

DIAGNOSTICS ASSESSMENT PROGRAMME

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

Funding variation consultation - themed comments

Theme: Phased roll out

Comment Number	Name and organisation	Stakeholder Comment	NICE response
1	Evelina London Children's Hospital, Association of Children's Diabetes Clinicians	<p>1. I think a phased roll out over 5 years is far too slow, this should be done as a priority in the next 1-2 years. This technology is currently available and we need a plan rolled out as soon as possible. Patients and families are aware that this technology exists and understandably want the best possible treatment for their diabetes now and not in 5 years time. The delay in roll out will increase inequity of access, we have seen this in access to CGM, those who could self fund did so whilst awaiting NHS funding. The NPDA data clearly shows this.</p> <p>Those who are able will also access non licensed alternatives as we have seen with 'on line looping'.</p> <p>Consideration should be given to getting the companies producing the technology to include as part of the package all components needed for the system including mobile phones. This is particularly relevant for children and young people who are unlikely to have access to a mobile phone in their day to day life.</p>	<p>Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.</p>
2	JDRF	<p>JDRF agrees with the funding variation request of a five year roll out for hybrid closed loop (HCL), particularly around the following areas:[see comments 16, and 31 to 33]</p>	<p>Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.</p>
3	Guy's & St Thomas NHS	<p>We are grateful to NHSE for pre-empting the impact of this MTA and developing an implementation proposal. Whilst it is understandable time will be required to enable</p>	<p>Thank you for your comments that NICE and NHS England have</p>

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	Foundation Trust	effective implementation of hybrid closed loops in the groups specified by the MTA, the forecasts and timescales extending to 5 years create several concerns.	considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
4	Diabetes Technology Network – UK (DTN–UK)	DTN-UK fully supports NHS England’s proposal for the adoption of a 5 year phased roll-out for the implementation of the above Multiple Technology Appraisal. The need to develop staffing expertise and clinical capacity to deliver this technology makes this a challenging but achievable timescale. DTN-UK are working alongside NHS England to produce guidance and education to support the implementation by helping to address some of the challenges identified.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
5	Medtronic	We agree that a phased roll-out of Hybrid Closed Loops (HCLs) is reasonable in terms of clinical capacity and patient onboarding.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
6	Diabetes UK	1. We strongly agree that “equitable, sustainable, and affordable patient access” to hybrid closed loop systems is vital and support robust measures being put in place to	Thank you for your comments that NICE and NHS England have

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		<p>enable the health system to achieve this. As is clearly evidenced in the randomised control trials and real world pilots of the technology evaluated during this appraisal, hybrid closed loop technology can provide huge benefits to people living with type 1 diabetes in improving their health outcomes and quality of life and mark a significant positive shift in diabetes care.</p> <p>This plan should rightly build on lessons learnt from the recent rollout of other diabetes technologies like continuous glucose monitoring and insulin pumps to ensure that the implementation of hybrid closed loop can be undertaken fairly and sustainably.</p> <p>We think that a phased five-year programme to ensure broad and fair adoption is a sensible compromise considering the current capacity within the system to deliver this technology but would also like to see an implementation process that can offer more precise projected timescales and allow services who are able to rollout quicker the flexibility to do so. For example, as most insulin pump warranties last for four years some teams may find it more natural use this as a timeframe to move some new pump users to hybrid closed loop compatible systems as they become due for an upgrade.</p> <p>We also look forward to hearing more details about the implementation plan as we near the conclusion of the appraisal and are keen to participate in the oversight group that will be set up to monitor and evaluate the progress of the rollout amongst other stakeholders.</p>	<p>considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.</p>
7	Insulet International Ltd	<p>Insulet International Ltd recognises the capacity challenge within the NHS and welcomes a programme of support for the implementation of Hybrid Closed Loop as the standard of care for people with Diabetes. We would encourage caution with extending this out to a 5 year implementation and believe that with the support of industry and with the right products, this could be expedited to bring more people to this high impact technology sooner.</p>	<p>Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the</p>

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			phased uptake approach. Please see section 4 of the final appraisal document.

