Lothian NHS Board

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

Telephone: 0131 536 9000
www.nhslothian.scot.nhs.uk

Date: 31/05/2024
Our Ref: 8750
Enquiries to loth.freedomofinfomation@nhs.scot

Dear

FREEDOM OF INFORMATION – DIABETES CLOSED LOOP TECHNOLOGY

I write in response to your request for information in relation to diabetes closed loop technology in NHS Lothian.

Question:

1. Please provide the number of type 1 diabetics, within the health board, who have access to a closed loop system.

Answer:

477 adults currently have access to a closed loop device.

Question:

2. All NHS Lothian targets related to the roll out of closed loop systems.

Answer:

There is not a specific target for roll out, we are working to use the funds made available to us to support the distribution of the devices on the basis of clinical priority.

Question:

3. All internal NHS Lothian correspondence regarding budget impacts on the roll out of the closed loop system.

Answer:

I have attached the relevant papers which were discussed at NHS Lothian's Corporate Management Team Meeting, Executive Leadership Team meeting and Strategic Planning and Performance Committee meeting.

The Equality and Children's Rights Impact Assessment is also available on our website at the following link: https://org.nhslothian.scot/equality-human-rights/impact-assessments/

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at www.itspublicknowledge.info/appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the reviewer at the address at the top of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI

Yours sincerely

ALISON MACDONALD
Executive Director of Nursing Midwifery and AHPs
Cc: Chief Executive

NHS LOTHIAN

4.

Corporate Management Team
5th December 2023

Director of Strategic Planning
Chief Officer, East Lothian IJB

TYPE 1 DIABETES MELLITUS (T1DM)
STRATEGIC DIRECTION AND FUTURE SERVICE MODEL: UPDATE

1 Purpose of the Report

1.1 The purpose of this report is to provide the Corporate Management Team with options for the future provision of technology for people with Type 1 Diabetes Mellitus (T1DM) in Lothian.

Any member wishing additional information should contact the Executive Lead in advance of the meeting.

2 Recommendations

CMT members are recommended to:

2.1 **Review** the three options summarised within this paper and outlined in detail including impacts and risks within the Difficult Choices Framework.

2.2 **Agree** which option CMT wishes to develop, and what specific work will be required.

2.3 **Note** that this is the first usage of the Difficult Choices Framework to come to CMT, and separately reflect on how this aids understanding.

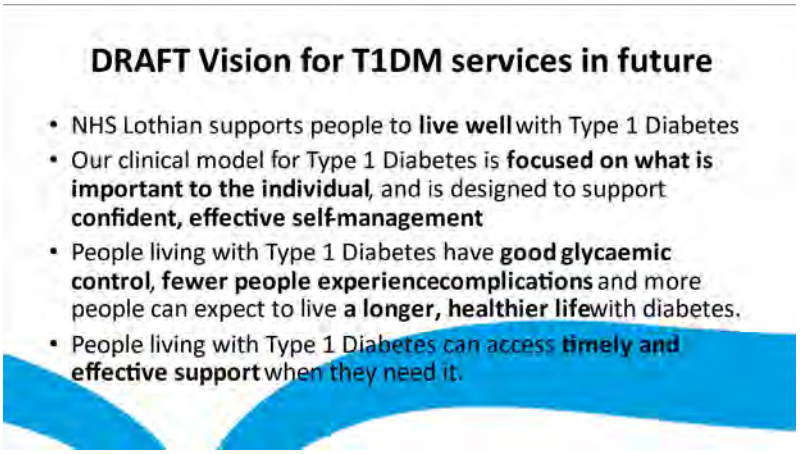
3 Discussion of Key Issues

Background

3.1 In February 2022, CMT commissioned a short life working group (SLWG) to review the model of care for T1DM in light of strategic drivers including health inequalities, finance, infrastructure, workforce and the emergence of new technologies.

3.2 In December 2022, the SLWG agreed a vision for T1DM services in future, as shown in figure 1, below:

Figure 1: Vision for T1DM services



3.3 An update on this work was presented to SCMT in September 2023. This update highlighted forecast gaps in funding for diabetes technologies including insulin pumps (CSII), flash and continuous glucose monitoring systems (FGM and CGM) and Hybrid Closed Loops (HCLs) plus associated staffing costs.

3.4 CMT noted progress to date, evolving challenges around delivery of the proposed future service model, and asked for more pragmatic work to be done to define options for diabetes technologies funding going forward, seeking to avoid a stop/start approach. Options were to include what could be done within existing service budgets on a whole system level.

Policy Context

3.5 SHTG Guidance issued in January 2022[1] recommends that HCL "*should be available to people with T1DM who, under their current diabetes plan, continue to have suboptimal glycaemic control, a high risk of severe hypoglycaemic or impaired awareness of hypoglycaemia; or experience diabetes-related distress…which is likely to be improved by moving to a closed loop system."*

3.6 The SG Diabetes Improvement Plan 2021-26 supports appropriate and timely access to technologies to improve glycaemic control and quality of life for people living with T1DM. Progress is measured in terms of the proportion of people with T1DM with access to FGM, CSII, CGM, CGM during pregnancy and HCLs, with a pending measure of those who are provided with technology within six months of referral. The plan also seeks to measure the proportion of people with T1DM in SIMD1 vs SIMD5 with access to diabetes technologies.

3.7 NICE[2] has published draft guidance which recommends that HCL should be available to people with T1DM who have an HbA1c>58 mmol/mol or disabling hypoglycaemia despite best possible management with at least one of an insulin pump, flash- or

[1] SHTG, *Closed loop systems and the artificial pancreas for the management of type 1 diabetes*, January 2022
[2] NICE, *Hybrid Closed Loop Systems for Managing Blood Glucose Levels in Type 1 Diabetes*, FINAL DRAFT, November 2023.

continuous glucose monitoring. The draft guidance also recommends that HCL be made available to children, young people and those with T1DM who are pregnant or planning to become pregnant. The draft guidance also reads that 'HCL systems are only recommended if the companies and NHS England agree a cost-effective price for the systems'. CMT members will be clear that NICE guidance applies only to England and Wales, albeit that it carries some influence over Scottish policy.

3.8 Diabetes Scotland have launched a public campaign in the Scottish Parliament in November 2023, entitled "Diabetes Tech Can't Wait". This campaign calls for 70% of people with T1DM to have access to HCL in Scotland by 2030 and aims to highlight disparity in access to technology across different Health Boards.

Strategic Context in Lothian

3.9 CMT members will recall that the strategic planning and commissioning of diabetes services for adults is delegated to Integration Authorities (IJB). For Children and Young People up to their 18th birthday, this responsibility sits with NHS Lothian.

3.10 The Lothian Strategic Development Framework (LSDF), which is owned by NHSL and our four IJBs prioritises the prevention of disease and the use of new technologies in its principles and assumptions. These also note that the system will be resource-constrained and that this will lead to the system needing to carefully consider the choices that it will need to make. The LSDF also explicitly prioritises the development of services for Children and Young People as an investment in prevention.

Benefits of Diabetes Technologies

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3.11 Age at onset T1DM is an important determinant of survival, as well as all cardiovascular outcomes, with highest excess risk in women. For those diagnosed youngest, life expectancy is reduced by:17·7 life-years (14·5–20·4) for women / 14·2 life-years (12·1–18·2) for men. Achieving better glycaemic control is essential to reducing this risk.

3.12 Clearly, the daily regime for management of T1DM places a mental, social, and physical burden on patients. A key attraction of the technologies discussed herein is that they have well-described benefits to mental health and general wellbeing. This is noted in both the SHTG and NICE assessments.

3.13 Diabetes technologies can reduce the frequency of mild and severe episodes of hypoglycaemia (thereby improving TIR), which also significantly improves quality of life.

3.14 HCL supports patients to improve glycaemic control and HbA1c. In a 'real-world' study performed by NHS England, the average improvement in HbA1c was 18 mmol/mol. Within NHS Lothian, almost twice as many people currently using HCL are meeting HbA1c targets, compared with those who are not. Audit within NHSL suggests that use of HCL improved time in range (TIR) for the cohort by 21%, and that those meeting the Hb1Ac target rose from 26% to 46%.

3.15 Research shows that Insulin pumps, CGM, and the DAFNE structured education course all support patients to improve glycaemic control and HbA1c. HCL has the biggest impact in terms of reduction in HbA1c, and also in improving quality of life.

3.16 HbA1c not only provides a reliable measure of chronic hyperglycemia but also correlates well with the risk of long-term diabetes complications. By supporting patients to reduce their Hba1c level, and increase their time in range, HCL is expected to reduce long-term complications of diabetes – including end-stage kidney disease, diabetic eye disease, lower limb amputation and cardiovascular disease.

3.17 The NICE and SHTG assessments suggest HCL is likely to be cost-effective but requires a reduction in the current cost of technology, which is currently being negotiated by NHS England with technology companies. There is, therefore, not currently a strongly-evidenced financial case for increasing access to these technologies. However NICE concluded that because quality of life is not well captured in cost-effectiveness models, it is almost certainly underestimated and that would particularly be the case in people with tight glycaemic control who often have a high mental burden.

3.18 Clinical and cost effectiveness is likely to be greatest in

- Women with T1DM planning pregnancy and who are pregnant
- in children and young people
- people with HbA1c>75 mmol/mol.

<u>T1DM in Lothian</u>

3.19 In Lothian, approximately 5,623 people live with T1DM, including 5,118 adults and 505 children. There are approximately 50 new diagnoses in children each year (although 83 children were diagnosed in 2022), and 124 new diagnoses in adults per year on average, based on the last four years. Every year, around 53 young people transition into the adult service.

