NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Equality impact assessment – Guidance development

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

The impact on equality has been assessed during this appraisal according to the principles of the NICE equality scheme.

Consultation

1. Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?

The following potential equality issues were identified during scoping:

- Some of the hybrid closed loop systems currently available in the UK are not licensed for use in children under 6 or 7 years old and in pregnancy.
- People with certain skin conditions or allergies may be unable to wear a sensor.
- People with learning difficulties and people whose vision or hearing does not allow recognition of pump signals and alarms may have difficulty in using the technologies.
- People who have had diabetes for many years and older people may have impaired awareness of hypoglycaemia.
- There may be a need for tighter glucose control in pregnant women.
- Younger children may need help to operate the device every time and toddlers may have more limited management options.
- People from ethnic minority are less likely to be offered technology as therapy; this may be because of a language barrier.
- People from lower socioeconomic groups and those who are less educated may be less likely to use the technology; this may be because of less awareness of their options.
- People with cystic fibrosis might be more likely to get diabetes.
- People with blood clotting disorders such as haemophilia might not be able to do finger prick testing

The committee noted that there are equality 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 struggle to maintain adequate glycaemic control due to language barriers, lower levels of education or learning difficulties, for example. A clinical expert said that NHS England has set out priorities for access to help reduce these healthcare inequalities. The positive recommendation for HCL systems, made by the committee could help improve access in these groups.

A clinical expert also highlighted that in addition to access, the effective use of technologies was an important consideration. They said that improved access to patient training was needed and that many centres were limited because they do not have enough trained staff in their clinical teams to provide this (see section 3.2 of the ACD).

The committee noted that people with sight impairments or who find it difficult to use touchscreens because of loss of feeling in fingertips or manual dexterity are also likely to find it hard to benefit from this kind of technology. It recommended that HCL systems should only be used if the person or their carer understands and is able to use them (see recommendation 1.4 of the ACD).

The committee understood that the evidence on the effectiveness of HCL in pregnancy was limited to only 1 small study. However, the committee thought that there could be greater benefits of HCL in pregnancy because glycaemic control is harder to maintain and there is a risk to both the mother and unborn baby. The committee also noted that it would be difficult to do studies in pregnancy because the duration of pregnancy is relatively short. This would complicate study design and data collection (see section 3.6 of the ACD). The committee concluded that the effectiveness of HCL systems in pregnancy would likely be greater than in the overall population. It recommended HCL systems as an option for managing blood glucose levels in type 1 diabetes in people who are pregnant or planning a pregnancy (see recommendation 1.2 of the ACD).

When considering HCL use in children the committee concluded that although there was some uncertainty, HCL was likely to be more cost effective in children than adults. The committee decided that the recommendations should be inclusive of children and adults and so recommended HCL systems as an option for managing blood glucose levels in type 1 diabetes in people rather than specifying children or adults (see recommendation 1.1 in the ACD).

2. Have any other potential equality issues been raised in the submissions, expert statements or external assessment report, and, if so, how has the committee addressed these?

A clinical expert statement said that the technology is very helpful in very young children (pre-school children) in whom glycaemic control can be difficult due to

varied activity levels and varied food intake. It is also helpful in young people undergoing puberty in whom both insulin resistance and compliance can impede attaining good diabetes control.

When considering HCL use in children the committee concluded that although there was some uncertainty, HCL was likely to be more cost effective in children than adults. The recommendations are inclusive of children and adults (see recommendation 1.1 in the ACD).

3. Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?

No other potential equality issues been identified by the committee.

4. Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

No

5. Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

Yes, people with sight impairments or who find it difficult to use touchscreens because of loss of feeling in fingertips or manual dexterity may not be able to use HCL systems themselves.

6. Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?

Yes, carers of people with diabetes who have sight impairments, loss of feelings in fingertips or loss of manual dexterity should be offered training to support the person with diabetes to use HCL systems. This also applies to parents and carers of young children, who would need training so they can support use of HCL systems in young children with diabetes. This is stated in section 1.4 of the ACD.

7. Have the committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?

Yes. Section 3.2 of the appraisal consultation describes the committee's considerations of access to technology and care. Sections 3.5 and 3.6 describe the committee's considerations of the clinical evidence for HCL in children and in pregnancy. Sections 3.11 and 3.12 describe the committee's considerations of the cost effectiveness of HCL in children and in pregnancy, respectively.

Approved by Associate Director (name): Rebecca Albrow

Date: 16/12/2022

Final appraisal document

1. Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?

At consultation, comments were received relating to the additional challenges associated with managing T1D in younger children. For example, their ability to recognise symptom of hypoglycaemia, unpredictable eating patterns, frequent unscheduled activity, and changes to their insulin requirements associated with growth. The committee addressed these issues by including a separate recommendation for children and young people without setting a specific HbA1c threshold (see recommendation 1.2 in the final appraisal document [FAD]).

A stakeholder also said that the recommendations should not disadvantage people who are unable to attend a structured education programme (for example, people unable to get time off due to work and/or carer roles, low socioeconomic conditions or proficiency in digital courses or unable to speak English). The committee decided to revise the wording of recommendation 1.5 to state that:

Only use HCL systems if the person or their carer:

- is able to use them and
- is offered approved face-to-face or digital structured education programmes or
- is competent in insulin dosing and adjustments.

At consultation, comments were also received that suggested different subgroups that should be considered in the assessment. These included:

- Peri-menopausal and menopausal women
- People with learning difficulties, impaired cognitive function due to age, mental health [conditions] or brain injury
- People with several chronic health conditions on multiple treatments trying to cope with them all
- People with complications of diabetes

- During chemotherapy
- People with extreme needle phobia
- Type 3c diabetes; cystic fibrosis related diabetes; those with a T2 diagnosis who actually have latent autoimmune diabetes in adults (LADA) or maturity-onset diabetes of the young (MODY).

A clinical expert said that some people with learning difficulties or impaired cognitive function, or other complications 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. 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. 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. However, it concluded that this was outside the scope of the appraisal(see section 3.23 of the FAD).

2. If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

No

3. If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

No

4. If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?

N/A

5. Have the committee's considerations of equality issues been described in the final appraisal document, and, if so, where?

Yes. Section 3.2 of the final appraisal document describes the committee's considerations of access to technology and care. Sections 3.7 and 3.8 describe the committee's considerations of the clinical evidence for HCL in children and in pregnancy. Sections 3.16 and 3.17 describe the committee's considerations of the

cost effectiveness of HCL in children and in pregnancy. Section 3.23 describes the committee's considerations of other types of diabetes that could benefit from HCL systems, including type 3c diabetes and cystic fibrosis diabetes.

Approved by Associate Director (name): Rebecca Albrow

Date: 21/06/2023