3.13 | | Although requires intensive education to start the systems once working this will reduce workload as people are better and require less support |

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| 552 | | recommendations | 1 Recommendations | 1.4 | is also attending a type 1 diabetes structured education programme. | What does this involve/actually mean?<br><br>Are all Health Boards going to have this available or is this just abother way to block access to a closed loop system?<br><br>Most patients/carers will be very experienced in diabetes technology and the condition so this should also be taken into account. |
| 557 | | recommendations | 1 Recommendations | 1.4 | is also attending a type 1 diabetes structured education programme. | Should this say:<br><br>is also attending, or has attended, a type 1 diabetes structured education programme?<br><br>I suspect the system can not accomodate continual structured education for those using hybrid closed loops. |
| 595 | | recommendations | 1 Recommendations | 1.4 | is also attending a type 1 diabetes structured education programme. | Should also include people who have already attended/completed a structured education programme as well as equivalent alternatives. Some people will have recieved equivalent education on an individual basis plus may be more appropriate for people needing more educational support. Also not always easy to access structured education without a substantial wait or offering not practical for many people due to economic circumstances, care responsibilty, work restrictions etc |
| 598 | Diabetes Technology Network -UK | recommendations | 1 Recommendations | 1.4 | | " is also attending" is confusing as it is in the present tense.<br>We believe that the international evidence on closed loops shows that people who have not been able to take on structured education can still have demonstrable benefits with HCLand the skills taught in structured education courses [ how to adjust insulin doses] are not relevant to closed loops - there is separate HCL specific education on how to bolus pre meals, how to identify infusion site failures adn deal with illness that must be taught - so we woudl recommend changing this to<br>" attendance at HCL specific education"<br><br>The Diabetes Technology Network is working on specific education modules that clarify the minimum education needed to gain the benefits of hybrid |

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| | | | | | | closed loop systems based on clinical expertise and experience within the UK but also from our international colleagues where HCL is more widely available and used |
| 616 | | recommendations | 1 Recommendations | 1.4 | | Sadly, not all areas have structured education courses. The "choice" to have them is a local commissioner choice, so that errant commissioner will also be excluding access to hybrid systems. Or maybe that is their intention? |
| 660 | Novo Nordisk UK | recommendations | 1 Recommendations | 1.4 | | We note the recommendation that hybrid closed loop systems should only be used if people with type 1 diabetes or their carers understand and are able to use them and are also attending a type 1 diabetes structured education programme.<br><br>We support the need for people with type 1 diabetes, for whom a hybrid closed loop system would be appropriate for their care, to be trained and provided with the necessary information about the use of this technology. However, we are mindful of the concerns raised by the committee, that improvements to the availability of, and access to, patient training are needed. This is a concern we have also heard from clinicians.<br><br>We feel it is therefore important that the NHS continues work to ensure access to diabetes education is improved, to ensure that this recommendation does not inadvertently act as a barrier to people being able to access hybrid closed loop systems. This must include the need for a flexible approach that will meet the needs of people living with type 1 diabetes, including considering the role that the delivery of virtual education content might play in helping to support improved access.<br><br>Ensuring better access to diabetes education and raising awareness amongst both healthcare professionals and those living with diabetes, about how technology can support people to manage their type 1 diabetes, will be key to avoid exacerbating any existing inequalities. For example, the National |

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| | | | | | | Paediatric Diabetes Audit for 2020/21 highlighted that lower use of insulin pumps was associated with ethnic minority status, with Black children and young people having the lowest use (27.4%) compared to 40.2% of White children. The audit also found that children and young people living in a less deprived area were more likely to be using an insulin pump, compared to those living in the most deprived areas (source Royal College of Paediatrics and Child Health. National Paediatric Diabetes Audit Annual Report 2020-21: Care Processes and Outcomes. 2022). It is vital that access to training and education for people living with type 1 diabetes and their carers is improved in order to address such inequalities.<br><br>NHS England has stressed how the long-term sustainability of health and social care depends on having the right digital foundations and how it will continue to work with local systems to "level up digital infrastructure" and to address health inequalities (source: NHS England. 2023/24 priorities and operational planning guidance. January 2023). It will thus be important for local health systems to ensure they implement the final guidance on the use of hybrid closed loop technology in a way that addresses any potential barriers to access, or implementation of the recommendations. |
| 669 | NHS England | recommendations | 1 Recommendations | 1.4 | | In the consultation documentation structured education for people living with Type 1 Diabetes is recommended as being mandatory, but NICE may wish to reconsider this. The experience from the implementation of Pumps is that it creates problems regarding access and especially barriers to those living in economically deprived communities and people with other protected characteristics. NICE might therefore consider that structure education should be routinely recommended and offered, but not necessarily mandated prior to access to the technology, in order to address these potential health inequalities. Of course, patient education in the use of the technology itself is essential. |

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| 674 | | recommendations | 1 Recommendations | 1.4 | | Should this refer specifically to active attendance at a programme for safe and effective use of the hybrid closed loop? |
| 678 | | recommendations | 1 Recommendations | 1.4 | | Bullet point (2) "is also attending a type 1 diabetes structured education programme" should preferably read "is also attending or has attended a type 1 diabetes structured education programme" otherwise it discriminates against those patients who have attended diabetes structured education programmes e.g. JIGSAW (QA Hospital, Portsmouth) in the past in an effort to improve their diabetes control and lower their HbA1c. |
| 706 | | recommendations | 1 Recommendations | 1.4 | is also attending a type 1 diabetes structured education programme. | I would suggest changing this to:<br><br>Is attending or has attended a structured education programme either in person or online or;<br><br>Is deemed by the consulting physician to have the requisite experience in lieu of structured education. |
| 719 | | recommendations | | 1.4 | Only use hybrid closed loop systems if the person or their carer:understands and is able to use them is also attending a type 1 diabetes structured education programme. | as per earlier comment I would put completed SE at the beginning of the selection algorithm<br>I would also insert a statement to the effect that not only should the patient and carers understand the system and what to do in the event of failure but there must also be sufficient understanding in primary care and non-diabetes hospital care |
| 732 | | recommendations | 1 Recommendations | 1.4 | | Whilst it is important that the individual undergoes training to use the closed loop system, in order to get the most benefit from it, it needs to be understood that access to structured programmes is variable across England and also that employers are not always sympathetic to allowing time off to attend a 3 or 5 day programme. The self employed can also find difficulty with this. It should be acceptable for a person to have training to use a HCL system, without having to attend a structured course. |
| 748 | King's College Hospital NHS Foundation Trust | recommendations | 1 Recommendations | 1.4 | type 1 diabetes structured | Is this a structured education programme specifically for insulin pump therapy e.g. pump-DAFNE? |

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| | | | | | education programme | |
| 767 | ABHI | | | | | **4. A flexible approach to education and training is needed to support adoption of the guidance**<br><br>ABHI members recognise that high quality, appropriate training is essential for optimal and safe use of HCL systems. Currently such training is well supported by several education programmes provided by the NHS, industry, patient support organisations and others. Funding for some 'structured' education programmes is not always in place or a specialist clinical team will want to use their own. These factors may pose a hurdle to access.<br><br>We propose the current recommendation is broadened to allow for clinical discretion in the education programmes which can be utilised. This would support the equity goals of the NHS and provide choice for people with T1D.<br><br>We suggest the existing recommendation is amended to read, *"…also attends an education programme approved by their specialist care team."* |

**THEME: SUPPORTIVE**

| Comment number | Organisation | Chapter Name | Section Header | Section Number | Selected Text | Comment |
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| 37 | | | | | | Very useful for all T1 sufferers.<br>Hopefully will be approved as will revolutionise the treatment and minimise long term effects of this condition |
| 52 | | recommendations | 1 Recommendations | 1.5 | Continuously managing blood glucose levels is a substantial mental load for people with type 1 diabetes | from a PPIE (public and patient involvement and engagement) perspective, I strongly agree with this as it would greatly decrease my mental load having had brittle diabetes for 42 years since I was a child and an average of above 8 HbA1c which I find impossible to control. Please feel free to contact me if I can be of any further assistance as a PPIE representative [redacted] |
| 53 | | recommendations | 1 Recommendations | 1.5 | Evidence suggests that the systems appear to be more effective for people with higher long-term average blood glucose (HbA1c) levels. But they are also effective for people with average HbA1c levels (the UK average HbA1c for people using a pump is around 64 mmol/mol [8.0%]). | Again, as someone with great experience of living with very brittle type 1 diabetes for over 40 years I strongly agree with this statement and feel this would benefit someone like me. The cost of this loop system would in the long term be less costly when considering the amount of treatment I have had to have for stage 4 retinopathy etc. It is paramount to try and get type 1 diabetics under control to prevent long term health complications and additional implications such as the possibility of losing ones eye sight creating depression as well as additional care requirement. |
| 55 | | committee-discussion | Conclusion | 3.16 | It noted the many uncaptured benefits in terms of reduced mental burden, reduced parent and carer anxiety, and improved quality of life. | Again I totally agree |
| 90 | University Hospitals Dorset Diabetes Service | committee-discussion | Access to technology and care | 3.2 | | The major rate limiting step to accessing technology in the management of type 1 diabetes for both clinicians and patients in agreement to fund such systems from CCG/ICBs. This has even been seen for sensors following last year's NICE guidance MArch 2023 publication, let alone the challenge of funding hybrid closed-loop systems. However, we very much welcome the NICE panel reviewing the possibility for HCL as a technology intervention and |

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| | | | | | | publishing NICE guidance to enable clinicians to engage with their fundholders around accessing these system for patients. |
| 98 | | | | | | I am delighted to see NICE putting time and thought into this proposal which I truely believe will have a giant positive impact on patients and their loved ones living with type 1 diabetes. Such an investment will do so much more than the paper mentions. Hits to the economy due to worker illness due to caring for chronic conditions like type 1 diabetes is greatly underestimated. Also, by providing more ways to lighten the burden on those with type 1 diabetes, the potential benefits and untapped resource of those persons could be major boosts from a economical and societal perspective. |
| 136 | Primary Care Diabetes Society | recommendations | | 1 | | The PCDS is pleased to see the development of this TA and welcomes the opportunity afforded to people with diabetes with access to technologies supporting self care. |
| 169 | | recommendations | 1 Recommendations | 1.3 | | Excellent point |
| 390 | | recommendations | 1 Recommendations | 1.2 | | I would support this |
| 401 | Families With Diabetes National Network | recommendations | 1 Recommendations | 1.5 | | There has been concern in feedback we have received about this so good that those already using will be able to continue. |
| 412 | | | | | | I'm a new diabetic. So no where near getting this technology. However I agree with the proposal. As sometime in the future. Hopefully I'll have access to it. Like with the CGM. Which is an absolute game changer in my life. Invest now to save in the future. |
| 475 | | | | | | Has all of the relevant evidence been taken into account? Yes I think it has.<br><br>Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? Yes.<br><br>Are the recommendations sound and a suitable basis for guidance to the NHS? Definitely yes, it will be life changing for all Type 1 diabetics.<br><br>Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful |

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| | | | | | | discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity? I think it's considered who gets priority and it makes sense to do it that way. |
| 476 | | | | | | I think this is a wonderful proposal. I am a type one diabetic who has struggled with keeping blood glucose levels in good range. I have lowered my hba1c to my personal best which is 9%. I frequenctly feel frustrated with my own control and have experienced burn out. I am hoping to have children in the future and having type 1 diabetes makes me very worried about pregnancy. This closed loop system would be very beneficial. |
| 519 | | recommendations | 1 Recommendations | 1.5 | These recommendations are not intended to affect use of hybrid closed loop systems that was started in the NHS before this guidance was published. People using hybrid closed loop systems outside these recommendations may continue until they and their NHS clinician consider it appropriate to stop | I think this is a really sensible and pragmatic guideline. |
| 647 | | information-about-hybrid-closed-loop-systems | The interventions | 2.5 | | It's great that personal preference is considered. |

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| 650 | | committee-discussion | Uncaptured benefits | 3.9 | uncaptured be | I completely agree with the committee's conclusions |
| 672 | | dap55-diabetes-mta-acd-final-no-acicdocx | | | | I thank NICE for the opportunity to comment on this document, which I believe is a very good summary and interpretation of the available data. I am commenting as a diabetes physician with specialist interest in adults with type 1 diabetes and as the chair of the Guideline Development Group for NG17, Type 1 diabetes in adults: diagnosis and management published in 2015. |
| 757 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | | I have no doubt that HCL tech has stopped numerous admissions to hospital for my T1 teen. Having access to this tech was life changing as a family. |
| 762 | | | | | | Introduction<br>ABHI welcomes the National Institute for Health and Care Excellence (NICE)'s draft appraisal of hybrid closed loop systems (HCL) for managing blood glucose levels in type 1 diabetes (T1D). HCL systems represent an important opportunity to make a step change in the management of this condition so that people with T1D can improve their health and quality of life.<br><br>We recognise the important work lead by NHS England (NHSE) to collect evidence of the utilisation of HCL systems in a real-world setting. That process engaged clinicians, people with diabetes, support groups, and industry (in the UK and internationally), amongst others, to work together with the intention of widening access to innovative diabetes management technology.<br><br>It is imperative that these recommendations focus on continuing that work to expand access. Though the draft appraisal is a strong stride forward, ABHI members have several concerns which we highlight below |

## THEME: TECHNOLOGY

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| 68 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | information-about-hybrid-closed-loop-systems | The interventions | 2.5 | The choice of components or system is based on a person's preference | This is not true in CYP<br>It will be guided by system licencing for age, total daily dose and patient weight; as well as patient's access to supporting technology such as smart phone<br>It should also be guided by SAFETY as indicated by appropriate clinical trials in patient group to use it and its components such as CGMs with accuracy data in this age group |
| 69 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | information-about-hybrid-closed-loop-systems | The interventions | 2.6 | CamAPS FX control algorithm (Camdiab) with Dexcom G6 CGM sensor (Dexcom) and either the Dana RS or Dana-I insulin pump (Advanced Therapeutics UK Ltd) | If we are mentioning Dana, CAMAPS FX system should also include compatibility with Ypsomed pump<br>Omnipod 5 with Dexcom G6. Although this is currently not available in the UK – it will be in summer<br><br>CAMAPSFX is currently the only HCL system licensed for children aged under 6 years |
| 70 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | information-about-hybrid-closed-loop-systems | Price | 2.8 | | Was Ypsomed system with CAMAPSFX included? |
| 89 | University Hospitals Dorset Diabetes Service | information-about-hybrid-closed-loop-systems | Price | 2.8 | | OmniPod system likely to be considerably more expensive than competitors over 4 years? |
| 129 | | | | | | There are refences to AHCL - while not defined the clear trend in HCL technology is to provide auto-tuning for pumps based on analysis of the rtCGM data - it seems unlikely that this will not help pump clinics, in the face of staff shortages, to maintain support. |
| 133 | | recommendations | 1 Recommendations | 1.5 | | Please will the NHS also investigate Tidepool, this is a closed loop app, surely this is more cost effective? |
| 140 | Primary Care Diabetes Society | committee-discussion | Uncaptured benefits | 3.9 | | THa appraisal should include some discussion around risks, as well as potential benefits, particularly with regard to inadvertent pump failure of disconnection, with resultant hyperglycaemia and potential consequences thereof. This applies to all clinical scenarios but particular attention should be given to children and women in pregnancy. |

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| 194 | | | | | | Small comment. Can we please include Ypsomed pump with CAMAPS as although it says the list is not exhaustive, this pump is currently being used with CAMAPS as well as Dana I and Dana RS pump, and is more cost effective. |
| 211 | | information-about-hybrid-closed-loop-systems | The interventions | 2.5 | | In the final sentence, the importance of ensuring that new HCL systems "show interoperability" can not be understated. This allows a degree of personal patient preference and, therefore, offers the potential for better outcomes from the use of the chosen technology/technologies. |
| 212 | | information-about-hybrid-closed-loop-systems | The interventions | 2.6 | | In this section Omnipod 5 (for use in combination with Dexcom G6) is listed but it is not currently available to patients in the UK. |
| 261 | | | | | | Have NICE considered the adhesive used on these sensors / pumps?<br><br>I used dexcom for 3 years before suffering something akin to chemical burns from changes to their adhesive. A proportion of the UK type 1 population have the same problem and this will prevent them being able to use the technology.<br><br>For reference<br>https://www.reddit.com/r/dexcom/comments/sahe1f/anybody_having_sever_reactions_to_their_dexcom_g6/<br><br>There is also a Facebook group with 18,000 members called "dexcom and libre rash". |
| 348 | Children and Young People's North East and North Cumbria Diabetes Network | information-about-hybrid-closed-loop-systems | The interventions | 2.6 | | Area of Discrimination (Age) As per the NICE recommendation that the first choice for all CYP is rt CGM, all CYP over age of 6yrs will be able to access a HCL if they wish as some of the available pump options have integrated algorithms. However, under the current guidance there will be a gap in funding the algorithm app for those under 6 years as the only licensed closed loops currently for this require separate funding for the app.<br><br>In addition -<br>1. CAMAPS FX system should also include compatibility with Ypsomed pump and Dexcom G6.<br><br>2. CAMAPSFX is currently the only HCL system licensed for children aged under 6 years<br><br>3. There is little guidance on how to determine if an HCL system is safe and proven effective. It has been demonstrated that CE marking is not a valid proxy for CGM and AID accuracy<br>For example, the Medtrum Nano System has CE marking for CYP and adults and was used on the UK HCL pilot and removed due to 12 patient safety concerns. (Pemberton JS, Wilmot EG, Barnard-Kelly K, Leelarathna L, Oliver N, Randell T, Taplin CE, Choudhary P, Adolfsson P. CGM accuracy: Contrasting CE marking with the governmental controls of the USA (FDA) and Australia (TGA) - A narrative review. Diabetes Obes Metab. 2022 Dec 30. doi: 10.1111/dom.14962. Epub ahead of print. PMID: 36585365.) |
| 379 | Gateshead Health NHS | information-about-hybrid- | The interventions | 2.6 | | Area of Discrimination (Age) As per the NICE recommendation that the first choice for all CYP is rt CGM, all CYP over age of 6yrs will be able to access a HCL if they wish as some of the available |

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| | Foundation Trust Paediatric Diabetes Service | closed-loop-systems | | | | pump options have integrated algorithms. However, under the current guidance there will be a gap in funding the algorithm app for those under 6 years as the only licensed closed loops currently for this require separate funding for the app.<br><br>1.CAMAPS FX system should also include compatibility with Ypsomed pump and Dexcom G6<br><br>2. CAMAPSFX is currently the only HCL system licensed for children aged under 6 years<br><br>3. There is little guidance on how to determine if an HCL system is safe and proven effective. It has been demonstrated that CE marking is not a valid proxy for CGM and AID accuracy. For example, the Medtrum Nano System has CE marking for CYP and adults and was used on the UK HCL pilot and removed due to 12 patient safety concerns.<br>Pemberton JS, Wilmot EG, Barnard-Kelly K, Leelarathna L, Oliver N, Randell T, Taplin CE, Choudhary P, Adolfsson P. CGM accuracy: Contrasting CE marking with the governmental controls of the USA (FDA) and Australia (TGA) - A narrative review. Diabetes Obes Metab. 2022 Dec 30. doi: 10.1111/dom.14962. Epub ahead of print. PMID: 36585365. |
| 366 | | information-about-hybrid-closed-loop-systems | The interventions | 2.5 | this appraisal considers HCL systems as a class of technologies rather than individual components or systems | The quality of the algorithm is critical and it is dodging the most important question if you do not evaluate the performance of the algorithm(s). |
| 367 | | information-about-hybrid-closed-loop-systems | 2 Information about hybrid closed loop systems | 2.6 | available:The smart guard control algorithm (Medtronic) with the guardian CGM sensor (Medtronic) and either the Minimed 670G or 780G insulin pump | I have experience of this system. The algorithm takes no account of the different absorption speeds of CHO with different GI s nor does it allow boluses to be extended over time. The choice of target BG level is restrictive, and in my view, too low. A good deal of mental effort is required, and a lot of sleep is lost. |
| 419 | British Society For Paediatric Endocrinology and Diabetes | information-about-hybrid-closed-loop-systems | The interventions | 2.6 | | CAMAPS FX system should also include compatibility with Ypsomed pump<br>Omnipod 5 with Dexcom G6 is currently not available in the UK<br><br>CAMAPSFX is currently the only HCL system licensed for children aged under 6 years |
| 466 | | | | | | This may be outside the scope of the document, but the report discusses the mental load of dealing with data and calculations. The burden and requirement to enter data on food/carbohydrate intake remains with a hybrid closed loop system (accurate carbohydrate counting is arguably one of the |

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| | | | | | | harder aspects of diabetes management; if this was always known, the correct insulin dosage would be easy to administer), but could be vastly reduced through app development and integration. MyFitnessPal (and others), for example, allow barcode scanning of any food to give data on nutritional values. Integration of a hybrid closed loop system with such technologies would enable more accurate carbohydrate counting and further increase effectiveness of the solution. |
| 502 | | information-about-hybrid-closed-loop-systems | The interventions | 2.5 | Any systems available in the future need to be able to show interoperability | Interoperability needs to be better defined here. Chances of Medtronic launching an interoperable system currently similar to a snowball's chance in hell |
| 503 | | information-about-hybrid-closed-loop-systems | The interventions | 2.6 | This is not an exhaustive list and other systems and interoperable component systems are available. | Guessing Ypsopump with CamAPS FX falls into this category |
| 528 | | committee-discussion | Comparators | 3.8 | | Having had to create DIY rtCGM from isCGM, it is incorrect to say the two are commensurate in terms of 'clinical effectiveness'. The difference is stark in terms of ability to control blood glucose preventatively, leaving patients to have to manufacture their own solutions to isCGM. |
| 546 | | committee-discussion | Evidence and generalisability | 3.2 | | Agree about it helping those that are difficult to help- recent patient reduced HbA1c from 122 to 56mmols - they have had intensive support without improvement for many years |
| 589 | | committee-discussion | Costs in the economic model | 3.13 | | Look at DIY systems and start supporting patients to use those and the drug company prices might start to drop. |
| 621 | | committee-discussion | Innovation | 3.15 | | Manufacturers of these devices (CGM and pumps) collect data from users. It is important that in negotiations with these manufacturers it is stressed that the ownership of the data should be regarded as the patients, or at the very least the NHS. Personally I have been in a hospital clinic when my Libre data was not available to the consultant. because they access the data through a third party website (LibreView). The data should be added automatically to the patient's NHS record and then the patient can determine who they choose to share this data with. |
| 661 | Novo Nordisk UK | information-about-hybrid-closed-loop-systems | The interventions | 2.5 | The choice of components or system is based on a person's preference. Any systems available in the future need to be able to show interoperability | We support the statement that the choice of components or system should be based on a person's preference. To ensure that people living with type 1 diabetes have sufficient opportunity to express their needs and preferences, we recommend that the wording is amended to make explicit reference to the need to adhere to a process of shared decision making between patients and clinicians in deciding which components and system is right for them.<br><br>We also support the statement that any systems available in the future need to be able to show interoperability. We believe this is a crucial principle in supporting choice for people with type 1 diabetes about how they manage their condition and to improve access to diabetes technology, making it easier for people with diabetes and for their healthcare professionals to link data and systems, to support the optimum management of their diabetes. |
| 756 | | information-about-hybrid- | The interventions | 2.6 | | Ypsopump also uses CamAPS FX |

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| | | closed-loop-systems | | | | |
| 71 | NHSE SE Region CYP Diabetes Transformation Clinical Leadership Team | information-about-hybrid-closed-loop-systems | Price | 2.9 | | Companies are going to have to reduce price substantially to meet measure of cost effectiveness of £20k/QALY – is this realistic?<br><br>In the committee meeting notes it states that the likelihood of HCL being cost effective at £20k/QALY is 21% and at £30k/QALY is 31% |
| 81 | | | | | | 2.<br>As a type 1 Diabetic I would say its important for an individual to use all available Hybrid systems with ease, and be happy with them, so a choice should be offered of type they prefer as they will be the ones wearing it 24 hours a day. I would personally feel the tubeless system to be a great way forward as a 67 year old waiting for first pump I would welcome that. As some people with anxiety due to diabetes and other problems this would be an easier option and less to worry about. This is my personal opinion but I know it depends on funding available but everyone should have choice. |
| 637 | | committee-discussion | Conclusion | 3.16 | So, there is uncertainty in the cost-effectiveness analyses with wide ranging ICERs depending on the scenarios tested. The committee concluded that at the current average price, HCL systems are unlikely to be cost effective, but it recognised the potential benefits to people. | Cost effectiveness<br><br>On this point of cost effectiveness, I hope it's ok to politely disagree with the conclusions outlined in this draft guidance doc.<br><br>Firstly, I currently use the non-HCL Omnipod Dash patch pump together with the Freestyle Libre 2 flash CGM to manage my T1D.<br><br>The soon-to-be released Omnipod 5 offers a HCL system that should cost the same as the Omnipod Dash but will be HCL-ready.<br><br>While the Omnipod 5 requires the Dexcom 6 real time CGM to offer it's HCL functions, it will potentially also soon work with the cheaper, widely available (within the UK) Dexcom One.<br><br>As I understand it, the Dexcom One is already cost-equivalent to the current Freestyle Libre 2.<br><br>I recognise that there will be additional costs for rolling out such HCl technology - NHS staff training, patient on-boarding and clinic care etc. - but doesn't this mean some HCL systems like that above, will be cost neutral compared to current choices when they become available?<br><br>Perhaps it's important for you to consider simple cost and cost neutrality as well as data driven clinical concepts like cost effectiveness?<br><br>This brings me to me to a second but related point.<br><br>I am not pregnant, nor under 18, and neither do I have poorly controlled blood sugars, so I would not qualify for a HCL under these draft guidelines. |

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| | | | | | | Similarly, to date, I have never qualified for a real time CGM – (although I gather, I may now be able to get the Dexcom One).<br><br>My point is that to acquire what I have always needed to achieve good control, I, like tens of thousands of other T1D's, have simply hacked my existing flash CGM using widely available computer codes.<br><br>This has given me a poor man's continuous CGM. All the data points I need. And good control.<br><br>I wonder what lengths you have gone to consider the available evidence from communities of self-motivated hackers for real world benefits of CGM? The same question now goes for HCL. Patients who have been using HCL for the longest time are the hackers.<br><br>Like tens of thousands of other Y1D's I too have now built my own HCL using similar readily available computer code on a compatible smartphone<br><br>I have done so because I have been a Type 1 Diabetic for over 40 years, have two serious complications that worry me greatly, and want something that unlike simple HBA1C, time-in-range, and cost-effectiveness cannot ever be quantified: to simply feel better.<br><br>My hacked CGM has given me this. Hope my new HCL will too – but<br>I am waiting to hear if an approved HCL will be readily available on the NHS before I fully turn to my self-built HCL system.<br><br>Intriguingly, a version of the self-made HCL system I have built – it's called Loop – has just received FDA clearance in the USA ( www.tidepool.org/tidepool-loop). As I understand it, for anyone with a smartphone wishing to build it, it will be cost-neutral when it is fully released.<br><br>However confident and ready I feel to use my own HCL, I would still rather have the CE marked, commercially released, and NHS-backed version, with-added-training and medical support thrown in.<br><br>Thank you very much for reading my comment – I'm ever so thankful for the hard work that goes into these exhaustive guidance reports and the great care I have always received from a brilliant NHS.<br><br>I wish everyone involved with this draft guidance well.<br><br>Best wishes,<br>[redacted] |

## THEME: THRESHOLD

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| 7 | PrescQIPP CIC | recommendations | 1 Recommendations | 1.1 | | Average HbA1c of 'around 64mmol/mol (8.0%)' is ambiguous and will lead to variation in implementation of the guidance, resulting in inequalities in access to treatment.<br><br>Clear unambiguous entry criteria need to be set out e.g. as specified in NICE TA151 which defines eligibility for an insulin pump as "HbA1c levels have remained high (that is, at 8.5% [69 mmol/mol] or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care." |
| 20 | | | | | | As a type 1 diabetic for 20+ years who has a A1C of approximately 6.5-7% I would recommend the system is made available for all type 1 diabetics. The mental strain required to maintain 'good' control of this condition is not necessarily linked to the individuals A1C level. An A1C level does not also show the full picture with spikes and dips in blood sugar levels. The long term benefits to individuals who are given the tools to better manage their condition are incalculably positive. What is calculable is the long term health benefits for well controlled diabetes and the financial, time and resource benefit to the NHS who will have fewer diabetics with health issues later down the line. |
| 21 | | | | | | I feel the HbA1c being set at 8% is unfair for the people who have a HbA1c under this. It would be much more fair to include everyone. |

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| 23 | | | | | | I know a lot of PwD who try very hard to control their diabetes and would have HbA1c<8% and to prevent them availing of the HCL does not seem fair or right and proper. I think that 1.1 should be wider so that people who are currently using all means at their disposal to control diabetes are given the opportunity of using HCL.<br>e.g. I know one young , 30s, person who has put themselves on a low carb diet to get better HbA1c results and he would not qualify if 1.1 is used.<br><br>Also, I use an insulin pump and I fairly insulin resistant and I have to change my canula site every 2 days after infisong approx 150 units. I have heard that preganant woman can use more than this daily so therefore would have to chnage their canula site every day, so maintaining god sites for the canula may become difficult for them. So, it sounds a good option, but their are practicalities like this that need to be considered.<br><br>1.4 - should read - HAS ATTENDED a t1 structured....<br><br>Also I have been using a DIY HCL for 3 years now, would I qualify for an NHS supplied version as because of the DIY system my HbA1c is well below the level stated in 1.1? |
| 24 | | recommendations | 1 Recommendations | 1.1 | | Speaking as a patient with T1D for over 30 years, the idea of introducing hybrid closed loop systems to the NHS is an exciting prospect; it provides the impression of a health service that is forward-looking, and intending to reduce long term costs as a result of complications; for many years it has not seemed as though it is the case.<br><br>I appreciate the intent with which these criteria have been set relating to the HbA1c value. Clearly, these systems are targeted at individuals who may benefit most from their usage.<br><br>However, as a patient whose HbA1c value falls below this threshold, I cannot help but be disappointed by the value ascribed, for a number |

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| | | | | | | of reasons.<br><br>Firstly, we have been here before; FGM/CGM has previously been prescribed within specific HbA1c ranges/other similar criteria, and subsequent to this decision, have then been suggested (by NICE) to the general population as it is clear there are more people who may benefit. I suspect this may be true of the closed loop systems, and by introducing this criteria, we are only inserting an artificial delay in terms of delivery nationwide. I urge the committee to be forward-looking, particularly given as I suspect a larger order with the healthcare companies involved in this consultation will result in a larger discount and a reduced per-patient cost.<br><br>Secondly, this may actively result in people, who are self-funding closed loop systems (pumps, rtCGM sensors, or both), manipulating their ongoing HbA1c results (and causing damage to their health temporarily) in an attempt to gain access to NHS funding for items that they are already paying for. Threshold values invariably have this effect, and I would urge the committee to provide decision-making capabilities to individual diabetes care centres, who have visibility of individuals' ongoing diabetes management, and would be in a position to support engaged patients, rather than leave them feeling like second-class citizens. Given that many diabetic specialist nurses are aware of these criteria, and may actively, or indirectly, encourage patients to fall within the criteria in a well-meaning attempt to get the best possible care for their patients, this problem cannot be overstated. I would be interested in the committee monitoring HbA1c values for well-controlled patients to see whether these increase in order to access appropriate funding.<br><br>Thirdly, the shift from child to adult care regimes. This funding will directly prohibit children who have already begun care regimes with hybrid closed loop systems from progressing with their pumps when they reach adulthood. The consequences of this may be dire, both from a physical and metal health capacity. I urge the committee to consider advancing care from children through to adulthood and not penalising them for growing up.<br><br>Fourthly, there are many individuals who simply control their diabetes as well as they can, and therefore do not meet these criteria. Diabetes is a lifelong condition and is a constant struggle, even for those most engaged with their illness and the many networks/communities/etc available to them. Mentally, it can be a burden. Providing access to new technology to support these individuals, who are doing well (but |

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| | | | | | | would like to do better) would be a rewarding choice for these patients. This is an opportunity for NICE to remove a postcode lottery/HbA1c lottery system, and equalise the care of diabetes regardless of whether an individual is above or below certain thresholds.<br><br>The NHS has done a fantastic job of caring for diabetics for many years, but the funding model for diabetes is antiquated, and I have no doubt the committee is aware of this. Please do not continue to apply barriers to entry for good diabetic care. Please do not add administrative burdens to an already burdensome illness. People should not have to fight with their diabetic nurses, endocrinologists, GPs and ICBs for access to technology that has been proven will improve the quality of their lives, and quite probably, extend them altogether. NICE and this committee are in a position to change this; I hope that you will. |
| 26 | | | | | | The HbA1c cut off is an improvement on NICE TA151 but this document ignores the burden that living with T1 places on individuals who work incredibly hard to achieve an HbA1c less than this.<br>I suspect people will let their control slip to access this techonology unless some formal screening of diabetes distress in included in the recommendations |
| 36 | | | | | | We are parents of a teenager with T1 . As a family we work so hard to maintain an HbA1C under 8mmol/l. We are constantly checking bloods and correcting, monitoring food, setting alarms at night to check on him so he does not have to. It has a massive psychological impact on the whole family. We feel it is grossly unfair to exclude those who work hard to stay in range from being eligible for the closed loop system. |

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| 41 | Bedfordshire, Milton Keynes, Luton Health and Care Partnership | recommendations | 1 Recommendations | 1.1 | average HbA1c of around 64 mmol/mol (8.0%) or more | The given HbA1c of 64mmol/mol could be ambiguous, however it would:<br><br>o Open up the options of CGM for existing CSII users who have a HBA1c of 64mmol/mol and can't get it lower.<br><br>o Allow us to consider CSII for patients using CGM or FGM at a lower HbA1c to current NICE for CSII (69mmol/mol). Clinician should have discretion in considering CSII start, because using CSII require prior patient education + engagement with clinical team (otherwise patient will not have sufficient skills to troubleshoot) |
| 51 | | | | | | It is important to understand that some people have artificially low HBA1C's because of overly prevalent hypoglycaemia. This means that an improvement of hba1c being defined as it going lower would be unfair to those who it could benefit from their hba1c being higher. Just because an individuals hba1c is not dramatically high does not mean they should be ignored when they could also benefit<br><br>The long term benefits of a closed loop system should be considered greatly not just the immediate upfront costs. |

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| 57 | | | | | | All diabetics have difficulty controlling their BG, not only those who have an HbA1c of 64 (8.0) or above. The document makes me feel I am being penalised for controlling my blood sugar so that it is lower than 64 but not in the non diabetic range. I still have mental strain, it still takes a lot of time out of my day, my family still suffer from mental load of living with a diabetic. Because I do all of this work on my diabetic control it does not mean that my body won't deteriorate because I am a diabetic and I should get the same help in controlling my BG with the closed loop as others and therefore improving my quality of life. I have been a diabetic for 50+ years and because of this do need help to stop complications. Am I being overlooked because I am older? Should I stop trying to control BG spikes and hypos so that I can be eligible for an integrated system? I feel that you are looking purely at the reduction of HbA1c as the main point and not considering the patient. Having had diabetes for so long means I am also at greater risk of hospitalisation and complications yet I am not going to be considered for an integrated pump because my HbA1c reduction will not be as great as some others who do not make the same effort in this as I do. Reducing HbA1c should not be the only measure of success. Exhaustion, burn out, mental fatigue, poor mood, sleep reduction for myself & family, worry about hypos are all major considerations and these are all relevant to me as well as those with a higher HbA1c. I urge you to consider widening the net to all diabetics who would benefit from the closed loop |

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| 58 | | | | | | It's a shame that once again the criteria for eligibility is being bad at managing your diabetes. What about those with good results like me who are in senior leadership role at work, caring for parents with Alzheimer's, menopausal and still go to great effort to keep in range. Ive read any thing can get my hands on about diabetes, am very strict with what I'll eat - low carb - exercise regularly and don't eat after 5pm which severely impacts my social life - and walking in the night to bolts. this behaviours how i keep in target. Everyone could do that but choose not too. I make Those behaviours to achieve HBA1C of 40 but also experience extreme mental fatigue and exhaustion and often in bed by 8:30 knackered. There is no let up with the constant threat of blindness, loss of limbs and kidney failure always on your mind. I hope this is extended to type 1's like myself too. |

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| 59 | | | | | | As a type 1 diabetic with an hba1c of 42, there is no way that I would be considered for a pump, let alone this system. Whilst I understand that these systems are very expensive and the money needs to be spent wisely, the whole system is so disheartening for many of us.<br><br>The press coverage states that 100000 type ones could benefit from this, but that leaves 300000 of us who won't. It feels like a 2 tier system, and the haves are about to have more, while the rest of us get nothing.<br><br>It is not possible to be slightly diabetic, or less diabetic than someone else. Personally my good control is achieved by an almost obsessive level of monitoring my glucose levels, and depriving myself of most carbs. This inevitably takes a massive mental toll. I do it because I have lost both friends and family members to the complications of diabetes, but it is so demotivating to know that by living so strictly I am depriving myself of the technology that could enable me to live more freely.<br><br>In summary, hurrah for the possibility of this becoming available for those currently desperately in need, but the basis of the NHS is that the same care is available to all, and this is so far from the truth of living with type 1 diabetes. Please please reconsider the requirements for qualifying for this life changing technology. |
| 85 | University Hospitals Dorset Diabetes Service | recommendations | 1 Recommendations | 1.1 | | I have read the background to the guidance formation and understand why an HbA1c of 64 mmol/mol might have been chosen following the findings from the NHSE HCL study. However the immediate obvious comment is that patients with type 1 diabetes maintaining good glycaemic control will miss out on the opportunity to receive funding for technology to help with diabetes management that would greatly improve her quality of life. |

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| 86 | University Hospitals Dorset Diabetes Service | recommendations | 1 Recommendations | 1.1 | | The decision to choose an HbA1c of 64 mmol/mol appears to be based on the criteria that we used for the NHS England trial in 570 participants for the hybrid closed-loop study. A number of other studies have shown that adults with an HbA1c of less than 64 mmol/mol still obtain benefits from a hybrid closed-loop system. I suspect that it is harder to prove cost effectiveness for the intervention in this group. |
| 91 | University Hospitals Dorset Diabetes Service | committee-discussion | Evidence and generalisability | 3.3 | | The NHSE pilot study is welcomed given that it provides an evidence base for HCL systems. However, its influence on the suggested guidance with regards to the HbA1c threshold where HCL systems can be considered does seem considerable. Clinicians are likely to face a considerable (and understandable) backlash from patients who are trying to maintain their HbA1c at less than 8.0% but who are prohibited from accessing HCL systems according to the NICE guidance proposal in its current format. |
| 99 | | recommendations | 1 Recommendations | 1.1 | | Although there is a need for those displaying hba1c levels of 8.0% and higher, in section 2.4 of this document you state that it is recommended for patients to have hba1c levels of 6.5% ot below. This leads me to ask, what about patients who are 6.6% to 7.9%, are they to be completely left out of this? Even if we take what is mentioned in section 3.7 into account?<br>Secondly, for how long does a patient need to have a hba1c of 8% before they can be considered? Six months, 12 months, 18 months, 24 months? By not specifiying a timeframe, this could harm access and cause disparity/inequality. |