3.20 In Lothian, the proportion of the T1DM cohorts with CSII and/or flash or continuous glucose monitoring is as shown in table 1;

Table 1: Proportion of those with T1DM using diabetes technologies

Pathways of Care	Measures of Care			
	Adults		Paediatrics	
	Lothian	Scotland	Lothian	Scotland
Flash Glucose Monitoring	38.4%	51.7%	25.9%	35.5%
Pump Therapy	20.8%	15.6%	66.3%	52%
Pump Users with HbA1c > 75mmol	11.6%	11.6%	8.2%	10%
Continuous Glucose Monitoring	7.8%	9.8%	54.1%	47.7%

Source: SCI Diabetes, 25th November 2023

3.21 It is estimated by the service that 75% of all adults with T1DM are using Freestyle Libre II CGM, prescribed via Primary Care. Freestyle Libre II is anticipated to become compatible with certain pumps to provide closed loop functionality in 2024 (Omnipod 5

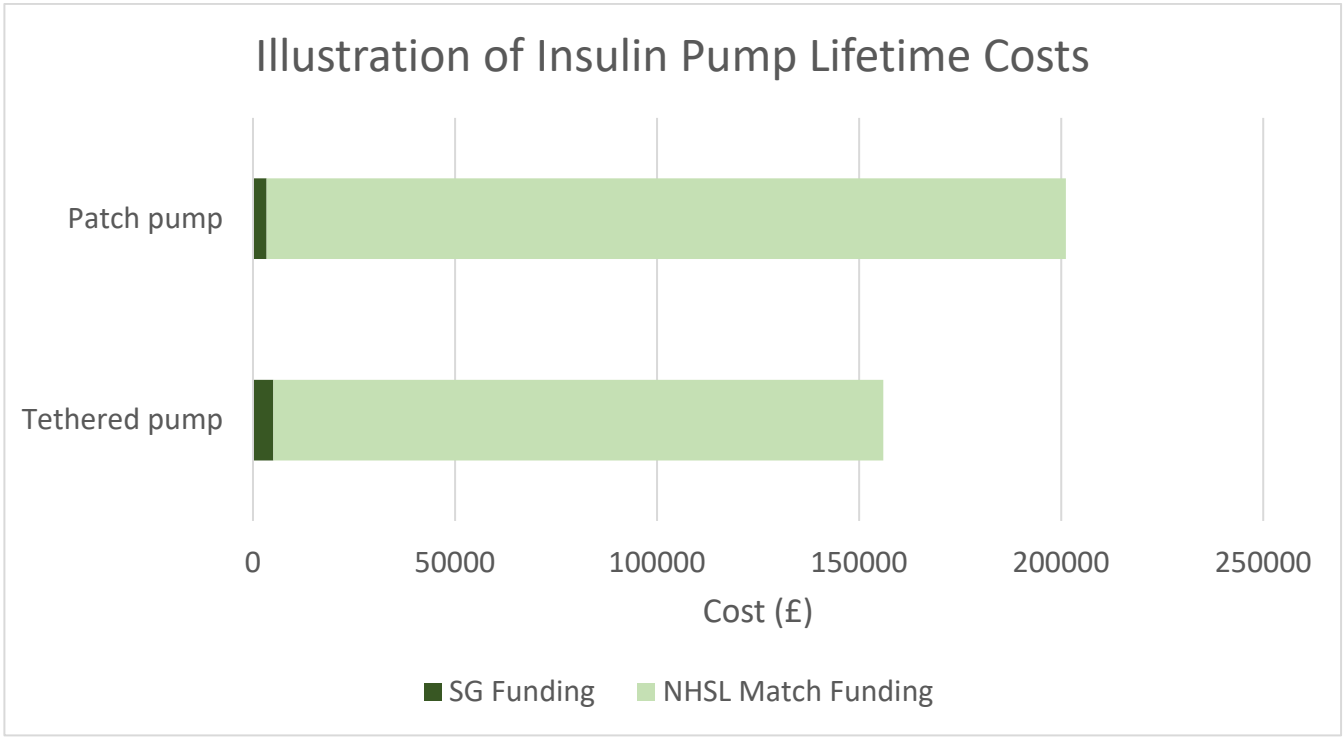
and Tandem T:Slim but not Medtronic devices). Children with T1DM are prescribed Libre II in primary care on diagnosis. This is at odds with the figures reported in SCI-Diabetes.

3.22 The service estimates that 31% of adults on pump therapy are using a HCL system, equating to around 6% of all adults with T1DM. The majority of other adults with pumps are likely to have a CGM through Freestyle libre, so will have both an insulin pump and a CGM but these are not linked to provide a closed loop system.

3.23 There is a separate budget for diabetes technology, which is agreed annually with IJBs. The Scottish Government periodically supplements this diabetes technology budget with ring-fenced non-recurring funding for diabetes technologies in both adult and paediatric diabetes services. The amount of money provided varies substantially from year to year and covers the initial purchase of technology but does not cover the lifelong costs. This has been a key cause of the forecast gap in funding for diabetes technology as the cost of ongoing replacements and consumables must then be met by the diabetes technology budget.

3.24 Figure 2 below demonstrates the balance between non-recurring SG funding for Diabetes technologies and NHSL recurrence. If a person received a "tethered" insulin pump at age 10 and then lived to age 70, NHS Lothian would meet the cost of 14 replacement pumps, and consumables over 59 years from core budgets. At today's prices, this would mean that lifetime pump therapy costs a total of £156,000, of which specific SG funding covers £5030 (3.33%). Diabetes services in Lothian plan to move more people with T1DM to Omnipod insulin pumps, which are patch pumps that can be linked with Libre II CGM to become a HCL. These pumps have a higher monthly cost but patients are not "tied in" to the device for four years.

Figure 2: Diabetes technologies funding gap illustration: lifetime insulin pump costs



Options for Diabetes Technologies

3.25 Following CMT, the T1DM short life working group agreed to outline three options for diabetes technology in future, and to assess each of those options against the Difficult Choices framework. The framework requires consideration of policy context, strategic context, performance, cost, quality, patient experience, equity, staff experience and environmental sustainability. Technical compliance was not considered applicable in this case.

3.26 The options are fully described in the table below. It should be noted that neither clinical service team is supportive of pursuing Option 1, given the likely detrimental impact on people living with T1DM.

Table 2: Options

Option 1	Working within current budgets to deliver Diabetes technologies	• Diabetes Tech will continue to be distributed to children & young people at a rate of 44 pumps and 12 CGM per annum • Replacement pumps & consumables will continue to be provided to those within children's services • In the adult service, no new pumps will be distributed from April 2024 • 575 of those within the adult service currently using pumps would no longer receive consumables, would stop using pumps and revert to Multiple Daily Injections of Insulin – a decision would need to be made around how to do this • Further pumps would need to be withdrawn in future years to achieve breakeven • Young people who transition to the adult service with tech will revert to Multiple Daily Injections of Insulin (MDI) • CGM for pregnant women will be limited to 12 months

Option 2	Working to current levels of T1DM technology distribution	• Total Lothian tech distribution = 154 pumps + 72 CGM per annum
		• Assume tech will continue to be distributed at current rates and in line with the current waiting list:
		  • Adults: 110 pumps/60 CGM, of which 45 for pregnant women
		  • Paediatrics: 44 pumps/12 CGM
		• Continue with all replacements, as they become due
		• 70% of all new and replacement pumps will be Omnipod 5
		• CGM for pregnant women will be limited to 12 months (women with Freestyle Libre CGM will revert back to this after 12 months)
		• An estimated 30% of adults not currently using Omnipod/T:slim as a pump, or who do not choose them as their new or replacement pump over the next 5 years will require funding for a different CGM.

Option 3	Increasing technologies distribution to achieve 50% of adults and 100% of children living with T1DM have access to a Hybrid Closed Loop within five years	• Total Lothian tech distribution = 344 pumps 15 CGM per annum
		• Assume tech will be distributed at these rates:
		  • Adults: 300 pumps/60 CGM (other than freestyle libre provided via Primary Care) of which 45 for pregnant women
		  • Paediatrics: 44 pumps/12 CGM plus 20 enhanced pumps a year (for 2 years), then 50 pumps a year from 25/26
		• Continue with all replacements, as they become due
		• Approximately 70% of all new and replacement pumps will be Omnipod 5. The remaining 30% will be Tandem T:slim or Ypso. These are the 3 least expensive HCL systems currently available in the UK
		• Pregnant women will continue with HCL beyond pregnancy

3.27 The following assumptions have been applied in consideration of the options:

- Within all options, distribution of Diabetes tech to Children & Young People continues at current rates, as a minimum
- Within all options, a specific CGM is provided to pregnant women but is limited to 12 months within Option 1 and Option 2 (pregnant women with Libre II CGM can revert to this CGM after 12 months)
- Total workforce does not change but flexes to meet the demands and challenges within the services
- Existing Diabetes Specialist Nurse projects to maximise resources will continue
- Type 2 Diabetes demand will continue to grow in the short-medium term
- As tech continues to be distributed, the majority of new and replacement tech users will move to Omnipod 5 Pump & Libre II CGM
- Within five years, all current pump users will be HCL users
- The child and adult T1DM population will continue to increase in line with current trends (approx. 124 newly diagnosed a year)

<u>Impact of each option</u>

3.28 Performance

Performance against measures in the Diabetes Improvement Plan will decrease if Option 1 is pursued. Both Option 2 and Option 3 would facilitate an improvement in performance – the extent to which is estimated here.

It could be assumed that Omnipod 5 pumps will be able to link with the Freestyle Libre II CGM in 2024. Adults with Libre II and with either an Omnipod 5 or T:Slim pump, or choosing one as a replacement would automatically have a Closed Loop System in 2024 for no additional cost.