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Funding variation consultation - themed comments

Theme: Clinical groups to prioritise

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8	Guy's & St Thomas NHS Foundation Trust	<p>A phased roll-out will be required. People who are younger and going through important milestones as well as pregnancy/post-partum period have a lot to benefit from HCL systems. Nevertheless, prioritising this group universally and diminishing the importance of HCL in older adults raises some concerns. This approach is not based on offering priority to those who can benefit the most on objectives assessed during the NICE MTA process. It also assumes that children and maternity services throughout England will be able to cope with the large volume of cases via major clinical cases. It is also based on the understanding that the benefits reviewed by NICE in pregnancy (based on a single licensed system for pregnancy) will be universally applicable to the more widely used systems not licensed in this setting which is different to clinical experience.</p> <p>The current groups also significantly disadvantage those that who are older with type 1 diabetes, despite the strong evidence that those from higher age groups (who often have type 1 diabetes for a longer duration) are at higher risk of sight or limb threatening complications, hypoglycaemia unawareness/ debilitating hypoglycaemia and therefore morbidity / mortality. It also must be noted that the NHSE HCL pilot in adults which formed the basis for the current MTA recommendations was in an adult cohort which are not included in the NHSE priority group. There are also a number of quality-of-life related reasons (ranging from cancer treatment, concurrent morbidity impacting on ability to self-manage, or work situations) which are more commonly seen in older groups and are also strong reasons to consider HCL.</p> <p>Phased roll-out with priority groups based on clinical need are needed within each category (eg children, young adults, pregnancy, adults and older adults) to ensure that those who can benefit the most across each group can access this sooner rather than be left to delays leading to medical and psychological morbidity.</p>	<p>Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.</p>

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9	Diabetes Technology Network – UK (DTN–UK)	DTN-UK agree with the clinical prioritisation suggested by NHS England, and aim to work with NHS England to produce guidance for clinical teams to support this approach at a local level.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
10	Medtronic	<p><i>“the phased rollout of HCL is not expected to adversely impact patient outcomes for people eligible for HCLs”....</i></p> <p>We are concerned that the phase roll out may, unintentionally, widen the significant inequity that currently exists in access to insulin pumps, by prioritising those patients already on a pump, as outlined in the “Targeted to optimise outcomes” section.</p>	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
11	Medtronic	<p><i>Targeted to optimise outcomes - the phased rollout will concentrate on those most likely to benefit. This will begin with populations where the demand is highest, specifically Children and Younger People (0-12) and their families, Children and Younger Adults (13 -19), pregnancy, existing adults who are pump users wishing to transition to HCL <u>and then extending to new pump users over time.</u></i></p> <p>To ensure equitable access to HCL therapy during the phased roll out, we ask that consideration is given to ensuring that all cohorts of eligible patients can access HCL therapy from the start of the phased roll out and not just those already on pumps. It is</p>	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.

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		unclear why targeting patient already on a pump would “optimise outcomes” compared to a patient not already on a pump.	
12	Diabetes UK	<p>1. We are very supportive of the proposal to prioritise children and young people and pleased to see a specific recommendation for them included in the updated eligibility criteria agreed by the committee.</p> <p>However, we also feel it is important that there is an explicit statement within the implementation plan that any children and young people using hybrid closed loop shouldn't face the possibility of having the technology taken away as they transition to adult services.</p>	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
13	Insulet International Ltd	Innovation should be viewed as a catalyst to reducing healthcare inequalities and so an expedited implementation of the roll out would bring equality sooner to the diabetes community. The extended approach proposed by NHS England has potential to build upon and exacerbate existing inequalities in accessing advance diabetes technologies. Those currently on pump therapy are already benefitting from preferential access and focusing on these people first expands the gap between them and those who may benefit but have disadvantaged access. Any approach on the roll out of HCL should actively provide equal access to people based on clinical need for the technology.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.