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| 105 | | recommendations | | 1 | | Have you considered that people with an HbA1c lower than 64 may be experiencing the same burden of strain etc that you describe accurately. Access to HCL could support them to maintain or improve their HbA1c without the stress etc.<br>In addition setting this recommendation at 64 mmol/mol iprovides a perverse incentive for those with slightly lower HBA1c who may benefit from the system |
| 107 | | | | | | This technology should be made available to all Type 1 diabetics that want it, as there is proof that it makes a difference to HbA1c and Time in Range. This will then prove even more cost effective, as the number of people requiring treatment for neuropathy and other diabetic complications will be reduced! |
| 109 | | recommendations | 1 Recommendations | 1.1 | | Taking the NHS Constitution's requirement of mental wellbeing and working to the limits of science as above, there is no logical reason why approval should be limited to those with an Hba1c of 8% or above.<br><br>To achieve a Hba1c below 8% requires constant commitment 24/7/365, this constant commitment and its effects on life and mental wellbeing will be relieved by the use of HCL, as required by the NHS Constitution.<br><br>There will be similar mental wellbeing benefits to the family of the person with diabetes - who are also covered by the requirements of the NHS Constitution. |
| 122 | | | | | | 8% is a number, shouldnt be used to decide if someone has trouble controlling diabetes. I am at 6.8% but still have problems with Hypos, hence why the number is lower. Feel the criteria is a bit crap and always goes by a number which shouldnt be used as a distinguishing feature of someones control |

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| 143 | | | | | | I am 58 and have had type 1 diabetes for 31 years. Life has been very hard before technology advancement gave us Libre and now dexcom one. Pregnancy was a very difficult time. Access to a pump would be amazing (I'm MDI). CGM has changed my life and health. Access to closed loops is a dream scenario. It's truly impossible to put into words how much effort and energy we type 1s have to invest in being our own pancreas. To have artificial help through a closed loop is a dream scenario. I appreciate the cost involved however the cost of healthcare when we are in difficulty is huge already and we can avoid it with wider access to tech. Please remove the Hba1c condition. Closed loops should be available to all type 1s. |
| 153 | | | | | | I don't understand why you need to have a Hba1c of above 64mmol to qualify for this technology. As someone with type 1 diabetes it requires significant mental workload to keep my blood sugars in a reasonable range so that my hba1c is around 45 to 50mmol. As stated in the documents, the closed loop system could improve my quality of life greatly so it seems very unfair that I am being denied access to this because my blood sugar is too well controlled. Surely there will be many people who would purposely raise their Hba1c levels in order to access this technology? Have you considered the possible cost to the NHS of this? Also is there any actual reasoning behind the figure of 64mmol? why not 62? or 58? this seems poorly thought out does not seem to be explained. |

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| 154 | | | | | | I think it is a tremendous shame that you have to have such a high HbA1C in order to qualify for a hybrid closed loop. There are many people who are achieving very good HbA1Cs but only because they are working incredibly hard, at the huge expense of their personal and professional lives. A hybrid closed loop would have an enormous impact, particularly on their sleep and productivity. And if the cost benefit analysis including contribution to the UK GDP then the cost would definitely pay for itself! |
| 156 | | | | | | After diagnosis aged 4 almost 22 years ago my daughter has worked exceptionally hard to bring down her HbA1c. I am self funding her sensors to close the loop and feel that we are penalised for our hard work. Not to mention that my husband is drawing his pension.<br>Long term by keeping good control she is keeping herself as healthy as possible as well as saving the NHS a fortune in keeping complications at bay. Please consider those of us putting in the work before guidance that it can only be given to those with a higher HbA1c |
| 164 | | recommendations | | 1.1 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following: | Of course, people with a higher HbA1c will see a greater improvement, but this treatment should also be considered for people with well managed T1D (and a HbA1c below average) as this will greatly support their management. |

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| 165 | | recommendations | 1 Recommendations | 1.5 | Evidence suggests that the systems appear to be more effective for people with higher long-term average blood glucose (HbA1c) levels. But they are also effective for people with average HbA1c levels (the UK average HbA1c for people using a pump is around 64 mmol/mol [8.0%]). | Of course, people with a higher HbA1c will see a greater improvement, but this treatment should also be considered for people with well managed T1D (and a HbA1c below average) as this will greatly support their management. |
| 166 | | | | | | Why is the criteria for being able to qualify for the closed loop set at HBA1c 8%?<br>The target rate set in NICE NG17 is <6.5%.<br><br>By suggesting in this draft people can't qualify between 6.5% and 8% is not acceptable and allows people to suffer with complications and possible early death for a cost of just over £5000 per year.<br>The cost per QALY should ensure anyone not reaching a target HBA1c less than 6.5% can benefit from this technology. |
| 183 | | recommendations | 1 Recommendations | 1.1 | | Often people with lower HBa1c actually work much harder and have a much higher mental load in order to achieve this.<br><br>It would be great if this could be rewarded with a closed loop system, rather than just those people with a higher HBa1c (although I know these people also work very hard).<br><br>Please remove the stipulated HBA1c and maybe consider the lengths an individual has gone to to achieve a great blood glucose and whether this alone deserves closed loop access.<br><br>Even better, offer it to all T1s, I'm sure cost analysis long term would be in favour of this. |
| 184 | | | | | | As the partner of somebody with T1D, I'm excited about the prospect of hybrid closed loops systems that have the capacity to be genuinely life-changing, however I would encourage a further review of the eligibility criteria. |

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| | | | | | | Whilst I recognise that those who are currently struggling to manage their condition are high priority, I believe use cases should be expanded for two reasons:<br><br>1. As a preventative measure: long-term healthcare implications from T1D are serious for affected individuals, but also consume a significant amount of NHS resource. It is my belief that a preventative approach can hugely increase quality of life for diabetics and, ultimately, reduce reliance on the NHS later in life.<br><br>2. For mental health of patients: my partner currently uses flash monitoring and a pump (subcutaneous infusion) which has meaningfully allowed him better control vs. manual blood tests and injections. However, this still requires constant attention and there are periods of huge frustration and upset when things do not go as planned. He never gets a day off, we wake frequently in the night to intervene, and he works hard to maintain a HbA1c as low as possible. There is a real risk that patients do themselves harm by allowing their condition to deteriorate in order to qualify for the freedom afforded by hybrid closed loop systems. I don't believe we should minimise the huge effort undertaken by T1Ds to control the condition, assuming they are 'OK' because the condition is largely controlled.<br><br>Alongside this, making systems more widely available will surely help to address high cost, enabling negotiation of lower rates based on order volumes. I believe the tech should be used as far as is reasonable.<br><br>Please take a broader view rather than a purely numerical focus - it will enhance so many lives. |
| 198 | | recommendations | 1 Recommendations | 1.5 | So, to ensure wider access, hybrid closed loop systems are recommended for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition, | Many people have difficulty managing their condition but somehow manage to keep their HbA1c under 64mmol/mol. They might have a 'good' HbA1c, but their quality of life is not good because of the relentless nature of T1D. |
| 201 | | committee-discussion | People with type 1 diabetes, families and carers | 3.1 | The committee concluded that managing type 1 diabetes is a substantial mental burden on people with diabetes and their families. It | Great, so why will HCL only be for those with an HbA1c over 64mmol/mol? |

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| | | | | | further concluded that automated technologies such as hybrid closed loop (HCL) systems can reduce some of the burden, and improve quality of life for people, their families and carers. | |
| 205 | | committee-discussion | Conclusion | 3.16 | people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0%) people who are pregnant or planning a pregnancy. | Great for these groups of people, I'm pleased for them. Not good news at all for those who long to have some relief from the relentless nature of T1D by way of an HCL but have an HbA1c which is too 'good'. |
| 206 | | | | | | Hybrid closed look should be for everyone with type 1 / 1.5 LADA Diabetes is too hard to manage daily. This technology should be made available and open to all people with type 1/1.5 Diabetes |
| 207 | | | | | | I think it is unreasonable to offer closed loop just based on an Hba1c number. Many people could benefit hugely who are currently operating below that number but have mental health issues due to the amount of time that has to be devoted to T1d.<br><br>Sections of the community already face discrimination in support & tech. There is nothing in this document that aims to solve that issue. |

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| 210 | | recommendations | 1 Recommendations | 1.1 | | This recommendation discriminates against patients who have an HbA1c of less than 8 %. From personal experience, I can say that despite their perceived success, achieving a lower HbA1c (e.g. mine is 6.1%) does not come without huge physical and emotional personal burden which entails tolerating many, many hypoglycaemic episodes (<3.9) to offset the many hyperglycaemic (>9.9) results. Have the incidence and detrimental effects of hypoglycaemia and quality of life of patients not using HCL been fully considered and compared with those on HCL treatment? Have any studies/evidence included patients with T1D with HbA1c of < 8% been taken into account? |
| 215 | | | | | | It is not only discriminate to offer it to pregnant / trying to get pregnant and poorly managed it will cause people who managing it well (which is no easy task) to badly manage it and purposely increase their a1c to be accepted for it. This is dangerous and unethical to make people feel this is their only way to be provided with this equipment.<br><br>Surely the cost will offset itself long term. People will have better A1c and therefore not as many repercussions health wise later in life.<br><br>I detest the comments about if it is fair to the tax payer in articles. No ones asks if MP expenses are fair to the tax payers. |

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| 216 | | | | | | Good afternoon,<br><br>It is wonderful the ptofrsss that has been made, however I feel that this penalises those with type 1 diabetes that have worked so hard to get and keep tight control. My daughter is 14 next month, she has been diagnosed 12 years this year. Her control is excellent usually around 48 however this comes with intense management. My daughter is continuing with this relentless regime with hope that there will be options like the closed loop. I fear that she and other diabetics will stop the good control in order to be able to access technology like this. It would be unfair that only certain haha1c would be able to access this. I also fear severe mental health repression if children and adults with good control do not have this opportunity. It's like government policy those that work are entitled to nothing and those that don't get everything, this should not be the same for medical conditions. |
| 237 | | | | | | I am concerned that these plans appear to target only a specific couple of groups: women who are (or plan to become) pregnant, and those with poor blood sugar level control. It seems to unfairly ignore or discriminate against other groups, and even penalises those who make great efforts to maintain good control and pursue a healthy lifestyle and diet. I do not believe that targeting specific groups, instead of a blanket, unbiased approach, is a fair or ethical way to tackle Type 1 diabetes. |
| 238 | | recommendations | 1 Recommendations | 1.1 | | Why should this be limited to those people who struggle to control their blood sugars. The challenge faced by those with an average HbA1c lower than 8 is the same.<br><br>This is like saying we only need to add parking sensors to the cars of those people who have previously hit something with their bumpers. |

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| 240 | | committee-discussion | Conclusion | 3.16 | | HCL should be readily available treatment for those people living with Type 1 diabetes having difficulties managing the condition and a HbA1c above 64 mmol/mol but also available to those who have a lower HbA1c.<br><br>See my earlier car parking sensor analogy. |
| 244 | | committee-discussion | Conclusion | 3.16 | people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0%) | The recommendation should read OR not AND. Hybrid closed loops are ideal for anyone who is struggling to control their diabetes - it takes away so much of the cognitive load and reduces diabetes distress. It is absurd that a patient with an HbA1c of 60mmol/mol who is struggling to manage with endless manual calculations, temporary basal rates and corrections might be denied HCL. |
| 245 | | | | | | This is a fantastic step forward and cannot wait to adopt this approach after 25 years of manual dosing. However, I worry, as was the case with qualifying for a flash glucose monitor that as someone that tries INCREDIBLY hard to manage my condition and does very well will the bottom of the pile for moving to the system. Why punish those that engage, and take great care and effort (but know we can still do better)? I encourage you to make this available for all that want it and take the long term view that whilst expensive initially, the long term costs of mis-management will be higher. |
| 249 | | | | | | Thank you so much for even considering this - it will make such a massive difference to those who will benefit from it. My main concern as a current user of the tandem t-slim2 (funded by the Nhs) and a Dexcom g6 user (funded my me) I am worried that because of my pump, my hba1c will not meet the criteria. Hence I will always have to fund the Dexcom. This is a big financial commitment and doesn't always immediately seems fair that some people qualify for both to be funded on the NHS but not all. It would be good if other considerations (in addition to hba1c could be reviewed as part of the qualification process). Many thanks |

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| 250 | | recommendations | 1 Recommendations | 1.1 | | Why is it only considered for those who have been unable to get hba1c below64mmol? Many people work extremely hard, causing much distress to achieve a good result and it seems they are being penalised for working so hard. |
| 258 | | | | | | All people living with type 1 should have access to this life-changing technology in order to improve their future and save money on the NHS in the long run. People who tirelessly manage the condition are rewarded with no support and less technology because of their efforts. It is mentally draining to live with and an unfair system which is discriminatory. |
| 262 | | | | | | I am very disappointed that the proposed criteria for access to this technology will exclude people with Hba1c lower than 8.0%. Many people with type 1 diabetes achieve a lower Hba1c than this, but at a huge cost to their mental health and well-being (including nightly disrupted sleep due to the need to monitor blood glucose and treat nocturnal hypoglycaemia or hyperglycaemia). The cost to the NHS of future “diabetes burnout” in these people has not been considered.<br><br>Also, Hba1c as a single data item excludes the impact of a wide standard deviation around average blood glucose for an individual. If blood glucose routinely varies from high to low levels, the Hba1c may be below 8.0%, but the adverse health consequences will be greater than for people with a slightly higher Hba1c whose blood glucose is relatively stable.<br><br>Another point to consider is that of co-morbidities. For example, if a patient has an Hba1c lower than 8.0% and also has proteinuria, should that extra risk not be considered when giving them access to hybrid closed loop technology? The future cost saving to the NHS in preventing the deterioration of an existing co-morbidity should be taken into account.<br><br>Finally, this proposed criteria creates a huge disincentive for people with type 1 diabetes to look after their condition to the best of their ability. It “rewards” those who are perhaps more careless in their self-care, and “punishes” those who micro-manage their condition to the detriment of their mental health. In fact, those who currently achieve lower Hba1c may have the best attitude and outlook to make the most effective use of this closed loop technology. |

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| | | | | | | I believe that all people with type 1 diabetes (a protected category under the Equality Act) should have access to this technology. |
| 264 | | recommendations | 1 Recommendations | 1.1 | | HbA1c boundaries feel very outdated in this guideline, firstly you run the risk of people deliberately running blood sugar high in order to get access to this system and secondly you are punishing people who are able to maintain better control by denying them access. This boundary also takes absolutely no consideration of the significant psychological factors present in those who manage to maintain an HBA1c of less than 8% including those who develop restrictive food practices, those who develop obsessional attitudes to management, those who teeter on the verge of burnout constantly, those who have significant anxiety regarding hyperglycemia and a plethora of other Diabetes related Distress states. It is stated later in the guidance 'that these systems' may reduce the mental load and improve people's quality of life.' so do only people with an HbA1c over 8% deserve that as a consideration? There are plenty of well-validated Diabetes Distress measures that could be used here. |
| 268 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | This is what I said in my initial comments- surely closed loop is suitable to help with this and should be one of the priority groups. |
| 273 | | | | | | I do not understand the reason for people with low hba1c being discriminated against and not being given access to this. Surely the fact they are engaged with their intensive diabetes management with positive results means they will provide good data for this. |
| 276 | | recommendations | 1 Recommendations | 1.1 | average HbA1c of around 64 mmol/mol (8.0%) | This disincentives those who are doing their best to maintain lower A1Cs with conventional treatment methods. Setting a threshold of 64mmol/mol will simply lead to those who are controlling diabetes well to deliberately relax their control to increase their eligibility |

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| 285 | | committee-discussion | Conclusion | 3.16 | This effect appears to be greater for people with higher baseline HbA1c levels | This is a red herring. Someone with well-controlled diabetes has simply less scope to improve their treatment, and their excellent control is likely the product of taking on a far greater mental load to achieve it. The most relevant question should be if the patient can use the treatment to maintain as near normal blood sugar levels as possible, not whether or not they can significantly improve them. |
| 300 | | | | | | I was intending and probably now will go ahead and build my own looping system as although I'm not amazingly technical I do have the technology using a Dash Omnipod , Libre and Miaomiao. I would have much preferred to use the official way to loop but can see this will take many years and after 38 years a type 1 I'm exhausted by the time I spend achieving regular good HBa1c's of 39/40 each year. My consultant has recommended I wait for the officially approved route but realistically I know this will take too long.<br><br>The only immediate way is to raise my HBa1c to 64 which seems counter intuitive so I would become eligible for looping. I would ask that this criteria is changed to include perhaps more motivated type 1s which would also demonstrate more immediately successful results. I do understand the cash constraints in these current times. |
| 334 | | recommendations | 1 Recommendations | 1.1 | | In my view picking a HbA1c of 8% is arbitrary. The reasons why someone has got an HbA1c of 8% is not explored and may be more linked to a lack of structured education, support and readiness to change. |

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| 338 | | recommendations | 1 Recommendations | 1.5 | | People can have difficulty managing their diabetes despite having a HbA1c under 8% (which is very high). Keeping blood glucose higher does not equal more difficulty, to some extent this includes less work, less hypos, less checking and to some extent less worries at least short term. Using 8% as the measure of who will get access or not would penalise those already working very hard on keeping their blood glucose in range and with associated risks (night time hypos etc) constant checking. |
| 345 | Children and Young People's North East and North Cumbria Diabetes Network | recommendations | 1 Recommendations | 1.5 | | 1. We challenge the chosen HbA1c cut off, and recommend it is lowered for children. Even in individuals who achieve optimal HbA1c under 53mmol/mol (in this study), a 2-fold risk in death from cardiovascular disease is seen, and this is most pronounced in those diagnosed with T1D under the age of 10 years. This translates to a 16-year reduced life expectancy in individuals with T1D (Rawshani Lancet 2018, Lind NEJM 2914). Further, the EDIC study demonstrated that early glycaemic control influences future long term diabetes complications, with lower levels of glycaemia in the first years at onset saving patient and health systems burden related to diabetes complications, this has been termed ‘’metabolic memory’’ (Steffes JAMA 2003, Lachin Diab Care 2021). It is therefore essential that we maintain good metabolic control by providing intensive management from diagnosis in children, by facilitating access to HCL.<br><br>We recommend lowering the target of HbA1c use to 48mmol/mol in children, who have the highest cardiovascular risks and risks of premature death over a lifetime, directly related to glycaemic load due to duration of diabetes. We also recommend that HbA1c cut offs align (and are reduced) for insulin pump therapy. |

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| 356 | | | | | | If it is safe then it should be given to all type one diabetes sufferers. This may help with economies of scale and be beneficial as it will reduce the long term health costs for type 1 sufferers |

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| 387 | | recommendations | 1 Recommendations | 1.5 | and have an HbA1c level of around 64 mmol/mol (8.0%) or more | As the parents of a type 1 diabetic child (now teenager) we have focused very hard on maintaining as low a HbA1c level as possible. Prior to being part of this trial we already had rigged up some monitoring alerts (using Nightscout open source tech). This gave us great visibility of her blood glucose levels but we still needed to act on this information. In practice this meant being woken up many times a week, getting out of bed and adjusting insulin levels or giving hypo-treatments. This was effective at keeping my daughter in range for a higher proportion of the time and her HbA1c at a good level, however, it was exhausting.<br><br>The new closed loop system has been incredibly life changing - particularly for this night time period. Nocturnal levels are now usually very steady and close to target. As we are asleep for about 30% of each day I think it's only possible to maintain a good low HbA1c level if this part of the day is being dealt with effectively and this is obviously much more challenging if it requires the person (or carers) to actively manage this.<br><br>For this reason I think limiting the closed loop system to people who have higher average HbA1c levels (about 8%) penalises people who are working very hard and experience 'substantial mental load for people with type 1 diabetes (and their families or carers)' (taken from the report's recommendations - ‘Why the committee made these recommendations’ section). Many diabetics may eventually find that it's just easier to have a higher HbA1c level rather than put in the considerable personal effort required to keep below this level without the help of the closed loop system - a perverse incentive. |

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| 394 | | | | | | Diabetes control is paramount to the long term health of an individual with type 1. The new closed loop systems offer those with type 1 the opportunity to have a life which not only reinforces this but also gives them a freedom which is denied with this condition. Parents of children with type 1 fight hard for excellent control but this comes at a great cost to them and the child. Diabetes burnout often creating significant mental health episodes for all. To prescribe this option based upon an HBA1C is short sighted and counterintuitive. This therapy will ultimately save the NHS millions with hospital stays reduced long term complications minimised and overall patient well being improved. The community have waited years for this treatment and now through a short sighted view will have it taken away unless they allow themselves to have poor control. The physical and emotional impacts of this condition are profound and to deny people this therapy will have far reaching consequences on the NHS for years to come. This battle was had with CGM and NICE guidelines changed due to the benefits this is exactly the same situation again. Treatment for a chronic condition should be the best on offer. Type 1 is unpredictable and erratic and this provides the NHS with the opportunity to create better long term outcomes for all with this condition. Those under the age of 18 suffer erratic numbers and control as hormones and insulin struggle to cope with the demands each expects of the body. This is only managed with sheer hard work from parents to keep their children safe and in range. Closed loop therapy should not be seen as a possibility it should be seen as a necessity particularly for those under 18s who live with this chronic limiting condition. |

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| 406 | | | | | | The recommendation to allow closed loop technology as a way of treating Type 1 diabetes is very welcomed and needed as the technology is widely available from multiple pump and cgm providers. However the implementation of it being restricted to those whose Hba1c is over 8mmol is concerning as Hba1c does not reflect the effort and struggles a type 1 diabetic goes through each day to manage their disease. A person with type 1 diabetes can have a Hba1c that is lower than 8mmol but struggle daily to achieve this, altering their lifestyle and dedicating a large proportion of time to achieve this. Being allowed closed loop technology would reduce this burden, allow a more flexible lifestyle and improve quality of life immensely.<br>Therefore looping should also be recommended for those who's quality of life would be improved from having the technology. |

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| 416 | British Society For Paediatric Endocrinology and Diabetes | recommendations | 1 Recommendations | 1.5 | Why the committee made these recommendations | We challenge the chosen HbA1c cut off, and recommend that it is lowered for children, to align with the NICE recommendations of an HbA1c target below 48mmol/mol.<br><br>There is a 16-year reduced life expectancy in individuals with T1D (Rawshani Lancet 2018). Even in individuals who achieve optimal HbA1c under 6.9% (<52mmol/mol), a 2-fold increased risk in death from cardiovascular disease is seen (Lind NEJM 2914). Further, the EDIC study demonstrated that early glycaemic control influences future long term diabetes complications, with lower levels of glycaemia in the first years at onset, saving patient and health systems the burden related to diabetes complications, a phenomenon termed ''metabolic memory'' (Steffes JAMA 2003, Lachin Diab Care 2021).<br>In addition to the influence of glycaemia on long term health and mortality, there is inadequate mention of the impact of T1D on parenting and family stress, quality of life for the child and parents, school attendance, educational attainment, the effect on parental employment, and mental health, which needs to be considered (Kimbell BMC Pediatrics 2021).<br><br>We therefore recommend lowering the target of HbA1c to 48mmol/mo. This cut off aligns with the NICE recommendations to achieve a target HbA1c of below 48mmol/mol in T1D.<br>We also recommend that HbA1c cut offs align (and are reduced) for insulin pump therapy (TA151). |

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| 426 | | recommendations | 1 Recommendations | 1.1 | 8.0 | I feel this cut off minimises and fails to acknowledge the hard work I put is as an adult with type 1 on MDI and dexcom with a HbA1c of 50-60.<br>I also work in type 1 diabetes as a dietitian and I see how much work and how much of a burden it is for children and adults to plan their life around diabetes in order to minimise the risk of complications which looms over them following diagnosis.<br>It is not fair that those with a lower HbA1c have reduced access to technology simply because they are working hard to manage their diabetes. A HbA1c <8% does not mean the daily burden of diabetes is any less, if anything the burden is perhaps more given the work, sacrifice and focus on health that achieving tighter control demands. Patients should not be forced to choose between better control and accessing quality of life saving technology. |
| 437 | | recommendations | 1 Recommendations | 1.1 | for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following: | I think this is unfair on people who work really hard on managing their glucose levels. The reason for some people having poor levels is because they can't be bothered looking after themselves. It would be rewarding a lack of self-care in some cases. |
| 439 | | recommendations | 1 Recommendations | 1.5 | Continuously managing blood glucose levels is a substantial mental load for people with type 1 diabetes (and their families or carers). | People work very hard to get their levels at a decent level. Even people with good hba1cs should be entitled to a closed loop system. My daughter has type 1 diabetes, currently wiht a good hba1c, and we are regularly up at night to treat highs and lows. Why should we not be entitled to closed loop? We lose out on a lot of sleep and it causes a lot of stress. |

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| 451 | | committee-discussion | Conclusion | 3.16 | people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0%) | No - it should be recommended for everyone with T1. Those with good levels put in a lot of work to maintain them - some of the stress needs taking away.<br>Has any research been done on those with poor/good levels and how much time they spend managing their condition? It would probably show that those with good levels are even more sleep deprived and stressed than those with poor levels. |
| 454 | Children & Young People's Diabetes Team, Somerset Foundation Trust | recommendations | 1 Recommendations | 1.1 | | Some concern that purely using the HbA1c cutoff of 64 mmol/mol is inadequate and creates the following issues:<br><br>1. This is a very significant proportion of our cohort and while we want to deliver this as quickly as possible, what constitutes appropriate workforce to safely deliver this in full needs to be addressed.<br><br>2. Concern that only recommending HbA1c 64 mmol/mol or above as criteria for recommendation may result in a perverse incentive to patients who have more tight control to deliberately relax that in order to be eligible to use this therapy.<br><br>3. This cut-off appears to have been taken from adult literature. Children should be seen as having unique needs. They will live with diabetes for far longer and so cost benefit from reducing complications would be greater. The average HbA1c may be lower in children than adults, especially earlier in their diagnosis, so this could mean more restrictive prescribing for this vulnerable cohort. We suggest scrapping the cut-off HbA1c of 64 mmol/mol in children altogether. It may be better to recommend to the whole paediatric age group, or if must be targetted therapy, use different criteria. These may include severe hypo's / hypo unawareness, QoL measures, diabetes distress, parental / carer burden of care, recurrent DKA, additional complex needs.<br><br>If keeping with HbA1c 64mmol/mol recommendation for all people, we feel that other criteria must also be included. Specifically:<br>A) For Children & Young People particularly, Quality of Life for them and also care burden for parents and carers, e.g. the overnight caring demands should be an element of eligibility considerations.<br><br>B) People who experience severe hypoglycaemic events. |

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| 468 | | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | | As with the introduction of 'flash' glucose monitoring, the guidelines might encourage some diabetics to worsen their self-care in order to increase eligibility for this system. |
| 469 | | recommendations | 1 Recommendations | 1.1 | | This technology should not be limited to only those with a Hba1c of above 64. This is because those with a hba1c lower than this more likely than not put a lot of effort, thought, time, and energy into lowering their hba1c. This burden needs to be eased by providing the technology to all with diabetes, regardless of hba1c. |
| 473 | | | | | | The HbA1C limit to qualify for this is set at 8% so this doesn't encourage people to control their diabetes well.<br>If they have poorly controlled diabetes, they will qualify for this whereas someone who works hard to control their diabetes will not qualify. Good control takes hard work and should be recognised by giving those with good control the same opportunities as those who don't. |
| 474 | | | | | | Closed loop systems should be made available to all type 1 diabetics. Those with HBA1C below 64 might be ‘doing well’ but the effort involved to keep a lower HBA1C levels is tremendous and can involved 100+ extra decisions per day. Risking diabetic burnout and eating disorders. Closed loop systems for all would bring T1’s in line with no diabetics, who have a functioning pancreas and therefore don’t have to put the immense effort in to managing their blood sugars. Closed loop systems for all would afford diabetics a degree of normality and flexibility with eating and surely must save money in the long run. |

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| 477 | | | | | | All this is very nice but we need to see insulin pump technology rolled out to all diabetics. By putting criteria like 8% or higher HbA1c you push some people into running higher blood sugars to get to an HbA1c above that number. It also creates bad feelings in those who manage to keep to below levels like 8 as if we are forgotten. As someone who after 10 years of asking managed to get an insulin pump the change is immense and not having to worry about needle phobics when eating in public is amazing. With looping technology to remove the 180 extra decisions I have to make a day to keep at an HbA1c below 8 which looping would be amazing. |
| 486 | | | | | | My partner and I are parents to a young child of six years old who was diagnosed with type 1 diabetes at the age of two years old. We also have my sister-in-law who was diagnosed with type 1 diabetes at 41 in the last couple of years.<br><br>We appreciate the opportunity to respond to this consultation and we are pleased that the hybrid closed loop system is being considered. However we do strongly disagree with the threshold of 64 mmol/ mol that has been suggested in the consultation. We would actually like to see this threshold removed as an indicator of getting access to this hybrid closed loop technology. We feel this would hugely limit the number of families, young people and adults getting access to what we feel maybe a life changing piece of technology. The threshold is far too high and ignores the numerous judgements and calculations that are constantly having to be done to keep numbers at a good level. Our daughter is on a pump and we work tirelessly to keep numbers close to the 48 mmol/ mol range. There is a lot of work that still needs to go into the managing of type 1 diabetes even when on a pump to keep her in range on a daily basis. We have to initiate temporary basals most evenings to either reduce the insulin due to the night time hypoglycaemia (hypos) episodes and on other nights are having to adjust the pump to a temporary basal to increase the insulin overnight so that the hyperglycaemia (hyper) episodes come back down to a normal range during her sleep. It can be quite petrifying to see her go so low in her sleep and to have a system that could know when to reduce or stop the insulin at these moments would be a game changer for us.<br><br>Over the past few years we as parents have both suffered from care |

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| | | | | | | givers burnout and have had to change our jobs to keep on top of things. We feel as parents that having access to hybrid closed loop systems can take away some of this burden and help to alleviate that caregiver anxiety that still happens. We also feel that whilst our daughter's numbers will look good over a three month period her daily charts can look incredibly erratic and we do have concerns that this affects her concentration at school as diabetes is constantly vying for her attention between hypos and hypers.<br><br>We would like the committee to reconsider this threshold so that more families can have access to this life changing technology and have a better quality of life. We do not want to be penalised for having good numbers by being denied access to the technology that can improve quality of life and prevent future complications. As our child is so young we do have concerns that there could be complications in the future and we would like to mitigate this as much as possible so she can lead a wonderful, normal healthy life.<br><br>Kind regards<br><br>[redacted] |

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| 488 | | | | | | Unfortunately the recommendation fails to deliver an optimum level of care to patients with T1DM. This is due to the criteria limiting access to the technology, which the patient experts have attempted to highlight as a key limitation of previous criteria relating to T1DM care and access to assistive technology. A patient's Hba1c test result should not be solely representative of a patient's need for technology access. To illustrate this, the following scenario is perfectly feasible:<br>Person A - On MDI - approx 8 injections per day to manage levels, including overnight injections and hypo treating, and corrections during the day. Significantly limits carb content of meals, generally avoids snacking and will bolus for all snacks consumed, avoids eating out, and limits exercise and other activities due to excess hypos/hypers. Achieves Hba1C of 55, considered by criteria not to require additional technology.<br>Person B - Also on MDI - injects approx 4 times per day, does not inject overnight and let's their levels run a little higher to avoid hypos at night. Eats normal carbohydrate meals, does snack but will bolus only if certain carb content, eats out occasionally and exercises as much as pre-diagnosis. As a result achieves Hba1C of 65 and is considered to require additional technology to help management.<br>Neither patient is neglecting their diabetes management, but it would be impossible to say that one patient is more in need, or deserving of, additional technology access than the other. In the above illustration, it could even be argued that Person A would get the greater health and quality of life benefit from the technology access. This demonstrates a clear and fundamental limitation of the eligibility criteria which could be viewed a very frustrating and demoralising to those achieving lower Hba1C results as a result of significant personal exertion and self-limitation.<br>As with access to insulin pumps in general, and glucose monitors previously, the criteria does not sufficiently address the social, mental and physical impacts that could be addressed through technology access, due to a focus plainly on the more measurable and direct consequences such as Hba1C. It is concerning that the review papers document in clear detail the magnitude of improvements to patient health and quality of life, indicating that the technology is viewed as the optimum care path for patients with T1DM, but the majority will nevertheless not be eligible for the treatment. The criteria proposed in the draft document will result in many in need of greater technology access being told once again that they are not eligible for the superior treatments which are made available to other patients, and unfortunately it is not as straightforward as using Hba1C as a barometer for identifying those most in need, as there is a lot of context behind each test result which would contradict the aims of the |

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| | | | | | | criteria. If approved in it's draft form, the criteria would increase the issue of technology access whereby patients are disincentivised from managing their condition as best they can due to feeling punished for achieving positive outcomes from their input. I would ask that NICE reviews the criteria for eligibility to ensure the technology is accessible to all those living with Type 1 Diabetes, given the clear clinical benefit identified for the research papers. |
| 489 | | | | | | I am pleased to see that hybrid closed loop systems are being reviewed as an option for type 1 diabetics. My greatest concern is that you want to make them only available to patients with above optimum HbA1c levels. Yes - their levels will undoubtedly improve with HCL, however those patients with 'acceptable' levels work hard and put themselves under constant pressure to do so resulting in untold stress which impacts their day to day lives. Improvement in diabetes care is not just about numbers, it is about giving patients a freedom of choice and help to live as normal a life as possible without the stress of their treatment hanging over them. |

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| 493 | | | | | | Couldn't agree more with Clinical Need. Exactly why mental health and sleep deprivation must form part of this criteria.<br><br>Those with good A1Cs will sleep less - that's a fact. That's because we use our existing tech to the best of our ability, setting alarms at night when high which wake us. Other T1s I know who have higher A1Cs than me turn off their high alarms at night so they can sleep. Yet your current guidelines will help them, not me. Those with good A1Cs are also at higher risk of hypos, as there's less room for error. Another way a HCL can help. |
| 509 | | recommendations | 1 Recommendations | 1.1 | | This should be available to all with type 1 diabetes. This criteria excludes those who would benefit most from looping. And potentially puts access to looping in the hands of those who may have zero interest in using it or using it properly. This criteria doesn't not take into account the mental health benefits and quality of life benefits of access to it. Plus the actual cost saving to the NHS by staying well and out of hospital, and the long term health benefits with avoiding diabetes related complications. This is poor choice of wording to suggest access be given to those 'having difficulty managing their diabetes'. Why are you rewarding those that may be not taking care of their diabetes and punishing those that do take the upmost care of their diabetes, this is all wrong. |
| 512 | | | | | | This life changing treatment should be made available to ALL Type 1 diabetics. To do otherwise is to penalize the sensible people who work studiously to control their glucose levels all day, every day. |

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| 517 | | | | | | As a type 1 diabetic, overall I think that this is a sound basis for providing recommendations, and a wide range of evidence has been reviewed. However, the evidence for recommending HbA1c threshold doesn't seem strong - particularly given the patient expert evidence on quality of life concerns, and that these things are known to be underestimated in the cost efficiency model - and the suggested threshold of 8.0% does not match the clinical guideline of <=6.5%. |
| 518 | | recommendations | 1 Recommendations | 1.1 | people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more | These two things are not mutually exclusive as they are presented here. A person with diabetes could be having a significant trouble managing their condition but keeping their HbA1c below 8.0. Arguably, these people have more to gain from access to closed loop systems than people who have a higher HbA1c but are more comfortable with their management.<br><br>In addition, having an HbA1c threshold could create incentives for people to worsen their management so that they could be eligible especially if they are already finding it difficult. |
| 521 | | recommendations | | 1.5 | But they are also effective for people with average HbA1c levels (the UK average HbA1c for people using a pump is around 64 mmol/mol [8.0%]). So, to ensure wider access, hybrid closed loop systems are recommended for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition, and have an HbA1c level of around 64 mmol/mol (8.0%) or more | I don't really think that an HbA1c threshold is suitable here in any event, but if one is to be used then perhaps it should be based on clinical guidance rather than the average of what people on insulin pumps can currently achieve. This in part because that threshold can never include the whole diabetic population regardless of their management as half of the insulin pump population will be below the average already.<br><br>Would NICE's overall guideline of <=6.5% suggest that a baseline of >6.5% is more clinically appropriate? |

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| 522 | | committee-discussion | 3 Committee discussion | 3.16 | HCL systems should be recommended for: people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0%) | In an ideal world, HCL systems should be recommended for people with type 1 diabetes who are having difficulty managing their condition - without an HbA1c threshold - or that the threshold should be the same as the clinical target from NICE. Otherwise it creates a grey area of people at increased clinical risk but who are not eligible for further support. In turn, this could create incentives for people to worsen their management, and increase their risk, to try to meet the criteria. |
| 524 | | recommendations | 1 Recommendations | 1.1 | | Hybrid closed loop (HCL) is only recommended for "people who are having difficulty managing their condition AND have an average HbA1c of around 8.0%.<br><br>Page 3 of the Committee papers however describes people with type1 "who are having difficulties managing their condition" as including "not maintaining HbA1c levels of 6.5% or below"<br>If 'difficulty' includes anyone with an HbA1c over 6.5%, then these people should all be offered HCL. |

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| 535 | | | | | | Why recommend for those with 8% or more? There has to be some element of parameter but please consider that everyone with T1D works incredibly hard to manage their critical condition and given the many thousands of factors, some may be below 8% but be foregoing other elements of quality of life that aren't visible. Would those people be eligible if they decided to neglect their control for e.g. a year in order to make themselves eligible? Please consider and maybe clarify why 8% has been chosen if A1C is meant to be lower than 6.5%... Is it because HCL provides benefit of 1.5%? If so, that is not a great/fair way of doing so and thereby potentially excluding thousands.<br><br>Essential that it is fully recognised that cost-effectiveness has so many factors and not just at point of purchase. Long term benefits will far outweigh the short term cost on the NHS that can't be accurately quantified<br><br>Section 2.1 does not mention any other complications e.g. mental health which is important to make clear (although mentioned later on the burden)<br><br>who decides what "difficulty managing condition" is?<br><br>Surely the way forward is to make this inclusive for everyone involved providing industry support is there. It is in everyone's best interests to deliver effective diabetes care!<br><br>It is obvious that those with higher baseline A1C will see a greater effect than those with lower A1C...<br><br>QUALITY OF LIFE is key here. |