Table 3: Impact on Performance

Performance Measure	**Current**	**Option 1**	**Option 2**	**Option 3**
Adults				
Pump Therapy	20.8%*	~12%**	~31%**	47%**
HCL	6%**		~31%**	~47%**

Children				
Pump therapy	65%*	~80%	~80%**	100%**
HCL		~80%	~80%**	~100%**

*According to SCI Diabetes
**Estimated

3.29 Cost

Libre 2 prescribing costs totalled £4.6m for the year to June 2023. It should be noted that a proportion of these costs will apply to patients with Type 2 Diabetes, as a total of 6,211 patients have been prescribed Libre during this period. 1,220 patients prescribed Libre during the period were "new".

The estimated costs associated with options 2 and 3 within adult services are included within table 4 below. Under Option 1, an overspend of £1,250,000 is projected at year end 2023/24, with an aim to get back to financial balance within 2024/25.

Table 4: Cost impact: Adult Services

			23/24	*24/25*	*25/26*	*26/27*	*27/28*
Option 2: Business as Usual	Patients on technology as at 5/10/23, replacement (70:30 OPD5 and other pumps) and consumables, plus additional 110 pumps per year and 15CGMs. Includes 45 pregnancy CGMs	Total Cost	4,212,064	4,366,671	5,555,090	5,625,440	5,831,758
		Deficit	(685,464)	(1,875,071)	(3,063,490)	(3,133,840)	(3,340,158)
Option 3a: Omnipod renewal plus 300 additional	Omnipod 5 on renewal (100%) plus 300 new per year. All patients on Libre 2	Total Cost	3,894,322	4,326,830	5,628,116	6,837,471	8,053,894
		Deficit	(367,722)	(1,835,230)	(3,136,516)	(4,345,871)	(5,562,294)
Option 3b: 70:30 OPD5/ Others HCL on renewal plus 300 additional. 70:30 OPD5/Others	Only 70% move to Omnipod 5 on renewal. The 30% using another pumps would receive a CGM to make a closed loop.	Total Cost	4,028,305	4,870,146	6,576,407	7,847,389	9,094,000
		Deficit	(501,705)	(2,378,546)	(4,084,807)	(5,355,789)	(6,602,400)

Table 5 below demonstrates the impact of continuing with the same level of technology distribution within Children's Services (associated with Option 1 and Option 2). Additional costs would be associated with Option 3.

Table 5: Cost impact: Children's Services

Detailed Summary - Baseline Update					
Qty	**2023/24**	**2024/25**	**2025/26**	**2026/27**	**2027/28**
	Children	**Children**	**Children**	**Children**	**Children**
Pumps (New)	44	44	44	44	44
Replacement Pumps (incl. transitions)	60	55	70	73	77
Transition (assume visitors revenue neutral)	(42)	(40)	(50)	(52)	(50)
Total Pumps Patients	365	369	363	355	349
CGMs (New)	12	12	12	12	12
Transition	(37)	(30)	(31)	(27)	(26)
Total CGMs (excl self funders and Libra)	317	299	280	265	251
	Children	**Children**	**Children**	**Children**	**Children**
Finances	**£'000**	**£'000**	**£'000**	**£'000**	**£'000**
Pump Purchases New	£119	£117	£117	£117	£117
Pump Purchases Replacement	£194	£135	£174	£214	£223
Pump Consumables Existing	£694	£710	£720	£702	£687
Pump Consumables New	£43	£44	£44	£44	£44
Pump Consumables Transfers in/out (incl Transitions)	(£37)	(£36)	(£45)	(£47)	(£45)
CGM New	£22	£17	£17	£17	£15
CGM Consumables - Existing	£815	£805	£760	£713	£676
CGM Transfers in / out (incl Transitions)	(£67)	(£37)	(£39)	(£34)	(£32)
Total Expenditure	£1,783	£1,754	£1,748	£1,726	£1,684
Total Budget - NHSL	£1,929	£1,333	£1,318	£1,318	£1,318
Projected Surplus / (Deficit) for pumps/ CGMs	£146	(£422)	(£430)	(£408)	(£366)
Additional Staffing Costs	£131	£109			
Total Funding Surplus / (Deficit)	**£14**	**(£531)**	**(£430)**	**(£408)**	**(£366)**

3.30 It could be speculated that, at today's prices, if 50% of adults and all children were provided with an Omnipod 5 insulin pump, the ongoing recurring cost would be £10.3m per annum. This is based on the monthly cost of Omnipod 5 (£3,353) and a total of 3064 users (2559 adults and 505 children). Libre II comes at an additional cost, which currently sits in primary care. It should be noted that the number of those living with T1DM is likely to increase, and the cost of technologies may change.

3.31 Savings

Future savings as a result of investment in diabetes technologies are currently speculative. For example: In 2010/11, the cost of T1DM complications to the NHS in the UK was estimated to be £719m. Extrapolating to the NHSL catchment population gives an annual figure of £9.8m. It is anticipated that increased use of HCL would result in a substantial reduction in diabetes complications and the costs associated with their management in the longer term. It could be anticipated that this would be linked to the proportion of those with T1DM who have access to HCL (approx. 55% of the population for Option 3) and the range of improvement in glycaemic control achieved.
It should be noted that the cost of current technologies is likely to reduce in future, which may change the balance between the cost of providing technologies and the savings that could be realised. Equally, technologies may evolve and increase in costs.

3.32 Quality

Scottish people with T1DM under the age of 50 have a three to four-fold increased risk of death compared to the general population, with almost half of this excess risk related to diabetic ketoacidosis and premature cardiovascular disease. Achieving better glycaemic control is essential to reducing this risk.

Research demonstrates that insulin pump therapy is associated with marked reductions in HbA1c, especially in those with high baseline HbA1c. Improving HbA1c indicates

better diabetes management, and reduces the likelihood of developing complications later in life. Pump therapy is independently associated with reduced DKA and severe hypoglycaemia requiring hospitalisation. Multiple studies have also shown that CGM significantly improves HbA1c levels while simultaneously decreasing and even preventing hypoglycaemia.

3.33 Patient Experience

Diabetes services in Lothian have received multiple positive testimonials from those who are using closed loop systems, with many reporting that they have found the technology "life-changing" or "game-changing", giving then increase confidence, improved quality of life and better sleep.

"With closed loop, my control has remained optimal and I spend a LOT less time thinking about diabetes…The improvement in my quality of life has been significant and should not be underestimated"

The "Tech Can't Wait" report from Diabetes Scotland also demonstrates positive impacts as a result of technologies including CSII, CGM and HCL in terms of improved blood sugar management, reduced risk of complications, impact on mental wellbeing and quality of life.

This suggests that the more technology we can distribute, the better patient experience is likely to be. Removing technologies from those who currently rely on it would likely result in poorer glycaemic control, an increase in episodes of hypoglycaemia and increased incidence of anxiety and depressive disorders.

3.34 Equity

Life expectancy of people in Scotland with T1DM is 12 years lower than those who do not have the condition, with deaths in young people accounting for a substantial proportion of this loss. Reducing access to technologies, in line with Option 1, would likely have a detrimental affect on glycaemic control and widen the equalities gap between those with T1DM and the general population.

The Diabetes Scotland "Tech Can't Wait" report highlights the potential for inequality in access to diabetes technologies, noting cases where people have needed to advocate strongly for themselves in order to access technology or have been refused access to technologies because their blood sugars are "too good", or "not good enough" or because their needs are "too complex". CMT will recall that data from our own services suggests that distribution of Hybrid Closed Loop and loopable pumps to those living in the most deprived areas is less than expected in Lothian, and that people living in deprived areas have less access to technology to support them in diabetes management. Data also shows that men represent 54.9% of the adult population with T1DM and 67.6% of all current HCL users. This suggests that women have less access to technologies to support them to manage their diabetes. Interestingly, recent survey work suggests that neither SIMD quintile or sex had any impact on interest in using HCL in Lothian.

While increasing distribution of diabetes technologies in line with the current waiting list will improve existing inequalities to some extent, inequality of access will likely continue. Those with the highest HbA1c stand to benefit the most from technology with respect to HbA1c lowering, and therefore reduction in complications. People from the most deprived quintiles 1 and 2 in Lothian currently account for 32% of the population

but represent 46% of all patients with HbA1c over 75mmol who do yet not have access to a pump.

79.7% of all adults from the most deprived quintile do not yet have any technology and are not on the waiting list, compared to 62.2% of all adults from the least deprived quintile who do not yet have any technology and are not on the waiting list.
This inequality will continue if the current waiting list is used to allocate pumps over the next 5 years.

3.35 Staff Experience

The adult Diabetes service experience significant challenges in terms of capacity and demand. Pressures include meeting increasing demand for antenatal care, supporting inpatients with Diabetes, and upskilling the staff caring for them to avoid iatrogenic DKA, managing demand to the telephone helpline and delivering planned return appointments. Work is ongoing to manage these challenges.

Pursuing Option 1 would likely increase demand for input from Diabetes Specialist nurses and Dieticians to support good glycaemic control in those who no longer have access to technologies, potentially impacting other areas of service. Removing access to technologies for long-standing patients is also likely to cause significant stress to and impact the wellbeing of staff working within Adult and Paediatric Diabetes services.

The service estimates that increasing distribution of diabetes technologies could allow staff time to be diverted to support these areas of pressure.

3.36 Environmental Sustainability

If more people are supported to access diabetes technologies, there will likely be greater opportunity for remote access to monitoring data, online appointments and online support, resulting in a likely reduction in health miles.

4 Key Risks

4.1 The risks associated with each of the options have been explored within the Choices template attached at Appendix II.

5 Risk Register

5.1 The most significant impact on the risk register would relate to the risk to financial balance. NHSL currently has a more than £100m structural deficit which it manages year-to-year, and is projecting a c. £20-25m deficit at the end of the 23-24 financial year. The current overspend on the technology budget is included in this, and as can be see from tables 4 and 5, this position would be worsened by adopting option 2, 3a, or 3b.