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Funding variation consultation - themed comments

Theme: Implementation

Comment Number	Name and organisation	Stakeholder Comment	
14	Evelina London Children's Hospital, Association of Children's Diabetes Clinicians	5. The operating model for access to HCL systems needs to be easy to use and negotiate. Any increase in paperwork and complexity will take clinicians away from being able to do the job of caring for patients which will subsequently increase the 'post code lottery'. Given that models are already in place for access to CGM and pumps NHSE should look at which of these seem to work best in a variety of areas. Patients need to be able to access care within their local vicinity in a timely manner.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
15	Ypsomed UK	Ypsomed commends the ambition of NICE with regards to the draft HCL guidelines as this represents a momentous opportunity to improve the lives of people with diabetes. However, the groups identified as those targeted to optimise outcomes come with their own set of challenges with respect to the current licencing restrictions of certain HCL systems in these groups. How will NICE address this in its final guidance?	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
16	JDRF	Targeted to optimise outcomes – JDRF agrees with the need for a pragmatic, phased approach to roll out. We believe that it would be beneficial to build in review points to the process, to assess if there are any unintended consequences in relation to those not already using technology, but still meeting the HbA1c criteria.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS

Comment Number	Name and organisation	Stakeholder Comment	
			England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
17	Guy's & St Thomas NHS Foundation Trust	The main issue NHSE is hoping to address is the systems current difficulties in implementing NICE TA 151 (insulin pumps), given that there is large variation and relatively low uptake. Planning is therefore needed. There is concern about the ability of the system to cope and support HCL. Since the original NICE TA (2003) and NICE TA 151 (2008), whilst there have been gradual improvements, the pace of change has been slow and has led to geographical variation, as well as variation in access based on social determinants such as socio-economic status and ethnicity. A lot of care and precision has been taken in drafting the current MTA to avoid these issues. Whilst time is required, delaying this for up to 5 years is likely to lead to inertia and not provide pressure for larger number of "non-major" centres to adopt the coming MTA in a reasonable time frame. This will be necessary to ensure people with type 1 diabetes served by them are not disadvantaged and high pressure is not placed on major centres either. To ensure changes are implemented across the range of services in England, a strong mandate such as the MTA is required to drive change within a more reasonable time frame rather than 5 years.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
18	Guy's & St Thomas NHS Foundation Trust	The plan is based on a focus on major clinical centres and assumption that these centres serve areas where health inequalities exist. Regional and national experience from colleagues is at complete odds to this. This model could therefore amplify variation whilst placing additional pressure on major centres which struggle with capacity and delivering services to a wide geography, rather than promote developments locally. A network-based approach could be considered but requires detailed planning to support the delivery of this and cannot be built on the assumption highlighted above.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.

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19	Guy's & St Thomas NHS Foundation Trust	In summary, whilst there may be a rationale for requesting a variation to the funding period, the proposed model is likely to introduce more geographical variation and inequalities. Phased and staggered implementation will be required but the groups considered require further detail and time periods of 5 years is likely to lead to inertia in a system that has lagged behind on NICE TA 151 which precedes this work, whilst disadvantaging individuals excluded from the current priority groups. Once the full wording of the MTA is available and funding information from NHSE can be detailed, a clearer implementation plan needs to be developed.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
20	Diabetes Technology Network – UK (DTN–UK)	DTN-UK are concerned that local Commissioners (Intermediate Care Boards) may see the timescale and opt to delay initiation of the implementation for the Multiple Technology Appraisal. We would be grateful if there could be clear direction included within the guidance that reflects the expectation that implementation will be initiated 3 months after the publication of the final Multiple Technology Appraisal, with the recognition that full implementation will require the recommended 5 year time frame.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
21	Diabetes UK	3. When possible it would be helpful to get further details on estimated costs and projections for the rollout, and how they may change under different scenarios in the implementation plan.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.

