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]