5.2 SHTG and NICE guidance suggest that there is the potential for wider adoption of technologies to lead to cost avoidance with a reduction in complications for individuals. However, there is also a noted challenge with the cost of technologies, and a need for a national agreement on the cost of these technologies.

5.3 The service has been clear that no resource could be reallocated from within its current operations, so this would not be a source of mitigation.

6 Impact on Inequality, Including Health Inequalities

6.1 As outlined above, there are significant inequalities in access to diabetes technology currently, and in outcomes. While technologies distribution could help to narrow the inequality gap between those living with T1DM and the general population, it would be beneficial to undertake an impact assessment to determine the best way forward within the preferred option.

7 Duty to Inform, Engage and Consult People who use our Services

7.1 The Short Life Workiing Group includes representation from the patient organisation Diabetes Scotland, and from patient representatives in order to engage with those living with T1DM in developing the new clinical model and implementation plan.

7.2 Diabetes Scotland gathers feedback from people with experience of using closed loop systems and those seeking access to the technology on a regular basis and collate and share the results of that work.

7.3 Both the adult and paediatric service have undertaken surveys, and gathered feedback from their patient populations which has been used to support the development of the options outlined.

7.4 Moving forward, the challenges are significant. Clear communication about the challenges we face is likely to be required.

8 Resource Implications

8.1 The resource implications associated with implementing future diabetes technology options are outlined in this paper.

Lois Marshall
Strategic Programme Manager – Outpatients and Associated Services

lois.marshall@nhslothian.scot.nhs.uk

Rebecca Miller
Head of Strategy Development

07824 606518
rebecca.miller@nhslothian.scot.nhs.uk

Appendix I – Glossary of terms
Appendix II – Difficult Choices framework template: T1DM

Appendix 1 – Glossary of terms

These definitions have been informed by the website of Diabetes Scotland.

CGM	**Continuous Glucose Monitoring** Continuous glucose monitors let you check your sugar levels without having to prick your fingers. You wear a small sensor on your body day and night that reads your sugar levels so you can see the information on your mobile, or other device. A Continuous Glucose Monitor transmits those readings via Bluetooth to a device or a mobile phone. Continuous Glucose Monitors can "talk" to an insulin pump, to become a hybrid closed loop.
CSII	**Continuous Subcutaneous Insulin Infusion** or insulin pump therapy. An insulin pump is a small electronic device that releases the regular insulin your body needs through the day and night — so you don't need to do insulin injections. An insulin pump can either be "tethered" or a "patch pump". **Tethered pumps** attach to your body and a small tube connects to your cannula. A **patch pump** sits directly on your skin and works by using a remote.
FGM	**Flash Glucose Monitoring** Flash glucose monitors let you check your sugar levels without you having to prick your fingers. You wear a small sensor on your body day and night that reads your sugar levels so you can see the information on your mobile, or other device. Readings are only given when you wave or scan your device over the sensor.
Freestyle Libre 2	**Freestyle Libre 2** is a type of glucose monitor. It originally provided flash glucose monitoring. A software upgrade earlier in 2023 means that Freestyle Libre 2 can now be used as a Continuous Glucose Monitor, with glucose levels transmitted by Bluetooth.
HCL	**Hybrid Closed Loop System** A closed loop system consists of a continuous glucose monitor and an insulin pump that talk to each other, via a computer programme on a smartphone or within the insulin pump. Hybrid Closed Loops are systems that are regulated and available to buy.
Omnipod 5	**Omnipod 5** is a type of "path" insulin pump. It can be integrated with a Dexcom 6 Continuous Glucose Monitor to become a hybrid closed loop. It is anticipated that the Omnipod 5 will also be become "loopable" with Freestyle Libre 2 early in 2024.

Impact & Risk Assessment to Support Service Planning Choices

This template should be used by services to collate information to inform decision-making in relation to service planning when a 'difficult choice' is recognised. The paper 'Assessing the impact of choices' (august 2023) should be read in advance of completing the form in order to ensure this is the correct template as opposed to alternatives e.g. business case.

Title of Choice	Roll-out of Diabetes Tech
Directorate / Service	Diabetes, Outpatients and Associated Services/Paediatrics
Date	November 2023
Service Lead	Julie Bladen/Allister Short
Finance Lead	Shona Binning
Strategic Planning Lead	Lois Marshall/Rebecca Miller

Please indicate which category (categories) this choice falls under:

Relates to stopping the provision of a service/treatment/function	X
Relates to not starting a service/treatment/function	X
Relates to a clinical service	X
Relates to a non-clinical service	
Relates to a policy directive	X
Does not relate to a policy directive	

Please indicate the committee/group that has undertaken the specialist assessment for each of the following impact/risk categories

Quality / Clinical Outcome	N/A
Performance	N/A
Compliance (state compliance with which legislation / standards)	N/A
Finance	N/A

Please indicate at which forum the Choice will be reviewed and decision-made

Decision-making forum	Corporate Management Team
Date	5th December 2023

If the decision requires to be endorsed, please indicate at which forum this will happen

Endorsed at	N/A
Date	N/A

Part 1: Outline the options within a choice

This section should be used to outline the various options within a choice. A choice may not be binary – either/or – there may be options within it. These should be summarised below, where possible, options should be described in sufficient detail to understand scope and scale (for example, using activity numbers)
Each option should then be feasibility assessed against the constraints – where possible this assessment should be quantified (for example: WTE required for service model is 'X'; workforce trajectories indicate staffing availability of 'y').

Where an option is deemed non-feasible due to constraints, this should be illustrated by shading the row grey.

A maximum of 3 options should be taken forward for full impact and risk assessment.

	Workforce	Revenue (budget)	Capital	Other
Constraint limit: (Set out the predicted WTE/budget(revenue)/capital/other factor)	N/A	Adult service: £2.492m including IJB £1m N/R contribution	N/A	N/A
Option 1: **Working within current budgets to deliver Diabetes Technologies** If no additional technology is issued in 2023/24, a deficit of approx. £1,250K will be incurred, moving to £2,528K on 2024/25 due to ongoing unfunded replacement programme and consumables costs. To achieve breakeven: • No replacement technology would be issued when existing pieces of kit expire. • No new consumables would be issued from April 2024 • Approximately 575 insulin pumps (half of those currently in use) would need to be withdrawn in April 2024, by NHSL no longer funding consumables, with patients returning to Multiple Daily Injections (MDI) to manage their diabetes.	No change	Achieve breakeven	N/A	N/A
Option 2: **Working to current levels of T1DM new technology distribution**	No change	Projected Adult Service Overspend on	N/A	N/A

If we work to current levels of technology distribution a deficit of approx. £699,464 will be incurred across both paediatrics and adults in 23/24 moving to £2,406,071 for both services combined in 2024/25 due to ongoing unfunded replacement programme and consumables costs. This would increase to 3,706,000 for both services combined in 27/28. 154 new pumps per year would be provided: • 110 new pumps per year (adult service) • 44 new pumps per year (paediatric service) 72 new Continuous Glucose Monitors a year would be provided in total • 60 new Continuous Glucose Monitors (adult service) 15 for all patients, 45 for pregnant women for 12 months • 12 new Continuous Glucose Monitors (paediatric service) targeted at under 5s. Distribution of new tech (Pumps and Continuous Glucose Monitors) would continue; • according to the current waiting list provided to those who have waited longest. • Technology will be provided in line with current agreed split in numbers between adults and paeds Replacement tech (and all consumables) would be provided as required: • Assumed **70%** of new and replacement patients in adults move to Omnipod 5 pump, 30% to other pumps. • In 24/25, anticipate approximately 200 replacements (adults) and 55 (paediatric) In 25/26, anticipate 290 replacements (adults) and 70 (paediatric) • Numbers include paediatric patients transitioning to adult service. • New prices assumed from 24/25 • Childrens service will fund the cost of any replacement pump due in the transition year • New pump patients in childrens service will be offered Tandem / Omnipod / Ypsomed and Libre (2 or 3) CGM		current patient profile: 23/24 (685,464) 24/25 (1,875,071) 25/26 (3,063,490) 26/27 (3,133,840) 27/28 (3,340,158) Projected Paediatric Service overspend on current patient profile: 23/24 £14K 24/25 (£531K) 25/26 (£430K) 26/27 (408K) 27/28 (366K)		

Option 3: **Increasing technologies distribution to achieve 100% of children and 50% of eligible adults living with T1DM have access to a Hybrid Closed Loop within five years.** Working to these levels of T1DM new technology distribution, a deficit of approx. £698K will be incurred across both paediatrics and adults, moving to £3,277K in 2024/25 due to ongoing unfunded replacement programme and consumables costs. This would increase to an overspend of 7,415K in 27/28 This will require 300 new pumps in the adult service a year. In the paediatric service this will require enhanced pump starts of 24 additional pumps a year in 23/24 and 24/25 (above the 44 as standard) and an increase in the standard annual pumps starts to 50 per year from 25/26. There would also be an increase to 90CGM a year in 23/24 and 24/25 and to 50 CGM a year from 25/26. There will be a resultant increase in the number of patients transitioning on technology into the adult service. Assumed 70% of new and replacement patients move to Omnipod 5 pump and continue to use Libre 2. Assumed 30% of patient use other pumps and would receive an appropriate CGM to make a closed loop system.	WTE: no change	Projected adult Overspend 23/24 (502K) 24/25 (2,378K) 25/26 (4,084K) 26/27 (5,355K) 27/28 (6,602K) Projected paediatric overspend 23/24 (196k) 24/25 (899K) 25/26 (842K) 26/27 (836K) 27/28 (813K)	N/A	N/A

Please list options that you propose to be taken forward:	
Option 1	Working within current budgets to deliver Diabetes technologies
Option 2	Working to current levels of T1DM technology distribution
Option 3	Increasing technologies distribution to achieve 100% of children and 50% of eligible adults living with T1DM have access to a Hybrid Closed Loop within five years

Part 2: Profiling the Choice

In this section, relevant profiling information is collated to understand the strategic alignment, policy position and benchmarked practice relating to the choice.