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22	Diabetes UK	<p>Appendix 1. We think that the high adoption scenario presents the best choice, offering this technology to the greatest number of eligible people.</p> <p>This acknowledges the low and uneven uptake of insulin pumps currently, with the National Diabetes Audit 2020/21 showing around 40% of people with type 1 would be eligible under NICE TA151, but with uptake rates being significantly lower than this in many areas.</p> <p>As part of our 2023 Diabetes is Serious report we conducted a survey of 11,000 people living with diabetes in England and, of the respondents with type 1, we found that 37% of those not currently on hybrid closed loop would be interested in using it. We suggest that this figure would likely rise significantly following further outreach and education when this guidance is published and the technology continues to develop in the coming years.</p> <p>References: https://diabetes-resources-production.s3.eu-west-1.amazonaws.com/resources-s3/public/2023-05/DUK_Diabetes%20is%20Serious%20Report%202023_Digital.pdf</p> <p>https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/national-diabetes-audit/dashboards</p>	<p>Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.</p>
23	Diabetes UK	<p>Appendix 1. We would suggest offering more defined milestones at different stages within the proposed schedule to help keep the roll-out on track and avoid delays that can create bottle-necks and compromise swift and equitable adoption.</p> <p>Furthermore, adding a statement to explain that services should aim to start developing pathways and considering initiation of their first eligible cohorts of people within a shorter timeframe may be helpful to ensure all areas are minded to begin their work to implement the guidance as soon as possible after publication.</p>	<p>Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.</p>

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		The shorter timescale for this initial work could be approximately three months, in line with the usual implementation period for technology appraisals, with the broader aim for full uptake within the five-year schedule proposed.	
24	Diabetes UK	1. Similarly, we think that the implementation plan could provide further clarity on what should happen post-pregnancy to women who are hybrid closed loop users, and believe that they should be supported to continue using the technology should they wish.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.

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Funding variation consultation - themed comments

Theme: Staff resources, training and education

Comment Number	Name and organisation	Stakeholder Comment	NICE response
25	Ypsomed UK	Has the level of support from industry in terms of training and support packages to address clinical capacity issues, particularly knowledge gaps, been considered in the phased rollout? Does the phased rollout depend on assistance from industry to up-skill and train both new and existing staff?	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
26	Diabetes UK	1. To assist diabetes teams with providing the specialist support required to enable people to benefit from this technology, we would point to the growing catalogue of virtual training packages and the role industry (i.e. pump manufacturers) can play in training. We would suggest that the implementation outlines in more detail the support that people learning to use these systems should expect from health care professionals and what training should be delivered. It could also helpfully outline the core skills that people living with diabetes should have to enable them to use hybrid closed loop effectively.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
27	Insulet International Ltd	Availability of personnel is imperative to the success of the implementation of the proposed NICE appraisal and we would remind NICE that there is much support already in place and funded both by Industry and by Health Care Professional bodies such as DTN (Diabetes Technology Network) therefore this is already underway and a focussed acceleration would	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS

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		enable NICE and NHS England to shorten the timeframe of this variation proposal.	England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
28	Insulet International Ltd	Hybrid Closed loop systems have been on the UK market for several years already and so are not completely without planning and resources currently. Capacity is supported by industry who also take on the financial costs of providing staff to initiate people on to therapy both in the comfort of their own homes and in hospital clinics and this is an additional element of the value proposition offered by industry which should be considered. We see that pathway proposals being developed, for example the DTN-UK best practice guidelines, rely extensively on Industry support to help expand capacity and this should also be considered as current activity	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.