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| 538 | | | | | | section 1.5 Concern this is aimed at those who have HbA1c higher than 8% Will this not lead to multiple people trying to demonstrate a lower control in order to qualify.<br>Concern that type 1 diabetic control is seen as constant. HbA1cs can vary enormously over a year, puberty, illness and stress being key factors in this variance.<br>Concern that those who are diligent and try really hard to keep their HbA1c as low as possible and are of the right mindset will be denied this system which will make their lives easier and also will have the potential to enable even greater diabetic control |
| 539 | | | | | | section 2.4 the NICE target is suggesting a HbA1c of 6.5%. as a target to reduce complications This is challenging to achieve reliably over months, especially with young people and teens, even those who focus heavily on their diabetic control. Many people have HbA1cs between 6.5 and 8% and possibly won't quality for this close loop system. I think these are the population to target, as they are achieving quite a good control and just need a bit more help which this intervention can give. A regular HbA1c above 8% without taking on diabetic advice quite bluntly can mean the person will be rewarded with this fantastic device for their lack of effort/incompetence. This is a strong statement, but I think some discretion is required rather than black and white numbers. |
| 541 | | recommendations | 1 Recommendations | 1.1 | | NICE type 1 diabetes HbA1c target is 48 so should use same . Also those who manage to achieve this target but with huge psychological effort should also eligible<br>As a diabetes nurse specialist I am very hopeful and keen that these systems are to be widely available to people with Type 1 diabetes |

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| 551 | | recommendations | 1 Recommendations | 1.1 | HbA1c of around 64 mmol/mol (8.0%) | This is discrimination against people who work hard to achieve and maintain a HbA1c in target.<br><br>As a carer of a child with Type 1 I have to constantly (24 hours a day 7 days a week) do the job of a closed loop system to keep achieve these levels - doing corrections/suspending insulin throughout the day and night. This has a severe negative impact on my mental and physical health, having to function and work full time with little sleep every night. I have not slept a full night since my daughter was diagnosed. This also impact on the child's health and education. Her consultant has confirmed that her insulin ratios can not be changed as there is no pattern so this manual intervention is required until a closed loop system is available.<br><br>To penanlise patients and their families with a lower HbA1c of this vital technology is very unfair and should be recconsidered. All Type 1 patients should be offered a closed loop system if this is their wish and will help to manage their condition and help reduce future costs to the Health Service due to avoiding possible complications. |
| 554 | | | | | | I think the closed loop should be available for all type 1 individuals as it will help in many ways not just for someone with HbA1c of 8 mls per ltr.Fpr example my 8 yr old son got diagnosed two years and we have hardly slept due to the intense workload that comes with type 1 diabetes . |

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| 556 | | recommendations | 1 Recommendations | 1.1 | have an average HbA1c of around 64 mmol/mol (8.0% | In spite of commentary later int he document that csii average is 64mmol/mol, does this disenfranchise thaose that are working really hard to achieve a better result?<br><br>Will it drive people who are doing well to drive for high average bg levels to access the technology?<br><br>Is 58mmol/mol a better target? This is in alignment with NG-17 and is still higher that WHO guidlelines. |
| 559 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | 48 mmol/mol (6.5%) | should this be the level that hybrid closed loops are considered, rather than 64mmol/mol? |
| 564 | | | | | | The document accurately reports greater benefit of HCL for patients with higher HbA1c, however statistically this will always be easier to achieve than smaller incremental changes for patients with lower HbA1c which would not mathematically show as significant improvements in comparison. Higher HbA1c patients tend to be omitting insulin delivery and not putting as much effort into diabetes management and so the addition of any insulin will show huge gains. This does not equate to good engagement in diabetes care and technology use over the longer term. |
| 572 | | committee-discussion | Conclusion | 3.16 | people with type 1 diabetes who are having difficulty managing their condition and who have an HbA1c of around 64 mmol/mol (8.0%) | Keeping the technology out of the hands of those that manage their condition well and who spend a great deal of time on it may lead to burn out or people allowing their sugars to elevate to gain acess to the system. This is not a good idea. The system should be available to all T1Ds regardless of HbA1c. |

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| 573 | | | | | | You will very likely be inundated by type 1 diabetics who have a HbA1c under 8%. That is the vast majority of people who already use an insulin pump or a continuous glucose monitoring system. It also includes me, a Diabetic of over 38 years who is mentally drained by the burden of this condition. An HbA1c criteria of 8% invites individuals to self harm by running dangerous blood glucose levels to obtain hybrid closed loop. This criteria should be removed in favour of a more relaxed approach to eligibility. |
| 575 | | recommendations | 1 Recommendations | 1.1 | | Para1.1 - 64 mmol/mol threshold does not consider the effort to get this lower and maintain a lower rate e.g. the constant monitoring and correcting. Setting at a high rate of 64 mmol/mol could act as an incentive to not effectively manage the condition in the medium-term in order to gain access to the hybrid closed loop. |
| 578 | | information-about-hybrid-closed-loop-systems | Type 1 diabetes | 2.4 | | Para 2.4 - Target rate is 48 mmol/mol so why have the recommendations been set at a higher rate of 64 mmol/mol? This discriminates against individuals who are working extremely hard (Type One Diabetes is very complex and to get near 48 mmol/mol takes a lot of hard work and constant adjustments/monitoring 24/7). Especially in children whose needs are constantly changing due to growth and development. Also in children, especially those diagnosed young, they have many years of managing this condition (parents/carers do) which increases their likelihood of long-term complications, therefore age should also be a factor when considering eligibility for HCL |

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| 582 | | committee-discussion | Conclusion | 3.16 | | Para 3.16 - the comment that HCL should be for all people with T1D who have difficulty managing their condition and HbA1C of 64 mmol/mol - all people with T1D have difficulty managing their condition, it is a constant relentless struggle even with lower HbA1C. Patients should not be penalised for managing their condition effectively and because at the time their efforts have been rewarded in a lower HbA1C. Unsure why 64mmol/mol has been considered, given that 59 mmol/mol is still outside the green 'safe' zone? |
| 583 | | recommendations | 1 Recommendations | 1.1 | | This could have perverse outcomes, for example someone who has a lower HbA1c, 7.8% for example, might reduce their control to raise it so they meet the threshold. Although recognised in the papers, the stress of managing T1 should not be underestimated or the lengths taken to get the support needed. |
| 606 | | | | | | The hybrid looping option should be avliable to all Type 1s not just those with poor control and Hbac1 over 8. My son has Hbac1 around 6 and that is through hard work and DIY looping.<br><br>Being able to use hybrid loop would give patients, majority who are children more flexibility and remove some of the intensive managementbof their T1 which can lead to 'burn out'.<br><br>Prevention of complication is better for the patient and NHS. |

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| 608 | | recommendations | 1 Recommendations | 1.1 | | Criteria is terrible. Why exclude people who work hard on their condition? The mental load of having T1 is *enormous*. I'm sick of being excluded from new tech for years and years (Freestyle Libre sensors) because I work so hard to keep my blood glucose in a good range. HELP ME. Make some of my efforts pay off with a little help by letting me access this tech!!!<br><br>I wish those who write the criteria would stop penalising and give every T1 access to this technology.<br><br>Also, Time in Target range is a much more accurate way of measuring how well patients are doing. If you have a lot of lows then your HBA1C is going to look lower than it otherwise would. Time in Target is what you need to base judgements about a patient's control on. |

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| 613 | | | | | | I am a parent of two Type 1 diabetic children. It is, quite honestly, exhausting helping them to manage their diabetes. It is a condition which takes it's emotional and physical toll on those who have it. Neither of my children are 'hypo aware' at night, which means that, for the last 9 years, it has been like continuously having a newborn in terms of lack of sleep and sleep disruption for us all. I do this because I fully understand the long term consequences of extended high blood sugar or extreme lows and I see it as my parental duty to keep my children safe. Partly due to this and partly through my children's commitment to managing their condition (the ceaseless nature of which impacts their mental health), my children have never had an hba1c over 8mmol. If my children had a closed loop system, our lives would be transformed: their physical and mental health would improve and we could all get the rest and sleep we so desperately need.<br><br>Therefore, whilst I appreciate the need for closed loop systems for those with hba1c levels over 8mmol, why penalise those children and parents who work diligently and tirelessly to help control their children's blood sugars?<br><br>If the NICE guidelines of optimal hba1c is 6.5mmol and under, why propose to issue closed loop systems to those with an hba1c over 8.0mmol? I fully support this, but why isn't the threshold lower? Surely, this would improve the long term health of these children and ultimately save the NHS millions in later life diabetic care? |

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| 626 | | recommendations | 1 Recommendations | 1.1 | | This is disappointing. This technology will be of great benefit to me but my good HBa1c appears to make me illegible for this. On a daily basis my glucose is too high and too low. E.g. in the last 90 days I have have 114 low glucose readings. Due to the low glucose events I cant do the interesting jobs I want to. I have to regularly treat or prevent hypos using sweets which is also making weight loss very difficult. Please try to get all type 1 diabetics eligible for this system if they want it. |
| 628 | | | | | | While I understand the need to produce guidelines which target NHS spending where it can be seen to have the most cost effective benefit. As a person with Type 1 diabetes who has consistently worked hard to reduce my HbA1C through adjusting pump settings, eating lower carbohydrate and assessing continually what I can do to have tighter control, I am looking at this document and seeing I am now being penalised for this hard work. Had I continued as I was with a HbA1C over 8.0 I would now be in the group being considered for a hybrid closed loop.<br><br>Please consider further guidance on giving access to rtCGM which integrates with existing pumps that users already have. |
| 638 | | | | | | Thus appears to be an excellent start point for HCL technology. As a t1 diabetic of 34 years on mdi I feel close to burn out often but because my control 'is too good' it appears I am not eligible. This woul be my only concern, that people who try extremely hard and put the time, effort and tears into getting good control ate dismissed regardless of their mental stress and strain and quality of life. I am hopeful that in time this will be available to all who feel it would be beneficial in their lives. |

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| 640 | | | | | | By only allowing those with poorly controlled diabetes (>8% hba1c) you're penalising those who work so hard to gain good control. Good control can be obtained through a strict lower carb diet and continuous monitoring, even in those who are insulin resistant. I feel as though I might as well eat what I want for a year and make all the right noises just so I can be eligible for the closed loop system. |
| 643 | | | | | | I think it's disgraceful that only people with poor control (HbA1c > 8%) should get access to this treatment. People with poor control have had the same access to information to control their diabetes, as people who do control it. The difference is discipline. I have made sacrifices every day of my life to control my diabetes, in the hope that one day I wouldn't need to; that I would get access to this kind of technology. Now you're saying that people who haven't been disciplined and haven't taken care of their diabetes deserve freedom from diabetes more than the rest of us.<br><br>This closed loop system would be life-changing for any Type 1.<br><br>This decision to restrict to poorly-controlled diabetics is completely immoral. You don't restrict cancer treatment to those who have lived a disciplined, healthy life. |
| 645 | | recommendations | 1 Recommendations | 1.1 | | This recommendation ignores the non-measurable impacts of T1D, the burden of which is reduced (though not completely removed) with a hybrid system. Even those with a lower HBA1C can struggle enormously with the relentlessness of this life-impacting condition.<br><br>It seems a backward move to require poor numbers in order to qualify, when achieving those averages without a hybrid system would be enormously time and labour-intensive for anyone. |

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| 652 | | | | | | This should be available to all. Many parents of diabetic children work hard day and night to keep their child's HBA1c within 'normal' range and are being discriminated because the HBA1c will be too low! This would be a game changer for lots of families. |
| 653 | | | | | | The Hybrid closed loop system, looks like an effective device to support in the management of type 1 diabetes. The continual monitoring and adjustment could significantly support, and reduce the daily mental strain that people with diabetes have to consider. I therefore feel it is unfair to only offer this to people with higher HB1Ac levels. Patients with a lower HB1ac level does not mean that they have an "easier" life. Infact they will probably be working non stop to achieve such tight control and should not be discounted from being offered a device that could further transform there life and mental wellbeing. This approach of only supporting those with higher blood sugars is very demotivating with those, who are very proactive and conscientious of there blood sugar levels. I would kindly request that you reconsider who this can be offered to, as this approach feel discriminative to people with diabetes who have a HB1ac of under 64 mmol/mol |
| 656 | | | | | | I dont think 8% is a fair hba1c as it penalises people with type 1 that are trying to control and having some success. A pump for me has given me extra control but I would love to have the cmg to give me that extra security with my control especially having a little one under 5 to look after. I would like to get tighter control and be healthier which having this would also help when I exercise to gain that reassurance. The hba1c should be those that have perfect control. |

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| 657 | | | | | | As a parent of a autistic child who has type 1 the focus for closed loop should not solely be on the hb1a1c. The mental health of the patient along with the caregiver is huge. We are fortunate to be on a closed loop pump. With the current guidelines my son would not qualify. Having a hb1a1c target as the threshold will only encourage poor management in order to qualify. Not to mention the long term risk of running such a high hb1a1c. Closed loop has changed our lives as parents and all should be able to benefit. |
| 664 | | | | | | Guideline suggests that Hybrid closed loop system should be offered to those children and young people who have average HbA1c of around 64<br>mmol/mol (8.0%) or more. It is a very fair recommendation, however, those who have better control should also have opportunity to benefit from this technology as their quality of life will improve. Moreover these families who put in a lot of effort to maintain good HbA1c and it is not fair on them to be left out from this useful technology that can reduce their burden.<br><br>Ideally HCL system should be available to all children with T1dm because of its proven benefits. |
| 671 | | | | | | I have been fortunate enough to have read your consultation on closed loop insulin pumps. This has the capability to transform patient's lives and the lives of their families.<br><br>From what I can glean the consultation states that it's use is only for people with HbA1c (blood glucose average) over 8.0%, as the largest benefits are seen above this level.<br><br>For children, who were for example within the range 6.5 - 7.8, it means a parent must get up in the night to keep your child in range - no closed loop insulin pump. I have seen families really struggle with this side of the condition. It doesn't just affect the long term complications of the patient (which will end up costing the NHS even more), but the functioning of the parents in day-to-day life. This can be catestrophic. |

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| | | | | | | Even though the benefits may not be as large as the patients who are above 8%, there will still be a benefit and these families are desperate.<br><br>Not enough research has been done in insulin sensitive children to say that they won't benefit when there is an indication that they will.<br><br>This technology has the capability to transform people's lives. It is my strong opinion shouldn't be restricted to HbA1c over 8.0% for children or those who are insulin sensitive. If it isn't restricted for pregnant women then this would imply that one of the reasons it isn't available for children who fall below 8% is a cost saving one.<br><br>If these children have access to this technology, it is my opinion that they will save costs in the long term by reducing the risk of long term complications and also hugely improve the strain of this condition on family life. |

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| 677 | | recommendations | 1 Recommendations | 1.1 | | Hybrid closed loop systems for managing blood glucose levels is the "holy grail" of treatment sought by type 1 diabetics!<br>In my opinion, the fact that it is proposed it should only be offered to type 1 diabetics with an HbA1c of 64mmol/mol and above is discriminatory against those patients who have tried tirelessly to manage their diabetes effectively over many years to reduce the likelihood of severe complications associated with poor blood glucose control eg. heart disease, kidney disease, circulatory problems resulting in amputation of lower limbs, retinopathy, neuropathy etc. and be a burden on the NHS.<br>I personally was diagnosed in April 1970 at the age of 16 after being admitted to hospital in a diabetic coma. Treatment then involved a two week stay in hospital, twice daily insulin injections using glass syringes (stored in IMS) with re-usable, thick stainless steel needles, glucose (diastix) and ketone (ketostix) monitoring by urine testing and with a diet of 250gms carbohydrate daily!<br>Times have moved on with the advent of disposable syringes and needles, blood glucose testing kits and now the Freestyle Libre 2 continuous blood monitoring which has proven to be an absolute game changer enabling patients to achieve much improved management of their blood glucose control. At the age of 69, after coping and managing my diabetes well fo 52 years, my current HbA1c is 61mmol/mol yet I would not qualify for this life changing treatment. I consider this grossly unfair given that many other type 1's have made little or no effort managing their condition and will qualify? I honestly feel this issue should be revisited as the assessment of ongoing quality of life for those patients with an HbA1c of less than 64mmol/mol does not appear to have been fairly/objectively taken into account. |

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| 681 | | recommendations | | 1.1 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following:continuous subcutaneous insulin infusionreal-time continuous glucose monitoring intermittently scanned continuous glucose monitoring. | Access should be available to all Type 1 patients. By limiting access to patients who are not keeping within range there is a danger that patients who are struggling but who mainly manage to keep within range will be discriminated against by being refused access to a technology known to reduce the burden on their mental health and save them from having health problems later on. |

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| 684 | | | | | | I have four main comments on this consultation regarding the requirement for groups other than pregnant women needing to have an HbA1c result of around 8.0% in order to qualify for access to Hybrid Closed Loop (HCL) technology:<br><br>• It discriminates against a child with type 1 diabetes when compared with an adult pregnant woman (Equality Act, 2010 section 19 (1) (2) - protected characteristic: Age group)<br><br>• It has conflicting views of the definition of 'difficulty' in managing diabetes, which is what qualifies a patient for access to HCL. The committee papers (page 3) say 'difficulty' is 'not maintaining HbA1c levels of 6.5% or below', but the consultation only gives access to those who are having 'difficulty' and have an HbA1c of 'around 8.0% or more'<br><br>• It states that adult pregnant women should have unrestricted access to HCL because their 'blood glucose control is harder to maintain' (section 3.6) but does not cite evidence or a comparator, such as against an adolescent in a growth spurt, for example<br><br>• According to the consultation, there is more evidence of the benefit of HCL for children than for pregnant women (section 3.5/3.6), but access is unrestricted for pregnant women and limited to HbA1c over 8.0% for children, despite there being only 29,000 children in the UK with type 1 (section 2.1). |
| 688 | | | | | | Closed loop should be available for all Type 1's, not just those with a high hbac1. Those with lower should not be penalised by being excluded from this technology which has life changing affects on health and mental well being |

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| 696 | | | | | | This sends a message that you should control your blood sugar poorly in the short term in order to be considered for this technology. Short term pain for long term gain. Offer it to everyone |
| 699 | | recommendations | 1 Recommendations | 1.5 | But they are also effective for people with average HbA1c levels (the UK average HbA1c for people using a pump is around 64 mmol/mol [8.0%]). | Make it available for everyone. It is ridiculous that it is only available to some type one diabetics. You are creating a horrible situation where some benefit and some don't. |
| 700 | | recommendations | 1 Recommendations | 1.5 | So, to ensure wider access, hybrid closed loop systems are recommended for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition, and have an HbA1c level of around 64 mmol/mol (8.0%) or more | I will allow my blood sugar management to go off track for a while, in order to be considered for this system. Short term pain for long term gain. |
| 701 | | recommendations | 1 Recommendations | 1.5 | have an HbA1c level of around 64 mmol/mol (8.0%) or more. | Should I get my HbA1c above this so I can get one? |
| 709 | | committee-discussion | Baseline characteristics and HbA1c effects | 3.7 | The baseline HbA1c from this data was 64 mmol/mol (8.0%) and the EAG applied the estimated HbA1c decrease from the RCT network meta-analysis of 3.1 mmol/mol (-0.29 percentage points) | Long term studies are few, however, they tend to support the view that 3.1 mmol/mol is on the low end of the estimates used for QALYS analysis. The below paper suggests that even at higher starting levels of Time in Range (or lower Hba1C levels), improvements of 0.75 percentage points can be achieved. (https://pubmed.ncbi.nlm.nih.gov/36030902/).<br><br>Given the distribution of Hba1C levels within the NHS Diabetes Audit compared to the RCT and NHS pilot outcomes, the mean reduction used in this assessment appears to be very low. |

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| 715 | | | | | | RCTs will use a higher than average HbA1C >8mmol eg Hovorka et al. with CamAPS as these will show significant results clearer. The national target is less than 6.5mmol. This is at odds with reported trials where eligibility is higher. The majority of patients who are engaged with their condition are aiming for a lower HbA1C and higher time in range as recommended by NICE and healthcare professionals - this takes daily engagement and is hard work. The consultation recommendations make these patients ineligible for closed loop technology. They should not be penalised for trying to stay healthy and avoid future complications. These patients typically have less hospital admissions and are on target for a lesser burden on the NHS. Removing this technology, or not providing it to those that express a wish to help manage their condition more effectively is likely to lead to a higher NHS cost long term. |

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| 724 | | | | | | I was concerned reading this document that a threshold of 64 mmol/mol is being recommended as the cut off for offering closed loop systems. In my clinical practice as a paediatrician I have regularly seen patients deriving significant benefit from HCL systems, even when their initial HbA1c is as low as 48 mmol/mol. These families are often already working very hard to achieve such excellent results, but HCL has allowed them to continue to achieve excellent results without the exhaustion of constant day and night attention to the diabetes. They've often improved their HbA1c further, although the relative drop is much less than someone who started with poorly controlled diabetes.<br><br>My particular concern is for the group with an HbA1c between 53 and 64. This group are often working very hard at their diabetes, facing the same exhaustion and burnout threats, but despite that for whatever reason unable to achieve a target HbA1c that would reduce further their risk of long term complications. It often feels like this group is being punished for working too hard - if they were more lazy their HbA1c would be higher and they would be entitled to extra tech to support them.<br><br>I would like to see guidance where all adults with the terrifying and exhausting condition of type 1 diabetes were offered the choice of this amazing breakthrough in technology.<br><br>  |

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| 731 | | recommendations | 1 Recommendations | 1.1 | have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following: | Because the HbA1c is an average, it can hide the highs and lows and not give a true picture of the difficulty controlling the blood glucose level.It is also skewed over the 12 weeks, giving more weight to the levels in the last 4 weeks leading up to the HbA1c reading. It is possible to have an HbA1c of <64, but for the person with diabetes to still be struggling with managing their condition. They may have a widely swinging blood glucose level (see-sawing), which can still produce an HbA1c in the target range. I think the recommendations should allow for this, such that it can be enough to have difficulty managing your diabetes, without having to have a high HbA1c. |
| 734 | | | | | | 1. The proposed baseline HbA1c of 64 mmol/mol (8.0%) is discriminatory for children with type 1 diabetes. No such threshold is established for people who are pregnant or planning pregnancy, while the consultation specifically mentions that there is more evidence of HCL system's effectiveness for children than for pregnant women. The number of children with type 1 diabetes in the UK is quite small - 29,000 children in total, which limits the overall cost burden associated with the funding of HCL for this target population.<br><br>2. According to the committee papers, NICE guidelines recommend that people with type 1 diabetes should aim for a target HbA1c level of 48 millimoles per mole (6.5%) or lower to minimise the risk of long term complications from diabetes. At the same time, the threshold for access to HCL systems is proposed at the level of 64 mmol/mol (8.0%). This approach lacks consistency and excludes a part of the patient population from access to treatment. |

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| 735 | | recommendations | 1 Recommendations | 1.1 | Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more | Even though the rate of reduction in the HbA1c slows as it approaches the optimum when using a HCL, I am unsure about how the committee can justify a threshold figure of 64mmol/mol, considering elsewhere in the document it states that the HbA1c level for a healthy person without diabetes is 48mmol/mol and below. It seems to be ridiculous that a qualifying figure is set above the ideal considering there is still a risk of<br>developing health complications below 64mmol/mol. Where is the data that supports the theory that sufferers between these 2 figures are at less risk of poor health, have less quality of life issues (Mental, Emotional and Physical) than those above 64 and for those in this band their quality of life is as for a non Diabetes T1 sufferer, below 48.<br>The committee are aware, (see section 3.1 of this document) but I think that it needs to be restated, that those sufferers and their parents/carers work really hard to lower the HbA1c levels. This is for all sufferers across the spectrum, and not just those above the 64 figure. There is also an acknowledgment that these issues are probably not adequately captured in the model.<br>I believe that setting the figure at 64mmol/mol discriminates, albeit unintentionally, against those sufferers and their parents/carers who are working really hard to achieve the optimum figure but have not quite got there. This is an ongoing activity, it doesn't stop, even when the ideal figure of 48 is achieved. Their effort is no less than those still on their journey above 64mmol/mol.<br>When considering the eligibility to have a HCL device, you need to remember the ongoing journey in getting to and maintaining a low HbA1c figure and not just the current level at that point in time.<br>The committee need to remember the statement about their being a "need in the NHS system to fail and qualifying for more sophisticated treatment methods etc" (see Patient and Carer Considerations) and not penalise those who are proactive and strive to improve the lives of themselves and their loved ones at great personal cost.<br>That is why these HCL devices need to be made avialable for ALL Diabetes T1 sufferers, to enable them to achieve and maintain as normal and healthy life as possible. |

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| 736 | | recommendations | 1 Recommendations | 1.5 | Clinical trial and real-world evidence shows that hybrid closed loop systems are more effective than standard care at maintaining blood glucose levels within a healthy range. Evidence suggests that the systems appear to be more effective for people with higher long-term average blood glucose (HbA1c) levels. But they are also effective for people with average HbA1c levels (the UK average HbA1c for people using a pump is around 64 mmol/mol [8.0%]). | The rate of change (improvement) in the HbA1c level will decrease as it approaches the optimum. This is not only true for HCL devices but for all forms of process improvement. Non the less these smaller incremental changes at the lower end are equally important to enable people to achieve and maintain as normal a life as possible, close to the optimum and should not be disregarded and marginalised because they are not as great as at the top end. They are still important but represent a different part of the reduction in HbA1c level and be treated as such. |
| 763 | ABHI | | | | | **1. The HbA1c baseline threshold at which HCL systems are recommended is too restrictive.**<br><br>The draft appraisal recommends HCL as an option for people with T1D who have difficulty managing their condition and have an average HbA1c of 8%.<br><br>The 12 randomised control studies assessed by the EAG identified a mean HbA1c baseline of 7.4% to 8.3%[1], with the median HbA1c baseline of nine studies at 7.6%. ([1]Public committee slides, www.nice.org.uk/guidance/gid-ta10845/documents/1)<br><br>The threshold needs to be lowered for the appraisal to be aligned with the clinical evidence and not unduly limit access to a technology for individuals for whom it has been shown to be effective |

**DIAGNOSTICS ASSESSMENT PROGRAMME**

**Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes**

**Diagnostics Consultation Document – Comments from companies in scope**

**Diagnostics Advisory Committee: 24 May 2023**

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| 1 | Advanced Therapeutics (UK)<br><br>Submitted via the web | Advanced Therapeutics (UK) Ltd Response to Nice HCL Appraisal<br><br>Hybrid Closed loop systems use an algorithm that takes CGM data and calculates how much insulin needs to be delivered to the patient at that particular time.<br><br>Because the CamAPS FX algorithm is constantly monitoring a patient's metabolic progress (re BG levels) it can be causing the pump to make many small altering dosage deliveries every hour via multiple small bolus adjustments instead of using the Dana pump's basal rate function. The algorithm also "learns" how that dose delivery has affected the patient's blood glucose levels and reacts accordingly.<br><br>It is vitally important in this respect that the insulin dose the algorithm has requested to be delivered is actually delivered so that it can calculate future doses accurately. | All costings are based upon information supplied by NHSE Supply Chain, with the sole exception of the costing of the FreeStyle Libre 2 sensor being taken from the NHS drug tariff. |

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| | | Pump delivery accuracy varies from one manufacturer's pump to another. With the Dana-i the bolus delivery accuracy at 0.04iu is ±4%. One tubed pump for example has a bolus delivery accuracy of ±30 (as stated in the manufacturers user guide as per their website).<br><br>Some tubeless pumps show delivery accuracy levels of ±0.05iu at a delivery rate of <1.0iu.<br>It is not the purpose of a hybrid closed loop algorithm to correct deficiencies in the accuracy of delivery of the insulin pump component of the system.<br><br>A NICE expert put forward an opinion (see Section 2.5 of the appraisal consultation document) that the pump used in a closed loop system is immaterial, but we would suggest that delivery accuracy has not been understood nor taken into account. A different UK expert who has studied this aspect of insulin pump use (Prof N Oliver) shares a different view in the co-authored paper below (1).<br><br>In two studies (Ziegler 2020(2) and Giardot 2020(3)) the Ypsopump fairs badly. In the Giardot paper (basal delivery), the Ypsopump demonstrated the largest error of all devices at the lowest dose of 0.1 iu/h. Similarly for a bolus of 0.1 iu Ziegler demonstrated the Ypsopump to have the widest range of values for a tubed pump well outside the ±15% they were looking for - not dissimilar to Omnipod. The Giarodot paper entitled "All Insulin Pumps are Not Equivalent" quotes their observations to be similar to the ±30% error reported by the manufacturer Ypsomed. The four studies show pumps to be inaccurate at low levels which is something clinicians should bear in mind when initiating pump therapy involving small doses of insulin. and two of them involve Ypsopump specifically.<br><br>Summary<br>- Closed loop systems consist of 3 main components, a glucose sensor, algorithm, and insulin pump. In closed loop systems, insulin delivery can be altered frequently every few minutes with varying small doses, aiming to emulate a healthy pancreas. The effectiveness of these systems depends upon each of the components performing its task to the highest level of accuracy. The algorithm is the brain of the system which | |

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| | | controls the pump based on sensor readings. If a sensor performs with a varying or low degree of accuracy the glucose levels would likely adversely be affected due to incorrect insulin delivery. Conversely, if insulin pumps vary in the ability to deliver small doses insulin accurately, the glucose levels would likely adversely be affected due to incorrect delivery of insulin. Based on the evidence below, it cannot be assumed that insulin pumps are equivalent in terms of accuracy when delivering lower doses of insulin.<br><br>Studies<br><br>1. Ralph Ziegler, Nick Oliver, et al. Evaluation of the Accuracy of Current Tubeless Pumps for Continuous Subcutaneous Insulin Infusion. Diabetes Technology & Therapeutics Volume 23, Number 5, 2021<br>“With regard to the use of pumps in artificial pancreas systems, short-term accuracy is especially important, because insulin delivery is frequently adapted to current glucose levels”.<br><br>2. Ralph Ziegler et al. Accuracy assessment of bolus and basal rate delivery of different insulin pump systems used in insulin pump therapy of children and adolescents. Pediatric Diabetes. 2020;21:649–656<br>“Considerable differences in insulin delivery accuracy were observed between the tested pumps. In general, when using very low doses, accuracy of insulin delivery is limited in most insulin pumps. This should be considered for CSII therapy in children”.<br><br>3. Sylvain Girardot et al. All Insulin Pumps Are Not Equivalent: A Bench Test Assessment for Several Basal Rates. Diabetes Technology & Therapeutics Volume 22, Number 6, 2020<br>CSII imprecision could be due to a variability in volume and/or frequency of strokes for every pump. Some models appear better adapted for the smallest insulin needs, or for inclusion in a CLS”.<br><br>4. Katharina Laubner et al. Comparative Dose Accuracy of Durable and Patch Insulin Pumps Under Laboratory Conditions. Diabetes Technology & Therapeutics Volume Volume 21, Number 7, 2019 | |

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| | | "This study demonstrates low accuracy for basal rates and single bolus deliveries at low insulin doses for both pump models. Clinicians should be aware of this variability when initiating insulin pump therapy especially in insulin-sensitive patients with low insulin dose requirements".<br><br>Re the comment Ypsopump being more cost effective when used in a closed loop system, was the extra cost of insulin cart use taken into consideration?<br><br>Based on an average adult in England, using an Ypsomed Pumpcart over 4 years will cost approximately £452 more than insulin from a 10ml vial as used for the Dana-i. It would be useful to know the exact overall cost difference once all factors are considered such as their more expensive consumables and their delivery charge.<br><br>Calculation as per the following: (Insulin costs as per the BNF)<br><br>Insulin daily requirement: 0.75u/kg/day (EMC states adults and children will require 0.5-1.0u/kg/day)<br>Average adult weight UK: 79kg (average male in England weighs 85.4kg and female 72.1kg)<br>Average TDD: 59.25 units/day<br>Novorapid 10ml vial (1000units): £14.08<br>Novorapid 5x1.6ml Pumpcart (800 units): £15.10<br><br>Annual insulin use: 59.25 x 365 = 21626 units<br>Novorapid vial: 21626 units requires 22 vials x £14.08 = £310<br>Pumpcart: 21626 units requires 28 pumpcarts x £15.10 = £423<br><br>Annual difference: £113/year<br>4-year difference: £452<br><br>In addition, we have been informed by our customers that Ypsomed infusion sets and basic Ypsomed cartridges are more expensive than the Dana equivalents. Can NICE confirm that these additional costs have been considered. | |

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| 2 | CamDiab | **1 Introduction**<br><br>We present the following two pieces of evidence in relation to "Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes [DAP55]":<br>• Cognitive development in children linked to hyperglycaemia<br>• Costs used by health economic model | EAG response not required. |
| 3 | CamDiab | **2 Cognitive development in children linked to hyperglycaemia**<br><br>We have reservations about the current recommendation to limit the provision of HCL therapy to children and young people with an HbA1c of 8.0% or above.<br><br>HbA1c is not necessarily reflective of glycaemic variability, meaning that even with an HbA1c <8.0%, children and young people may be experiencing periods of clinically significant hypo- and hyperglycaemia. When using HCL therapy, children have significantly higher variability of insulin requirements compared to adolescents and adults, reflecting their underlying higher glycaemic variability and closed-loop's ability to address this by adjusting insulin delivery accordingly (doi: 10.2337/dc18- 2625).<br><br>The "Questions on the external assessment report for clinical experts" section recognises the negative impact of hypoglycaemia on learning, **but does not appear to take into account more recent evidence on the negative effects of hyperglycaemia on cognitive ability and brain development**. In her 2021 longitudinal study (doi: 10.2337/dc20-2125), Mauras et al showed that children (mean age 7 years at baseline) with type 1 diabetes had lower cognitive scores and lower total, grey and white matter brain volumes than age-matched controls and that these differences were associated with metrics of hyperglycaemia and persisted over time.<br><br>**Arguably, it is therefore of high importance to reduce time in hyperglycaemia for all children with T1D, regardless of baseline HbA1c, to facilitate optimal brain development and allow children and young people to reach their full potential**. In the paediatric age-group, HCL therapy improves glycaemic control primarily by reducing time | Thank you for your statemet. The EAG followed the expert input when developing the scope in relation to difficulty in managing diabetes and that was defined as: *for the purpose of this review, difficulty refers to (1) not maintaining HbA1c levels of 6.5% (48 mmol/mol) or below (for pregnant women/those planning pregnancies: not maintaining fasting plasma glucose levels of 5.2 mmol/l or below, or not maintaining non-fasting plasma glucose of 7.7 mmol/L (one hour after eating)/ 6.3 mmol/L (two hours after eating)), (2) not maintaining at least 70% time in range of 3.9 -10 mmol/l, or (3) repeated hypoglycaemia that causes anxiety about recurrence and is associated with a significant adverse effect on quality of life.* |

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| | | in hyperglycaemia and is therefore well-placed to address this important issue. | |
| 4 | CamDiab | **3 Costs used by health economic model**<br><br>When the original submission by CamDiab was made in June 2022, the cost of CamAPS FX app was £840 pa when working with Dana-I pump (Sooil, South Korea). Since then the cost of the CamAPS FX was reduced to one-off cost of £800 over 4 years (i.e. £200 pa, **i.e. the cost was reduced four-fold**) when working with YpsoPump (Ypsomed, Switzerland).<br><br>Additionally, the CamAPS FX will be available from March 2023 in the UK with FreeStyle Libre 3 (Abbott Diabetes Care, USA). The cost of FreeStyle Libre 3 is at par with iCGM and thus **the premium cost of CGM compared to iCGM used by the health economic model does not apply when contrasting HCL vs comparator**.<br><br>The present health economic calculations using RCTs data are flawed in any case: The health economic efficacy assessment utilised exclusively RCTs which applied CGM in the comparator group but costed iCGM in the comparator for the health economic calculations. This is incorrect unless it can be demonstrated that a therapy with iCGM and CGM provide the same outcomes. This is not the case, no such evidence exists. **The health economic calculations should have used CGM in the comparator and not iCGM.** | The costs supplied by NHSE Supply Chain have been updated. The effectiveness of CSII+isCGM is now estimated separately from that of CSII+rtCGM, with its costs being revised to be based upon the Freestyle Libre 2 rather than the Freestyle Libre 3. |
| 5 | **Dexcom International** | The EAG committee draft recommendations state that HCLs are recommended as an option for managing blood glucose levels for people with T1D who have difficulty managing their diabetes and who had an average HbA1c of 8.0% (64mmol/mol). This recommendation excludes people with diabetes with A1c below 8.0% (6.5 – 7.9).<br><br>NICE's own recommendations is that people with T1D should aim for a target HbA1c level of 6.5% or lower (48 mmol/mol) to minimize the risk of | Comment on ACD draft recommendation. No EAG reponse required. |

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| | | long-term complications. The Diabetes Control and Complications Trial (DCCT), a prospective randomized controlled trial of intensive (mean A1C about 7.0% [53 mmol/mol]) versus standard (mean A1C about 9.0% [75 mmol/mol]) glycemic control in patients with type 1 diabetes, showed that better glycemic control is associated with 50–76% reductions in rates of development and progression of microvascular (retinopathy, neuropathy, and diabetic kidney disease) complications. https://diabetesjournals.org/care/article/42/Supplement_1/S61/30946/6-Glycemic-Targets-Standards-of-Medical-Care-in. EDIC trial has demonstrated long-term microvascular benefits over two decades following DCCT. Similar results are seen in the long-term follow-up of UKPDS type 2 diabetes cohort.<br><br>Thus, evidence suggests that achieving A1c targets of <7.0% has been shown to reduce microvascular complications of both type 1 and type 2 diabetes when initiated early in the course of disease. Committee's decision to cap HCLs to patients at HbA1c ≥8.0% will exclude diabetic patients with HbA1c in the range of 7.0 to 8.0% as well as moderate to high-risk population i.e., < 7.0% who experiences hypoglycemia.<br><br>Additionally, short term complications produced by high glucose variability (GV) or glucose excursions should be considered. People with diabetes (PWD) with HBA1c < 8.0% may experience short-term glycemic variability with episodes of hypo- and hyperglycemia. A1c is a good indicator if patients with diabetes are always on the high blood glucose levels but it does not measure GV (ACCORD trial: https://diabetesjournals.org/care/article/43/6/1169/35683)<br><br>PWD have glycemic variability where night-time insulin requirements are variable than daytime for not just adults but children as well as adolescents. These glycemic variations have been well addressed by HCLs ( doi: 10.2337/dc15-2623); (doi: 10.2337/dc18-2625). | |
| 6 | Dexcom International | • "Problematic hypoglycemia" should be an independent indication. HCLs has shown to be effective in vulnerable sub-populations which are at moderate to high risk of hypoglycemia. According to Anderson study (DTT 2019), HCLs when compared to SAP therapy were safe and | There is an absence of evidence on hypoglycaemia. The EAG presented scenarios based upon hypoglycaemia |