Please provide relevant detail against each of the profiling elements, indicating the relative relevance to each option(s) – for example, option x defines a deviation from national strategy y.

Please describe how each option aligns to the Lothian Strategic Development Framework (LSDF). In particular, whether any option deviates from the principles and fixed points, or any aspects of the delivery plans:

The LSDF makes a specific commitment to "bring forward cases to invest in technologies which support self care and self management of long term conditions such as diabetes".

The vision of the Lothian Strategic Development Framework reads:

- People in Lothian lead longer, healthier lives, with better outcomes from the care & treatment we provide
- We connect health and social care services seamlessly, wrapping around the person in their home
- We improve performance across our system, with better experiences for those that live in Lothian, and those who work for and with us

Diabetes technologies, including hybrid closed loops, are expected to support delivery of this vision, improving overall population health and outcomes of care. It is anticipated that technologies would support a reduction in inequalities between those with Type 1 Diabetes and the general population, as clinical trials have demonstrated the effectiveness of technologies in increasing "time in range", reducing HbA1c, and reducing the frequency of hypoglycaemia.

In addition, many people with Type 1 Diabetes work incredibly hard to achieve good control and can experience diabetes distress, including feeling overwhelmed by the emotional and physical effort involved. Technology can help to reduce this distress, as evidenced by patient testimonials received by the adults diabetes service:

'It has given me great freedom in my life. Before the closed loop system my diabetes was forefront in my mind at all times'.

'I can now almost forget that I am a diabetic'

'I now have the option to be spontaneous'

'My sleep has greatly improved and my first period of more than 4 hours of sleep occurred after having control IQ. I now regularly sleep for 5 to 6 hours straight'

While support beyond provision of kit is required, it is anticipated that more people could be supported to lead longer and healthier lives at home as diabetes technologies evolve, and user input is minimised.

While Option 1 would support financial balance in the short-term, it would deviate from our agreed strategic direction, as it is very likely that people with T1DM would achieve poorer outcomes and that their experience would deteriorate.

<u>Effective use of the workforce</u>

It is anticipated that increasing use of technologies would support effective use of the available workforce.

For example, service clinicians report that young people at transition would often require significant support and clinical input in managing their diabetes, including clinic appointments and remote support to achieve good glucose control. As more young people are using technologies, this requirement for input has reduced, freeing up capacity to address other service pressures.

Diabetes technology is one of a number of subspecialities managed by Diabetes Specialist Nurses. Within the nursing service, there are a number of areas of increasing and/or unmet need, including increasing demand for antenatal care, poor inpatient care for people with diabetes and iatrogenic DKA incidence, an inability to meet Return Waiting List demand and difficulties managing volume of calls to the telephone helpline. These challenges could be addressed more effectively if demand for support to achieve good glycaemic control were reduced through the introduction of additional technologies.

Options 2 and 3 would support improvement in patient experience and outcomes for a wider range of Diabetes patients, as capacity would be freed up to address some of the pressures outlined above, including supporting changes in care models.

It is anticipated that Option 1 would contribute to deterioration in terms of the Return Waiting List, appropriate support to inpatients with Diabetes, community nursing support and the responsiveness of the telephone helpline.

Clinical model and effective use of physical infrastructure

It is expected that the future model of care for Diabetes, including the use of diabetes technology, could reduce demand for physical clinical space, as support could be provided virtually. This would also require development of monitoring options to suit people living with T1DM – in line with the LSDF principle to avoid bringing people into hospital unless clinically required. Evidence from elsewhere including NHS Dumfries and Galloway and NHS Forth Valley has demonstrated an increase in the number of people taking up monitoring as a result of changes such as this, which is expected will lead to improvements in patient outcomes.

Please describe the policy framework relating to the choice
Outline whether any of the options deviates from policy or Scottish Government directive. Provide as much information as possible as to the extent of any deviation:

Option 1 would deviate from guidance, including that provided within SIGN Guideline 116, and guidance provided by the Scottish Health Technologies Group (SHTG) in January 2022 regarding Closed Loops. Option 1 also deviates from SG policy, as outlined in the Diabetes Improvement Plan 2021-26, which supports timely access to technologies for people living with Type 1 Diabetes.

Options 2 and 3 are more aligned to guidance and policy. While there are not specific targets in place in terms of the number or proportion of people with T1DM who should be provided with technologies, it could be argued that Option 3 is most aligned to policy and guidance, as it maximises the proportion of people who can access technology with the expectation that their glycaemic control can be improved, and/or diabetes distress would be reduced.

Relevant guidance and policy is outlined in more detail below:

SIGN 116 – Nov 2017

- CSII therapy is associated with modest improvements in glycaemic control and should be considered for patients unable to achieve their glycaemic targets.
- CSII therapy should be considered in patients who experience recurring episodes of severe hypoglycaemia.

(CSII is Continuous Subcutaneous Insulin Infusion pump therapy)

SHTG January 2022
Single hormone closed loop systems should be available to people with type 1 diabetes (paediatric and adult) who:

- under their current diabetes care plan, continue to have suboptimal glycaemic control, a high risk of severe hypoglycaemia, or impaired awareness of hypoglycaemia, or
- experience diabetes-related distress, measured using a validated tool, that adversely affects quality of life or their ability to manage diabetes, and which is likely to be improved by moving to a closed loop system

SG Diabetes Improvement Plan 2021-2026
Commitment 2.2: We will support appropriate and timely access to technologies to improve glycaemic control and quality of life for people living with type 1 diabetes
In line with best practice and analysis from health economists, we should aim to ensure all people that would benefit from these therapies have access at the earliest opportunity.

To ensure progress against this commitment we will review the:
% of people with type 1 diabetes who have access to flash glucose monitoring
% of people with type 1 diabetes who have access to insulin pump therapy
% of people with type 1 diabetes starting on insulin pump therapy within six months of referral
% of people with type 1 diabetes who have access to continuous glucose monitoring
% of women with type 1 diabetes who have access to continuous glucose monitoring during pregnancy
% of people with type 1 diabetes who have access to closed loop/Artificial Pancreas Systems (both single and dual hormone)
% of people with type 1 diabetes in SIMD1 vs SIMD5 with access to diabetes technologies

Commitment 2.5: We will continue to support improvements in care and outcomes
% of people with type 1 diabetes who are recorded as having one or more episodes of DKA in one year
% of people with type 1 diabetes with optimal glycaemic control
% of people with type 1 diabetes with a BP <= 130/80mmHg
% of people with type 1 diabetes with HbA1c >75mmol/l and a systolic BP > over 130 mmHg
Data from international health services to benchmark against the most advanced diabetes services

Scottish Diabetes Survey 2022
% of people with type 1 diabetes who achieve optimal glycaemic control (HbA1c<58mmol/mol in adults) at one year post diagnosis with the aim of 58% of people achieving this
% of people with type 1 diabetes with optimal glycaemic control of HbA1c below 58mmol/mol (any duration, all age groups)

Priority 4 - Equity of Access
To reduce the impact of deprivation, ethnicity and other factors which can disadvantage diabetes care and outcomes for people.

SHTG Adaption, 1st November 2020
Continuous glucose monitoring (CGM) should be offered to all pregnant women with type 1 diabetes (T1DM). The case for adopting CGM in pregnant women with T1DM is supported by the clinical evidence. SHTG advice is required to inform adoption, particularly for pregnant women with T1DM who are considered amongst the highest priority for the technology.

NICE Guideline (updated 2020) Diabetes in pregnancy: management from preconception to the postnatal period
1.3.17 Offer real-time continuous glucose monitoring (rtCGM) to all pregnant women with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes. [2020]
1.3.18 Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to pregnant women with type 1 diabetes who are unable to use rtCGM or express a clear preference for iCGM. [2020]

NICE Guideline (provisional November 2023)
In England and Wales there is a legally binding guarantee through the Nov 2023 NICE that HCL should be available to people with HbA1c of 58 mmol/mol (7.5%) or more, or have disabling hypoglycaemia, despite best possible management with at least 1 of the following: • continuous subcutaneous insulin

infusion (CSII) • real-time continuous glucose monitoring • intermittently scanned continuous glucose monitoring. an HBa1c>64 mmol/mol and pregnant women. NHS England are developing a strategy to implement this over 5 years. In Scotland the SHTG indications are wider because they include diabetes distress.

The NHS Lothian Equality and Human Rights Strategy 2023-2028 and the Public Sector Equality Duty (PSED)
Equality and human rights are a central part of our planning, decision-making, delivery and reporting. The Public Sector Equality Duty (PSED) requires public bodies be proactive, and to reduce and remove the systemic inequalities related to disability, race, sex and the other protected characteristics in the Equality Act 2010. In addition The Fairer Scotland Duty places a legal responsibility on public bodies in Scotland to pay due regard to (actively consider) how they can reduce inequalities of outcome, caused by socio-economic disadvantage, when making strategic decisions.

Please describe how each option compares to the practice in other Health Boards in Scotland **and to any health system outside of Scotland:**
Option 1: Currently, 20% of adults in Lothian are using CSII therapy, compared to 15% across Scotland. Removing pumps from 500 people would reduce NHS Lothian's performance to 10%.