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Funding variation consultation - themed comments

Theme: Equity of access

Comment Number	Name and organisation	Stakeholder Comment	NICE response
29	Evelina London Children's Hospital, Association of Children's Diabetes Clinicians	4. Restriction of this technology to certain groups for 5 years will result in increased inequity of access during this time period with those in certain racial and socioeconomic groups being disadvantaged. Whilst I appreciate that this may even out with time, 5 years is a long time, half a decade, and this time has the potential to lead to significant health deterioration and the development of complications.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
30	Ypsomed UK	Ypsomed is acutely aware of the impact healthcare inequality has with regards to access to technology. Only by offering a wide selection of HCL systems and associated technologies can Diabetes care teams be able to address any compatibility issues and ensure that most patients can benefit from HCL therapy. The guidelines should advocate that, capacity and capability permitting, Diabetes centres and commissioners should not restrict the options available.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
31	JDRF	Variations in access – there is currently a postcode lottery across England with regards to devices for the management of type 1 diabetes. For example, we know of one teenager who lives in a rural part of England, and has to travel five hours to London for her diabetes clinic, in order to access a suitable continuous glucose	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS

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		monitor and insulin pump. Since obtaining a hybrid closed loop, her HbA1c has improved and she is able to participate in sports and other activities with her peers.	England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
32	JDRF	Healthcare inequalities - JDRF's 2020 Pathway to Choice report ¹ , 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. We hope that with the continued investment in workforce training and staff capacity this funding variation will bring can address these issues. We would also like to see NHSE work with the device manufacturers to enable those without access to mobile phones, laptops and the internet to be able to still access HCL.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
33	JDRF	Variation in procurement - As stated above in comment [31], not all areas of England offer the full range of continuous glucose monitors and insulin pumps. JDRF hopes that a new procurement framework will provide the greatest amount of choice of devices for people with type 1 diabetes, no matter where they live.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
34	Diabetes UK	4. It would also be helpful to get further detail on how equitable rollout will be achieved in implementation plan.	Thank you for your comments that NICE and NHS England have

¹ JDRF, Pathway to Choice, 2020; <https://jdrf.org.uk/resources/pathway-to-choice/>

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		<p>As noted here, there has been very significant progress made in the last five years to offer Flash glucose monitoring and continuous glucose monitoring universally to people with type 1 diabetes, but audits show slower improvement for insulin pumps with greater inequality gaps according to ethnicity and deprivation levels.</p> <p>Addressing and overcoming these specific barriers to pump technology will be key to removing potential inequalities in hybrid closed loop technology uptake.</p>	<p>considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.</p>
35	Insulet International Ltd	<p>Offering Choice in diabetes management technology to people with diabetes is imperative both in terms of type and available range within a class. Therefore, it is important that implementation plans address this. The current proposal to focus on those most likely to benefit does not appear to differ much from current practice that has resulted in uptake of insulin pump therapy hitting a ceiling of 18-20% of users over the past few years, and is influenced by not only access to diabetes services, but also potential implicit biases held by health care professionals on who can benefit on socioeconomic and ethnic grounds. A different approach on the roll out of HCL that actively provides equal access to people based on clinical need for the technology is required. Hybrid closed loop systems are not limited to improving glycemic control but also have shown improvements in quality of life that may not be apparent until this point to people who are on multiple daily injections.</p>	<p>Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.</p>

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Funding variation consultation - themed comments