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| | | effective for treating people with type 1 diabetes by reducing the risk and frequency of hypoglycemia while improving time in range and reducing hyperglycemia. The % TBR (3.9 mmol/l) decreased significantly in HCLs than in SAPs (7.2% ± 5.3% to 2.0% ±1.4% vs (5.8% ± 4.7% to 4.8% ± 4.5%); p=0.001<br>• We would like to point out that time below range (<3.9 mmol/l) should be used as a proxy for hypoglycemia. Eight RCTs were used in the network Meta-analyses (NMA) to assess time below range (TBR) (<3.9 mmol/l) when comparing HCL to CSII+CGM. The draft MTA assessment report states (page 87), that the time <3.9 mmol/L is small at baseline (<6%) in both arms, implying not much room for change. The report comments that studies had small effect size and occasionally reached statistical significance however 4 studies showed statistical significance for time below range favoring HCLs. It should be noted that any time in this hypoglycemic range <3.9 mmol/l (<70 mg/dl) is not good for the patient and any decrease in this hypoglycemia time is a better outcome. The relative decreases in TBR are important to note (e.g., Tauschman 2018 showed a -23% relative decrease in TBR) even when the absolute decreases are small. Or the relative difference in TBR is large between groups at end of study (e.g., Benhamou 2019, Kariyawasam 2022) ~50% better for HCL. Thus indicating that HCLs showed better relative differences in TBR when compared to CSII+CGM. | (both severe and non-severe) being proportionate to the TBR. These were considered by Committee. |
| 7 | Dexcom International | • It is concerning to use the same base case from the EAG report for evaluating the cost-effectiveness of HCL systems in patients with type 1 DM (ICER of 179k GBP/QALY) despite the existing flaws in the modelling approach including misappropriation of clinical evidence of rtCGM+CSII to isCGM+CSII, lack of QoL benefits for HCL, and exclusion of SHE and NSHE events from the base case.<br><br>• QoL benefits of HCL systems and impact on cost-effectiveness analysis: The components of quality-of-life benefits that are expected with the use of HCL by patients with Type 1 DM include improvement in quality-adjusted life years due to reduction in diabetes complications, avoidance of diabetes-specific disutilities (Fear of Hypo), and additional utility benefits due to improvement in the process of care( avoidance of fingersticks, reduction in day to day | The quality of life effects of both severe and non-severe hypoglycaemia is reviewed in some detail in the EAG report, with appropriate scenario analyses being presented. It should also be noted that the algorithms for translating numbers of hypoglycaemic events into quality of life use the HFS fear of hypoglycaemia questionnaire results.<br>The EAG is providing exploratory analyses which adjust the treatment effect for the baseline HbA1c. |

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| | | diabetes burden and decision making, disease stress). The current cost-effectiveness model only captures the QoL benefit from the avoidance of microvascular and macrovascular complications and does not consider any additional QoL benefits due to improvement in the process of care. The current draft guidance includes positive language that acknowledges the patients, carers, and clinical experts' perspectives on the improvement in the quality of life of patients and their families, however, no attempt was made to quantify the additional benefits and incorporate them in the cost-effectiveness assumptions. The scenario analyses done by EAG only consider a utility due to the avoidance of acute events (severe hypoglycaemia). The previous assessments by NICE for use of insulin pumps (TA151) set the standard of testing additional utility values due to a reduction in disease burden. Similar to TA151, the EAG could have used assumed utility values of 0.005-0.05 QALY for the expected improvement in the process of care and its impact on patients' QoL. The table below provides multiple scenarios, and it clearly shows that the inclusion of even a small additional utility will reduce the ICER significantly. Assuming a utility of 0.01 for the HCL systems will reduce the ICER by 50% (from £177,814/QALY to £83,425/QALY). | |

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**Table: Impact of QoL benefits of HCL systems on ICER**

| | Net Costs | Life expectancy (years) | HCL QoL ben Utility (annu |
|---|---|---|---|
| **Current Base Case** | 28,628 | 18.216 | 0 |
| Scenario 1 | 28,628 | 18.216 | 0.005 |
| Scenario 2 | 28,628 | 18.216 | 0.01 |
| Scenario 3 | 28,628 | 18.216 | 0.015 |
| Scenario 4 | 28,628 | 18.216 | 0.02 |
| Scenario 5 | 28,628 | 18.216 | 0.025 |
| Scenario 6 | 28,628 | 18.216 | 0.03 |
| Scenario 7 | 28,628 | 18.216 | 0.035 |
| Scenario 8 | 28,628 | 18.216 | 0.04 |
| Scenario 9 | 28,628 | 18.216 | 0.045 |

- The relationship between HbA1c level at baseline and treatment effect: Previous studies have shown a dose-response relationship between HbA1c at baseline and the expected improvement in glycaemic control manifested by a drop in HbA1c at follow-up. The combined mean HbA1c at baseline for the RCTs' populations in the NMA is 7.6%. The draft recommendations suggest a cutoff point of 8% HbA1c for eligibility for HCL. The base case assumption around the treatment effect should be higher than 0.29. The NHSE study shows that patients with baseline HbA1c of 9.4 experienced a 1.5 drop on average. The expected drop in HbA1c in patients with 8% should be a value between 0.29 and 1.5%. It is important to update the base case for cost-effectiveness evaluation to reflect the expected clinical effect.

- Distributional Cost-effectiveness analysis to address health inequalities: The committee highlighted the clinical experts' opinions on the value of automation offered by HCL systems. This automation of diabetes and insulin management can help reduce some of the inequalities for people with poorly controlled diabetes due to language barriers, a lower level of education, or a learning disability. We believe

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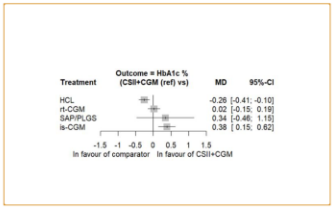
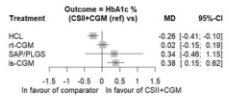
| | | that cost-effectiveness analyses should incorporate the impact of different interventions on the social distribution of health. It is important to understand how the current standard of care could be affecting the outcomes of patients with lower socioeconomic status, lower educational levels, or with learning disabilities who are facing challenges with managing their diabetes that results in poor outcomes. | |
| 8a | **Medtronic** | **Consultation question 1: has all of the relevant evidence been taken into account?**<br><br>**The EAG concluded that "*the relevance of the RCT populations and outcome measure results for the decision problem is debatable and not easy to judge*"**<br><br>We agree with the EAG conclusions that *"the relevance of the RCT populations and outcome measure results for the decision problem is debatable and not easy to judge"*. The studies included in the network meta-analysis (NMA) are not reflective of the currently available hybrid closed loop (HCL) technologies nor the average HbA1c levels of people with T1D in NHS England.<br><br>The effect size from the NMA used in the base case, shows a very modest reduction in HbA1c of 0.29% which is at odds with the much larger reduction in HbA1c achieved with current advanced algorithm hybrid closed loop (AHCL) technologies as reported in more recent studies[1–5]) and the substantial body of real-world evidence including the recent NHS England observational study in approximately 900 people with Type 1 diabetes.<br><br>NICE health technology evaluations: the manual (PMG36) states that: *"In general, all model parameter values used in base-case, sensitivity, scenario and subgroup analyses should be both **clinically plausible** and should use methods that are consistent with the data. Results from analyses that do not meet these criteria will not usually be suitable for decision making.* | The EAG conducted a weighing analsysis by SE (ornage box – to the left) and N (clear box – to the right). The results remained unchanged. The EAG is not clear on what factors should be considered when weighing the studies with HbA1c > 8%, can you please elaborate?<br><br>  <br><br>  <br> |

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| | | **We suggest that the 0.29% effect size from the NMA is not clinically plausible and is substantially lower than that observed in clinical practice in NHS England. We are concerned that the efficacy outcomes in the base case are based solely on this pessimistic effect size of 0.29%.**<br><br>We are concerned that the studies included in the NMA are not representative for the population defined in draft recommendation because the relevant evidence for HCL with a baseline HbA1c ≥8 has not been included and the most recent, clinically relevant evidence has not been considered.<br><br>No weighting has been given to RCT data with a baseline HbA1c>8%. The inclusion of this evidence in populations with higher baseline HbA1c is essential for the NMA as the reductions in HbA1c increase with increasing baseline HbA1c.<br><br>**We ask the committee to give more weighting to this body of evidence to help address the uncertainty in the effect size and determining the true ICER.**<br><br>The following RCTs have not been captured in the review and may be of interest<br><br>• The recently published **ADAPT RCT**[1] included UK participants and investigated the effect of AHCL on HbA1c compared with multiple day injections (MDI) plus flash glucose monitoring (FGM) or continuous glucose monitoring (CGM) in sub-optimally controlled adult patients with T1D. The HbA1c reduction in intervention arm of ADAPT was 1.4% greater than the comparator which reflects the standard of care in NHS England. This is a remarkably similar reduction in HbA1c to that seen in the NHS England observational study and was achieved regardless of starting technology. This effect is also over 5 times higher than the 0.29% reported in the network meta-analysis.<br><br>• The results from **NCT04914910** have been shared with NICE as Academic in Confidence [AIC] ahead of publication. The RCT | ADAPT RCT: thank you for highlighting this study. However, this study is not relavent to the NICE scope (NICE comparator CSII + rtCGM/isCGM).<br>NCT04914910: this study is now included in the regression requested. However, the EAG did request for additional data (sample size by group) to be able to calculate the SE. Therefore it was not possible to include in the NMA. |

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| | | compared an automated insulin delivery (AID) system with insulin pump and CGM / isCGM, usual care (UC).<br><br>[redacted]<br><br>**We ask the Committee to consider that the NMA findings need to be put into perspective with ADAPT and NCT04914910 to account for the higher effect size observed in HCL users with baseline HbA1c ≥8%** | |
| 8b | Medtronic | **Key limitations of the network meta-analysis are as follows:**<br><br>• The average baseline HbA1c in the studies included in the network meta-analysis is 7.5% which is not in line with the HbA1c stated in scope which specifies studies with a baseline HbA1c >8%.<br><br>• 63% of Type 1 in NHS England have HbA1c>7.5% (National Diabetes Audit 2021), while the participants in the selected studies for the NMA were a well-controlled population with a baseline HbA1c of 7.5% before introduction of the HCL system.<br><br>• The study selection for the NMA is not representative of the newest generation of MiniMed 780G and Control-IQ hybrid closed loop | • The population definition was: People who have T1DM who are having difficulty managing their condition despite prior use of at least one of the following technologies: continuous subcutaneous insulin infusion, real time continuous glucose monitoring, flash glucose monitoring[ab]<br><br>[a] For the purpose of this review, difficulty refers to (1) not maintaining HbA1c levels of 6.5% (48 mmol/mol) or below (for pregnant women/those planning pregnancies: not |

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| | | technologies currently in use in NHS England, which correct for hyperglycaemia. Control-IQ is not represented in any of the studies and MiniMed780G is the intervention in adults in only 1/12 of the studies. This 780G study is not powered to measure HbA1c as it is a safety study, not clinical effectiveness.<br><br>• Studies included are mainly safety studies with 11/12 studies having Time in Range (TIR) as the primary endpoint; these studies were not powered to measure HbA1c reduction as the sample sizes were too small.<br><br>• HbA1c reduction is greater from higher starting point so has a non-linear relationship. Most of the studies selected for NMA were not powered for the secondary endpoint of HbA1c and assumptions re TIR conversion to HbA1c are not validated and should be interpreted with caution.<br><br>• As described the MTA assessment report, studies were heterogeneous in terms of population, age groups, gender, RCT design (parallel cross over), numbers of participants and variable adjustment methods for determining mean difference between intervention and comparators. Studies did not consistently describe comparators. Cross-over studies did not provide data at different cross-over time points. | maintaining fasting plasma glucose levels of 5.2 mmol/l or below, or not maintaining non-fasting plasma glucose of 7.7 mmol/L (one hour after eating)/ 6.3 mmol/L (two hours after eating)), (2) not maintaining at least 70% time in range of 3.9 -10 mmol/l, or (3) repeated hypoglycaemia that causes anxiety about recurrence and is associated with a significant adverse effect on quality of life.<br>[b] Pregnant women and those planning pregnancies will not be required to have previously used CSII and self-monitoring of blood glucose or glucose monitoring (rt-CGM/flash glucose monitoring) with multiple daily injections.<br><br>• The EAG discussed the limitations of RCT and observational evidence. The outcome estimates reported for observational studies were quantitatively broadly in line with those from the RCTs.<br>• The study selection did not include the generation of the technology. The scope evaluated the technology as a whole rather than by model/generation.<br>• The EAG was requested to conduct a regression analysis. This work will be shared. |
| 8c | Medtronic | **Uncaptured Quality of life benefits**<br><br>The committee agreed that there were potential quality of life benefits of HCL systems not captured in the model, including the effect on learning and education, ability to work, mental burden and fear of hypoglycaemic | Exploratory analyses around hypoglycaemic events capture the effects upon the fear of hypoglycaemic events due to the algorithms using the HFS fear of hypoglycaemic events questionnaire. |

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| | | events. The committee concluded that these uncaptured benefits were likely to undervalue the effect of HCL systems on quality of life. This has the effect of falsely inflating the ICER.<br><br>This was considered in the economic modelling for the diagnostic guidance on sensor augmented pumps, DG21. They reported that the ICER changed substantially when a utility increment of 0.0329 was applied to represent a reduction in fear of hypoglycaemia.<br><br>**We ask that the Committee take account of these uncaptured benefits and consider a willingness to pay threshold of up to £30,000/ QALY.** | It is correct that any additional quality of life effects from learning and education, ability to work and mental burden are not included due to a lack of any reasonable estimates for these. |
| 9 | Medtronic | **Consultation Question 2: Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?**<br><br>**Clinical Effectiveness**<br><br>The EAG concluded that ***"the relevance of the RCT populations and outcome measure results for the decision problem is debatable and not easy to judge".***<br><br>*We suggest that the interpretation of the results is factually incorrect as the key driver of the effect size, baseline HbA1c, is not taken into account and data for populations with higher HbA1c has not been taken into account in the recommendation despite availability of more recent RCT and rea- l world evidence*<br><br>**We ask the Committee to interpret the NMA results in statistical context of:**<br><br>a) The effect estimate of 0.29% reduction in HbA1c applies to a population with average baseline HbA1c of 7.5%.<br><br>b) The results from NCT04914910 and the NHS England pilot data confirm that baseline HbA1c is a key driver of the effect size | The EAG presented the threshold analysis to committee as a confidential appendix. Stakeholder comments will be discussed at the second committee meeting on 24 May 2023 and these discussions will inform any ongoing price negotiations.<br><br>The EAG provided scenario analyses incorporating quality of life effects from hypoglycaemic events and the fear of them as noted above due to the algorithms using the HFS, and augmented these with scenario analyses of carers and (both) parents being similarly affected.<br><br>The EAG is revising the NMA to provide clinical estimates for CSII+isCGM and CSII+rtCGM separately, and is revising its costing of CSII+isCGM to reflect the drug tariff price of the Freestyle Libre 2.<br><br>The EAG has provided an extensie review of the costs of hypoglycaemia and incorporates wht it feels is a reasonable cost for this base upon the review. NHS reference costs provide a poor guide, not being specific to hypoglycaemia and not be incurred by those who are not admitted. Not all severe hypoglycaemia results in an admission. |

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| | | observed with HCL therapy. As suggested by regression modelling (Pickup et al 20196) and the most recent evidence, for the population in scope of the draft recommendation with a baseline HbA1c>8%, the reduction of HbA1c is approximately 1%.<br><br>c) The NMA relies on RCT data only and the real-world evidence (RWE) effectiveness should be considered in balance.<br><br>**Base case assumptions**<br><br>The base case takes the effect size from the NMA where studies have a mean HbA1c of 7.5% at the baseline and selects a different baseline HbA1c of 8% from the National Diabetes Audit of people on insulin pumps. HbA1c reduction is greater from higher starting point so has a non-linear relationship therefore selecting a higher baseline HbA1c then applying the effect size from a NMA with a lower average HbA1c is incorrect methodology and requires an adjustment of the effect size to account for the higher baseline HbA1c.<br><br>**Cost Effectiveness**<br><br>The EAG produced a threshold analysis to calculate the price that gives an ICER of £20,000 however this is provided to the Committee as a confidential appendix and has not been shared within the consultation so we do not have the opportunity to comment on this analysis.<br><br>**As this threshold analysis is likely to inform pricing discussions with NHS England, we ask that it is shared with consultees along with the preferred assumption for the ICER of the Committee.**<br><br>At the committee meeting, the EAG presented the HbA1c net improvement threshold analyses (fig 1) using both the national diabetes audit CSII patient baseline characteristics (HbA1c 8.0%) and the NHSE adult pilot baseline characteristics (HbA1c 9.4%) | |

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| | | Using the NHSE adult pilot baseline characteristics data and HbA1c change (-1.5%) results in a large decrease in the ICER from the base case (£12,398 compared with £179k per QALY gained).<br><br>In light of the [redacted], the 1.4 % reduction reported in the ADAPT RCT and the 1.5% reduction reported in the NHS England pilot study, **we ask the Committee to consider a mid-point estimate reduction in HbA1c of around 1%** (estimated from Figure 1; NB: this threshold analysis chart (fig1) was presented to the committee however exact numbers have not been shared as part of the consultation).<br><br>Figure 1 | |

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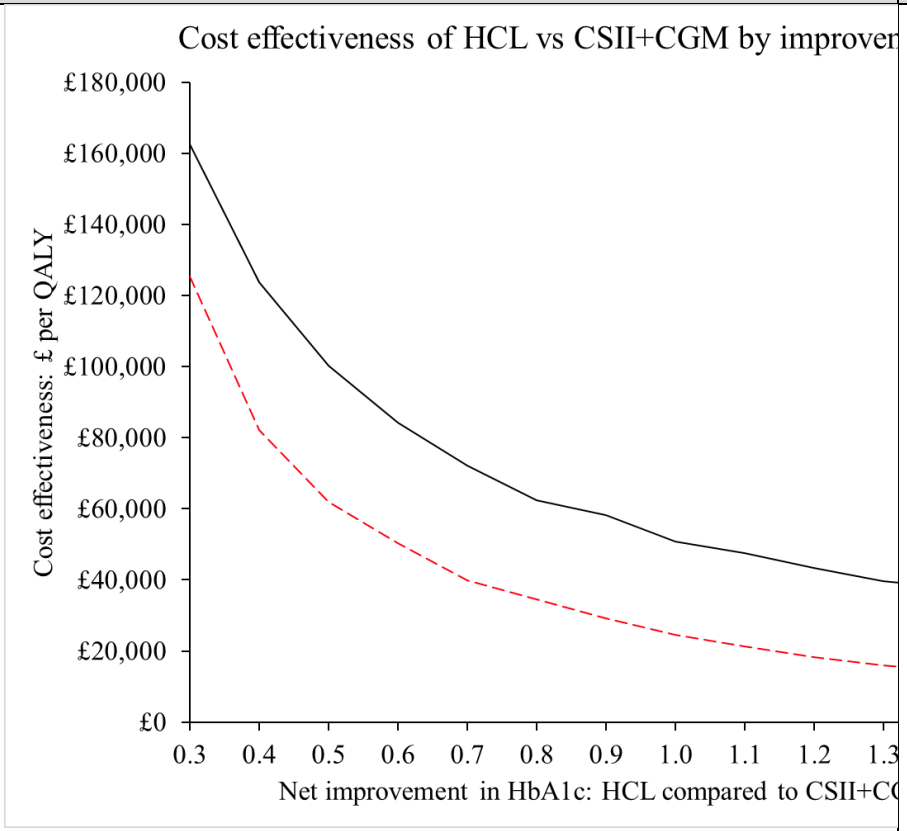
| | |  <br>**Additional factors likely to reduce the ICER further are:**<br>• Uncaptured disutilities in the model for hypoglycaemia, mental burden and patient and carer anxiety, the true ICER is likely to be lower than this. | |

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| | | • Clinical experts have advised the committee that the cost of HCL for those on rt-CGM / CSII are over estimated as most CSII currently have an algorithm embedded at no extra cost.<br><br>• Costs for isCGM have been incorrectly applied to outcome effects of rtCGM, which has the effect of inflating the ICER.<br><br>• Input costs for severe hypoglycaemic events may be an underestimation. The base case assumed a cost of £628 for those requiring medical attention. The National Schedule of NHS Costs 2020-217 reported costs on HRGs KB01B, KB01C, KB01D, KB01F, KB02G and KB01H: Diabetes with Hypoglycaemic Disorders, with CC Score 0 - 8+. Reference costs ranged from £516 to £772 with a weighted average £688 for non-elective short stay and £3,020 for non-elective long stay.<br><br>**Change of comparators from scope**<br><br>Given the change of the scope after the Committee meeting, including MDI with isCGM as a comparator we ask the Committee to explicitly put the current base case into perspective of outcomes being driven by baseline HbA1c, and discuss the 10-fold lower ICER when using the NHSE observational study outcomes and the ADAPT results in the base case analysis of clinical and cost effectiveness. | |
| 10 | Medtronic | **Consultation question 3: are the provisional recommendations sound and a suitable basis for guidance to the NHS?**<br><br>We agree that the provisional recommendations are sound with regards to offering access to people who are having difficulty managing their condition despite optimal management with at least 1 of the following: continuous subcutaneous insulin infusion, real-time continuous glucose monitoring, intermittently scanned continuous glucose monitoring. | Views for the committee. No EAG reposne required. |

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| | | The committee preferred a baseline HbA1c of 64 mmol/mol (8.0%) for use in the model as this widens access to people who cannot maintain their target HbA1c resulting in them having an HbA1c of around 64 mmol/mol (8.0%).<br><br>We agree with the committee's preference for the lower baseline HbA1c however, even at this lower level, this may preclude some people from accessing HCL therapy who work exceptionally hard to maintain HbA1below this level.<br><br>The HbA1c target level for control in adults in the current NICE guideline NG17 is 6.5% and achieving this level of control can involve a significant burden in terms of quality of life. Restricting access to HCL to those with HbA1c around 8% means that those below that level would need to lose control in order to access HCL therapy. | |
| 11 | Medtronic | **Consultation Question 4: Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?**<br><br>We agree with the widening of the recommendations to people who are on isCGM or rtCGM alone as restricting the recommendations to those already on a pump would build on the existing inequity of access that exists with pumps. | No EAG reponse required. |
| 12 | Medtronic | **Committee papers EAG Comments on Assessment Report p365**<br><br>In response to a consultee comment (committee papers p365) the EAG responded that *"It is not appropriate to separately model the cost effectiveness of HCL against CSII+rtCGM and CSII+isCGM as* ***this could result in perverse incentives for patients to seek to adopt the more costly CSII+rtCGM".***<br><br>It is unclear what is meant by perverse incentives. Please provide the rationale for not evaluating the separate comparators in terms of NICE | The EAG is now providing separate clinical effectiveness estimates for CSII+rtCGM and CSII+isCGM and will incorporate these in the economic modelling. |

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| | | methods where clinical effectiveness is evaluated independently from cost effectiveness.<br><br>The recently published NICE Guidance on CGM for T1 recommends that adults with type 1 diabetes are offered a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring, based on their individual preferences, needs, characteristics, and the functionality of the devices available" so the description of "perverse incentive" in relationship to rtCGM is entirely inappropriate.<br><br>RtCGM and isCGM have a different clinical outcomes as reflected by evidence base including the very recent publication of 24-month results from the randomised ALERTT1 trial [ref] and it is inappropriate to assume the same efficacy for isCGM and rtCGM as was done for the base case.<br><br>**Given that CSII+rtCGM and CSII+isCGM have not been modelled separately and this has resulted in an inflated ICER, we ask the committee to make allowance for this when deciding on their preferred ICER.** | |
| 13 | Medtronic | **ACD Page 6, para 3.** *"Any systems available in the future need to be able to show interoperability and be equivalent to current systems in terms of patient benefits".*<br><br>We suggest that this sentence is amended for clarification to "*Any systems available in the future need to be able to show **data** interoperability and be equivalent to current systems in terms of patient benefits".* | For the ACD. No EAG response required |
| 14 | Medtronic | 1) Choudhary P, Kolassa R, Keuthage W, et al. Advanced hybrid closed loop therapy versus conventional treatment in adults with type 1 diabetes (ADAPT): a randomised controlled study. *Lancet Diabetes Endocrinol*. 2022;10(10):720-731. doi:10.1016/S2213-8587(22)00212-1<br>2) Arrieta A, Battelino T, Scaramuzza AE, et al. Comparison of MiniMed TM 780G system performance in users aged below and above 15 | Please see response above for ADAPT study |

| Comment Number | Name and organisation | Stakeholder Comment | EAG considerations |
|---|---|---|---|
| | | years: Evidence from 12,870 real-world users. *Diabetes Obes Metab*. Published online April 11, 2022:dom.14714. doi:10.1111/dom.14714<br>3) Ekhlaspour L, Town M, Raghinaru D, Lum JW, Brown SA, Buckingham BA. Glycemic Outcomes in Baseline Hemoglobin A1C Subgroups in the International Diabetes Closed-Loop Trial. *Diabetes Technol Ther*. 2022;24(8):588-591. doi:10.1089/dia.2021.0524<br>4) Breton MD, Kovatchev BP. One Year Real-World Use of the Control-IQ Advanced Hybrid Closed-Loop Technology. *Diabetes Technol Ther*. 2021;23(9):601-608. doi:10.1089/dia.2021.0097<br>5) Castañeda J, Mathieu C, Aanstoot HJ, et al. Predictors of time in target glucose range in real-world users of the MiniMed 780G system. *Diabetes Obes Metab*. 2022;24(11):2212-2221. doi:10.1111/dom.14807<br>6) Pickup JC. Is insulin pump therapy effective in Type 1 diabetes? *Diabet Med.* 2019;36(3):269-278. doi:10.1111/dme.13793<br>7) https://www.england.nhs.uk/publication/2020-21-national-cost-collection-data-publication/ accessed Jan23 | |
| 15 | **Tandem Diabetes Care Inc** | We request that NICE consider the following additional information:<br><br>In response to EAG's comment that the Breton et al (2020) study was not included when reviewing hybrid closed loop (HCL) vs predive low glucose suspend (PLGS) because "> 10% not on prior intervention pump or monitor, results were not reported separately/stratified by prior intervention)" – please refer to page 17 of the supplementary appendix with the stratification by prior therapy, which is available at: https://www.nejm.org/doi/suppl/10.1056/NEJMoa2004736/suppl_file/nejmoa2004736_appendix.pdf<br><br>A study that should have been included in the clinical review of RCTs comparing HCL to PLGS:<br>Brown SA, Beck RW, Raghinaru D, Buckingham BA, Laffel LM, et al. Glycemic Outcomes of Use of CLC Versus PLGS in Type 1 Diabetes: A Randomized Controlled Trial. Diabetes Care 2020;43:1822-1828. https://doi.org/10.2337/dc20-0124<br><br>Supplemental appendix is available at: | Breton et al (2020): thank you for highlighting the appendix. The appendix does not stratify the data in a format that can be used in an NMA. The scope states: *People who have T1DM who are having difficulty managing their condition despite prior use of at least one of the following technologies: continuous subcutaneous insulin infusion, real time continuous glucose monitoring, flash glucose monitoring.* However, the results presented on page 17 does not present (pump/pump+CGM/CGM only) as one group.<br><br>Brown: Of the 112 participants in the Closed loop control (CLC) group in the preceding study, 109 consented to continue in the extension phase. The 109 particpant had CLC as prior intervention which does not meet the scope. |

| Comment Number | Name and organisation | Stakeholder Comment | EAG considerations |
|---|---|---|---|
| | | https://diabetesjournals.figshare.com/articles/figure/Glycemic_Outcomes_of_Use_of_CLC_vs_PLGS_in_Type_1_Diabetes_A_Randomized_Controlled_Trial/12240968 | |
| 16 | Tandem Diabetes Care Inc | We are concerned with NICE's Recommendation 1.1, which recommends hybrid closed loop systems for people with Type 1 diabetes who are having difficulty managing their condition and have an average HbA1c level of 8.0% and higher for the following reasons:<br>• The randomized controlled trials (RCTs) used to determine the clinical benefit for the cost-effectiveness model's base case (-0.28% HbA1c) had an average baseline HbA1c of 7.5%.<br>• NICE guidelines (NG3, NG17, NG18) recommend a target goal of HbA1c goal of 6.5% or lower for people with Type 1 diabetes to minimize risk of long-term complications. Thus, limiting hybrid closed loop system access to people with 8.0% or higher excludes a large segment of the population with Type 1 diabetes who would greatly benefit from reaching target goal.<br>• The Diabetes Control and Complications Trial (DCCT) found intensive therapy (mean HbA1c about 7%) delays the onset and slows the progression of retinopathy, nephropathy, and neuropathy by 35% to 76% compared to standard therapy (mean HbA1c about 9%).[1] These microvascular benefits persist for two decades as seen with follow up of DCCT cohorts in the Epidemiology of Diabetes Intervention and Complications (EDIC) study.[2]<br>• Based on the National Diabetes Audit, about 2/3 of the population with Type 1 diabetes in NHS England have HbA1c > 7.5%.<br>• A threshold of HbA1c of 8.0% or greater may result in perverse incentives to poorly manage glycemic levels to become eligible for hybrid closed loop systems.<br>[1] Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of | For the ACD. No EAG response required |

| Comment Number | Name and organisation | Stakeholder Comment | EAG considerations |
|---|---|---|---|
| | | long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977–986. DOI: 10.1056/NEJM199309303291401<br>[2] Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group. Effect of intensive diabetes therapy on the progression of diabetic retinopathy in patients with type 1 diabetes: 18 years of follow-up in the DCCT/EDIC. Diabetes 2015;64:631–642. | |
| 17 | Tandem Diabetes Care Inc | We are concerned that the base case cost-effectiveness model significantly underestimates the quality of life (QOL) benefit of hybrid closed loop systems, resulting in a much larger ICER (£179K/QALY) than expected. The base case does not account for hypoglycemic events nor other uncaptured QOL benefits, such as improved sleep, decreased mental burden, ability to work, etc. While the scenario analysis includes severe and non-severe hypoglycemia events and disutility values based on reported improvements in the Hypoglycemia Fear Survey, which improved ICERs (ranging from £121K/QALY to £170K/QALY), QOL benefits for hybrid closed loop systems remain underestimated due to uncaptured benefits. Additionally, severe and non-severe hypoglycemia becomes an increasing concern when targeting an HbA1c goal of 6.5% and lower. Since cost-effectiveness results from the base case are used to inform decision-making and policy, we urge NICE to consider this significant model limitation when determining the pricing required for hybrid closed loop systems to be considered “cost-effective.” | As noted above, the possible effects upon fear of hypoglycaemia and hypoglycaemic events for the patient, parents and carers have been included. These are speculative due to there being no good data and event rates having to be inferred from time below range estimates. They are not included in the base case for this reason, but were presented to and considered by the committee. |
| 18 | **Ypsomed Limited**<br><br>Submitted via the web | Ypsomed are overall delighted by the announcement by NICE of the proposed guidelines on the future availability of closed loop systems for people living with T1 Diabetes in England. We welcome the step forward in accelerating the access of new technologies to support those living with Type 1 diabetes, their families, and carers.<br><br>The novel way in which the NHS Hybrid Closed Loop pilot was designed to provide NICE with real-world data to support recommendations is commended.<br><br>The following feedback from Ypsomed highlights the need for clarity in the recommendations to ensure guidance is interpreted and implemented to | For the ACD. No EAG response required. |

| Comment Number | Name and organisation | Stakeholder Comment | EAG considerations |
|---|---|---|---|
| | | avoid health inequalities in relation to the use of Diabetes Tech being exacerbated. | |
| 19 | Ypsomed Limited | Recommendations 1.2<br><br>• Clearly state in the guidance which commercially available systems are licensed for use in pregnancy. | For the ACD. No EAG response required. |
| 20 | Ypsomed Limited | Recommendations 1.3<br><br>• Approx 30-40% NHS trusts procure Diabetes Tech via the NHS Supply Chain National Tender, the remaining ICS have their own preferred pump list. Recommend a national pricing and procurement infrastructure to aid adoption and uptake whilst minimising 'postcode lottery' of access. Thus, ensuring equitable access to the same portfolio of products. | For the ACD. No EAG response required. |
| 21 | Ypsomed Limited | Recommendations 1.3<br><br>There is a need to increase capacity and capability of the healthcare professionals who will be implementing and supporting the use of the HCL systems. | For the ACD. No EAG response required. |
| 22 | Ypsomed Limited | Recommendations 1.4<br><br>• Structured education needs to be widely available in a format that is accessible to the majority, non-traditional methods of implementation should be considered. It is established that structured education can be a barrier to accessing diabetes technologies. | For the ACD. No EAG response required. |
| 23 | Ypsomed Limited | Recommendations 1.5<br><br>• How will existing HCL users be assessed at renewal? If HbA1c has improved and is lower than 8% will the system be renewed or removed?<br>• PWD who are currently using self-funded ''DIY' HCL systems, with HbA1Cs less than 8% won't meet the criteria, how will they be assessed? | For the ACD. No EAG response required. |
| 24 | Ypsomed Limited | Section 2.1 Type 1 diabetes<br><br>• The quantitative research doesn't accurately describe the reduced burden on mental health of PWD and their families and carers. It is necessary to take into consideration such things as the improvement in | For the ACD. No EAG response required. |

| Comment Number | Name and organisation | Stakeholder Comment | EAG considerations |
|---|---|---|---|
| | | sleep disturbance/deprivation, burn out of carers, days lost at work / school etc. in addition to the reduction in HbA1c | |
| 25 | Ypsomed Limited | Section 2.6 The interventions<br><br>• The report should include all current commercially available Hybrid Closed Loop Systems in England – Ypsopump with Cam APS FX and Dexcom G6 or FSL3 is not listed whereby others that are not currently commercially available are listed. Recommend listing all commercially available systems at time of publication. | For the ACD. No EAG response required. |
| 26 | Ypsomed Limited | Section 2.6 The interventions<br>• Clearly state in the guidance which commercially available systems are licensed for use in pregnancy and young | For the ACD. No EAG response required. |
| 27 | Ypsomed Limited | Section 2.8 Price<br>Ypsomed understands the NHS is experiencing the most severe funding pressures in its 70-year history. Balancing rising demand whilst commissioning new technologies poses a great challenge. Ypsomed's mylife Loop system comprising of Ypsopump + Dexcom G6 or Freestyle Libre 3 + CamAPS FX algorithm is priced between [redacted] (depending on the choice of sensor used) for a 4-year period. The mylife Loop system cost [redacted]. | Costs for HCL are sourced from the NHS Supply Chain. |
| 28 | Ypsomed Limited | Section 3.2 Committee discussion - Access to technology and care<br><br>• Approx 30-40% NHS trusts procure Diabetes Tech via the NHS Supply Chain National Tender, the remaining ICS have their own preferred pump list. Recommend a national pricing and procurement infrastructure to aid adoption and uptake whilst minimising 'postcode lottery' of access. Thus, ensuring equitable access to the same portfolio of products. | For the ACD. No EAG response required. |
| 29 | Ypsomed Limited | Section 3.2 Committee discussion - Access to technology and care<br><br>NHS England is currently undertaking an Assessment of: Blood glucose and ketone meters, testing strips and associated consumables, provided a clear rationale for doing so, NHS England may issue one or more commissioning recommendations covering topics, including but not limited | For the ACD. No EAG response required. |

| Comment Number | Name and organisation | Stakeholder Comment | EAG considerations |
|---|---|---|---|
| | | to:<br>• Products it considers the NHS should prioritise for use<br>• Guidance and/or resources to enable patients to safely change products, where clinically appropriate; and/or<br>• Improvement opportunities<br><br>We recommend that a similar assessment is conducted for the final guidance for hybrid closed loop systems to expand appropriate access without limitations. | |
| 30 | Ypsomed Limited | Section 3.4 Committee discussion - Baseline characteristics<br><br>• People with T1 Diabetes with HbA1c lower than 8% may be experiencing repeated hypoglycaemic events that impact heavily on QOL, a HCL system would benefit them.<br>• People with T1 Diabetes and carers of people with T1 Diabetes who have worked tirelessly, often at a detriment to their QOL and gained HbA1c less than 8% are being excluded from a system that would benefit them by reducing the burden of management.<br>• How will existing Hybrid Closed Loop users be assessed at renewal? If HbA1c has improved and is lower than 8% will the system be renewed or removed?<br>• People with T1 Diabetes who are currently using self-funded ‘‘DIY’ HCL systems, with HbA1Cs less than 8% won’t meet the criteria, how will they be assessed? | For the ACD. No EAG response required. |
| 31 | Ypsomed Limited | Section 3.5 Committee discussion - Children<br><br>• Clearly state in the guidance which commercially available systems are licensed for use in the young. | For the ACD. No EAG response required. |
| 32 | Ypsomed Limited | Section 3.6 committee discussion - Pregnancy<br><br>• Clearly state in the guidance which commercially available systems are licensed for use in pregnancy. | For the ACD. No EAG response required. |
| 33 | Ypsomed Limited | Section 3.9 committee discussion – uncaptured benefits<br><br>• HCL systems can benefit those with learning difficulties, Diabetes burnout, impaired cognitive function due to age or illness. | For the ACD. No EAG response required. |

| Comment Number | Name and organisation | Stakeholder Comment | EAG considerations |
|---|---|---|---|
| 34 | Ypsomed Limited | Section 4.3 implementation<br><br>• There is a need to increase the capacity and capability of the skilled healthcare professionals who are implementing and supporting the use of the HCL systems. | For the ACD. No EAG response required. |

**DAP55 Diabetes HCL MTA Request for further analyses – POST ACD**

**Title**: **Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes**

**Produced by:** Warwick Evidence

Division of Health Sciences

Warwick Medical School, University of Warwick

[redacted]

**Date completed:** 19.05.2023

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**Declared competing interests of the authors**

*None*

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## Regression analyses

The EAG identified eight studies that reported change in HbA1c for an HCL recipient adult population. The evidence included 6 RCTs (Tauschmann (1), Thabit (2), McAuley (3), Brown (4), Boughton (5), and Bergenstahl (6)) and two single arm studies (Beato vibora (7), and NHS adult pilot study). Appendix 1 provides an overview of study characteristics.