Option 2: Currently 20% of adults in Lothian are using CSII pump therapy. Providing 110 pumps a year over 5 years would result in approximately 26% of the population compared to 15% nationally currently. However it is not clear what the national Scottish average will be in 5 years time as all NHS Health Boards aim to increase access to technologies.

Current technology distribution in Lothian compared to Scottish average (Data correct as at July 2023)

	Adults 18+		Children 0-17	
	Lothian	Scotland	Lothian	Scotland
Flash Glucose Monitoring	39%	52%	28%	38%
Pump Therapy	20%	15%	65%	50%
Pump Users with HbA1c > 75mmol/mol	12%	12%	9%	10%
Continuous Glucose Monitoring	7%	9%	51%	43%

Option 1

Option 1 would require technology to be withdrawn from approximately half of all current users. In terms of pump therapy, this would mean that Lothian's technology distribution would fall to approx. 12% of adults aged 18+

Option 2 – current levels of T1 tech

Continuing to distribute new technology at current levels would see a gradual increase in the proportion of adults using pump therapy, for example. Within five years, 550 additional people with T1DM would have access to a pump. This would increase the proportion of adults in Lothian on pump therapy to approximately 31%

Option 3 – 50% within five years

Increasing distribution of new technology to approximately 300 people per annum would see an additional 1500 people with T1DM gain access to a pump. This would increase the proportion of adults in Lothian on pump therapy to approximately 47%

Part 3: Impact & Risk Assessment of Options

The short-list options should each be profiled against the following parameters in order to characterise the choice. No impact / risk scoring system is used – impact should be described and quantified in terms

of scale (for example, number of patients impacted; financial cost (cost avoided)). Quantification is crucial to allow a comparison between options. Where appropriate published evidence or locally collected data should be appended to the assessment. The impact and risk should be described – impact refers to 'what is certain to happen'; risk refers to 'what is likely to happen'. Please indicate the likelihood of the risk becoming an issue (refer to comparable internal and/or external experience) Please complete the following template for **each** choice.		
Option 1: Working within current budgets to deliver Diabetes Technologies Removal of around 500 pumps from current users in year 1 No further distribution of new technologies for people with T1DM		
Please describe the **risks and impacts** of this option against each of the impact factors listed:		
Performance (access)	Impacts	Proportion of people with T1DM utilising technologies would fall, in all categories The waiting list would have to be closed down as the service would no longer exist. Consideration would need to be given to waiting list governance.
	Risks	NHS Lothian's performance compared to other Boards in terms of technology distribution and particularly pumps would fall. Currently, 20% of adults in Lothian are using CSII therapy, compared to 15% across Scotland. Removing pumps from 500+ people would reduce NHS Lothian's performance to 10%.
Cost	Impacts	Reduction in technologies-related costs, including cost of pumps/CGM and related consumables revenue costs. Able to achieve financial balance within the service. Total Daily Dose of Insulin could increase for those reverting to MDI, resulting in increased prescribing costs, incurred within Primary Care. Increase in direct and non-direct costs of T1DM and T1DM complications, as a result of increased admission rates and/or treatment for diabetes related issues. It is difficult to quantify these costs as evidence is limited. A Kings College study in 2019 estimated that direct/indirect cost savings of £5585/£8400 per person could be made over a five year period if a person with sub-optimal control was able to achieve good control. If we assumed the reverse for the 575 people who would stop using pumps, NHSL could incur direct/indirect costs of £3.2m/£4.8m over five years.
	Risks	There is a risk that the savings achieved through not distributing technologies will be matched or outweighed against the additional costs of managing increased complications By removing this type of treatment for diabetes NHSL may be left vulnerable to legal action, with associated costs.
Quality (Clinical outcomes)	Impacts	Roughly half of those with T1DM currently on pump therapy in Lothian would discontinue pump therapy and revert to Multiple Daily Injections (MDI).

	Risks	There is a risk that those who discontinue pump therapy would experience deterioration in glucose control. This could lead to a higher risk of DKA and severe hypoglycaemia, an increase in developing complications, or progression of established complications, including renal function, retinal damage, neuropathy, foot ulceration. The expectation is that Diabetes distress will increase and mental health will decrease. The landmark DCCT trial saw reductions in complications over a six-year period of intensive control**. Closed loop achieves similar improvements to HbA1c as the DCCT trial.** Withdrawing technology from current users could see the opposite effect to some extent: Retinopathy development: reduced 76% Retinopathy progression: reduced 54% Sight-threatening retinopathy: reduced 47% Diabetic kidney disease (albuminuria): reduced 54% Neuropathy development: 60% reduced Cardiovascular disease: reduced 42% Death: reduced 33%
Patient experience	Impacts	Patients are likely to experience increased episodes of hypoglycaemia It is likely that those patients in whom pump therapy is discontinued would experience increased incidence of anxiety and depressive disorders.
	Risks	Risk that patients will be extremely frustrated at the increases in waiting times for technology, particularly if technology is withdrawn and/or waiting times appear to become open-ended. This will result in a large increase in complaints and will lead to a risk of litigation.
Equity	Impacts	Life expectancy of people in Scotland with T1DM is 12 years lower than those who do not have the condition, with deaths in young people accounting for a substantial proportion of this loss of life. Scottish people with T1DM under the age of 50 have a three- to fourfold increase risk of death compared to the general population, with almost half of this excess risk related to diabetic ketoacidosis and premature cardiovascular disease.
	Risks	Reducing access to technologies is likely to have a detrimental affect on glycaemic control, which will widen the equalities gap between those with T1DM and the general population.
Staff experience	Impacts	Increased demand for input from Diabetes Specialist Nurses and Dieticians to support good glycaemic control in those who no longer have access to diabetes technologies Removing access to technologies for long-standing patients is likely to cause significant stress to and impact the wellbeing of clinicians working within Diabetes services. It is likely that in order to manage this other areas of the service would be impacted by this increased workload. Consultant clinics may need to be cancelled in order to support the nursing teams to support the transfer of patients from technology to MDI. Individual requirements would be variable, and may need multiple interventions. Patients that have been prioritised for technology are those that had struggled to manage their diabetes.

	Risks	Risk of burnout among diabetes clinicians who are exposed to additional stressors Risk that staff may experience aggression from people with T1DM who are distressed and/or frustrated by the removal of diabetes technologies Likely that staff will become overwhelmed with the patient response, which could lead to increased sickness absence and resignations.
Environmental sustainability	Impacts	It is anticipated that those who revert to Multiple Daily Injection to manage their diabetes will require additional support, which may require more face-to-face input from specialist clinicians. This may result in additional trips to hospital. It is difficult to quantify this, alongside the environmental impact on producing, procuring and supplying technologies.
	Risks	Risk of increased carbon emissions as a result of additional journeys to hospital.
Technical / compliance	Impacts	N/A
	Risks	N/A
With cognisance of the above impact and risk assessment, please indicate any specific considerations in relation to the impact on / risk to particular groups (note, impacts on patients and staff should be recorded in the table above):		
Other services within NHS Lothian		There will be increased attendance at front door hospital services, as a result of complications and those that are unable to access the Diabetes service due to the volume of work, and the inability of the service to be as responsive. Potential for increased input required from other services, which support people with Diabetes complications and/or provide psychological support Potential for increased demand to General Practice and Primary Care services Decreased ability to support inpatient areas
Health Board (NHS Lothian)		Reputational risk to NHS Lothian, if technologies are withdrawn from current users.
Partner organisations including IJBs		
Scottish Government		

Other (please state)	
Please consider whether the impact / risk profile for any of the impact factors changes over time. Describe why this would happen and the extent of the change:	
Medium-term (2-5 years)	
Long-term (6-10 years)	
Extended (10+ years)	The impact of withdrawing technologies in terms of increased complications and associated costs is likely to increase with time.

Part 3: Impact & Risk Assessment of Options

The short-list options should each be profiled against the following parameters in order to characterise the choice. No impact / risk scoring system is used – impact should be described and quantified in terms of scale (for example, number of patients impacted; financial cost (cost avoided)). Quantification is crucial to allow a comparison between options. Where appropriate published evidence or locally collected data should be appended to the assessment.

The impact and risk should be described – impact refers to 'what is certain to happen'; risk refers to 'what is likely to happen'. Please indicate the likelihood of the risk becoming an issue (refer to comparable internal and/or external experience)

Please complete the following template for **each** choice.

Option 2:
Working to current levels of T1DM tech distribution for adults:

- 154 new pumps distributed a year: 110 new pumps (adults) and 44 pumps (paediatrics)
- 72 GCM distributed a year: 60 CGM: 15 CGM (adults non-pregnancy) 45 (adults pregnancy – for 12 months TBC) and 12 CGM: Paediatrics (under 5s)
- Replacement tech will continue to be provided: 200 in 24/25, 290 in 25/26 (adults) 55 in 24/25, 70 in 25/26 (paeds)
- Numbers include paediatric patients transitioning to the adult service.
- The pumps would be distributed in line with the current split between adults and paediatrics and would be distributed according to the current waiting lists.
- Predicted WTE = the same. This can be managed within the existing resource.
- Delivering this number of starts allows current educators to maintain competence within the field with reduced ability to train additional staff.
- There is capacity in the adult services to manage more complex starts with an option to offer 1 :1 starts for people with additional support needs or who cannot manage in a group setting.