Theme: Pricing and commercial framework

Comment Number	Name and organisation	Stakeholder Comment	NICE response
36	Evelina London Children's Hospital, Association of Children's Diabetes Clinicians	2. An NHSE formal procurement is sensible but should not delay patient accessibility given that this technology is already available. We have already had a significant delay in putting a plan for this technology in place. Initially I was asked as an expert panel member, then it was changed into a technology appraisal and now we are being asked to approve further delay. We need to progress forward with getting this technology available to patients as standard treatment as soon as possible. National cost effectiveness needs to be focussed on patient needs and requirements. The cheapest solution may not be suitable for what patients want and will use so the model of 'cost effectiveness' needs to ensure patient involvement including patients of all ages/races/socioeconomic groups. Manufacturers do need to ensure good cost effectiveness but the plan must also be commercially viable to enable companies to continue to improve and develop the technology.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
37	Evelina London Children's Hospital, Association of Children's Diabetes Clinicians	3. HCL systems may result in some increased costs but given that patients do now have access to CGM and insulin pumps the benefit of having the 2 work together is likely to offset the additional costs. Improved diabetes control with reduced complications/paramedic call outs/hospital admissions/lost work days/lost school days need to be considered for both patients and carers. Overall improvement of diabetes control is also likely to impact on mental health and wellbeing and have a knock on effect to the aforementioned.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
38	Ypsomed UK	Are alternative scenarios being considered if a cost-effective price for HCL systems cannot be reached with all current suppliers? Will the guidelines be re-drafted to be less ambitious in scope or potentially seek to adjust the timeline for rollout?	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to

Comment Number	Name and organisation	Stakeholder Comment	NICE response
			extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
39	Guy's & St Thomas NHS Foundation Trust	Furthermore, development of framework for technology procurement, whilst important, has been in progress for some time. This should not be an additional reason for delaying implementation for the specified time beyond a few months.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
40	Diabetes UK	2. We support the ambition to set a cost-effective price for the range of systems in the ongoing NHS Supply Chain exercise that can offer a wide choice of hybrid closed loop options for people to choose in a clear framework for the whole system. This can greatly reduce unwarranted regional variation and we hope for a positive outcome in the negotiations with suppliers.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
41	Insulet International Ltd	It must be noted that there is already a commercial framework in place that is national in nature therefore meeting the needs of the system today. It is not clear why current	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to

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		framework agreements cannot be applied or amended to deliver solutions that are in line with the NICE recommendations.	extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
42	Insulet International Ltd	<p>We are uncertain how NHS England, together with NICE have arrived at a cost-effective price for HCL systems. The threshold cost that has been cited is [REDACTED] on average over 4 years. Looking at the base case analysis of the cost effectiveness modelling, and the results file provided during the MTA consultation, we have identified that the threshold price for an HCL system, pump and sensor, over 4 years to achieve an ICER of £20,000 is £17,780. This base case received substantial critical feedback as undervaluing the technology category and the impact of things like hypoglycaemia. The definition of the cost effectiveness threshold should reflect cost utility analyses done incorporating the recommendations made during the consultation period to appropriately represent the value of HCL technologies.</p> <p>Additionally, cost utility should not be used as a sole criteria to assess price or value of HCL systems as there are significant uncertainties around the key inputs and elements of value such as 'service' are not considered at all where they would be within a normal tender process.</p>	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.
43	Insulet International Ltd	Focusing on existing pump users that are compatible with HCL is not necessarily a low-cost option. As this process has taken a four to five year perspective, all of these people will come to end of warranty at some point. Assuming a large number go ahead with a new pump to be paid in advance, there will be a large cost for new pumps for these people during this time, funded by the NHS. Thus, existing HCL compatible pump users will still incur pump costs that needs to be factored into budget impact calculations. It should be noted that not all systems come with a high upfront cost or 4 year lock in and this is a value that provides clinical flexibility and a factor that should be taken into account when considering budget impact on the NHS and affordability.	Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal

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			document.

DIAGNOSTICS ASSESSMENT PROGRAMME

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

Funding variation consultation - themed comments

Theme: Editorial

Comment Number	Name and organisation	Stakeholder Comment	NICE response
44	Diabetes UK	<p>We would ask that the language used in this document and further publications from the appraisal aim to be person-centred and avoids terms like “glycaemic control” in favour of others like “glycaemic management” to avoid the impression that they are imparting judgement on people living with diabetes.</p> <p>Reference: https://www.england.nhs.uk/wp-content/uploads/2018/06/language-matters.pdf</p>	<p>Thank you for your comments that NICE and NHS England have considered. NICE has agreed to extend the normal period of compliance to 5-years. NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. Please see section 4 of the final appraisal document.</p>