In addition, NICE drew our attention to an abstract of the Steno trial (8)(ACD). The Steno was an RCT study reporting a change of [redacted] NICE requested a regression analysis of effect size vs. baseline and taking into consideration the NHS pilot study. The included studies were predominantly conducted in adult populations, however the age distribution varied considerable between studies; the age range of the additional abstract population was not disclosed (Table 1, Table 2). It should be emphasized that the number of studies is relatively small and that they are heterogeneous in design, duration, and age range of patients.

**Table 1. Main characteristics of studies included in the regression**

| Study | Country | Inclusion criteria | Age | Pre-intervention | Duration of intervention/comparator | Pre-comparator |
|---|---|---|---|---|---|---|
| McAwley (Cross-over) | Australia *N*=30 | Diag: ≥ 10 yr ; Age ≥ 60 yr; using pump; HbA1c ≤10.5% ; no dementia. | Elderly , 67 yr (± 5) | Multidisciplinary education from diabetes nurse educators, dietitians, endocrinologists 3 to 6 week run-in period with standard SAP therapy | 16 weeks | As for intervention |
| Brown (Parallel-group) | USA *N = 168* | Diag ≥ 1 year; age ≥ 14 y; insulin ≥ 1 year; HbA1c 5.4 to 10.6% | 14 to 71 years | Run-period lasting 2 to 8 weeks to train patients on using devices | 26 weeks | Run-period lasting 2 to 8 weeks to train patients on using devices |
| Thabit 2015 adult arm (Cross-over) | UK, Germany, Austria *N*=33 | Diag: ≥ 0.5yr previous; age ≥18 y; pump ≥ 0.5y; HbA1c 7.5% to 10%; | Adults, 40 yr (±9·4) | run-in period lasting 4 to 6 weeks, training regarding the use of the insulin pump and the CGM device | 12 weeks | SAP (Identical insulin pumps and continuous glucose-monitoring devices were used during the |
| Boughton (Cross-over) | UK, Austria *N*= 37 | Diag: ≥ 1 yr ; Age ≥ 60 yr; pump ≥3 months; HbA1c ≤10·0%. No current use of a closed-loop system, no more than 1 severe in preceding 6 months | Elderly, 68 yr (62 to 70) | Baseline measurements and questionnaires. Study device training in SAP mode (auto mode disabled) for 3-4 week run-in period.<br><br>If assigned to HCL first, this was used at home over 16 weeks | 16 weeks | Same as intervention |
| Tauschmann 2018 [53] | UK, US N= 86 | Diag: ≥ 1yr previous; age | Children and young | a run-in period of at least 4 | 12 weeks | training on the effective |

| | | | | | | |
|---|---|---|---|---|---|---|
| (Parallel) | | ≥ 6 to 20 yr ; pump ≥3 months; HbA1c 7.5% to 10%; no CGM previous 3 months | adults 22yr (13 to 26) | weeks. Participants were trained to perform a glucose sensor calibration check before breakfast and evening meals. | | use of real-time continuous glucose monitoring for optimisation of insulin therapy. |
| Bergenstahl (Cross-over) | N=112 | Diag: ≥ 1 year; Age 14 to 29 yr ; HbA1c 7·0% to 11·0% ; Excluded if ≥ 1 severe hypo. | 14 to 29 yr | | | |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Beato vibora (Single-arm) | N=52 | HbA1c % 7.23 (± 0.86); Preg: women excluded | Adult 43 yr (±12) | | | |
| NHS pilot study (Single-arm) | England N = 640 (63 Lost to Fup) | NHS services adults with Type 1 diabetes managed with an insulin pump and flash glucose monitor with an HbA1c ≥ 8.5% ; Age > 18 yr. | Adult median 40 (IQR: 28, 50). | Patients enrolled in the study were on CSII therapy which is one of NICE criteria to switch to HCL | 5 months | NA |

## Table 2. Summary of HbA1c (mean, SD) reported in regression studies

| **HbA1c%** | McAwley | Brown | Thabit 2015 adult arm | Boughton | Tauschmann 2018 | Bergenstahl | [redacted] | Beato vibora (single arm) | NHS pilot study (single arm) |
|---|---|---|---|---|---|---|---|---|---|
| **Baseline** | 7.5 (6) | 7.40 (9.6) | 7.6 (0.9) | 7.5 (1.0) | 8.0 (0.6) | 7.9 (0.7) | [redacted] | 7.23 (0.86) | 9.4 (0.8) |
| **Endline** | *7.3 (7.1,7.5) | 7.06 (0.79) | 7.3 (0.8) | 6.7 (0.7) | 7.4 (0.6) | 7.6 (0.6) | [redacted] | 6.67 (0.61) | 7.9 (0.8) |
| **median IQR* | | | | | | | | | |

## Unweighted regression analyses

Briefly, we performed unweighted (Figure 1) the included studies and a range of sensitivity analyses. We were unable to weight the Steno trial (8) because of missing data, and therefor the weighted regressions does not include this study.

**Figure 1. Results of unweighted regression**

The regression slope for all nine studies and for the seven RCTs were similar. The EAG would like to highlight that: a] it was not possible to estimate a variance around the Steno abstract (8), b] two RCTs, Thabit (2) and McAuley (3) yielded almost identical results only differing in the uncertainty around effect size; these regressions appear reasonably consistent with the result from the NHS pilot study. A much flatter regression was obtained after the exclusion of data from the Steno abstract (8)from the RCTs regression. The RCT of Boughton (5) included elderly patients in comparison to the other RCTs. The exclusion of Boughton from the regression of RCTs resulted in a somewhat steeper regression slope than that of all RCTs (or all studies) but consistent with the NHS pilot study that exhibited larger effect size at a higher baseline value. Sensitivity analyses yielded similar regression slopes to the analysis of all nine studies.:

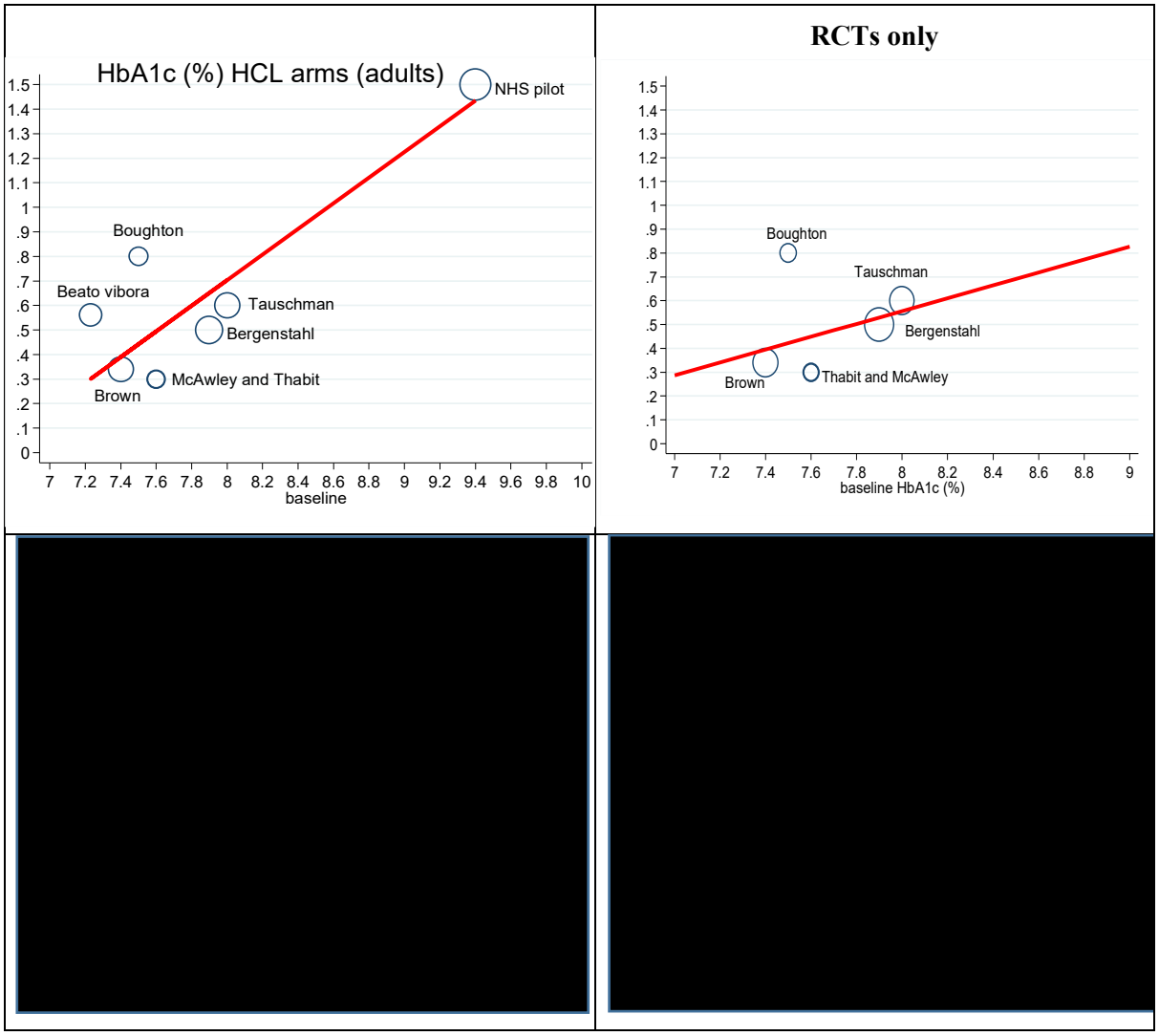
Sensitivity analysis one: including RCTs+ NHS and excluding Boughton,

Sensitivity analysis two: including RCTs + NHS and excluding Boughton and Steno abstract.

## Weighted regression analyses

The weighted regression relates to the inverse of the standard error (SE) of the effect size. The analyses are presented in ***Figure 2*** where the vertical axis is the effect size.

**Figure 2. Results of weighted regression**




The inclusion of all studies (including the NHS Pilot) resulted in a regression line that aligns with the NHS pilot study. The weighted regression of RCT studies indicated a poor alignment with the NHS pilot study and with Steno abstract ([redacted]). The EAG notes the large effect size of Boughton, and this may be an outlier.

## Regression analyses: baseline HbA1c (%) vs. net change in HbA1c. in HCL RCTs

Seven RCTs with sufficient reported data were included: five compared HCL vs. CSII+rtCGM (Benhamou (9), Boughton (5), Tauschmann (1), Ware A (10), and Ware B (11)), and two compared HCL with CSII+CGM (Thabit (adults) and Thabit (children)). The effect size was defined as the

change in (HbA1c %) in the HCL arm minus that in the comparator arm (net change in HbA1c). The change in HbA1c (%) was calculated from the HbA1c% at the start of the intervention minus that at the end of the study or treatment period (for cross over trials). All studies reported greater reduction in HbA1c % in the HCL arm than the comparator arm (net change negative). Where baseline HbA1c % differed between arms, a pooled estimate was calculated weighted by the number of participants per arm. The Benhamou RCT (9) was a cross over design and baseline HbA1c % for each treatment group required estimation from available but incomplete reported data, resulting in two differing estimates. Studies reported precision for each arm to only a single decimal point; calculation of difference between arms consequently had little precision (

***Table 3***).

Linear weighted regression analyses were conducted using the "*metareg*" command in Stata. Three weightings were explored: A] according to SD _effect size; B] according to SE_effect size; and C] according to sample size. It should be noted that relatively few studies were available and that baseline HbA1c% contributes to both ordinate and abscissa axes of regressions. Input data and output regression parameters (slope and constant) are summarised in the tables below.

## Regression using all seven studies, and sensitivity analyses omitting specified studies

A] With Benhamou baseline HbA1c at 7.69 %

Data used are summarised in Table 3 and regression parameters in subsequent Tables.

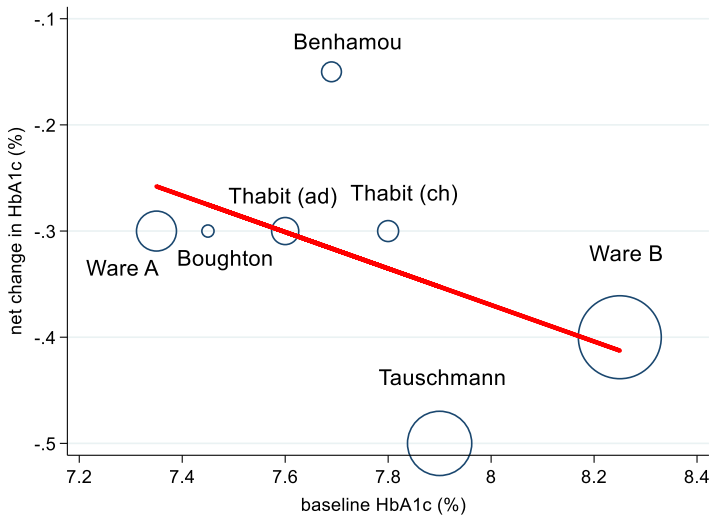
| Base lineline HbA1c | change | change_sd | N | change_se | Study |
|---|---|---|---|---|---|
| 7.69* | -.15** | .107 | 126 | .009532 | Benhamou |
| 7.45 | -.3 | .095 | 37 | .015618 | Boughton |
| 7.9 | -.5 | .027 | 86 | .002911 | Tauschmann |
| 7.35 | -.3 | .039 | 69 | .004695 | Ware A |
| 8.25 | -.4 | .026 | 133 | .002254 | Ware B |
| 7.6 | -.3 | .056 | 65 | .006946 | Thabit (adult) |
| 7.8 | -.3 | .063 | 49 | .009 | Thabit (children) |
| ** baseline calculated; ** effect size as reported by authors* | | | | | |
| Base lineline HbA1c | change | change_sd | N | change_se | Study |
| 7.69* | -.15** | .107 | 126 | .009532 | Benhamou |
| 7.45 | -.3 | .095 | 37 | .015618 | Boughton |
| 7.9 | -.5 | .027 | 86 | .002911 | Tauschmann |
| 7.35 | -.3 | .039 | 69 | .004695 | Ware A |
| 8.25 | -.4 | .026 | 133 | .002254 | Ware B |
| 7.6 | -.3 | .056 | 65 | .006946 | Thabit (adult) |
| 7.8 | -.3 | .063 | 49 | .009 | Thabit (children) |
| ** baseline calculated; ** effect size as reported by authors* | | | | | |

**Table 3. Values used for regression analysis (seven studies HCL vs. comparator)**

## Table 4. Regression parameters according to different weighting

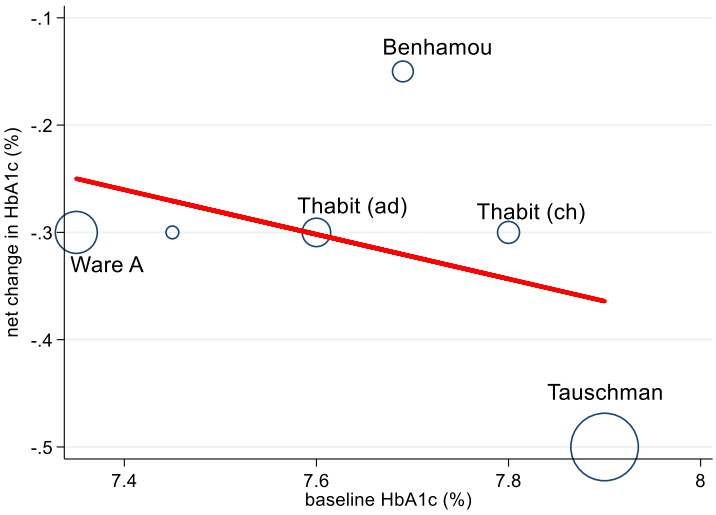
| All seven studies, no omissions. HCL vs comparator | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.17103 | 0.140234 | -1.22 | 0.223 | -0.44588 | 0.103828 |
| A] | const | 0.98399 | 1.087889 | 0.9 | 0.366 | -1.14822 | 3.116223 |
| B] | gradient | -0.17184 | 0.155735 | -1.1 | 0.27 | -0.47707 | 0.133399 |
| B] | const | 1.005037 | 1.203178 | 0.84 | 0.404 | -1.35315 | 3.363224 |
| C] | gradient | -0.13149 | 109.912 | 0 | 0.999 | -215.555 | 215.2921 |
| C] | const | 0.687012 | 835.9046 | 0 | 0.999 | -1637.66 | 1639.03 |

Example of regression plot (B] weighting)



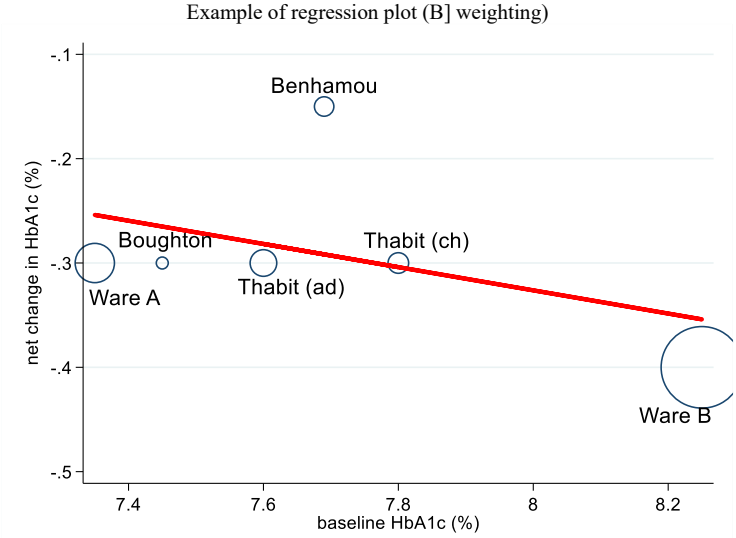

| Ware B omitted (leaving 6 studies) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.26181 | 0.221574 | -1.18 | 0.237 | -0.69609 | 0.172466 |
| A] | const | 1.670811 | 1.693593 | 0.99 | 0.324 | -1.64857 | 4.990191 |
| B] | gradient | -0.20768 | 0.276716 | -0.75 | 0.453 | -0.75003 | 0.334675 |
| B] | const | 1.276505 | 2.112549 | 0.6 | 0.546 | -2.86402 | 5.417025 |
| C] | gradient | -0.13002 | 130.9565 | 0 | 0.999 | -256.8 | 256.54 |
| C] | const | 0.676001 | 993.1718 | 0 | 0.999 | -1945.91 | 1947.257 |

Example of regression plot (B] weighting)



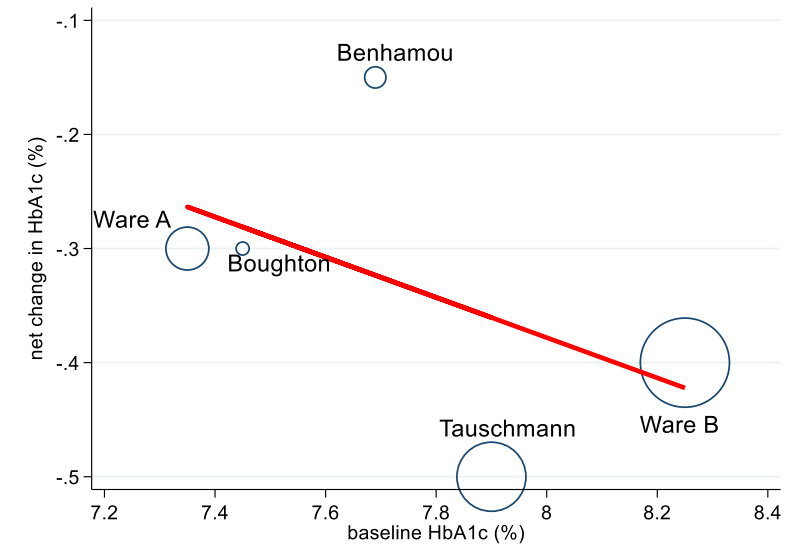
| Tauschmann omitted (leaving 6 studies) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.1282 | 0.047824 | -2.68 | 0.007 | -0.22193 | -0.03447 |
| A] | const | 0.664941 | 0.377723 | 1.76 | 0.078 | -0.07538 | 1.405264 |
| B] | gradient | -0.11122 | 0.107936 | -1.03 | 0.303 | -0.32277 | 0.100327 |
| B] | const | 0.563567 | 0.830801 | 0.68 | 0.498 | -1.06477 | 2.191907 |
| C] | gradient | -0.03928 | 119.6547 | 0 | 1 | -234.558 | 234.4796 |
| C] | const | -7.3E-05 | 907.1575 | 0 | 1 | -1778 | 1777.996 |

Example of regression plot (B] weighting)



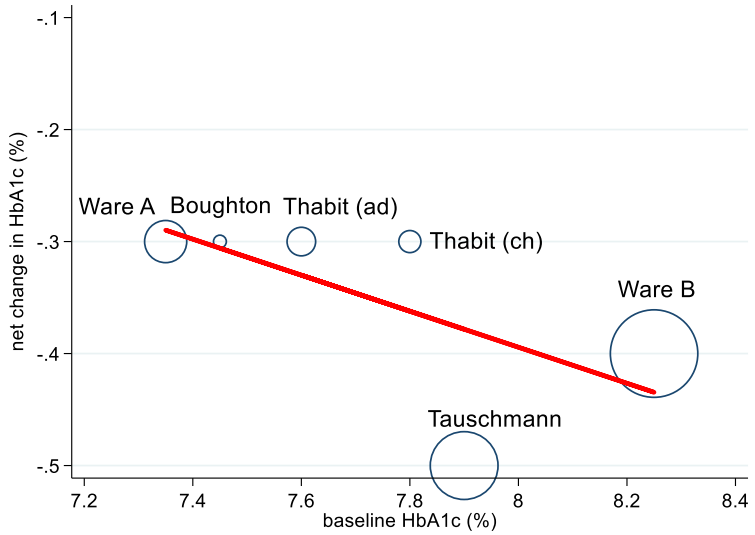

| Thabit (ad) and Thabit (ch) omitted (leaving 5 studies; HCL vs. CSII+rtCGM) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.17052 | 0.162566 | -1.05 | 0.294 | -0.48915 | 0.1481 |
| A] | const | 0.970578 | 1.263572 | 0.77 | 0.442 | -1.50598 | 3.447133 |
| B] | gradient | -0.17635 | 0.173486 | -1.02 | 0.309 | -0.51638 | 0.163674 |
| B] | const | 1.032739 | 1.342045 | 0.77 | 0.442 | -1.59762 | 3.663099 |
| C] | gradient | -0.20488 | 128.1507 | 0 | 0.999 | -251.376 | 250.9659 |
| C] | const | 1.224049 | 965.8973 | 0 | 0.999 | -1891.9 | 1894.348 |

Example of regression plot (B] weighting)



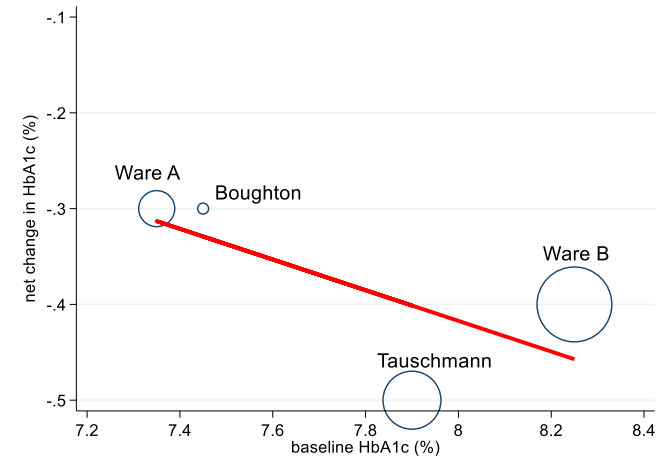
| Benhamou omitted (leaving 6 studies) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.15883 | 0.132808 | -1.2 | 0.232 | -0.41913 | 0.101472 |
| A] | const | 0.87173 | 1.031556 | 0.85 | 0.398 | -1.15008 | 2.893543 |
| B] | gradient | -0.16089 | 0.140545 | -1.14 | 0.252 | -0.43635 | 0.114577 |
| B] | const | 0.892741 | 1.086689 | 0.82 | 0.411 | -1.23713 | 3.022612 |
| C] | gradient | -0.14359 | 110.2468 | 0 | 0.999 | -216.223 | 215.9361 |
| C] | const | 0.772869 | 838.1186 | 0 | 0.999 | -1641.91 | 1643.455 |

Example of regression plot (B] weighting)




| Thabit (ad) Thabit (ch) Benhamou omitted (leaving 4 studies HCL vs. CSII+rtCGM) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.15059 | 0.151852 | -0.99 | 0.321 | -0.44821 | 0.147034 |
| A] | const | 0.786018 | 1.182914 | 0.66 | 0.506 | -1.53245 | 3.104486 |
| B] | gradient | -0.16015 | 0.152868 | -1.05 | 0.295 | -0.45976 | 0.139468 |
| B] | const | 0.864007 | 1.18434 | 0.73 | 0.466 | -1.45726 | 3.18527 |
| C] | gradient | -0.24017 | 129.8923 | 0 | 0.999 | -254.824 | 254.344 |
| C] | const | 1.478451 | 977.908 | 0 | 0.999 | -1915.19 | 1918.143 |

Example of regression plot (B] weighting)



B] With Benhamou baseline HbA1c at 7.26 %

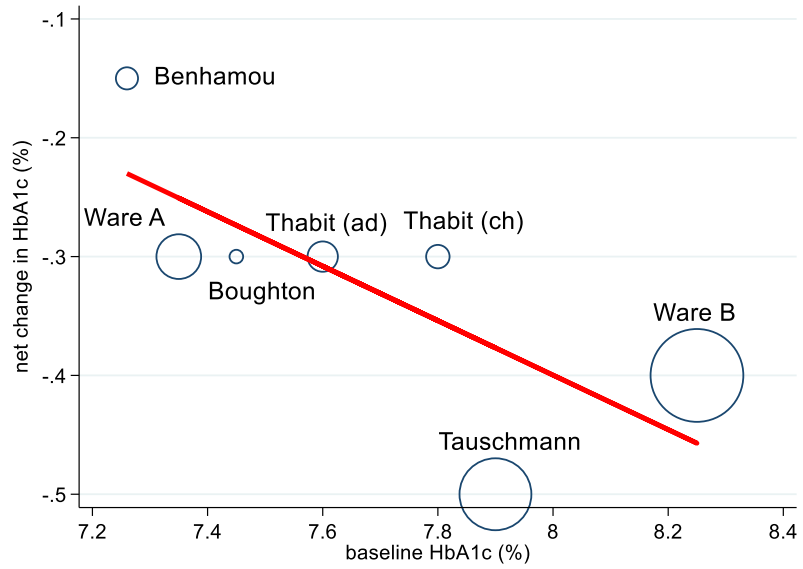
**Table 5. Values used for regression analysis (seven studies HCL vs. comparator)**

| bline | change | change_sd | N | change_se | Study |
|---|---|---|---|---|---|
| 7.26* | -.15** | .107 | 126 | .009532 | Benhamou |
| 7.45 | -.3 | .095 | 37 | .015618 | Boughton |
| 7.9 | -.5 | .027 | 86 | .002911 | Tauschmann |
| 7.35 | -.3 | .039 | 69 | .004695 | Ware A |
| 8.25 | -.4 | .026 | 133 | .002254 | Ware B |
| 7.6 | -.3 | .056 | 65 | .006946 | Thabit (adult) |
| 7.8 | -.3 | .063 | 49 | .009 | Thabit (children) |
| ** baseline calculated; ** effect size as reported by authors* | | | | | |

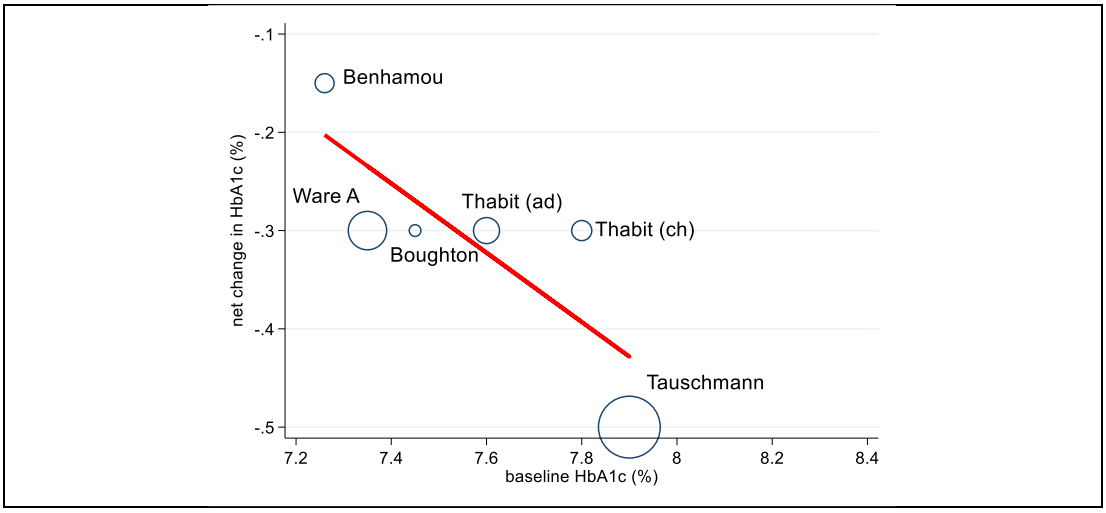
**Table 6. Regression parameters according to different weighting**

| All seven studies, no omissions. HCL vs comparator | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.20465 | 0.121344 | -1.69 | 0.092 | -0.44248 | 0.033175 |
| A] | const | 1.236406 | 0.937519 | 1.32 | 0.187 | -0.6011 | 3.07391 |
| B] | gradient | -0.22926 | 0.126537 | -1.81 | 0.07 | -0.47727 | 0.018744 |
| B] | const | 1.43435 | 0.970074 | 1.48 | 0.139 | -0.46696 | 3.335661 |
| C] | gradient | -0.17124 | 105.8368 | 0 | 0.999 | -207.608 | 207.2651 |
| C] | const | 0.986728 | 803.386 | 0 | 0.999 | -1573.62 | 1575.594 |

Example of regression plot (B] weighting)

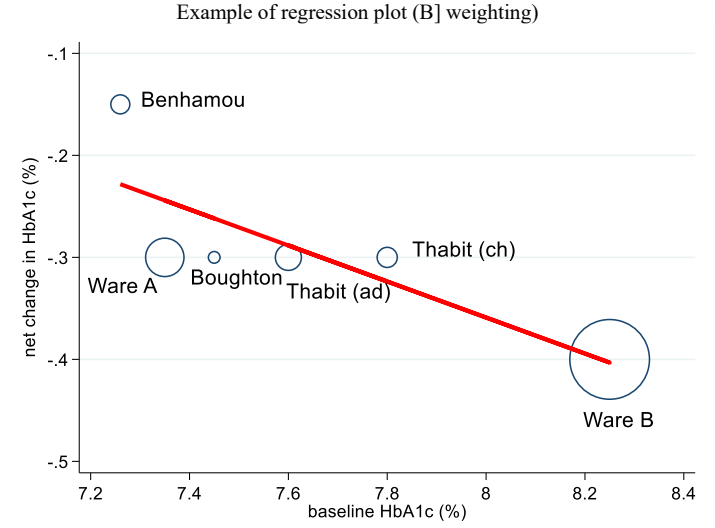



| Ware B omitted (leaving 6 studies) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.35105 | 0.147791 | -2.38 | 0.018 | -0.64071 | -0.06138 |
| A] | const | 2.331102 | 1.125704 | 2.07 | 0.038 | 0.124763 | 4.537442 |
| B] | gradient | -0.3526 | 0.148927 | -2.37 | 0.018 | -0.64449 | -0.06071 |
| B] | const | 2.357208 | 1.126537 | 2.09 | 0.036 | 0.149235 | 4.56518 |
| C] | gradient | -0.18701 | 125.3056 | 0 | 0.999 | -245.782 | 245.4075 |
| C] | const | 1.105242 | 948.4467 | 0 | 0.999 | -1857.82 | 1860.027 |
| Example of regression plot (B] weighting) | | | | | | | |



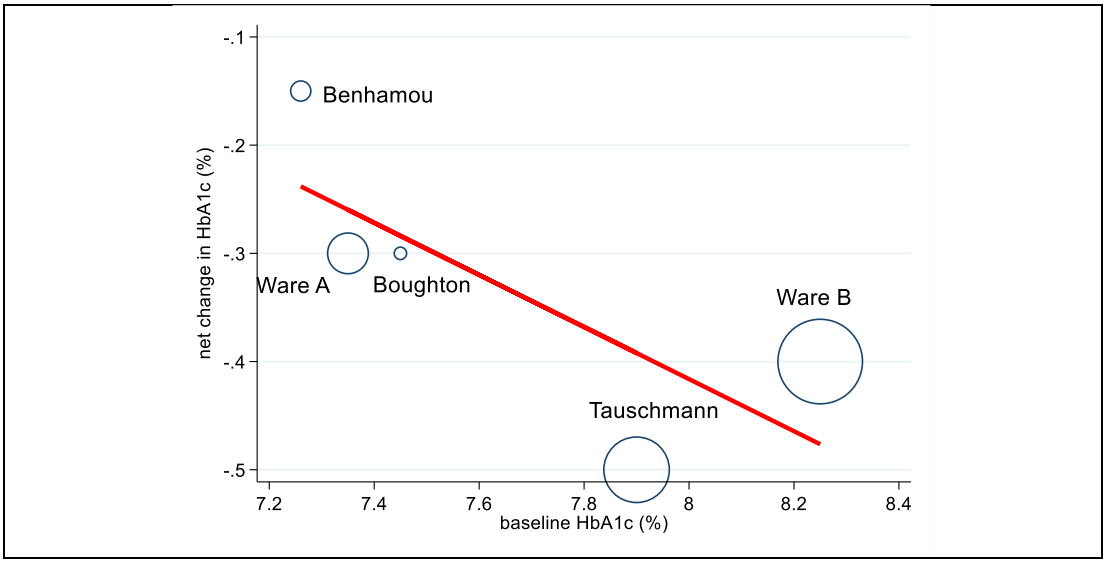

| Tauschmann omitted (leaving 6 studies) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.13559 | 0.046234 | -2.93 | 0.003 | -0.2262 | -0.04497 |
| A] | const | 0.721449 | 0.364599 | 1.98 | 0.048 | 0.006847 | 1.436051 |
| B] | gradient | -0.17667 | 0.065167 | -2.71 | 0.007 | -0.30439 | -0.04895 |
| B] | const | 1.05436 | 0.497174 | 2.12 | 0.034 | 0.079916 | 2.028803 |
| C] | gradient | -0.08991 | 115.44 | 0 | 0.999 | -226.348 | 226.1684 |
| C] | const | 0.382169 | 873.403 | 0 | 1 | -1711.46 | 1712.221 |

Example of regression plot (B] weighting)



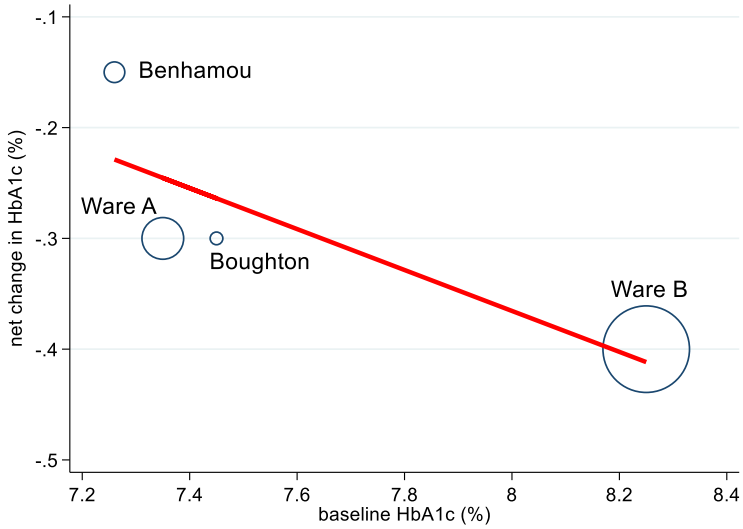

| Thabit (ad) and Thabit (ch) omitted (leaving 5 studies; HCL vs. CSII+rtCGM) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.21233 | 0.137403 | -1.55 | 0.122 | -0.48164 | 0.056972 |
| A] | const | 1.282354 | 1.061282 | 1.21 | 0.227 | -0.79772 | 3.362429 |
| B] | gradient | -0.24074 | 0.139568 | -1.72 | 0.085 | -0.51429 | 0.032803 |
| B] | const | 1.509729 | 1.068033 | 1.41 | 0.157 | -0.58358 | 3.603034 |
| C] | gradient | -0.26889 | 125.5266 | 0 | 0.998 | -246.297 | 245.7588 |
| C] | const | 1.700214 | 943.2939 | 0 | 0.999 | -1847.12 | 1850.522 |

Example of regression plot (B] weighting)



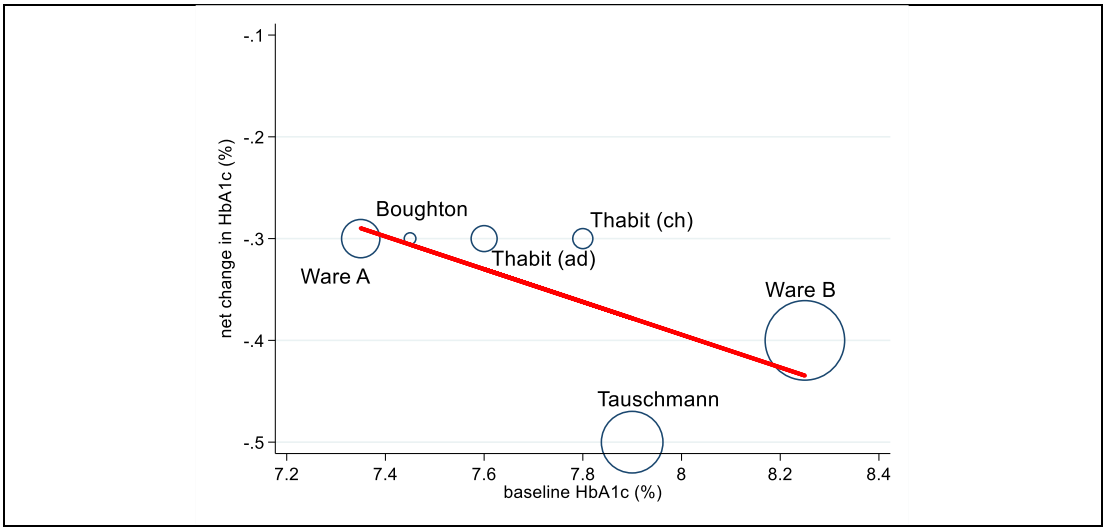

| Thabit (ad) Thabit (ch) Tauschmann omitted (leaving 4 studies; HCL vs. CSII+rtCGM) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.13094 | 0.047824 | -2.74 | 0.006 | -0.22468 | -0.03721 |
| A] | const | 0.679522 | 0.379409 | 1.79 | 0.073 | -0.06411 | 1.423151 |
| B] | gradient | -0.18476 | 0.103873 | -1.78 | 0.075 | -0.38835 | 0.01883 |
| B] | const | 1.112601 | 0.788409 | 1.41 | 0.158 | -0.43265 | 2.657855 |
| C] | gradient | -0.15741 | 157.3033 | 0 | 0.999 | -308.466 | 308.1514 |
| C] | const | 0.878134 | 1174.13 | 0 | 0.999 | -2300.37 | 2302.131 |

Example of regression plot (B] weighting)



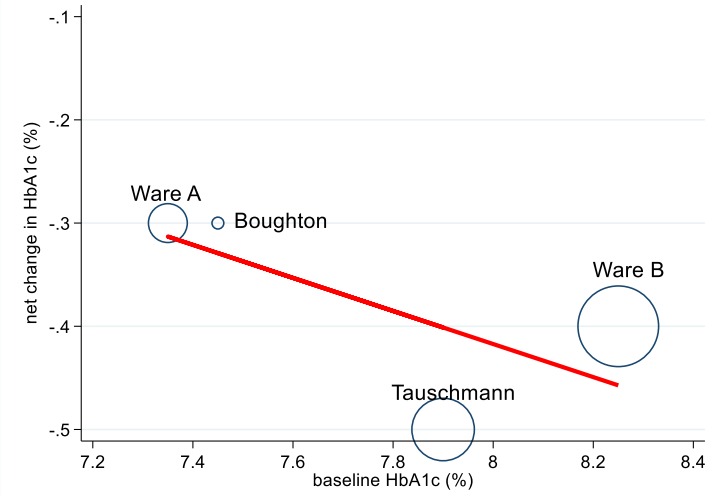

| Benhamou omitted | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.15883 | 0.132808 | -1.2 | 0.232 | -0.41913 | 0.101472 |
| A] | const | 0.87173 | 1.031556 | 0.85 | 0.398 | -1.15008 | 2.893543 |
| B] | gradient | -0.16089 | 0.140545 | -1.14 | 0.252 | -0.43635 | 0.114577 |
| B] | const | 0.892741 | 1.086689 | 0.82 | 0.411 | -1.23713 | 3.022612 |
| C] | gradient | -0.14359 | 110.2468 | 0 | 0.999 | -216.223 | 215.9361 |
| C] | const | 0.772869 | 838.1186 | 0 | 0.999 | -1641.91 | 1643.455 |

Example of regression plot (B] weighting)




| Thabit (ad), Thabit (ch) Benhamou omitted (leaving 4 studies HCL vs. CSII+rtCGM) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Weight | | Coefficient | SE | z | P>\|z\| | 95% ci | 95% ci |
| A] | gradient | -0.15059 | 0.151852 | -0.99 | 0.321 | -0.44821 | 0.147034 |
| A] | const | 0.786018 | 1.182914 | 0.66 | 0.506 | -1.53245 | 3.104486 |
| B] | gradient | -0.16015 | 0.152868 | -1.05 | 0.295 | -0.45976 | 0.139468 |
| B] | const | 0.864007 | 1.18434 | 0.73 | 0.466 | -1.45726 | 3.18527 |
| C] | gradient | -0.24017 | 129.8923 | 0 | 0.999 | -254.824 | 254.344 |
| C] | const | 1.478451 | 977.908 | 0 | 0.999 | -1915.19 | 1918.143 |

Example of regression plot (B] weighting)




## Summary and discussion

There were few studies available for this analyses, those that were available were heterogeneous (e.g. with regard to study design and age distribution of participants). Effect size precision was poor because values reported by authors were usually rounded to a single decimal place. Baseline HbA1c (%) in Benhamou et al. (9), was incompletely recorded and required estimation from textual data and published supplementary material; of the two estimates the 7.69% (based on Supplementary data) reasonably aligned with the pooled baseline for all studies and therefore on balance this value is preferred. Because of paucity of studies and alignment with NMA, the EAG included Benhamou in the analysis. Consequent to data deficiencies, the confidence intervals around regression parameters

were wide with P values for one or both parameters exceeding 0.05; an exception was when baseline for Benhamou was set at 7.26% and the study of Tauschman was omitted. Omission of Tauschman, one of the five studies of HCL vs. CSII+rtCGM, did not appear to justify the economic analysis. The regression selected for the use in economic analysis was based on using Benhamou baseline at 7.69%, weighting by effect size sd and omitting the Thabit studies. Omission or inclusion of Thabit studies and use of A] or B] weighting had minimal influence on regression lines (Figure 3).