Please describe the **risks and impacts** of this option against each of the impact factors listed:

Performance (access)	Impacts	• The percentage of people with type 1 diabetes who have access to insulin pump therapy would increase: • In 5 years' time there will be approx 1901 adults with pumps in the adult service (including those that transition from paediatrics over the next 5 years). This will mean approximately 31% of the adult type 1 population will have pumps in 5 years team. This is also taking into account the growth in the size of the T1D population with approximately 124 newly diagnosed adults annually. • It is estimated that all those with pumps will have HCL in 5 years time due to advances in technology. • In 5 years' time in the paediatric service there will be approximately 605 children with pumps. This will mean approximately 80% of the paediatric type 1 population will have pumps. • The percentage of people with type 1 diabetes who have access to continuous glucose monitoring is currently 75%. • The percentage of women with type 1 diabetes who will have access to continuous glucose monitoring during pregnancy will be 100%. • The Waiting list size, and the waiting times from referral for a pump to receiving a pump would double. There would be an average waiting time of over 9 years for adults to receive a pump by year 5. The waiting times in the paediatric service are 2 1/2 years and this would also increase.

	Risks	Risk that patients will be extremely frustrated at the increases in waiting times for technology, as waiting times continue to increase to many years. This is will lead to complaints and may lead to a risk of litigation. The % of people with type 1 diabetes starting on insulin pump therapy within six months of referral would not be achieved, and will wait many years. NHS Lothian's performance compared to other Boards in terms of technology distribution and particularly pumps would fall. Clinical outcomes will be negatively affected as those that are struggling to manage their diabetes on MDI, are unable to access the technology that would support better clinical care.
Cost	Impacts	This option will result in an overspend by year in adult service: 23/24 (685,464) 24/25 (1,875,071) 25/26 (3,063,490) 26/27 (3,133,840) 27/28 (3,340,158) Assumed 70% of new and replacement patients move to Omnipod 5 pump and continue to use Libre 2. Overspend by year in paediatric service 23/24 £14K 24/25 (£531K) 25/26 (£430K) 26/27 (408K) 27/28 (366K) Both adults and paediatrics have implemented a policy for pump choice that delivers best value for money whilst maintaining clinical performance of technology. Libre 2 is on the primary care tariff which all T1 patients have access to, and as it is becoming loopable with Omnipod in 2024, this is the preferred non tethered pump being made available in NHSL. A tethered pump from Insulet which is loopable with Libre 3, at a cost for secondary care, is cheaper than the alternatives (Medtronic & Dexcom) and is also available. Medtronic is no longer offered as a choice in Lothian. In spite of choices available 70% of patients are choosing Omnipod which will allow NHSL to provide HCL from 2024 at no extra cost to current Omnipod users, and will allow new patients on Omnipod to utilise HCL immediately.
	Risks	There will be a financial risk to NHS Lothian from this overspend. The Diabetes technology landscape is very fast moving. It is a highly competitive arena and the advances in technology make future modelling complex. It is expected that as the numbers of patients with access to technology increase across England, Wales and Scotland, the prices are likely to reduce due to economies of scale. Conversely, as the technology develops older versions will rapidly become suboptimal and alternatives will be sought. In order to mitigate this, the adult and paediatric services will work together with industry colleagues, national procurement, with the Scotland wide Diabetes MCN and with other partner organisations to continue to review policy decisions to ensure financial decisions are made with as much pre-sight as possible (EG: current movement to Omnipod 5 system to enable HCL as it is expected to become available in 2024)

		In attempting to work within financial constraints and therefore choosing the most cost effective options to provide as many patients as possible with technology. Adults who already have T:slim and Omnipod pumps, or who choose these as new pumps over the next year will be on closed loop by this time next year (due to the update of Libre 2 CGM and tech developments allowing this to link with these devices from next year). Libre 2 CGM is provided in primary care and 75% of all adults in Lothian have this. Adults who have chosen to use a Medtronic pump will not be able to link this pump to the Freestyle CGM. So although they may have a pump and a CGM to be able to access a Closed Loop System they will need to go onto a waiting list to receive a separate funded CGM and will need to wait for this. It was not clear previously that Freestyle Libre would only ink with T:slim and Omni pod so they were not able to take this into account when choosing which pump to use. Equally there are some Medtronic users that are on HCL as the CGM system came as part of the SG funded call off contract in 2022/3, and so there is another level of inequity in the system
Quality (Clinical outcomes)	Impacts	Research shows that insulin pump therapy is associated with marked falls in HbA1c especially in those with high baseline HbA1c. The better your HbA1c value over longer periods of time, this indicates the better management of your diabetes and the less likely you are to develop complications from diabetes later in life. Pump therapy is independently associated with reduced DKA and Severe Hypoglycamia requiring Hospitalisation rates. Pump therapy is an effective option for intensive insulin therapy in people with diabetes for improving suboptimal glycaemic control. Since the introduction of CGM, multiple studies have shown that CGM use significantly improves HbA1c levels, while simultaneously decreasing and even preventing hypoglycemia. . Studies also show that people who wear CGM experienced less diabetes distress and improved
	Risks	Using an insulin pump alone can pose a risk to DKA as the pump only delivers short acting insulin. If there is an issue with insulin delivery, the person could be completely insulin deficient within 3- hours. Good education at the start of pump use and throughout is key to preventing this. Risk that only a small percentage of patients are able to achieve a reduction in Hba1c leading to a greater proportion of patients being at risk of complications.
Patient experience	Impacts	Recent research, including the Diabetes Scotland Tech Can't Wait Campaign shows the positive impacts on the patients that are able to access new technologies in terms of reduction in Hba1c and impact on wellbeing and quality of life.
	Risks	As patients are told they will need to wait 9 years for a pump when they are added to the pump waiting list there is likely to be a risk that this impacts patient wellbeing and patient motivation. Patient complaints will increase.

Equity	Impacts	The percentage of people with type 1 diabetes in SIMD1 vs SIMD5 with access to diabetes technologies would be in proportion to the SIMD split of the NHS Lothian Type 1 diabetes population (after 5 years) If 110 pumps are given out each year in the adult service in line with the current waiting list then in 5 years time pumps will be approximately distributed in line with the SIMD profile of the Type 1 Diabetes population: SIMD Q 1 2 3 4 5 CSII in 5yr % 12 18 17 22 30 SIMD pop % 11 21 17 20 28 This will improve the inequality of distribution from the current distribution where people from SIMD 1 account for 6% of pumps, although they account for 11% of the population and people from SIMD 5 account for 38% of all pumps distributed to date although they account for 28% of the population. However those with the highest HbA1c stand to benefit the most from technology with respect to HbA1c lowering, and therefore reduction in complications. People from the most deprived quintiles 1 and 2 in Lothian currently account for 32% of the population but represent 46% of all patients with HbA1c over 75mmol who do yet not have access to a pump. 79.7% of all adults from the most deprived quintile do not yet have any technology and are not on the waiting list, compared to 62.2% of all adults from the least deprived quintile who do not yet have any technology and are not on the waiting list. This inequality will continue if the current waiting list is used to allocate pumps over the next 5 years. Men currently account for 68% of all those with a closed loop system and women account for 32%. However men account for 55% of the T1D population and women account for 45%. In line with SHTG guidance pregnant women with Type 1 diabetes are offered CGM. Due to the current financial situation, currently pregnant patients are only funded for 12 months. (TBC)
Staff experience (workforce)	Impacts	In this option, the service will continue to be unable to meet the needs for all diabetes patients (t1 and 2) as these populations grow, but the staffing numbers remain the same. Even with changes in model of care, the demand will outstrip capacity over time, as we see more patients in an inpatient setting requiring specialist diabetes care whilst also managing return patients to the outpatient service.
	Risks	Direct patient contact – management of angry, upset, distressed patients There will be a marked increase in complaints Front door, OP and IP staff dealing with more patients in Diabetic distress (both clinically and psychologically) It is expected that use of the current Diabetes Helpline across sites will increase to well beyond 100 calls per day, with no additional staff resource to support

Environmental sustainability	Impacts	As more people supported to access pumps and CGM, greater opportunity for online appointments, and online support. Team can access pump and CGM data remotely – this will result in a reduction in health miles for this patient group.
	Risks	n/a
Technical / compliance	Impacts	N/a
	Risks	

With cognisance of the above impact and risk assessment, please indicate any specific considerations in relation to the impact on / risk to particular groups (note, impacts on patients and staff should be recorded in the table above):	
Other services within NHS Lothian	
Health Board (NHS Lothian)	Increase in complaints to the board, and pressure on the board via complaints to local press Diabetes Scotland #Techcan'twait campaign and supporting data likely to highlight if NHS Lothian is not delivering access to tech in line with other areas.
Partner organisations including IJBs	Pressure to increase budget provided to support adult patients with Type 1 diabetes.
Scottish Government	Pressure from patients, patient groups and campaigning groups including Diabetes Scotland to increase support for technology.
Other (please state)	

Please consider whether the impact / risk profile for any of the impact factors changes over time. Describe why this would happen and the extent of the change:	
Medium-term (2-5 years)	The pressure on the teams, NHS board and Scottish Government to increase access to technology is likely to increase over time. Interest across all patient groups and ages in technology is likely to increase over time leading to increased demand
Long-term (6-10 years)	

Extended (10+ years)	Reduction in Diabetes complications from t1 Diabetes

Part 3: Impact & Risk Assessment of Options

The short-list options should each be profiled against the following parameters in order to characterise the choice. No impact / risk scoring system is used – impact should be described and quantified in terms of scale (for example, number of patients impacted; financial cost (cost avoided)). Quantification is crucial to allow a comparison between options. Where appropriate published evidence or locally collected data should be appended to the assessment.

The impact and risk should be described – impact refers to 'what is certain to happen'; risk refers to 'what is likely to happen'. Please indicate the likelihood of the risk becoming an issue (refer to comparable internal and/or external experience)

Please complete the following template for **each** choice.

Option 3:

Expand HCL use in NHS Lothian (adults)

There are two main categories for HCL starts:

1. People currently using 'HCL-ready' insulin pumps who require funding for compatible continuous glucose monitors (CGM) or to be linked to Libre 2 (available 2024) at no additional cost

2. People currently on insulin injections (MDI) who require funding for insulin pump and compatible CGM to create a closed loop system

Category 1

People in this category are already established on insulin pumps and the process of converting to a new CGM system would be delivered by the relevant company. Approximately 535 individuals are currently on potential HCL pumps and it is expected that 80% of patients would like to move to HCL.