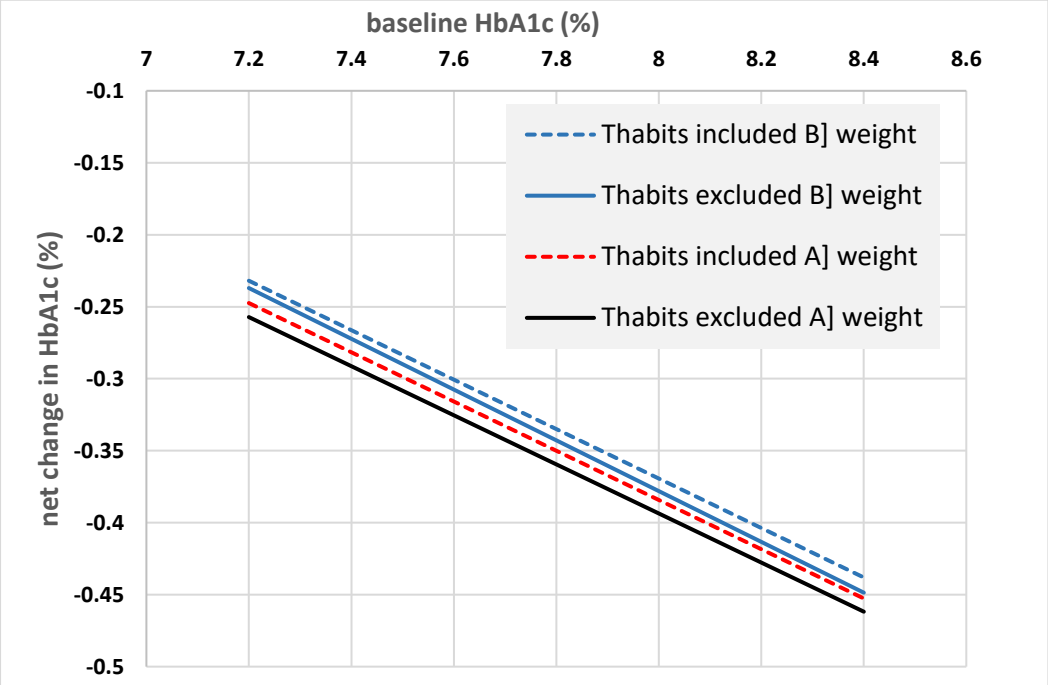



**Figure 3. Regression lines with Benhamou baseline set at 7.69%. The black line was selected for THE economic analysis**

## HCL performance in pregnancy

The EAG identified four studies describing HCL use in pregnancy. The studies included: a] a cross over RCT by Stewart et al., 2018 (12), with 16 patients; b] the AiDAPT trial (13), [redacted] that was submitted by the company; c] an RCT identified as CRYSTAL which is currently still recruiting patients (14). These studies were different from the nine studies in relation to gender, age, and patient characteristics and therefore excluded from the regression. HbA1c values were not consistently reported across studies. For instance, the AiDAP trial (13) reported mean HbA1c % at baseline (7.6%), however this was not reported at endline. AiDAP trial reported the percentage of patients that satisfied NICE targets of <6.5 % for HbA1c and therefore this data could not be synthesised.

Stewart (12) reported HbA1c values to a single decimal point. Baseline HbA1c was 6.6% (SD 2.8) that dropped to 6.4% (SD 2.7) at endline. The EAG estimated the change from baseline was following the *metan* command in Stata by employing the number of participants, effect size, SD of effect size

(Figure 4). We plotted the change in HbA1c of the HCL group in comparison to the regression line of all nine studies discussed earlier (Figure 4). Baseline HbA1c (%) was lower in Stewart (12) than that reported in other studies which indicates minimal improvement. The SD for baseline change was relatively large with only 16 participants in the trial.

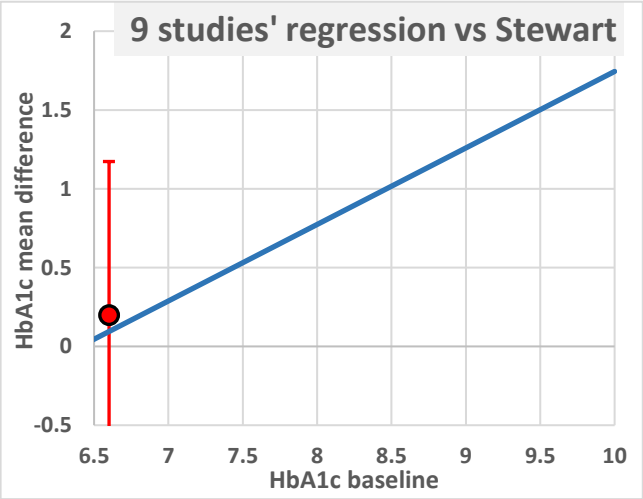



**Figure 4. Effect size and baseline HbA1c (%) from Stewart et al. 2018, compared to the regression line of the nine studies**
*Red circle = estimate using metan command for mean difference.*

# Indirect comparison - published data on isCGM compared with rtCGM

## Results

The EAG followed a pragmatic approach (following discussions with NICE technical team) and included studies from NG17 that involved rtCGM in comparison to isCGM. Three additional studies were included to the original NMA that was reported in the EAG report. Characteristics of included studies are presented in Table 7. The EAG did not have access to the full-text publication of the abstract submitted by the company (8). This abstract was not included in the main indirect comparison (the EAG evaluated the abstract and results remained similar to the main analysis)

**Table 7. Main characteristics of studies included in the NMA**

| Study | Country | Inclusion criteria | Age | Pre-intervention | Duration of intervention/comparison |
|---|---|---|---|---|---|
| Stewart (12) (Cross-over) | England N=16 | Women (singleton pregnancy); Diag: ≥ 1 yr prior to pregnancy; age 18-45 yr; HbA1c (8% (±1.1); Excluded if insulin dose ≥ 1.5 units/k | Pregnant, 32.8 (±5) yr | 30-60 minute training session on device for closed loop group | 4 weeks |
| Von dem Berg (15) (Cross-over) | Germany N=38 | Pump ≥3 months; total insulin > 8 U/day; HbA1c 7.4% (±0.9); no severe hypo in last 3 months | Pre-school and school children; 2 to14 yr | System briefing by diabetes educators for participants and parents | 8 weeks |
| Ware A (10) (Cross-over) | Austria, Germany, Luxembourg, and the UK N = 74 | Diag: ≥ 0.5yr previous; pump ≥3 months; HbA1c < 11% no previous HCL.. | Very young children 1 to 7 yr | caregivers were trained in the use of the trial glucose sensor, the trial insulin pump, and the CamAPS FX application. The application was used in open-loop mode for 2 to 4 weeks during the run-in period. | 16 weeks |
| Ware B (11) (Parallel-group) | UK, USA N=135 | Diag: ≥ 1yr previous; pump ≥3 months; HbA1c 7.5% to 10%; | Children /adolescents 6 to 18 yr | 14 days run-in period, Masked CGM (Freestyle Libre Pro FGM system) whilst wearing their own insulin pump. After run-in, intervention participants and parents trained to use study insulin pump and study CGM, used in open loop mode for 3-4 weeks. | 24 weeks |
| Collyns (16) (Cross-over) | New Zealand N = 59 | Diag: ≥ 1 yr; age 7 to 80 yr ; pump ≥6 | Children 7-13,N 19, adolescents14- | Two to 4 week run-in phase | 4 weeks |

| | | | | | |
|---|---|---|---|---|---|
| | | months ; daily insulin min 8 units ; HbA1c < 10% ; no pregnancy. | 21 N 14, adults 22-80yr N 26 | | |
| Benhamou (9) (Cross-over) | France N = 63 | Diag: ≥ 2yr previous; aged ≥18 years ; ≤ 50 U per day; HbA1c ≤ 10% | Adults, 48·2 yr (±13·4) | 2 week run-in, where patients used Medtronic 640g with smartguard | two consecutive crossover cycles of 4 week treatment periods |
| Kariyawasam (17) (Cross-over) | France N= 22 | Diag: ≥ 1 yr ; Age 6 to 12 yrs; pump ≥3 months; HbA1c ≤9·0%; hospital 3days then 6 wks post-hospital phase | Young, 6-12 years | Training session from investigators and clinical staff on how to insert and calibrate subcutaneous CGM, interpret data on the DexCom, and adjust insulin dose. | 6 weeks |
| ALERT1 (18) rtCGM vs isCGM (Parallel-group) | Belgium N = 254 | Diag ≥ 6 mon; age ≥ 18 yr; MDI/pump; HbA1c ≤10·0%; 6 month of isCGM; | mean age 42.8 to 43.0 yrs | 28-30 day run-in period | 6 months |
| CORRIDA (19) rtCGM vs isCGM (Parallel-group) | Parague N= 60 | Diag > 2 yrs; age ≥ 18 yr; no severe hypo in past 6 mon; | mean age 38.6 (±13) yrs | Both groups received training in the use of their respective CGM systems | 4 weeks |
| I-HART (20) rtCGM vs isCGM (Parallel-group) | UK N= 36 | Diag > 3 yrs; MDI > 6 mon; age ≥ 18 yr; severe hypo in the last 12 mon | Median agae 49.5 yrs | undergone T1D education, either as a group or in a one to one session with a specialist educato | 16 week |
| McAuley (3) (Cross-over) | Australia N=30 | Diag: ≥ 10 yr ; Age ≥ 60 yr; using pump; HbA1c ≤10.5% ; no dementia. | Elderly , 67 yr (± 5) | Multidisciplinary education from diabetes nurse educators, dietitians, endocrinologists 3 to 6 week run-in period with standard SAP therapy | 16 weeks |
| Thabit (2) (Cross-over) | UK, Germany, Austria N=33 | Diag: ≥ 0.5yr previous; age ≥18 y; pump ≥ 0.5y; HbA1c 7.5% to 10%; | Adults, 40 yr (±9·4) | run-in period lasting 4 to 6 weeks, training regarding the use of the insulin pump and the CGM device | 12 weeks |
| Boughton (5) (Cross-over) | UK, Austria N= 37 | Diag: ≥ 1 yr ; Age ≥ 60 yr; pump ≥3 months; HbA1c ≤10·0%. No current use of a closed-loop system, no more than 1 | Elderly, 68 yr (62 to 70) | Baseline measurements and questionnaires. Study device training in SAP mode (auto mode disabled) for 3-4 week run-in period. | 16 weeks |

| | | | | | |
|---|---|---|---|---|---|
| | | severe in preceding 6 months | | If assigned to HCL first, this was used at home over 16 weeks | |
| Tauschmann (1)<br><br>(Parallel-group) | UK, US<br>N= 86 | Diag: ≥ 1yr previous; age ≥ 6 to 20 yr ; pump ≥3 months; HbA1c 7.5% to 10%; no CGM previous 3 months | Children and young adults 22yr (13 to 26) | a run-in period of at least 4 weeks. Participants were trained to perform a glucose sensor calibration check before breakfast and evening meals. | 12 weeks |
| Bergenstahl (6)<br>(Cross-over) | 112 | Diag: ≥ 1 year; Age 14 to 29 yr ; HbA1c 7·0% to 11·0% ; Excluded if ≥ 1 severe hypo. | 14 to 29 yr | | |

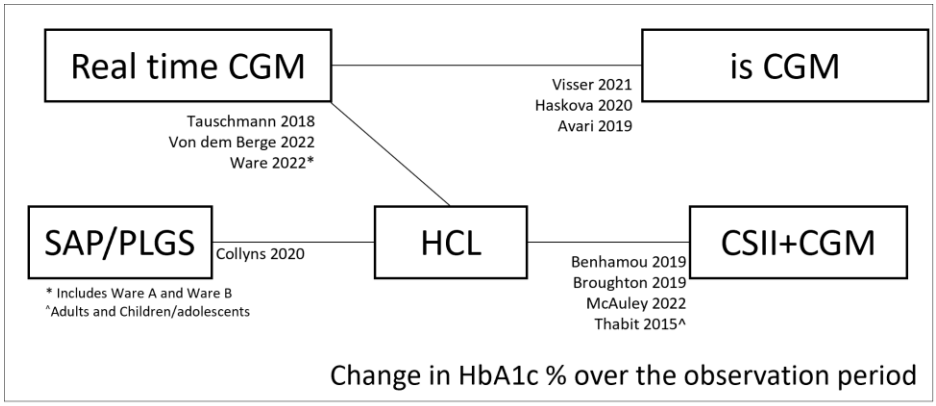
Briefly, two studies (CORRIDA and I-1HART CGM) reported five outcomes that included HbA1c%, time in range (% between 3.9 and 10 mmol/l), Time above range (% above 10 mmol/l), and time below range (% below 3.9 and 3.0 mmol/l). One study (ALERTT1) reported three outcomes that included HbA1c %, time in range (% between 3.9-10 mmol/l), and TBR 3.0. Studies were heterogeneous in terms of population, age groups, gender, RCT design (parallel cross over), numbers of participants and variable adjustment methods for determining mean difference between intervention and comparators. Additionally, the rtCGM vs isCGM involved participants on multiple daily injections and/or pump therapy. Studies did not consistently describe comparators. Cross-over studies did not provide data at different cross-over time points.

**Table 8. Results of the NMA including additional treatment groups post ACD**

| **Reference CSII+CGM** | **HbA1c %** | **Time in range (% between 3.9-10 mmol/l)** | **Time above range (% above 10 mmol/l)** | **Time below range (% below 3.9 mmol/l)** | **Time below range (% below < 3.0 mmol/l)** |
|---|---|---|---|---|---|
| HCL | -0.26<br>(-0.41, -0.10) | 8.38<br>(6.26, 10.50) | -7.83<br>(-11.18, -4.49) | -0.47<br>(-3.15, 2.21) | -0.03<br>(-0.20, 0.14) |
| rt-CGM | 0.02<br>(-0.15, 0.19) | -0.22<br>(-2.75, 2.30) | -0.57<br>(-4.39, 3.24) | 0.36<br>(-2.61, 3.34) | -0.03<br>(-0.26, 0.19) |
| is-CGM | 0.38<br>(0.15, 0.62) | -6.27<br>(-10.24, -2.31) | 5.12<br>(-0.70, 10.95) | -3.91<br>(-8.02, 0.20) | 0.29<br>(-0.05, 0.64) |
| SAP/PLGS | 0.34<br>(-0.46, 1.15) | -4.12<br>(-21.13, 12.90) | 4.27<br>(-2.90, 11.43) | -0.07<br>(-4.63, 4.49) | 0.07<br>(-1.33, 1.47) |

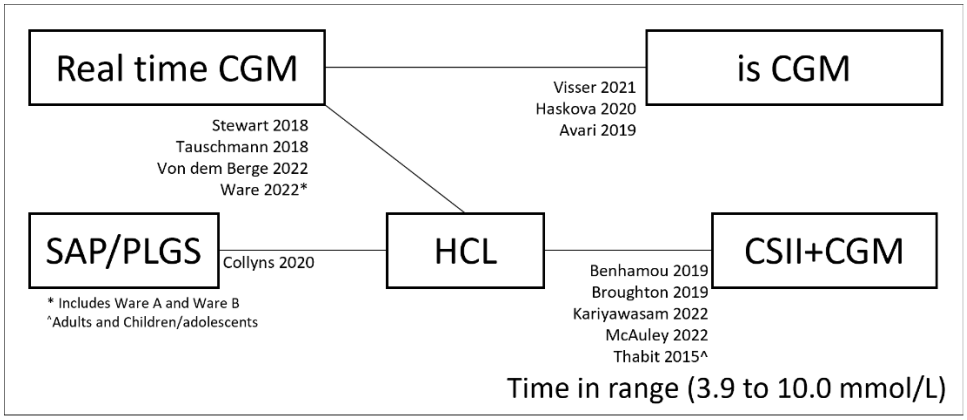
## Change in HbA1c level (%)

There were 13 estimates from 12 studies informed this outcome. HCL demonstrated superiority and this was statistically significantly. isCGM group did not perform as well as other groups, and this was statistically significant.


Real time CGM
is CGM
Visser 2021
Haskova 2020
Avari 2019
Tauschmann 2018
Von dem Berge 2022
Ware 2022*
SAP/PLGS
Collyns 2020
HCL
CSII+CGM
Benhamou 2019
Broughton 2019
McAuley 2022
Thabit 2015^
* Includes Ware A and Ware B
^Adults and Children/adolescents
Change in HbA1c % over the observation period

## Time in target range (% between 3.9-10 mmol/l)

There were 15 estimates from 14 studies included in this network. HCL was the only treatment that demonstrated significant superiority in comparison to the reference treatment (CSII+CGM).




## Time below target range (% below 3.9 and 3.0 mmol/l)

There were 9 estimates that were included in the analysis for both the TBR 3.9 mmol/L (9 studies Figure 5) and TBR 3.0 mmol/L (10 studies,

Figure ***6***) outcomes. For both outcomes, there were no statistically significant differences between the reference treatment of CSII+CGM and the other treatment groups.

*Figure 5. network map of the NMA of the outcome time below target range (% below 3.9 mmol/l)*

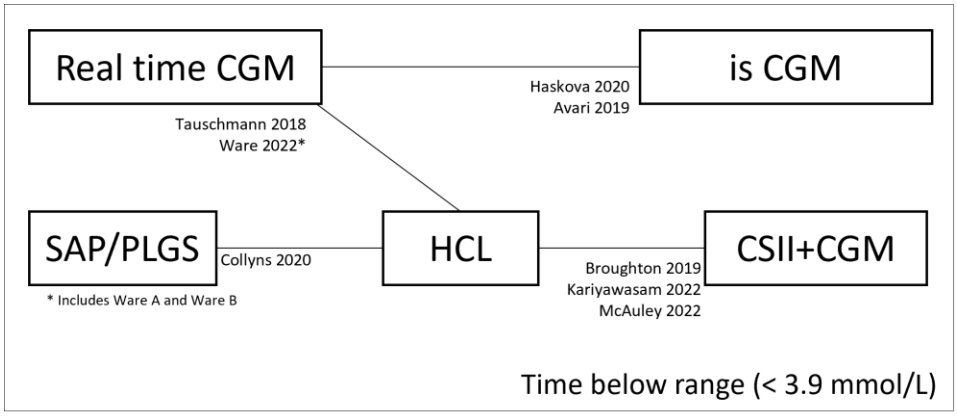
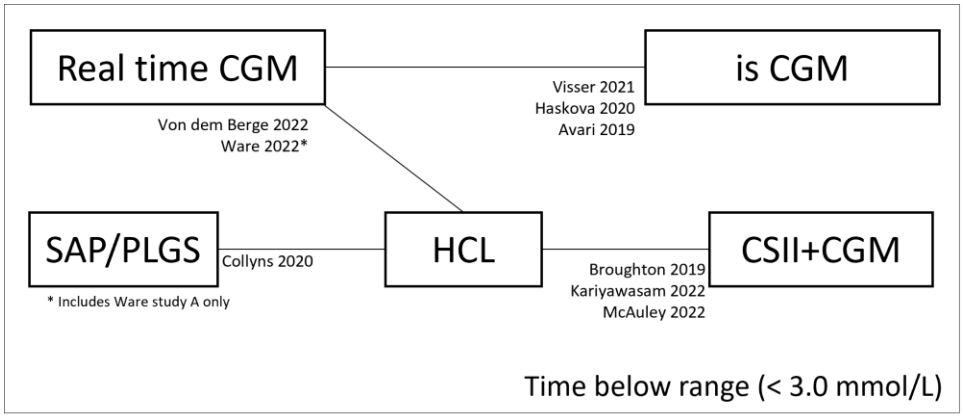



**Figure 6. Network map of the NMA of the outcome time below target range (% below 3.00 mmol/l)**




## Time above target range (% above 10 mmol/l)

There were 14 estimates from 13 studies that were included in this analysis. HCL demonstrated superiority and that was statistically significant. The other treatment groups were did not show significant difference in comparison to the reference group (CSII+CGM).

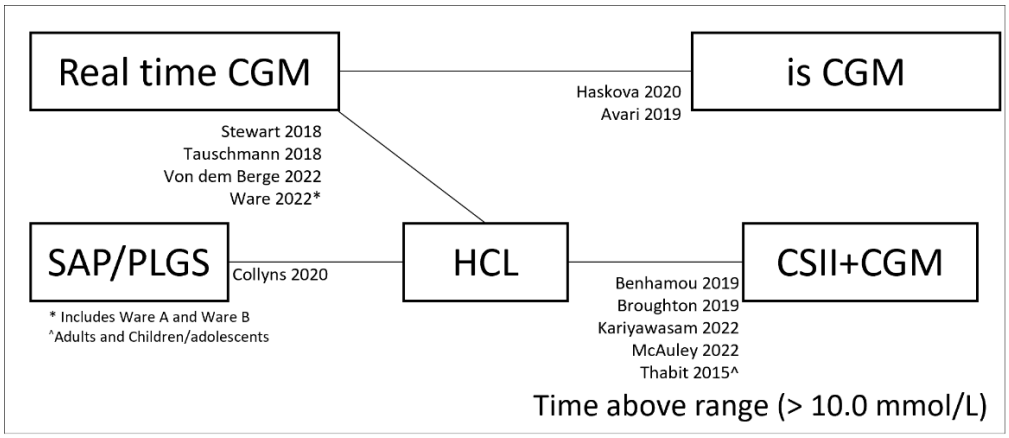



***Figure 7. Network map of the outcome time above target range (% above 10.0 mmol/l)***

## The costs of stroke

The previous EAG report drew its costs from NG17, uprating these for inflation to yield a cost of a stroke of £4,728 in the first year and £175 in subsequent years. NG17 notes that these costs were based upon work completed for the NICE cardiovascular disease risk guidance: CG181. CG181 is reported as calculating first 6 month and 1 year post event costs using information from the NHS drug tariff, NHS reference costs, PSSRU Unit Costs of Health and Social Care and the BNF. The EAG has not been able to source the relevant costs in the CG181 publicly available documents.

Insulet highlights a paper within the literature (21) that estimated the costs of stroke patients using data from the medical records of 84,184 English, Welsh and Northern Ireland NHS patients with a diagnosis of stroke between April 2015 and March 2016, as included within the Sentinel Stroke National Audit Programme. An individual patient simulation model was constructed which estimated first year and subsequent year healthcare costs, when uprated by 9.3% for inflation, of £14,702 and £1,233 respectively and social care costs of £9,811 and £5,219 respectively, yielding an average total five year cost of £46,039.

The total 5 year health and social care costs increased markedly with age. For ischaemic stroke these were reasonably constant at around £20k for those between 25 years and 60 years of age, increasing thereafter. For intracerebral haemorrhage these increase from around £20k for those of 25 years of age to around £32k to £35k for those between 40 years and 60 years of age, increasing thereafter. Around 60% of patients appear to have been classified as having ischaemic stroke.

A possible problem with the analysis is that it is not all the estimated costs might relate solely to stroke. Within the healthcare cost elements the authors tried to control for this by only including ambulance, MRI and CT scans, thrombolysis, acute stroke unit care, rehabilitation stroke unit care, general medical ward care, community rehabilitation, GP visits, secondary prevention and ESD therapists. The balance between these costs is not stated and general medical ward care is of particular concern. The social care cost elements may be more subject to this criticism. It is also unclear whether care home costs took into account self-funding.

Given the baseline mean age of 43 years within the modelling for the current assessment and of 40 years within the NHSE adult pilot the total five year health care costs estimated by Xu et al appear to be around 40-45% of their overall mean estimate for ischaemic stroke and around 70% of their overall mean cost for intracerebral haemorrhage. Unfortunately, it is not possible to further disaggregate these percentages when applying them to healthcare costs and social care costs. Applying them uncritically suggests healthcare costs of £7,680 in the first year and £644 in subsequent years, social care costs of £5,125 in the first year and £2,726 in subsequent years and total costs of £12,805 in the first year and £3,370 in subsequent years.

But it should also be noted that beyond 60 years of age the estimated costs increase. Some if not much of the time modelled as being spent with stroke in the modelling for the current assessment will occur later in life and above the age of 60 years.

A possible additional source for the first year and subsequent costs of stroke are the UKPDS estimates for T2DM patients, as presented in UKPDS 84. The main benefit of this is that it controls for the costs associated with the other complications of diabetes and can be used to calculate the additional costs of stroke compared to having no complications, albeit in a T2DM population. Inpatient costs are estimated separately from non-inpatient costs, the latter covering elements such as GP visits using questionnaire data. A drawback is that it does not present any estimates of the social care costs. For stroke, uprating by 15.7% for inflation, these healthcare costs over and above the costs of having no complications are as below.

**Table 9. UKPDS 84 costs of stroke: T2DM patients**

| Gender | Male | Male | Female | Female |
|---|---|---|---|---|
| Age | 40 | 60 | 40 | 60 |
| Non-fatal stroke | £5,610 | £7,989 | £6,011 | £8,360 |
| History of stroke | £625 | £1,030 | £673 | £1,115 |
| Fatal stroke | £3,517 | £4,044 | £3,727 | £4,198 |

These are higher than those drawn from NG17. They are reasonably aligned with the health care costs for 40 year olds estimated by the EAG from Xu et al, though the estimates of Xu et al (21) increase more rapidly with age. The EAG will revise its base case costs of stroke estimates to the UKPDS 84 health care costs for a 40 year old female, providing scenarios of (A) the UKPDS 84 health care costs for a 60 year old female, (B) adding 30%[1] of the social care costs of £5,125 for the first year and £2,726 in subsequent years and (C) applying the original EAG report costs to illustrate the effect of this change.

## Baseline HbA1c and net change in HbA1c

As reviewed in more detail in section "Regression analyses: baseline HbA1c (%) vs. net change in HbA1c. in HCL RCTs" earlier, comments have been received and opinions expressed at the last Committee meeting that a worse baseline HbA1c is typically associated with a greater capacity to benefit. The EAG preferred regression of the net effect HbA1c by baseline HbA1c for HCL over CSII+rtCGM is, as per the NMA, to weight studies by their standard errors and to include Benhamou but with the additional required assumption of a baseline 7.69% for Benhamou (9).

[1] Based upon the proportion self funding their residential care as estimated by Meades and Hye, 2003, when estimating the costs of blindness.

The NMA results that suggest little difference in net effect between the HCL versus CSII+rtCGM studies and the Thabit studies of HCL against CSII+CGM, the latter actually suggesting a smaller effect size. It may be reasonable to include the Thabit studies within the regression of net effect against baseline, in effect assuming Thabit to be HCL against CSII+rtCGM. This has little effect upon the regressions' central estimates as outlined below.

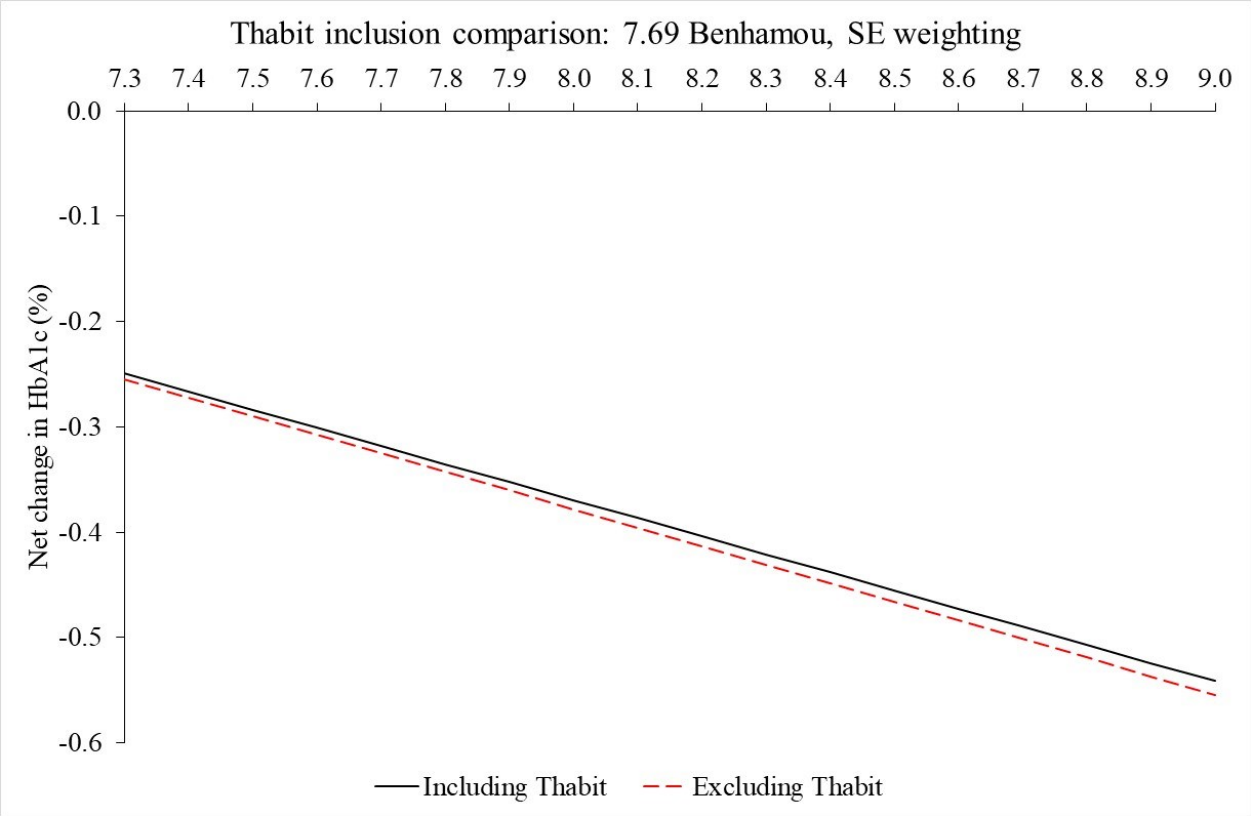



**Figure 8. Net change in HbA1c by baseline HbA1c: HCL vs CSII+rtCGM**

For the overall weighted mean baseline of around 7.8% the NMA estimates a net effect for HCL over CSII+rtCGM of -0.28% while the above regressions estimate a net effect size of around -0.34%. While imperfect, given the centrality of the NMA to the clinical effect estimates and the uncertainty surrounding the regressions the EAG will apply the slope parameter of the regression that excludes the Thabit (2) studies to the central NMA estimate at the mean baseline of 7.8% to arrive at the following estimated net effect sizes for HCL against CSII+rtCGM.

**Table 10. Exploration of HbA1c net effect by baseline HbA1c: HCL vs CSII+rtCGM**

| Baseline HbA1c (%) | 7.4 | 7.6 | 7.8 | 8.0 | 8.2 | 8.4 | 8.6 | 8.8 | 9.0 |
|---|---|---|---|---|---|---|---|---|---|
| Net HbA1c (%) | -0.21 | -0.24 | -0.28 | -0.32 | -0.35 | -0.39 | -0.42 | -0.46 | -0.49 |

When coupled with the net effect from the NMA for rtCGM against rtCGM of -0.36% this results in the following net effects.

**Table 11. Using single regression: modelled effect sizes by baseline HbA1c**

| Baseline HbA1c (%) | 7.4 | 7.6 | 7.8 | 8.0 | 8.2 | 8.4 | 8.6 | 8.8 | 9.0 |
|---|---|---|---|---|---|---|---|---|---|
| CSII+isCGM (%) | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| CSII+rtCGM (%) | -0.36 | -0.36 | -0.36 | -0.36 | -0.36 | -0.36 | -0.36 | -0.36 | -0.36 |
| HCL (%) | -0.57 | -0.60 | -0.64 | -0.68 | -0.71 | -0.75 | -0.78 | -0.82 | -0.85 |

The above scenario analyses do not apply any adjustment for the effect of baseline HbA1c upon the net effect of rtCGM against isCGM. The EAG views this regression as highly uncertain and unreliable, also bearing in mind that much of the comparison was between MDI+rtCGM and MDI+isCGM rather than between CSII+rtCGM and CSII+isCGM. However, for completeness a similar exercise can be performed. Noting the weighted mean baseline of 7.5% across the relevant studies the regression estimates a net effect of -0.30% compared to the NMA estimate of -0.36%. As a consequence, the EAG will similarly apply the regression slope to the NMA estimate at a baseline of 7.5% to arrive at the following net effects by baseline HbA1c.

**Table 12. Speculation on HbA1c net effect by baseline HbA1c: rtCGM vs isCGM**

| Baseline HbA1c (%) | 7.4 | 7.6 | 7.8 | 8.0 | 8.2 | 8.4 | 8.6 | 8.8 | 9.0 |
|---|---|---|---|---|---|---|---|---|---|
| Net HbA1c (%) | -0.35 | -0.37 | -0.38 | -0.40 | -0.42 | -0.43 | -0.45 | -0.46 | -0.48 |

When coupled with the net effects for HCL against CSII+rtCGM this results in the following net effects for HCL against CSII+isCGM.

**Table 13. Using both regression: modelled effect sizes by baseline HbA1c**

| Baseline HbA1c (%) | 7.4 | 7.6 | 7.8 | 8.0 | 8.2 | 8.4 | 8.6 | 8.8 | 9.0 |
|---|---|---|---|---|---|---|---|---|---|
| CSII+isCGM (%) | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| CSII+rtCGM (%) | -0.35 | -0.37 | -0.38 | -0.40 | -0.42 | -0.43 | -0.45 | -0.46 | -0.48 |
| HCL (%) | -0.56 | -0.61 | -0.66 | -0.71 | -0.77 | -0.82 | -0.87 | -0.92 | -0.97 |

## Estimating rates of SHEs and NSHEs

The previous EAG report estimated rates of SHEs and NSHEs based upon what it felt were reasonable baseline rates for HCL, coupled with an assumption that the rates of SHEs were proportionate to TBR < 3.0 mmol/l and NSHEs were proportionate to TBR < 3.9 mmol/l. When coupled with mean baseline values within the HCL studies of 0.64 for TBR < 3.0 mmol/l and 4.56 for TBR < 3.9 mmol/l the NMA provides the following estimates for TBR.

**Table 14. NMA implied TBR values**

| | TBR < 3.0 | TBR < 3.9 |
|---|---|---|
| HCL | 3.73 | 0.64 |
| CSII+rtCGM | 4.56 | 0.64 |
| CSII+isCGM | 0.29 | 0.96 |

The value for CSII+isCGM for TBR < 3.9 mmol/l is very much less than that of CSII+rtCGM. It should be noted that the isCGM versus rtCGM studies this is based upon had somewhat higher absolute TBR baseline values than the HCL studies. NG17 estimated a ratio between isCGM and rtCGM of 94% for NHSEs and 73% for SHEs. When exploring the rates of NHSEs the EAG will typically apply the 94% ratio from NG17, but will provide a scenario analysis that applies the full set of NMA estimates.

These ratios are applied to the HCL rates of 20.8 for NHSEs and 0.26 for SHEs, as tabled below, with the EAG also providing scenarios for NHSEs of rates of 57.2 and 13.0.

**Table 15.Exploratory rates of SHEs and NSHEs**

| | NSHEs | | SHEs |
|---|---|---|---|
| | NMA and NG17 | NMA alone | NMA alone |
| HCL | 20.80 | 20.80 | 0.26 |
| CSII+rtCGM | 25.43 | 25.43 | 0.26 |
| CSII+isCGM | 24.03 | 1.60 | 0.39 |

Note that NG17 estimated for rtCGM annual rates of 0.19 for SHEs and 20.5 for NSHEs. A full account of the NHSE and SHE rates assumed for HCL is provided in the original EAG report.

## Valuing SHEs

The EAG retains its preference for Gordon et al for valuing NHSEs for the reasons outlined in its original report. This also outlined that Gordon et al observed very few severe hypoglycaemic episodes, and suggested that Nauck et al (22) provided an estimate that was reasonably representative of the alternatives within the literature.

The EAG exploration of hypoglycaemic events will use Gordon et al (23) to value non-severe hypoglycaemic and Nauck et al (22) to value severe hypoglycaemic. Scenarios using only Gordon et al and the historically more commonly applied Currie et al (24) will be presented.

# Costing NHSEs

In common with a number of other NICE assessments, including NG17, the EAG previously assumed that NSHEs result in no costs to the NHS or PSS.

NG17 highlighted Geelhoed et al who surveyed 1,631 European T1DM patients and defined NSHEs on the basis of hypoglycaemia symptoms having occurred during the previous seven days or episodes of blood glucose below 3.1mmol/l which they could manage without third party assistance. Data was also collected on healthcare resource use following an NSHE. The mean weekly frequency of 1.8 NSHEs, or an annual rate of 91, was somewhat higher than those of NG17 and of the EAG exploratory analyses. Following an NHSE 2.3% of T1DM patients contacted a health care professional and SMBG increased by 12%, with 13.6% also reducing their insulin dose. These estimates, if a GP appointment is assumed, the increase in monitoring only applies for the week after experiencing an NSHE and the reduced insulin dose is ignored, might suggest an additional cost of £2.15 following an NSHE, or given the average weekly rate of 1.8 for modelling purposes around £1.20 per event.

In contrast to this, Brod et al (25) surveyed 193 and 192 UK patients with T1DM and T2DM respectively who had had at least one NSHE during the past month. Among the T1DM patients 47% experienced NSHEs between daily and weekly, 28% several times to once per month and the remainder less frequently than this. Arbitrarily assuming 10, 3 and 0.25 per month respectively suggests a roughly similar mean frequency to the 1.8 per week of Geelhoed et al (26). Across all UK patients 25.7% "*contacted a healthcare professional after last NSHE*", this not being limited to primary care. This is an order of magnitude greater than Geelhoed (26) estimated, part of which may be due to the longer recall period. Assuming that the contacts are per month with an NHSE rather than per event suggests costs that are roughly three times those of Geelhoed (26) or around £3.60.

Orozco-Beltrán (27) surveyed 294 Spanish patients with T1DM and an average of 1.7 NHSEs per week. They report that NHSEs were associated with an additional SMBG cost of £1.20 per event, while 8% of daytime and 12% of nocturnal last NHSEs during the study period led to a healthcare contact. The balance between daytime and nocturnal events is only provided across T1DM and T2DM patients but suggests and overall contact rate of 8.9%. Assuming these are GP visits suggests a total cost per event of £4.93.

The EAG will present a scenario that costs NHSEs at £5 per event. This is unlikely to have any material effect upon results.

The common weekly rate of around 1.8 NSHEs within the three papers may suggest an additional scenario of an annual 90 NHSEs, but it should be borne in mind that these rates were among patients responding to questionnaires about NSHEs so may not be a representative sample.

## Costs of the technologies

The costings used in the previous EAG report incorrectly applied the costs of the Freestyle Libre 3 to CSII+isCGM. These should have applied the costs of the Freestyle Libre 2, and have taken into account the costs of Dexcom One sensor use.

The previous EAG costings also slightly inflated the costs of HCL systems to take into account some sensors not lasting their full lifespan for reasons such as them being accidentally knocked, using survival curve data supplied by the companies. All the companies have since indicated that users can phone for a free replacement sensor should this occur. As a consequence, the EAG removes this element from the costing.

The costs for HCL and CSII+rtCGM have been provided by NHS supply chain. These do not include any volume discounts or any proposed future discounts and are based upon the costs current on the NHS supply chain system. It is assumed that only 10% of Dexcom 6 users require a receiver. The EAG has estimated costs for CSII+isCGM by using the CSII+rtCGM costs and substituting the NHS drug tariff isCGM sensor and transmitter costs for the rtCGM costs.

Professor Partha Kar has provided market share estimates for most systems. The EAG takes the midpoint of these estimates; e.g. the Minimed 780G market share estimates of 60% to 65% result in a 62.5% estimate. For systems without a market share estimate the residual market share is split equally between them, indicated by an asterix in the tables which follow.

Given the uncertainty around market shares in addition to the base case weighted average costs the EAG also supplies in the appendix a full set of scenario analyses that apply the lowest cost system within each sub-type. Note that for CSII+rtCGM this retains the balance of 3% Freestyle Libre 3 and 97% Dexcom 6, and similarly for CSII+isCGM this retains the balance of 80% Freestyle Libre 2 and 20% Dexcom One. These lowest system costing analyses worsen the HCL versus pooled CSII+CGM base case ICER by 10% and the scenario analyses ICERs by between 10% and 12%.

This results in the following HCL system costs.

**Table 16. HCL System costs**

| | Year 1 | Years 2-4 | 4 Year | Share |
|---|---|---|---|---|
| Ypsomed | £8,171 | £5,706 | £25,289 | 10%* |
| Advanced Therapeutics | £7,650 | £4,975 | £22,575 | 10%* |
| Air Liquide | £7,785 | £4,980 | £22,724 | 18% |
| Medtronic | £8,051 | £4,768 | £22,355 | 63% |
| HCL weighted average | £7,976 | £4,920 | £22,735 | |
| HCL cheapest | £8,051 | £4,768 | £22,355 | |

**Table 17. CSII+rtCGM System costs**

| | Year 1 | Years 2-4 | 4 Year | Share |
|---|---|---|---|---|
| CSII+rtCGM: Freestyle Libre 3 | | | | 3% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+rtCGM: Dexcom 6 | | | | 97% |

| | | | | |
|---|---|---|---|---|
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+rtCGM weighted average | £6,675 | £4,891 | £21,348 | |
| CSII+rtCGM cheapest | £7,205 | £4,319 | £20,163 | |

**Table 18. CSII+isCGM System costs**

| | Year 1 | Years 2-4 | 4 Year | Share |
|---|---|---|---|---|
| CSII+isCGM: Freestyle Libre 2 | | | | 80% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+rtCGM: Dexcom One | | | | 20% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+isCGM weighted average | £4,951 | £3,168 | £14,454 | |
| CSII+isCGM cheapest | £5,482 | £2,596 | £13,270 | |

Due to different effect estimates for CSII+rtCGM and CSII+isCGM these are modelled separately. When results are pooled assuming that CSII+CGM is 90% CSII+isCGM and 10% CSII+rtCGM this results in the following base case treatment costs. Note that the Year 1 and Years 2-4 costs are applied in the model, the annual average being presented here to ease comparison.

**Table 19. Base case treatment costs: weighted average**

| | Year 1 | Years 2-4 | 4 Year | Annual |
|---|---|---|---|---|
| HCL | £7,976 | £4,920 | £22,735 | £5,684 |
| CSII+rtCGM | £6,675 | £4,891 | £21,348 | £5,337 |
| CSII+isCGM | £4,951 | £3,168 | £14,454 | £3,614 |
| CSII pooled (90% CSII+isCGM) | £5,124 | £3,340 | £15,144 | £3,786 |

**Table 20. Treatment cost scenario: lowest cost system**

| | Year 1 | Years 2-4 | 4 Year | Annual |
|---|---|---|---|---|
| HCL | £8,051 | £4,768 | £22,355 | £5,589 |
| CSII+rtCGM | £7,205 | £4,319 | £20,163 | £5,041 |
| CSII+isCGM | £5,482 | £2,596 | £13,270 | £3,317 |
| CSII pooled (90% CSII+isCGM) | £5,654 | £2,768 | £13,959 | £3,490 |

Due to the Freestyle Libre 3 being relatively new to the market and also rather cheaper than the Dexcom 6 if the Freestyle Libre 3 becomes more prevalent the cost of CSII+rtCGM will fall

somewhat. But due to it being assumed that 90% of CSII+CGM is CSII+isCGM even if all CSII+rtCGM used the Freestyle Libre 3 the pooled annual average cost of CSII+CGM would only fall by around £140. The EAG does not explore this further.

An additional £830 is added to these annual costs to account for insulin, lancets and test strips, these estimates being taken from the Medtronic submission. Routine outpatient costs add a further annual £640.

## Analyses

In addition to its base case the EAG presents the following scenarios:

- SA01: Applying the regression results for net effect for HCL over CSII+rtCGM by baseline HbA1c.
- SA02: Applying the regression results for both net effect for HCL over CSII+rtCGM by baseline HbA1c and net effect for rtCGM over isCGM by baseline HbA1c.
- SA03: Applying the various costs of stroke as outlined above.
- SA04: Assuming an annual 0.045% worsening in HbA1c.
- SA05: Applying the NMA HbA1c results that exclude Benhamou.
- SA06: Adjusting the costs of complications to account for their possible overestimation within the iQVIA Core Diabetes Model, as described in greater detail in the original EAG report.
- SA07: Estimating NSHEs using annual rates of (A) 20.8, (B) 57.2, (C) 13.0 and (D) 90.0 for HCL as outlined above.
- SA08: Estimating HSEs using annual rates of 20.8 for NSHEs and 0.64 for SHEs for HCL as outlined above.
- SA09: SA08 and valuing HEs using (A) Currie et al and (B) Gordon et al
- SA10: SA08 and assuming SHE costs of (A) £36 for non-medical and £628 for medical, and (B) £381 on average.
- SA11: SA08 with NSHE £5 cost per event.
- SA12: SA08 with double the HE quality of life effect to account for possible carer effects.
- SA13: Estimating NSHE for CSII+isCGM using the NMA TBR < 3.9 mmol/l estimates.

These are presented for the weighted average costing below, and for the cheapest system costing in the appendix. For reasons of space SA01 and SA02 are presented graphically, with the full set of results being in the appendix.

## Results: Base case: Weighted average costing of technologies

The revised base case estimates the following.

**Table 21. Base case: Disaggregate outcomes**

| | CSII+ | | HCL | | |
|---|---|---|---|---|---|
| | isCGM | rtCGM | HCL | vs isCGM | vs rtCGM |
| LYs Undiscounted | 32.499 | 32.962 | 33.471 | 0.972 | 0.509 |
| QALYs | | | | | |
| CDM modelled | 14.232 | 14.400 | 14.581 | 0.349 | 0.181 |
| NHSEs | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| SHEs | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Total QALYs | 14.232 | 14.400 | 14.581 | 0.349 | 0.181 |
| Costs | | | | | |
| Treatment | £85,540 | £119,353 | £127,707 | £42,168 | £8,355 |
| Routine OP | £12,182 | £12,279 | £12,393 | £211 | £114 |
| HEs | £0 | £0 | £0 | £0 | £0 |
| Other management | £1,700 | £1,722 | £1,742 | £43 | £21 |
| CVD | £4,878 | £4,663 | £4,479 | -£399 | -£184 |
| Renal | £10,365 | £9,774 | £9,284 | -£1,080 | -£490 |
| Neuropathy/Amp. | £889 | £877 | £816 | -£72 | -£61 |
| Eye | £18,270 | £15,745 | £14,262 | -£4,008 | -£1,483 |
| Total Costs | £133,824 | £164,412 | £170,685 | £36,861 | £6,273 |

**Table 22. Base case: Summary**

| | CSII+isCGM | CSII+rtCGM | HybCL |
|---|---|---|---|
| LYs Undiscounted | 32.499 | 32.962 | 33.471 |
| Total QALYs | 14.232 | 14.400 | 14.581 |
| Total Costs | £133,824 | £164,412 | £170,685 |
| ICER: fully incremental | Reference | Ext.Dom. | £105,620 |
| ICER: pooled CSII+CGM | Reference | | £101,753 |

## Results: Scenario analyses: Weighted average costing of technologies

In the fully incremental analyses, including SA01 and SA02, CSII+rtCGM is extended dominated throughout.

**Table 23. Scenario analyses: Fully incremental analyses**

| | Description | CSII+isCGM | CSII+rtCGM | HybCL |
|---|---|---|---|---|
| BASE | Base case | Reference | Ext.Dom. | £105,620 |
| SA03A | Stroke costs 60 year old | Reference | Ext.Dom. | £105,565 |
| SA03B | Stroke costs with social care costs | Reference | Ext.Dom. | £105,549 |
| SA03C | Stroke costs previous EAG base case | Reference | Ext.Dom. | £105,664 |
| SA04 | Annual 0.045% HbA1c worsening | Reference | Ext.Dom. | £99,958 |
| SA05 | Excluding Benhamou | Reference | Ext.Dom. | £109,831 |
| SA06 | Adjusted complication costs | Reference | Ext.Dom. | £111,139 |
| SA07A | NSHEs HCL 20.8 annual | Reference | Ext.Dom. | £104,271 |
| SA07B | NSHEs HCL 57.2 annual | Reference | Ext.Dom. | £104,000 |
| SA07C | NSHEs HCL 13.0 annual | Reference | Ext.Dom. | £104,484 |
| SA07D | NSHEs HCL 90.0 annual | Reference | Ext.Dom. | £103,974 |
| SA08 | SA07A plus SHEs | Reference | Ext.Dom. | £85,970 |
| SA09A | SA08 using Currie values | Reference | Ext.Dom. | £90,516 |
| SA09B | SA08 using Gordon values | Reference | Ext.Dom. | £101,022 |
| SA10A | SA08 with £36/£628 SHE cost | Reference | Ext.Dom. | £85,665 |
| SA10B | SA08 with £381 SHE cost | Reference | Ext.Dom. | £84,982 |
| SA11 | SA08 with NSHE cost £5 | Reference | Ext.Dom. | £85,324 |
| SA12 | SA08 with double HE QoL | Reference | Ext.Dom. | £73,169 |
| SA13 | SA08 with NSHE from NMA | Reference | Ext.Dom. | £99,126 |

**Table 24. Scenario analyses: HCL vs pooled CSII+CGM analyses**

| | Description | Net QALY | Net Cost | ICER |
|---|---|---|---|---|
| BASE | Base case | 0.467 | £33,802 | £101,753 |
| SA03A | Stroke costs 60 year old | 0.332 | £33,784 | £101,697 |
| SA03B | Stroke costs with social care costs | 0.332 | £33,778 | £101,681 |
| SA03C | Stroke costs previous EAG base case | 0.332 | £33,817 | £101,799 |
| SA04 | Annual 0.045% HbA1c worsening | 0.328 | £31,946 | £97,396 |
| SA05 | Excluding Benhamou | 0.315 | £33,405 | £105,981 |
| SA06 | Adjusted complication costs | 0.332 | £35,617 | £107,215 |
| SA07A | NSHEs HCL 20.8 annual | 0.337 | £33,802 | £100,307 |
| SA07B | NSHEs HCL 57.2 annual | 0.338 | £33,802 | £100,004 |
| SA07C | NSHEs HCL 13.0 annual | 0.336 | £33,802 | £100,538 |
| SA07D | NSHEs HCL 90.0 annual | 0.338 | £33,802 | £99,967 |
| SA08 | SA07A plus SHEs | 0.399 | £33,358 | £83,520 |
| SA09A | SA08 using Currie values | 0.384 | £33,358 | £86,907 |
| SA09B | SA08 using Gordon values | 0.343 | £33,358 | £97,310 |
| SA10A | SA08 with £36/£628 SHE cost | 0.399 | £33,242 | £83,230 |
| SA10B | SA08 with £381 SHE cost | 0.399 | £32,982 | £82,580 |
| SA11 | SA08 with NSHE cost £5 | 0.399 | £33,069 | £82,797 |
| SA12 | SA08 with double HE QoL | 0.403 | £33,358 | £71,491 |
| SA13 | SA08 with NSHE from NMA | 0.349 | £33,358 | £95,615 |

For the pooled analyses that apply the regression of the net effect of HCL over CSII+rtCGM, SA01, and that apply this and the regression of the net effect of isCGM over rtCGM, SA02 the following results.

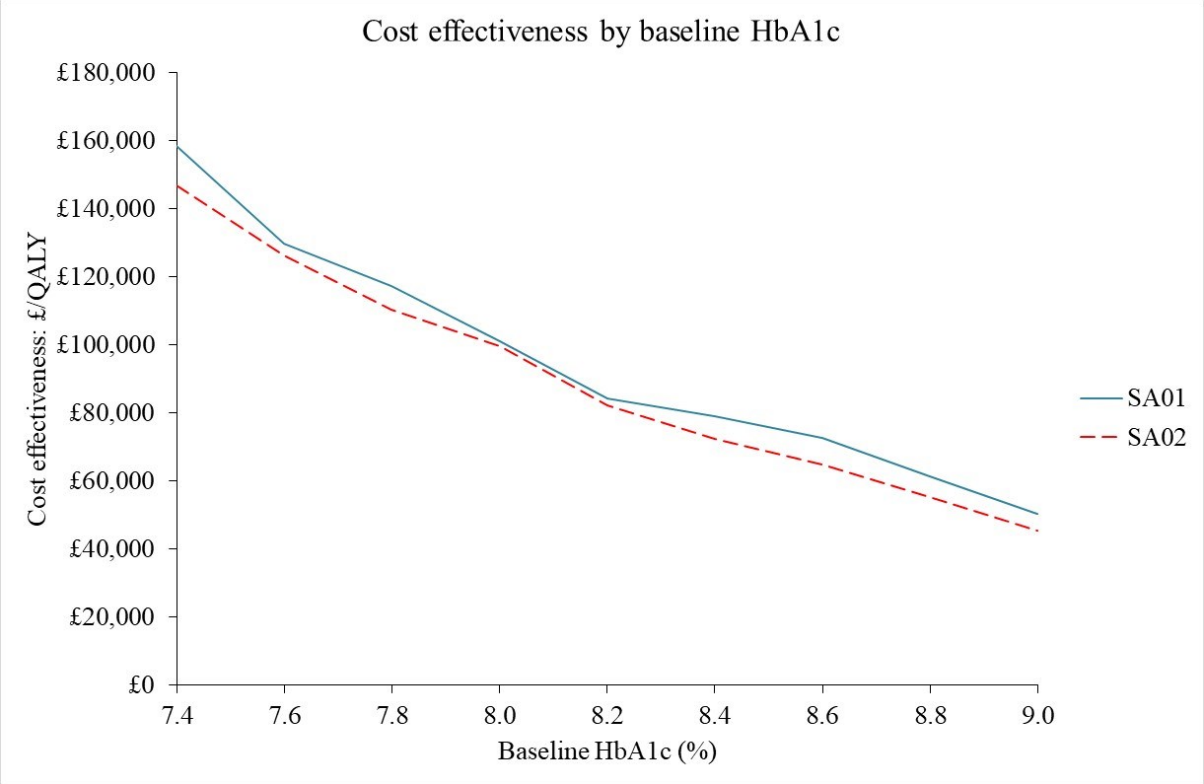



**Figure 9. Scenario analyses: net effects by baseline HbA1c**

Note that for a baseline of 8.0% SA01 estimates and ICER of £101,146 per QALY while SA02 estimates an ICER of £99,544 per QALY. These are slightly lower than the base case £101,753 per QALY due to it being assumed that the regression is centred around the trial baseline HbA1c values which are that bit less than 8.0%.

## Results: Comparison with NG17

NG17 estimated an annual cost of rtCGM of £2,000 based upon the September 2020 ceiling cost permitted for pregnant women in the NHSE and NHS Improvement funding document and an annual isCGM cost of £910 based upon 26 Freestyle Libre 2 sensors costing £35 each. This yielded an annual net cost for rtCGM compared to isCGM of £1,090. This compares to the current assessment's annual net cost for CSII+rtCGM compared to CSII+isCGM of £1,723, or roughly 60% higher.

The NG17 modelled a total net cost for rtCGM compared to isCGM was £14,512 with net QALYs of 0.123 and an implied ICER of £118k per QALY.

The most comparable EAG analysis is SA09 which estimates a total net cost for CSII+rtCGM compared to CSII+isCGM of £30,084, roughly double that of NG17. Net gains are also greater at 0.236 QALYs, yielding an ICER of £127k per QALY which is reasonably aligned with that of NG17.

The implied NG17 ICER of £118k per QALY for rtCGM compared to isCGM is presumably the reason why, though both rtCGM and isCGM were approved under NG17, the recommendation was that "*when choosing a CGM device … if multiple devices meet their needs and preferences, offer the device with the lowest cost*". This and/or patient preferences may explain the current preponderance of isCGM, and why if HCL is recommended it will mainly displace isCGM.

## Results: Validity of pooling CSII+isCGM and CSII+rtCGM

The EAG has presented fully incremental results in line with the NICE methods guide. It then pools the modelled results for CSII+isCGM and CSII+rtCGM with their total costs and total QALYs being weighted 90% and 10% respectively.

This glosses over that the baseline for CSII+isCGM is 8.00% but the baseline for CSII+rtCGM includes the net effect so is 8.00% - 0.36% = 7.64%. If this is felt to be the true picture it is unproblematic, but there may be some concerns about this.

An alternative is to model both CSII+isCGM patients and CSII+rtCGM patients having a baseline of 8.00% with the net effect of HCL compared to CSII+isCGM being -0.64% and the net effect of HCL compared to CSII+rtCGM being -0.28%. Adopting this approach and pooling 90:10 results in a total net cost of £33,717, a net 0.330 QALY gain and an ICER of £102,050 per QALY which is very similar to the £101,753 per QALY of the base case.

This approach can be criticised due to the common baseline HbA1c suggesting that the CSII+isCGM and CSII+rtCGM patient populations are different, and so may beg more questions than it answers.

## Questions for Committee

Economic questions:

1. Is a 90% share for CSII+isCGM the most reasonable estimate?
2. How reasonable are the market share costing assumptions and what weight should be given to the scenario that assumes the cheapest system will be mainly used?
3. Should one or both of the regressions of net change by baseline HbA1c be applied?
4. Should estimates of severe hypoglycaemic events be included and if so what are the most reasonable estimates, how should they be valued in terms of the quality of life of patients and possibly carers, and what cost should be applied?
5. Should estimates of non-severe hypoglycaemic events be included and if so what are the most reasonable estimates, how should they be valued in terms of the quality of life of patients and possibly carers, and what cost should be applied?

**Table 25. Incremental analysis: weighted average costing**

| | Description | CSII+isCGM | CSII+rtCGM | HybCL |
|---|---|---|---|---|
| BASE | Base case | Reference | Ext.Dom. | £105,620 |
| SA01A | HCL-rtCGM regression, baseline HbA1c 7.4% | Reference | Ext.Dom. | £160,700 |
| SA01B | HCL-rtCGM regression, baseline HbA1c 7.6% | Reference | Ext.Dom. | £133,382 |
| SA01C | HCL-rtCGM regression, baseline HbA1c 7.8% | Reference | Ext.Dom. | £120,924 |
| SA01D | HCL-rtCGM regression, baseline HbA1c 8% | Reference | Ext.Dom. | £105,053 |
| SA01E | HCL-rtCGM regression, baseline HbA1c 8.2% | Reference | Ext.Dom. | £87,375 |
| SA01F | HCL-rtCGM regression, baseline HbA1c 8.4% | Reference | Ext.Dom. | £81,780 |
| SA01G | HCL-rtCGM regression, baseline HbA1c 8.6% | Reference | Ext.Dom. | £75,545 |
| SA01H | HCL-rtCGM regression, baseline HbA1c 8.8% | Reference | Ext.Dom. | £64,255 |
| SA01I | HCL-rtCGM regression, baseline HbA1c 9% | Reference | Ext.Dom. | £52,980 |
| SA02A | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.4% | Reference | Ext.Dom. | £150,086 |
| SA02B | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.6% | Reference | Ext.Dom. | £129,407 |
| SA02C | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.8% | Reference | Ext.Dom. | £113,742 |
| SA02D | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8% | Reference | Ext.Dom. | £101,816 |
| SA02E | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.2% | Reference | Ext.Dom. | £84,500 |
| SA02F | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.4% | Reference | Ext.Dom. | £74,194 |
| SA02G | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.6% | Reference | Ext.Dom. | £67,379 |
| SA02H | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.8% | Reference | Ext.Dom. | £57,288 |
| SA02I | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 9% | Reference | Ext.Dom. | £47,109 |
| SA03A | Stroke costs 60 year old | Reference | Ext.Dom. | £105,565 |
| SA03B | Stroke costs with social care costs | Reference | Ext.Dom. | £105,549 |
| SA03C | Stroke costs as per previous EAG base case | Reference | Ext.Dom. | £105,664 |
| SA04 | Annual 0.045% HbA1c worsening | Reference | Ext.Dom. | £99,958 |
| SA05 | Excluding Benhamou | Reference | Ext.Dom. | £109,831 |
| SA06 | Adjusted complication costs | Reference | Ext.Dom. | £111,139 |
| SA07A | Include NSHEs with HCL 20.8 annual (base TBR < 3.9 and NG17) | Reference | Ext.Dom. | £104,271 |
| SA07B | Include NSHEs with HCL 57.2 annual (base TBR < 3.9 and NG17) | Reference | Ext.Dom. | £104,000 |
| SA07C | Include NSHEs with HCL 13.0 annual (base TBR < 3.9 and NG17) | Reference | Ext.Dom. | £104,484 |
| SA07D | Include NSHEs with HCL 90.0 annual (base TBR < 3.9 and NG17) | Reference | Ext.Dom. | £103,974 |
| SA08 | Include NSHEs as per SA07A and SHEs (base TBR < 3.0) | Reference | Ext.Dom. | £85,970 |
| SA09A | SA08 using Currie values for NSHE and SHE | Reference | Ext.Dom. | £90,516 |
| SA09B | SA08 using Gordon values for NSHE and SHE | Reference | Ext.Dom. | £101,022 |
| SA10A | SA08 with £36/£628 SHE cost | Reference | Ext.Dom. | £85,665 |
| SA10B | SA08 with £381 SHE cost | Reference | Ext.Dom. | £84,982 |
| SA11 | SA08 with NSHE cost £5 | Reference | Ext.Dom. | £85,324 |
| SA12 | SA08 with double HE quality of life effect | Reference | Ext.Dom. | £73,169 |
| SA13 | SA08 but NSHE all TBR < 3.9 estimates | Reference | Ext.Dom. | £99,126 |

## Table 26. Pooled analysis: HCL vs CSII+CGM: weighted average costing

| | Description | Net QALY | Net Cost | ICER |
|---|---|---|---|---|
| BASE | Base case | 0.332 | £33,802 | £101,753 |
| SA01A | HCL-rtCGM regression, baseline HbA1c 7.4% | 0.228 | £36,109 | £158,444 |
| SA01B | HCL-rtCGM regression, baseline HbA1c 7.6% | 0.273 | £35,410 | £129,896 |
| SA01C | HCL-rtCGM regression, baseline HbA1c 7.8% | 0.292 | £34,249 | £117,410 |
| SA01D | HCL-rtCGM regression, baseline HbA1c 8% | 0.331 | £33,500 | £101,146 |
| SA01E | HCL-rtCGM regression, baseline HbA1c 8.2% | 0.386 | £32,522 | £84,231 |
| SA01F | HCL-rtCGM regression, baseline HbA1c 8.4% | 0.398 | £31,496 | £79,037 |
| SA01G | HCL-rtCGM regression, baseline HbA1c 8.6% | 0.415 | £30,049 | £72,478 |
| SA01H | HCL-rtCGM regression, baseline HbA1c 8.8% | 0.467 | £28,591 | £61,222 |
| SA01I | HCL-rtCGM regression, baseline HbA1c 9% | 0.541 | £27,207 | £50,243 |
| SA02A | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.4% | 0.247 | £36,335 | £146,869 |
| SA02B | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.6% | 0.280 | £35,392 | £126,265 |
| SA02C | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.8% | 0.309 | £34,095 | £110,341 |
| SA02D | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8% | 0.334 | £33,287 | £99,544 |
| SA02E | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.2% | 0.394 | £32,331 | £82,058 |
| SA02F | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.4% | 0.426 | £30,852 | £72,371 |
| SA02G | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.6% | 0.460 | £29,827 | £64,883 |
| SA02H | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.8% | 0.519 | £28,603 | £55,112 |
| SA02I | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 9% | 0.590 | £26,696 | £45,277 |
| SA03A | Stroke costs 60 year old | 0.332 | £33,784 | £101,697 |
| SA03B | Stroke costs with social care costs | 0.332 | £33,778 | £101,681 |
| SA03C | Stroke costs as per previous EAG base case | 0.332 | £33,817 | £101,799 |
| SA04 | Annual 0.045% HbA1c worsening | 0.328 | £31,946 | £97,396 |
| SA05 | Excluding Benhamou | 0.315 | £33,405 | £105,981 |
| SA06 | Adjusted complication costs | 0.332 | £35,617 | £107,215 |
| SA07A | Include NSHEs with HCL 20.8 annual (base TBR < 3.9 and NG17) | 0.337 | £33,802 | £100,307 |
| SA07B | Include NSHEs with HCL 57.2 annual (base TBR < 3.9 and NG17) | 0.338 | £33,802 | £100,004 |
| SA07C | Include NSHEs with HCL 13.0 annual (base TBR < 3.9 and NG17) | 0.336 | £33,802 | £100,538 |
| SA07D | Include NSHEs with HCL 90.0 annual (base TBR < 3.9 and NG17) | 0.338 | £33,802 | £99,967 |
| SA08 | Include NSHEs as per SA07A and SHEs (base TBR < 3.0) | 0.399 | £33,358 | £83,520 |
| SA09A | SA08 using Currie values for NSHE and SHE | 0.384 | £33,358 | £86,907 |
| SA09B | SA08 using Gordon values for NSHE and SHE | 0.343 | £33,358 | £97,310 |
| SA10A | SA08 with £36/£628 SHE cost | 0.399 | £33,242 | £83,230 |
| SA10B | SA08 with £381 SHE cost | 0.399 | £32,982 | £82,580 |
| SA11 | SA08 with NSHE cost £5 | 0.399 | £33,069 | £82,797 |
| SA12 | SA08 with double HE quality of life effect | 0.467 | £33,358 | £71,491 |
| SA13 | SA08 but NSHE all TBR < 3.9 estimates | 0.349 | £33,358 | £95,615 |

## Table 27. Incremental analysis: least costly system costing

| | Description | CSII+isCGM | CSII+rtCGM | HybCL |
|---|---|---|---|---|
| BASE | Base case | Reference | Ext.Dom. | £115,473 |
| SA01A | HCL-rtCGM regression, baseline HbA1c 7.4% | Reference | Ext.Dom. | £175,019 |
| SA01B | HCL-rtCGM regression, baseline HbA1c 7.6% | Reference | Ext.Dom. | £145,456 |
| SA01C | HCL-rtCGM regression, baseline HbA1c 7.8% | Reference | Ext.Dom. | £132,139 |
| SA01D | HCL-rtCGM regression, baseline HbA1c 8% | Reference | Ext.Dom. | £114,936 |
| SA01E | HCL-rtCGM regression, baseline HbA1c 8.2% | Reference | Ext.Dom. | £95,753 |
| SA01F | HCL-rtCGM regression, baseline HbA1c 8.4% | Reference | Ext.Dom. | £89,822 |
| SA01G | HCL-rtCGM regression, baseline HbA1c 8.6% | Reference | Ext.Dom. | £83,266 |
| SA01H | HCL-rtCGM regression, baseline HbA1c 8.8% | Reference | Ext.Dom. | £71,068 |
| SA01I | HCL-rtCGM regression, baseline HbA1c 9% | Reference | Ext.Dom. | £58,800 |
| SA02A | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.4% | Reference | Ext.Dom. | £163,368 |
| SA02B | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.6% | Reference | Ext.Dom. | £141,113 |
| SA02C | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.8% | Reference | Ext.Dom. | £124,333 |
| SA02D | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8% | Reference | Ext.Dom. | £111,448 |
| SA02E | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.2% | Reference | Ext.Dom. | £92,657 |
| SA02F | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.4% | Reference | Ext.Dom. | £81,628 |
| SA02G | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.6% | Reference | Ext.Dom. | £74,325 |
| SA02H | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.8% | Reference | Ext.Dom. | £63,368 |
| SA02I | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 9% | Reference | Ext.Dom. | £52,379 |
| SA03A | Stroke costs 60 year old | Reference | Ext.Dom. | £115,418 |
| SA03B | Stroke costs with social care costs | Reference | Ext.Dom. | £115,402 |
| SA03C | Stroke costs as per previous EAG base case | Reference | Ext.Dom. | £115,517 |
| SA04 | Annual 0.045% HbA1c worsening | Reference | Ext.Dom. | £109,582 |
| SA05 | Excluding Benhamou | Reference | Ext.Dom. | £120,196 |
| SA06 | Adjusted complication costs | Reference | Ext.Dom. | £120,993 |
| SA07A | Include NSHEs with HCL 20.8 annual (base TBR < 3.9 and NG17) | Reference | Ext.Dom. | £113,998 |
| SA07B | Include NSHEs with HCL 57.2 annual (base TBR < 3.9 and NG17) | Reference | Ext.Dom. | £113,702 |
| SA07C | Include NSHEs with HCL 13.0 annual (base TBR < 3.9 and NG17) | Reference | Ext.Dom. | £114,232 |
| SA07D | Include NSHEs with HCL 90.0 annual (base TBR < 3.9 and NG17) | Reference | Ext.Dom. | £113,673 |
| SA08 | Include NSHEs as per SA07A and SHEs (base TBR < 3.0) | Reference | Ext.Dom. | £94,100 |
| SA09A | SA08 using Currie values for NSHE and SHE | Reference | Ext.Dom. | £99,075 |
| SA09B | SA08 using Gordon values for NSHE and SHE | Reference | Ext.Dom. | £110,575 |
| SA10A | SA08 with £36/£628 SHE cost | Reference | Ext.Dom. | £93,795 |
| SA10B | SA08 with £381 SHE cost | Reference | Ext.Dom. | £93,111 |
| SA11 | SA08 with NSHE cost £5 | Reference | Ext.Dom. | £93,453 |
| SA12 | SA08 with double HE quality of life effect | Reference | Ext.Dom. | £80,087 |
| SA13 | SA08 but NSHE all TBR < 3.9 estimates | Reference | Ext.Dom. | £108,499 |

## Table 28. Pooled analysis: HCL vs CSII+CGM: least costly system costing

| | Description | Net QALY | Net Cost | ICER |
|---|---|---|---|---|
| BASE | Base case | 0.332 | £37,246 | £112,118 |
| SA01A | HCL-rtCGM regression, baseline HbA1c 7.4% | 0.228 | £39,622 | £173,858 |
| SA01B | HCL-rtCGM regression, baseline HbA1c 7.6% | 0.273 | £38,903 | £142,711 |
| SA01C | HCL-rtCGM regression, baseline HbA1c 7.8% | 0.292 | £37,718 | £129,305 |
| SA01D | HCL-rtCGM regression, baseline HbA1c 8% | 0.331 | £36,943 | £111,544 |
| SA01E | HCL-rtCGM regression, baseline HbA1c 8.2% | 0.386 | £35,937 | £93,078 |
| SA01F | HCL-rtCGM regression, baseline HbA1c 8.4% | 0.398 | £34,888 | £87,549 |
| SA01G | HCL-rtCGM regression, baseline HbA1c 8.6% | 0.415 | £33,422 | £80,612 |
| SA01H | HCL-rtCGM regression, baseline HbA1c 8.8% | 0.467 | £31,929 | £68,370 |
| SA01I | HCL-rtCGM regression, baseline HbA1c 9% | 0.541 | £30,502 | £56,329 |
| SA02A | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.4% | 0.247 | £39,846 | £161,060 |
| SA02B | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.6% | 0.280 | £38,885 | £138,727 |
| SA02C | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 7.8% | 0.309 | £37,563 | £121,564 |
| SA02D | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8% | 0.334 | £36,733 | £109,847 |
| SA02E | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.2% | 0.394 | £35,747 | £90,729 |
| SA02F | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.4% | 0.426 | £34,243 | £80,325 |
| SA02G | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.6% | 0.460 | £33,195 | £72,210 |
| SA02H | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 8.8% | 0.519 | £31,937 | £61,535 |
| SA02I | HCL-rtCGM and rtCGM-isCGM regressions, baseline HbA1c 9% | 0.590 | £29,989 | £50,863 |
| SA03A | Stroke costs 60 year old | 0.332 | £37,227 | £112,062 |
| SA03B | Stroke costs with social care costs | 0.332 | £37,222 | £112,046 |
| SA03C | Stroke costs as per previous EAG base case | 0.332 | £37,261 | £112,163 |
| SA04 | Annual 0.045% HbA1c worsening | 0.328 | £35,311 | £107,656 |
| SA05 | Excluding Benhamou | 0.315 | £36,851 | £116,912 |
| SA06 | Adjusted complication costs | 0.332 | £39,060 | £117,580 |
| SA07A | Include NSHEs with HCL 20.8 annual (base TBR < 3.9 and NG17) | 0.337 | £37,246 | £110,525 |
| SA07B | Include NSHEs with HCL 57.2 annual (base TBR < 3.9 and NG17) | 0.338 | £37,246 | £110,191 |
| SA07C | Include NSHEs with HCL 13.0 annual (base TBR < 3.9 and NG17) | 0.336 | £37,246 | £110,779 |
| SA07D | Include NSHEs with HCL 90.0 annual (base TBR < 3.9 and NG17) | 0.338 | £37,246 | £110,150 |
| SA08 | Include NSHEs as per SA07A and SHEs (base TBR < 3.0) | 0.399 | £36,801 | £92,141 |
| SA09A | SA08 using Currie values for NSHE and SHE | 0.384 | £36,801 | £95,877 |
| SA09B | SA08 using Gordon values for NSHE and SHE | 0.343 | £36,801 | £107,355 |
| SA10A | SA08 with £36/£628 SHE cost | 0.399 | £36,685 | £91,851 |
| SA10B | SA08 with £381 SHE cost | 0.399 | £36,426 | £91,201 |
| SA11 | SA08 with NSHE cost £5 | 0.399 | £36,512 | £91,418 |
| SA12 | SA08 with double HE quality of life effect | 0.467 | £36,801 | £78,870 |
| SA13 | SA08 but NSHE all TBR < 3.9 estimates | 0.349 | £36,801 | £105,485 |

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**Additional Requests (22.05.2023)**

**Appendix: Exploratory paediatric modelling**

As reviewed in the previous EAG report, the EAG has concerns about the reliability of using the iQVIA CDM to model a paediatric population. Exploratory analysis using the EAG NMA results for the subset of paediatric studies and a scenario analysis that applies the NHSE paediatric pilot results are presented. Given the mean baseline age the time horizon is extended to the iQVIA CDM maximum of 80 years.

**Table 1: Previous EAG exploratory paediatric modelling: HbA1c (s.e.) changes**

| | NMA | NMA paed. |
|---|---|---|
| HCL | -0.28% (0.033%) | -0.31% (0.059%) |
| CSII+rtCGM[1] | 0.00% | 0.00% |

Restricting HCL studies to the paediatric subset had little effect upon the central estimate of the NMA. Given the revised NMA of the current report and its explicit inclusion of rtCGM and isCGM a further exploration can be made that applies the current NMA net effect for rtCGM over isCGM of -0.36%. But it should be noted that all rtCGM vs isCGM studies were in an adult population. This results in the following HbA1c effect estimates.

**Table 2: Previous EAG exploratory paediatric modelling: HbA1c (s.e.) changes**

| | |
|---|---|
| HCL | -0.67% |
| CSII+rtCGM | -0.36% |
| CSII+isCGM | 0.00% |

As before, the EAG applies these effect estimates to a paediatric population drawn from the NHSE paediatric pilot with the additional assumption that none have developed any of the complications of diabetes at baseline.

A further complicating factor is that CSII+rtCGM may be used more in the paediatric population than in the adult population. Due to CSII+rtCGM being more expensive than CSII+isCGM and extendedly dominated by CSII+isCGM and HCL, increasing its use improves the cost effectiveness of HCL compared to CSII+CGM. For instance, the pooled base case weighted average costing ICER within the adult modelling is £101,753 per QALY

[1] May include Thabit which did not specify whether it was CSII+rtCGM or CSII+isCGM

if CSII+CGM is 90% CSII+isCGM. This improves to £95,160 per QALY if the proportion that is CSII+isCGM falls to 75%. For this reason, due to the uncertainty around market shares the EAG presents a set of exploratory analyses based upon a 90% market share for CSII+isCGM and another set of exploratory analyses based upon a market share of 75% for CSII+isCGM.

**Table 3: Fully incremental analyses: Unaffected by CSII+isCGM to CSII+rtCGM split**

| | Description | CSII+isCGM | CSII+rtCGM | HybCL |
|---|---|---|---|---|
| BASE | Base case | Reference | Ext.Dom. | £88,180 |
| SA01 | 0.045% annual worsening | Reference | Ext.Dom. | £73,241 |
| SA02 | Pittsburg CVD risk equations | Reference | Ext.Dom. | £101,409 |
| SA03 | Adjusted complication costs | Reference | Ext.Dom. | £102,382 |
| SA04A | NSHEs HCL 20.8 annual | Reference | Ext.Dom. | £86,917 |
| SA04B | NSHEs HCL 57.2 annual | Reference | Ext.Dom. | £86,615 |
| SA04C | NSHEs HCL 13.0 annual | Reference | Ext.Dom. | £87,126 |
| SA04D | NSHEs HCL 90.0 annual | Reference | Ext.Dom. | £86,558 |
| SA05 | SA04A plus SHEs | Reference | Ext.Dom. | £70,747 |
| SA06A | SA05 using Currie values | Reference | Ext.Dom. | £74,230 |
| SA06B | SA05 using Gordon values | Reference | Ext.Dom. | £83,818 |
| SA07 | SA05 HE QoL x3 10 years, x2 after | Reference | Ext.Dom. | £56,432 |

As in the adult modelling CSII+rtCGM is extended dominated throughout.

**Table 4: Pooled CGM analyses 90% CSII+isCGM and 10% CSII+rtCGM**

| | Description | Net QALY | Net Cost | ICER |
|---|---|---|---|---|
| BASE | Base case | 0.416 | £35,439 | £85,086 |
| SA01 | 0.045% annual worsening | 0.483 | £33,975 | £70,269 |
| SA02 | Pittsburg CVD risk equations | 0.361 | £35,188 | £97,448 |
| SA03 | Adjusted complication costs | 0.416 | £41,340 | £99,257 |
| SA04A | NSHEs HCL 20.8 annual | 0.423 | £35,439 | £83,723 |
| SA04B | NSHEs HCL 57.2 annual | 0.425 | £35,439 | £83,391 |
| SA04C | NSHEs HCL 13.0 annual | 0.422 | £35,439 | £83,951 |
| SA04D | NSHEs HCL 90.0 annual | 0.425 | £35,439 | £83,323 |
| SA05 | SA04A plus SHEs | 0.507 | £34,842 | £68,722 |
| SA06A | SA05 using Currie values | 0.489 | £34,842 | £71,241 |
| SA06B | SA05 using Gordon values | 0.431 | £34,842 | £80,827 |
| SA07 | SA05 HE QoL x3 10 years, x2 after | 0.632 | £34,842 | £55,135 |

**Table 5: Pooled CGM analyses 75% CSII+isCGM and 25% CSII+rtCGM**

| | Description | Net QALY | Net Cost | ICER |
|---|---|---|---|---|
| BASE | Base case | 0.378 | £30,133 | £79,664 |
| SA01 | 0.045% annual worsening | 0.442 | £28,799 | £65,119 |
| SA02 | Pittsburg CVD risk equations | 0.331 | £30,016 | £90,614 |
| SA03 | Adjusted complication costs | 0.378 | £35,471 | £93,778 |
| SA04A | NSHEs HCL 20.8 annual | 0.386 | £30,133 | £78,152 |
| SA04B | NSHEs HCL 57.2 annual | 0.387 | £30,133 | £77,773 |
| SA04C | NSHEs HCL 13.0 annual | 0.384 | £30,133 | £78,406 |
| SA04D | NSHEs HCL 90.0 annual | 0.388 | £30,133 | £77,690 |
| SA05 | SA04A plus SHEs | 0.455 | £29,637 | £65,108 |
| SA06A | SA05 using Currie values | 0.448 | £29,637 | £66,082 |
| SA06B | SA05 using Gordon values | 0.392 | £29,637 | £75,595 |
| SA07 | SA05 HE QoL x3 10 years, x2 after | 0.561 | £29,637 | £52,784 |

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# Log of assumptions used in the calculation of costs

## Costs used in the updated model presented to the committee at the second committee meeting

### Table 1 HCL system costs

| | Year 1 | Years 2-4 | 4 Year | Share |
|---|---|---|---|---|
| Ypsomed | £8,171 | £5,706 | £25,289 | 10%* |
| Advanced Therapeutics | £7,650 | £4,975 | £22,575 | 10%* |
| Air Liquide | £7,785 | £4,980 | £22,724 | 18% |
| Medtronic | £8,051 | £4,768 | £22,355 | 63% |
| HCL weighted average | £7,976 | £4,920 | £22,735 | |

### Table 2 CSII+rtCGM system costs

| | Year 1 | Years 2-4 | 4 Year | Share |
|---|---|---|---|---|
| CSII+rtCGM: Freestyle Libre 3 | | | | 3% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+rtCGM: Dexcom 6 | | | | 97% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+rtCGM weighted average | £6,675 | £4,891 | £21,348 | |

### Table 3 CSII+isCGM system costs

| | Year 1 | Years 2-4 | 4 Year | Share |
|---|---|---|---|---|
| CSII+isCGM: Freestyle Libre 2 | | | | 80% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+rtCGM: Dexcom One | | | | 20% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |

| | | | | |
|---|---|---|---|---|
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+isCGM weighted average | £4,951 | £3,168 | £14,454 | |

## Assumptions used in the calculation of these costs

1 Costs were provided by NHS supply chain in April 2023.

2 Only 10% of Dexcom 6 users require a receiver.

3 The cost of the Guardian 4 System CGM Starter Kit + 5 x Sensors was not included in the calculation of the Medtronic HCL system cost.

## Assumptions preferred by the committee

4 Use of market share data to calculate weighted average system costs. Professor Partha Kar provided market share estimates for most systems. The EAG took the midpoint of these estimates. For systems without a market share estimate, the residual market share is split equally between them, indicated by a star in the tables above.

## Changes made to correct factual errors after the committee meeting

5 The costs in the table above incorporated an annual cost of £800 per year for the CamAPS FX algorithm when used with the Ypsomed mylife YpsoPump in a HCL system. This is incorrect and has been changed to a single cost of £800 in year 1 (no cost for CamAPS in years 2-4).

6 For the Ypsomed my life YpsoPump, a change was made to account for Teflon infusion sets being used and only 120 annually rather than steel and 180 annually. This reduced annual costs of the YpsoPump system by £624.

7 For the Ypsomed my life YpsoPump, an allowance of £8 for batteries was made in the first year and £4 thereafter, to be aligned with the other costings.

8 The Freestyle Libre 3 sensor cost was revised from £48.29 to £43.00 to reflect the recent price change. This reduced annual costs of the CSII+rtCGM systems using the Freestyle Libre 3 by £138.

9 The Air Liquide Tandem t:slim X2 insulin pump uses Control-IQ technology as the algorithm, not the CamAPS FX. The cost of the CamAPS FX algorithm (£840 annual cost) was removed from the Air Liquide HCL system.

10 Only 10% of Dexcom One users require a receiver.

## Resulting costs for use in the committee preferred base case

**Table 4 HCL system costs**

| | Year 1 | Years 2-4 | 4 Year | Share |
|---|---|---|---|---|
| Ypsomed: Dexcom 6 | £7,555 | £4,286 | £20,413 | 10%* |
| Advanced Therapeutics | £7,650 | £4,975 | £22,575 | 10%* |
| Air Liquide | £6,945 | £4,140 | £19,364 | 18% |
| Medtronic | £8,051 | £4,768 | £22,355 | 63% |
| HCL weighted average | £7,767 | £4,631 | £21,659 | |

**Table 5 CSII+rtCGM system costs**

| | Year 1 | Years 2-4 | 4 Year | Share |
|---|---|---|---|---|
| CSII+rtCGM: Freestyle Libre 3 | | | | 3% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+rtCGM: Dexcom 6 | | | | 97% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+rtCGM weighted average | £6,463 | £4,679 | £20,500 | |

**Table 6 CSII+isCGM system costs**

| | Year 1 | Years 2-4 | 4 Year | Share |
|---|---|---|---|---|
| CSII+isCGM: Freestyle Libre 2 | | | | 80% |

| | | | | |
|---|---|---|---|---|
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+rtCGM: Dexcom One | | | | 20% |
| Ypsomed | [redacted] | [redacted] | [redacted] | 33%* |
| Medtronic | [redacted] | [redacted] | [redacted] | 33% |
| Insulet | [redacted] | [redacted] | [redacted] | 33%* |
| CSII+isCGM weighted average | £4,744 | £2,960 | £13,627 | |

## Committee preferred base case

- 7.5% HbA1c at baseline
- Including the regression analysis
- Different effect sizes versus CSII+isCGM and CSII+rtCGM
  - -0.59% gain from HCL over CSII+isCGM
  - -0.23% gain for HCL over CSII+rtCGM
- Adjusted complications cost to account for possible overestimation in the iQVIA CDM
- NSHE and SHE included for both QoL and costs
- NSHE costed at £5
- No carer QoL effect from NSHE and SHE
- 60 year time horizon and maintenance of HbA1c effects
- Updated stroke costs

## Resulting ICER and threshold cost

**Table 7 Base case incremental cost effectiveness ratio (ICER)**

| | **Incremental cost** | **Incremental QALY** | **ICER** |
|---|---|---|---|
| Base case (pooled CSII+CGM vs HCL) | £34,949 | 0.336 | £104,003 |

The committee preferred a maximum acceptable ICER of £20,000 per QALY gained. This results in a threshold 4-year cost of [redacted].

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**DIAGNOSTICS ASSESSMENT PROGRAMME**

# Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

## Diagnostics Consultation Document Comments – NICE response summary

## Diagnostics Advisory Committee date: 24 May 2023

**Contents**

## THEME: ACCESS AND EQUALITY

| Example comments | NICE response |
|---|---|
| • Often T1Ds will travel considerable distances to attend clinic with the trained staff and the access to the technology they need. The postcode lottery also affects which HCL system the patient will be able to access.<br>• We had to apply 3 times for pump funding for our daughter - despite full support from the hospital team, the CCG kept refusing. In the end I had to involve my MP. Not everyone has the mental resilience or the economic status (access to laptop etc.) to be able to do this and it is unfair that you should have to.<br>• It is vital that the uptake of HCL should reflect the diversity of the T1 community. It would be a tragedy if the same inequalities in the uptake of CGM are seen with HCL, as the most deprived socioeconomic strata are likely to derive the most benefit.<br>• Some who have sight loss find using the various technologies difficult, as the technologies themselves often have no accessibility features. These systems seem to be no different. | Thank you for your comments which the committee considered.<br><br>A clinical expert said that NHS England has set out priorities for access to help reduce these healthcare inequalities.<br><br>A clinical expert also highlighted that the effective use of technologies was an important consideration. They said that improvements to the availability of and access to patient training were needed. They noted that many centres were limited because they do not have enough trained staff in their clinical teams to provide this. The committee concluded that improvements were needed to make sure there was no postcode lottery in access to technology and care. It further concluded that people should be supported to use the systems (see section 3.2 of the final appraisal document [FAD]). |

## THEME: COMPATABILITY WITH TA151

| Example comments | NICE response |
|---|---|
| • This is not compatible with current NICE recommendations for pump therapy (TA151), which is only possible in children aged under 12 years, and in those aged 12 years and over with an HbA1c over 69mmol/mol [8.5%].<br>• One fundamental issue is how this aligns with existing TA guidance specifically TA151 for Insulin Pumps… A specific aspect, that requires consideration, is the impact of the guidance on children under the age of 12 years. We would be grateful if HCL therapy could be considered as a treatment option for all children under the age of 12 years, regardless of their average HbA1c. | Thank you for your comments which the committee considered.<br><br>The committee concluded that although there was some uncertainty, HCL systems are likely to be more cost effective for children than adults. Therefore it recommended HCL systems as an option for managing blood glucose levels in type 1 diabetes for children and young people, without setting a specific HbA1c threshold. These considerations are in section 3.16 of the FAD. |

## THEME: COMPARATOR

| Example comments | NICE response |
|---|---|
| • Following NICE's March 2022 guidance publication, it would be anticipated that most people with type 1 diabetes now have access to at least a sensor to help with type 1 diabetes management. A much larger group for comparison to HCL use in current clinical practice would therefore have been people with type 1 diabetes on rtCGM or isCGM alone, rather than those using the systems with pumps." Is there any reason why these suggested comparator groups were not chosen?<br>• …I think a better comparator group for this guidance would have been HCL outcomes versus patients on a sensor alone, and not necessarily CSII. Even this guidance comment acknowledges that around 75% of people with diabetes nationally are not on a CSII.<br>• The recommendation was for people not reaching targets with 1 therapy - so unclear why the comparators are "dual therapy" with non-integrated sensor augmented pump or isCGM plus CSII. | Thank you for your comments which the committee considered.<br><br>The population in the economic model was people on a single technology (CSII, rtCGM, or isCGM). In the model they could then move to a non-integrated system or to a HCL system. The comparators used for the economic modelling were CSII plus rtCGM (non-integrated) and CSII plus isCGM (non-integrated).<br><br>A clinical expert explained that around 80% of people now have a CGM device (see section 3.10 of the FAD). |

## THEME: COMPLICATIONS

| Example comments | NICE response |
| --- | --- |
| • Dropping an HbA1c too quickly, especially when retinopathy is present can be very detrimental on eye health. Has this been taken into consideration?<br>• Almost half of the individuals with Type 1 Diabetes experience hypoglycaemia during the night… Usually, this event is not followed by any oral health related behaviour e.g. rinsing mouth with water… and can contribute to the development of long term oral health complications. | Thank you for your comments which the committee considered.<br><br>Eye related complications were included in the economic model, however it did not include oral health complications. |

## THEME: COST EFFECTIVENESS AND MODEL

| Example comments | NICE response |
|---|---|
| • It is concerning to use the same base case from the EAG report for evaluating the cost-effectiveness of HCL systems in patients with type 1 DM … despite the … exclusion of SHE and NSHE events from the base case.<br>• The EAC has assumed NSHE have no cost to the NHS. Brod et al (2011) and Orozco-Beltran et al. (2014) report that 8% - 25% of NSHE are associated with additional HCP appointments in people with T1D … this could represent a substantial cost to the NHS.<br>• The present health economic calculations using RCTs data are flawed… The… efficacy assessment utilised exclusively RCTs which applied [rtCGM] in the comparator group but costed [isCGM] in the comparator for the health economic calculations. This is incorrect unless it can be demonstrated that a therapy with [isCGM] and [rtCGM] provide the same outcomes... The health economic calculations should have used [rt]CGM in the comparator and not [is]CGM. | Thank you for your comments which the committee considered.<br><br>The economic model was updated after consultation. In the updated economic model, non-severe hypoglycaemic events and severe hypoglycaemic events were included in scenario analyses. The EAG also did a scenario analysis where non-severe hypoglycaemic events were costed at £5 per event. The committee concluded that its preferred base case included non-severe and severe hypoglycaemic events with non-severe events costed at £5 per event (see section 3.11 of the FAD). The committee's preferred base case and the resulting ICER is described in section 3.19 of the FAD.<br><br>In the updated economic model, the EAG also did another network meta-analysis, which included a comparison between isCGM and rtCGM. The committee concluded that although these results were uncertain, they indicate an approximate difference in effect in HbA1c changes between HCL systems and CSII plus isCGM, and a difference in effect between rtCGM and isCGM (see section 3.5 of the FAD). |

## THEME: COSTS

| Example comments | NICE response |
| --- | --- |
| • The final TA needs an accompanying resource template, broken down for each ICS.<br>• It is very unclear… what price point will need to be reached for this guideline to be agreed and published. This needs to be much clearer… as we anticipate that new systems will enter the market - ICB's / other decision makers will need clarity on whether each new system will be included in prescribable options.<br>• The EAG produced a threshold analysis to calculate the price that gives an ICER of £20,000… this has not been shared within the consultation so we do not have the opportunity to comment on this analysis. As this… is likely to inform pricing discussions with NHS England, we ask that it is shared with consultees along with the preferred assumption for the ICER of the Committee. | Thank you for your comments which the committee considered.<br><br>As part of the appraisal process, a resource impact assessment will be produced. NHS England will use the threshold price in the commercial negotiations.<br><br>The committee's preferred base case and the resulting ICER is described in section 3.19 of the FAD . |

## THEME: CHILDREN AND YOUNG PEOPLE

| Example comments | NICE response |
|---|---|
| • There are significant additional challenges associated with managing T1D in younger children… recognising and expressing the symptoms of hypoglycaemia, unpredictability of eating patterns, frequent unscheduled activity, and changing insulin requirements associated with growth. HCL therapy provides additional clinical benefits, compared with standard insulin pump and CGM options, in overcoming these difficulties."<br>• HCL therapy is already viewed as standard practice in many centres, particularly for very young children, and there is a risk that this guidance will result in a backwards step in paediatric diabetes management… it will build in the requirement for a high HbA1c with the associated long-term effects on metabolic memory and risk of diabetes complications before this technology can be considered. | Thank you for your comments which the committee considered.<br><br>Clinical experts explained that children and young people could have added benefits from HCL systems. For example, HCL systems 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. In older children, HCL systems can help with glucose control during the physiological changes that happen at puberty. So HCL systems could provide children and young people, and their families, with more freedom and reduce the mental burden on parents and carers (see section 3.16 of the FAD). Considering these points, the committee thought that HCL systems could benefit all children and young people with type 1 diabetes irrespective of their HbA1c level.<br><br>The committee concluded that although there was some uncertainty, HCL systems are likely to be more cost effective for children than adults. Therefore, it decided to recommend HCL systems as an option for managing blood glucose levels in type 1 diabetes for children and young people, without setting a specific HbA1c threshold (see section 3.16 and recommendation 1.2 of the FAD). |

## THEME: EDITORIAL

| Example comments | NICE response |
|---|---|
| In relation to section 2.3 of the ACD, which states that HbA1c level is the average plasma glucose over the last 3 months.<br>• should read over preceding 8-12 weeks<br><br>In relation to section 3.3:<br>"Most RCTs included children and young adults. A clinical expert said that most people using CSII in their clinics were adults."<br>• This statement may be misleading in the current context. I would suggest removing this as it does not add much value to this section. | Thank you for your comments which the committee considered.<br><br>All editorial comments were considered by the technical team and changes made to the FAD where appropriate. |

## THEME: EVIDENCE

| Example comments | NICE response |
|---|---|
| • With Omnipod 5, adults experienced a significant reduction in diabetes distress ($p<0.0001$) on the Type 1 Diabetes Distress Scale (T1DDS) (Polonsky 2022). This type of evidence indicates that the impact on mental burden of diabetes is an important factor without which the cost effectiveness of HCL cannot reliably be estimated.<br>• The results from NCT04914910 [Steno 780G Study] have been shared with NICE as Academic in Confidence [AIC] ahead of publication. The RCT compared an automated insulin delivery (AID) system with insulin pump and CGM / isCGM, usual care (UC).<br>• I would like to draw the committees attention to the following… large randomised controlled trial currently on-going in the UK: NCT04938557 (Automated Insulin Delivery Amongst Pregnant Women With Type 1 Diabetes [AiDAPT]) | Thank you for your comments which the committee considered.<br><br>All comments that suggested new or further evidence were considered by NICE and the EAG.<br><br>The committee considered a paper by Polonsky et al. (2022) which evaluated psychosocial outcomes for adults with type 1 diabetes using an automated insulin delivery system. The EAG explained that although this study reported improvements in various psychosocial outcomes such as diabetes distress, these could not be mapped onto EQ 5D for use in the economic model (see section 3.13 of the FAD).<br><br>The EAG considered the Steno 780G study for the regression analysis but were unable to weight the Steno trial because of missing data, and therefore the weighted regressions do not include this study.<br><br>The EAG considered the Automated insulin Delivery Amongst Pregnant women with Type 1 diabetes (AiDAPT) trial. The primary outcome of the AiDAPT trial was the percentage of time in the target range for pregnancy (18 to 48 mmol/mol [3.8% to 6.5%]). The results showed a statistically significant increase in time in the pregnancy-specific target range in the HCL systems group compared with the group having standard insulin delivery. The EAG explained that the trial reported mean HbA1c percentage at baseline, but did not report an end point HbA1c or change in HbA1c so this data could not be used in the network meta-analysis (see section 3.8 of the FAD). |

## THEME: HYPOGLYCAEMIA

| Example comments | NICE response |
|---|---|
| • Can consideration be given to people who have difficulty managing their diabetes due to disabling hypos that impact on their quality of life/ability to work etc. This group are often achieving a HbA1c below these targets due to the number of hypos they are experiencing<br>• NICE guidance TA151 makes clear that insulin pump therapy is recommended as a treatment option for adults and children 12 years and older with T1D who experience disabling hypoglycaemia. | Thank you for your comments which the committee considered.<br><br>The committee decided to revise recommendation 1.1 to state that 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:<br>• continuous subcutaneous insulin infusion (CSII)<br>• real-time continuous glucose monitoring<br>• intermittently scanned continuous glucose monitoring. |

## THEME: IMPLEMENTATION

| Example comments | NICE response |
|---|---|
| • …should include a recommendation to NHSE and the other bodies in devolved nations, to consider funding resources for these devices. Many ICS already operate with funding challenges. Even if considered cost-effective, may systems may consider that such devices are not affordable without funding to support implementation. Without new funding stream, this may impact other service provision and/or other service users.<br>• We wondered if some advice about an initial step-wise approach to prioritisation of eligible patients would be useful.<br>• There is a need to increase capacity and capability of the healthcare professionals who will be implementing and supporting the use of the HCL systems. | Thank you for your comments which the committee considered.<br><br>Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication. The normal period of compliance has been extended to 5 years for this technology because NHS England submitted a funding variation request, which was accepted by NICE after a period of public consultation.<br>Full details of NHS England's justification for the funding variation request are in section 4.1 of the FAD.<br><br>Based on the commercial framework and the recommendations in this guidance, NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach (see section 4.2 of the FAD). |

## THEME: INNOVATION

| Example comments | NICE response |
|---|---|
| • The principle of a closed loop system has been considered for decades to be the 'holy grail' of diabetes treatment short of a cure. To declare such a treatment option as 'not sufficiently innovative' is astonishing.<br>• This recent systematic review (Syeed et al 2022) includes eight criteria to determine innovation attributes. The algorithm used to integrate rtGCM data with CSII would fall within these criteria which would justify consideration of a higher ICER, namely, 'novelty, step-change, an improvement over existing technologies, substantial benefits, an improvement over existing technologies, convenience and/or adherence, added value, acceptable cost, and uncounted benefits'.<br>• The changes that HCL make to HbA1c coupled with QoL improvements are truly innovative from a patient/caregiver perspective | Thank you for your comments which the committee considered.<br><br>The committee noted that HCL systems enhance existing devices by using an algorithm to integrate rtCGM data with CSII. The committee concluded that although HCL systems provide an alternative treatment option for people with type 1 diabetes, it thought an ICER of £20,000 per QALY gained was acceptable. See section 3.21 of the FAD. |

## THEME: MENTAL BURDEN

| Example comments | NICE response |
|---|---|
| • This is a condition that requires CONSTANT monitoring, awareness and cautiousness (of what we eat, insulin dose, activities we do etc). It isn't just a mental load, it's mentally exhausting and debilitating.<br>• …I suffer with lack of sleep due to CGM alarm waking me due to hypos through the night, and through the day, and I am constantly recalculating insulin doses trying to solve hypos, and it has caused very low mood, exhaustion, and anxiety…<br>• The stress of T1D and managing glucose levels is playing a part in increasing depression leading to more suicide attempts.<br>• Mental health should also play a part in how people are assessed for eligibility. | Thank you for your comments which the committee considered.<br><br>Clinical experts expressed concerns that the reduced mental burden that HCL systems provide may not be captured adequately in the model. The committee concluded that because of these uncaptured benefits, the health economic model was likely to undervalue the effect of HCL systems on quality of life.<br><br>The committee considered a paper by Polonsky et al. (2022) which evaluated psychosocial outcomes for adults with type 1 diabetes using an automated insulin delivery system. The EAG explained that although this study reported improvements in various psychosocial outcomes such as diabetes distress, these could not be mapped onto EQ 5D for use in the economic model (see section 3.13 of the FAD). |

## THEME: OTHER MEASUREMENT CRITERIA

| Example comments | NICE response |
| --- | --- |
| • HbA1c can be a misleading metric... there is now evidence to suggest TIR is a more important and revealing metric... Two patients may have identical HbA1c results, but very different TIR. The... patient with lower TIR is at higher risk of complications.<br>• Time in Range (TIR) and Coefficient of Variation (%CoV) data... provide a more complete picture of diabetic control. | Thank you for your comments which the committee considered.<br><br>The committee considered that time in range is an important measure for people with type 1 diabetes, but the economic model is based on change in HbA1c data. So time in range could not be directly modelled. |

## THEME: OTHER SUBGROUPS

| Example comments | NICE response |
|---|---|
| A number of comments suggested different subgroups that should be considered in the assessment. These suggestions included:<br>• Peri-menopausal and menopausal women<br>• Those with learning difficulties, impaired cognitive function due to age, mental health [conditions] or brain injury<br>• Those with several chronic health conditions on multiple treatments trying to cope with them all<br>• People with complications of diabetes<br>• During chemotherapy<br>• During puberty<br>• Those with extreme needle phobia<br>• Type 3c diabetes; cystic fibrosis related diabetes; those with a T2 diagnosis who are actually LADA/MODY<br>• Those already on pumps with CGM; those who are currently self-funding closed loop. | Thank you for your comments which the committee considered.<br><br>A clinical expert said that some people with learning difficulties or impaired cognitive function are likely to have HbA1c levels above 58 mmol/mol (7.5%) and so would be covered by the revised threshold in recommendation 1.1.<br><br>The committee considered other types of diabetes that could benefit from HCL systems: type 3c diabetes in which the pancreas is damaged and stops producing enough insulin for the body; and cystic fibrosis diabetes in which build-up of mucus causes inflammation and scarring of the pancreas, which then cannot produce enough insulin for the body. The committee noted that no evidence was found on the use of HCL systems for these conditions. It considered that the clinical benefits in people with these conditions were likely to be similar to the clinical benefits for people with type 1 diabetes. It concluded that HCL systems could be useful in this group but this was outside NICE's scope for HCL systems in type 1 diabetes (see section 3.23 of the FAD).<br><br>The committee considered people with type 1 diabetes who are self-funding HCL systems or using DIY-looping to manage blood glucose levels. It concluded that people who are self-funding should be considered at an individual level. |

## THEME: PREGNANCY

| Example comments | NICE response |
|---|---|
| • I have been through 2 pregnancies with Type 1 diabetes and it is extremely difficult. I would wholeheartedly agree that this solution would benefit pregnant people.<br>• What is recommended after pregnancy? Continue or discontinue hybrid closed loop?<br>• How would we define “planning a pregnancy”?<br>• None of the current closed loop systems are licensed in pregnancy, the target glucose cannot be changed (factory setting) and therefore doesn’t fit with our current pregnancy guidelines | Thank you for your comments which the committee considered.<br><br>The committee recommended HCL systems as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy (see recommendation 1.3 in the FAD).<br><br>The implementation of HCL systems before and after pregnancy will be managed by NHS England. |

## THEME: QUALITY OF LIFE

| Example comments | NICE response |
|---|---|
| • The closed loop system has completely changed my life. It has allowed me to carry on working in my job as an NHS nurse, a job I have 20 years experience in but was struggling to manage. It has reduced my time in hospital as inpatient and outpatient, allowed me to continue to contribute to society as professional care giver and as a tax payer rather than being a recipient of benefits and care.<br>• The control IQ technology has taken away so much of the fear and effect of night time hypos/hypers.<br>• I do not believe the quality adjusted life year figure used in the analyses takes full consideration of the benefits gained from better sleep with no CGM alarms for both patient and partner, improved quality of family life without having to deal with both severe and non-severe hypos, reduced worry about diabetes complications, reduction/exclusion of hypoglycaemic episodes interrupting daily life.<br>• | Thank you for your comments which the committee considered.<br><br>The economic model was updated after consultation. In the updated economic model, non-severe hypoglycaemic events and severe hypoglycaemic events were included in scenario analyses. The committee concluded that its preferred base case included non-severe and severe hypoglycaemic events and the disutility associated with these events, with non-severe events costed at £5 per event. (see section 3.11 of the FAD).<br><br>In the updated economic model, the EAG did an exploratory analysis for adults which doubled the quality of life effects associated with non-severe and severe hypoglycaemic events. This was done to account for the effect on carers and/or families (see section 3.12 of the FAD).<br><br>In the updated exploratory modelling for children and young people, a scenario analysis included an estimate of carer disutility. In this analysis the quality-of-life effects associated with non-severe hypoglycaemic events and severe hypoglycaemic events were tripled for 10 years and then doubled for the remaining years. This was to account for the effect on quality of life for a child with type 1 diabetes, as well as the effect on 2 parents caring for the child.<br><br>The committee noted that these analyses were exploratory because there was no good data to show the effect that HCL systems have on the quality of life of a person caring for someone with type 1 diabetes. It concluded that the impact on carer quality of life could not be captured accurately in the modelling (see section 3.12 of the FAD). |

## THEME: RECOMMENDATIONS

| Example comments | NICE response |
|---|---|
| • …it is quite possible to have a reasonable HbA1c whilst having highly uncontrolled Type 1 diabetes (high - low swings, excessive hypoglycaemic episodes) it seems inappropriate to recommend the technology only if both factors are met. Please consider changing this to "or".<br>• …"optimal management" seems conflicting and unnecessary here. If someone is having difficulty managing their condition, or has an HbA1c above … 6.5% let alone above … 8.0%, then their management cannot be "optimal".<br>• …"having difficulty" is too easy [to] misinterpret. This should be a measure of the burden of diabetes, for example, how often the patient checks their glucose during the day, how often do they check their glucose during the night, how many corrections (insulin or glucose) do they make every day, do they restrict their diet solely to achieve their HbA1c value. | Thank you for your comments which the committee considered.<br><br>The committee considered the wording of recommendation 1.1 and decided to include disabling hypoglycaemia as a separate factor, that is independent of the HbA1 requirement. Recommendation 1.1 now states that:<br><br>“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:<br>• continuous subcutaneous insulin infusion (CSII)<br>• real-time continuous glucose monitoring<br>• intermittently scanned continuous glucose monitoring. |

## THEME: STRUCTURED EDUCATION

| Example comments | NICE response |
|---|---|
| • We need to ensure we aren't disadvantaging those who are unable to attend a programme. (e.g., those unable to get time off due to work/carer roles and very often low socioeconomic conditions or proficiency in digital courses or unable to speak English)<br>• Improvements to the availability of, and access to, patient training are needed.<br>• I would suggest changing the wording to "offering approved structured education programmes (face to face or digital) or ensuring person with diabetes demonstrates equivalent competencies in functional insulin dosing".<br>• There is separate HCL specific education on how to bolus pre meals, how to identify infusion site failures and deal with illness … change to " attendance at HCL specific education" | Thank you for your comments which the committee considered.<br><br>The wording of recommendation 1.5 has now been revised to state that:<br><br>Only use HCL systems if the person or their carer:<br>• is able to use them and<br>• is offered approved face-to-face or digital structured education programmes, or<br>• is competent in insulin dosing and adjustments. |

## THEME: SUPPORTIVE

| Example comments | NICE response |
| --- | --- |
| • I think this is a wonderful proposal. I am a type one diabetic who has struggled with keeping blood glucose levels in good range. I have lowered my hba1c to my personal best which is 9%. I frequenctly feel frustrated with my own control and have experienced burn out. I am hoping to have children in the future and having type 1 diabetes makes me very worried about pregnancy. This closed loop system would be very beneficial.<br>• The PCDS is pleased to see the development of this TA and welcomes the opportunity afforded to people with diabetes with access to technologies supporting self care.<br>• I think this is a really sensible and pragmatic guideline. | Thank you for your comments which the committee considered. |

## THEME: TECHNOLOGY

| Example comments | NICE response |
|---|---|
| • Based on the evidence below, it cannot be assumed that insulin pumps are equivalent in terms of accuracy when delivering lower doses of insulin.<br>• Clearly state in the guidance which commercially available systems are licensed for use in pregnancy and young<br>• We recommend that the wording is amended to make explicit reference to the need to adhere to a process of shared decision making between patients and clinicians in deciding which components and system is right for them. | Thank you for your comments which the committee considered.<br><br>Section 2.5 of the FAD has been updated to state that: The choice of components or system is based on a person's preference and whether the system has the appropriate license for use. Whether HCL systems are licensed for use in pregnancy or in children or young people may differ. Any future systems comprised of components from different manufacturers must show interoperability and be equivalent to current systems in terms of patient benefits. |

## THEME: THRESHOLD

| Example comments | NICE response |
| --- | --- |
| • Access should be available to all Type 1 patients<br>• …my good control is achieved by an almost obsessive level of monitoring my glucose levels, and depriving myself of most carbs …it is so demotivating to know that by living so strictly I am depriving myself of the technology that could enable me to live more freely.<br>• …the closed loop system could improve my quality of life greatly so it seems very unfair that I am being denied access to this because my blood sugar is too well controlled.<br>• There is a real risk that patients do themselves harm by allowing their condition to deteriorate in order to qualify for the freedom afforded by hybrid closed loop systems. | Thank you for your comments which the committee considered.<br><br>In the updated economic analysis, the EAG did some exploratory regression analyses comparing baseline HbA1c with HbA1c change. The committee said that although the regression analyses were uncertain, they indicated a greater HbA1c effect size as the baseline HbA1c increases, which reflected what clinical experts expect to see in practice. It concluded that the regression analyses should be included in the economic modelling (see section 3.6 in the FAD).<br><br>The committee preferred a baseline HbA1c of 58 mmol/mol (7.5%) because this is a common clinical target for people who have a higher HbA1c. The studies used in the preferred regression analysis also had a mean baseline HbA1c of 7.5%. The committee recalled the uncertainty in the regression analyses and concluded that it was unclear what the true HbA1c effect estimate would be. Without any directly observed data, a decrease of 7 mmol/mol (-0.59 percentage points) from a baseline of 58 mmol/mol (7.5%) was a reasonable estimate. It further concluded that the change in HbA1c substantially affected the ICER, and whether HCL systems could be considered cost effective (see section 3.9 of the FAD).<br><br>Therefore the committee decided to change the HbA1c threshold in recommendation 1.1 from around 64 mmol/mol (8.0%) or more, to 58 mmol/mol (7.5%) or more. |