There is a smaller cohort of people on 'non-loopable' pumps, most of whom are coming towards the end of their current warranty and will be in the process of converting to a new pump soon. It would be most cost effective for people currently on 'non-loopable' pumps to convert to Omnipod 5 (with Libre 2) or Ypsopump with Libre 3.

Category 2

Based on SHTG and DTN guidance it is conceivable that up to 70% of people with T1 diabetes may be eligible for and elect to use HCL. The combination of current HCL users (6% of the total T1 population) and those in category 1 (11% of the total T1 population) would take NHS Lothian to ~17% of adults with type 1 diabetes. Therefore the following new groups should be made priority to maximise the benefits of HCL and help equalise some of the current inequalities in provision:

- People with HbA1c >75 mmol/mol
- People with HbA1c >53 mmol/mol and significant microvascular complications (i.e. greater than mild background retinopathy)
- People with HbA1c >53 mmol and background retinopathy
- People with substantial diabetes distress / burnout

This is in addition to the existing priority criteria:

- Recurrent severe hypoglycaemia
- Significant impaired awareness of hypoglycaemia

The number of people with HbA1c >75 mmol/mol (not currently on CSII) is 1145 and are those at highest risk of complications and premature mortality. Modelling assumptions are based on interest in HCL by age group[12]. It is estimated that 463 people would be interested/eligible for HCL in this group.

The number of people with HbA1c >53 mmol/mol and significant microvascular complications (not currently on CSII) is currently 409 and are in urgent need of intensified glucose control to reduce their progression to sight-threatening eye complications / renal failure. Modelling assumptions are based on interest in HCL by age group[12]. It is estimated that 154 people would be interested/eligible for HCL in this group.

The number of people with HbA1c >53 mmol/mol and background retinopathy (not currently on CSII) is 740 and are in need of intensified glucose control to reduce their progression to more significant complications. Modelling assumptions are based on interest in HCL by age group[12]. It is estimated that 283 people would be interested/eligible for HCL in this group.

It is harder to quantify people with substantial diabetes distress / burnout but this is likely to be a small number of people, as almost all of these individuals will also fit in to one of the other priority criteria described. The majority of people with recurrent severe hypoglycaemia and/or significant impaired awareness of hypoglycaemia have already have been converted to HCL and future numbers in this category are also likely to be low.

Due to the current financial situation, pregnant patients are only funded for 12 months. Under this option, these patients will continue on HCL beyond the end of their pregnancy.

Paediatrics will offer HCL for 100% patients. This will require enhanced pump starts of 24 additional pumps a year in 23/24 and 24/25 (above the 44 as standard) and an increase in annual technology starts to 50 per year from 25/26. There would also be an an increase to 90CGM a year in 23/24 and 24/25 and to 50 CGM a year from 25/26. There will be a resultant increase in the number of patients transitioning on technology into the adult service.

Please describe the **risks and impacts** of this option against each of the impact factors listed:

Performance (access)	Impacts	300 Adult HCL starts per year and all Paediatric newly diagnosed. Those that are already on Omnipod will be able to have access to HCL with Libre 2. The linking of the 2 systems will be undertaken by the tech company (Abbott). HCL use in Lothian will move from 6% to approximately 35% over a 3-year period (50% over 5 years in line with England & Wales), and 70% by 2030 (Diabetes Scotland "Tech can't Wait").
	Risks	Waiting times have been based on expected referral rates and population trajectories of newly diagnosed patients. Any differences in real referral activity will affect modelling. There will be high demand for Abbott to link patients to their Libre 2 CGM, so any delays in access will be due to the capacity of the company. Modelling has also been based on Paediatrics moving to a 6 month waiting list for all eligible T1 patients, with the resultant transition numbers into the adult service.
Cost	Impacts	Projected adult Overspend 23/24 (502K) 24/25 (2,378K) 25/26 (4,084K) 26/27 (5,355K) 27/28 (6,602K)

		Projected paediatric overspend 23/24 (196k) 24/25 (899K) 25/26 (842K) 26/27 (836K) 27/28 (813K) These numbers assume 70% of new and replacement adult patients move to Omnipod 5 pump and continue to use Libre 2, and 30% are on a tethered pump with a CGM that is a cost to NHSL secondary care budget. It also includes the cost of transitioning patients from paediatrics. Both adults and paediatrics have implemented a policy for pump choice that delivers best value for money whilst maintaining clinical performance of technology. Libre 2 is on the primary care tariff which all T1 patients have access to, and as it is becoming loopable with Omnipod in 2024, this is the preferred non tethered pump being made available in NHSL. A tethered pump from Insulet which is loopable with Libre 3, at a cost for secondary care, is cheaper than the alternatives (Medtronic & Dexcom) and is also available. Medtronic is no longer offered as a choice in Lothian. In spite of choices available 70% of patients are choosing Omnipod which will allow NHSL to provide HCL from 2024 at no extra cost to current Omnipod users, and will allow new patients on Omnipod to utilise HCL immediately. Cost savings have been well documented in studies. For example, a King's College study undertaken in 2019, identified that over a 5 year period, patients who achieve a target HbA1c have reduced chronic complications including diabetic ketoacidosis. Currently in Lothian there are 1232 with Type 1 diabetes who have an A1c of >75mmol/mol. Should 50% of these patients who are not on HCL, move to HCL therapy, and should they also be able to achieve a target Hba1c, it is estimated that the direct cost savings of £5585/ indirect £8400 could be made over a 5 year period. So for 616 patients direct savings could be £3.44m/ indirect 5.17m. However currently 11% of those with HCL in Lothian have an A1c of >75mmol/mol so cost savings may not be equal for all patients. In 2010/11 the cost of T1 diabetes complications to the NHS in the UK was estimated at £719m – an annual figure of £9.8m for NHSL which will be much higher in 2023. However as identified in the NICE appraisal document guidance (Nov 2023), at the current average price, HCL systems are unlikely to be cost effective in the long term, but it is recognised that there are real potential benefits to people.
	Risks	The Diabetes technology landscape is very fast moving. It is a highly competitive arena and the advances in technology make future modelling complex. It is expected that as the numbers of patients with access to technology increase across England, Wales and Scotland, the prices are likely to reduce due to economies of scale. Conversely, as the technology develops older versions will rapidly become suboptimal and alternatives will be sought. In order to mitigate this, the adult and paediatric services will work together with industry colleagues, national procurement, with the Scotland wide Diabetes MCN and with other partner organisations to continue to review policy decisions to ensure financial decisions are made with as much pre-sight as possible (EG: current movement to Omnipod 5 system to enable HCL as it is expected to become available in 2024)

Quality (Clinical outcomes)	Impacts	Closed loop achieves similar improvements to HbA1c to those observed in DCCT (a landmark study conducted in the 1980's that proved over decades the impact on health and clinical outcomes long term, of tight glucose control) and, unlike intensive control in DCCT, reduces hypoglycaemia risk. Closed loop is also likely to result in sustained reduction in HbA1c, as opposed to DCCT (where the benefit disappeared at the conclusion of the study). Closed loop systems are improving at a rapid rate and the benefits derived from them will increase with advances in technology. Glycaemic control improvement with HCL is well documented with at least 18mmol/mol reduction on average. In Lothian there are approximately 1232 patients with T1 Diabetes who have an HbA1c of over 75mmol/mol. Reducing the time a patient spends with high glucose readings will reduce the risk of DKA. The outcomes with intensive control have shown: Retinopathy development: reduced 76% Retinopathy progression: reduced 54% Sight-threatening retinopathy: reduced 47% Diabetic kidney disease (albuminuria): reduced 54% Neuropathy development: 60% reduced Cardiovascular disease: reduced 42% Death: reduced 33% It is also accepted that the earlier a patient moves onto diabetes technology, the greatest impact on long term clinical outcomes.
	Risks	Using an insulin pump alone can pose a risk to DKA as the pump only delivers short acting insulin. If there is an issue with insulin delivery, the person could be completely insulin deficient within 3- hours. Good education at the start of pump use and throughout is key to preventing this. With HCL, risk is much, much lower because these systems mandate use of real time CGM. Patients using them will be alerted when glucose levels rise to dangerous levels. This is not guaranteed in people using MDI.
Patient experience	Impacts	The service has reviewed onboarding pathways and has developed a menu of options to assure the right support is available for each patient, and that the model of care is not limiting access. Patients will be onboarded through one of 4 pathways: (i) Group start F2F (ii) fast track pathway (iii) 1:1 enhanced start & (iv) ANIA pathway (national) These pathways optimise staffing resource, releasing time for follow up as required, allowing an increase in the number of patients being supported to start HCL per year. The daily relentless unremitting burden of T1 diabetes is eased significantly with HCL. Many research studies have demonstrated that people with diabetes and their families report improved sleep and feeling less worried about the possibility of having low or high blood sugar. The impact on QOL and diabetes distress not only for the patients, but close family and friends is well documented. HCL is a life-changing development for patients, impacting QOL in all aspects including access and performance in employment, physical and psychological health, feeling safe and freedom of living life.
	Risks	HCL tech failure is mitigated by patient training at on-boarding stage regarding MDI and Finger prick testing. Pumps are sent out within 24-48 hours as standard. The systems still requires a high amount of human interaction. Patients using these pumps still need to change their cannula, giving set and reservoir every few days

<table>
<tr><td></td><td></td><td>and their CGM device every 14 days. They must be able and willing to use the insulin pump, CGM and other system components, demonstrate carb-counting skills and respond to pumps alerts and reminders</td></tr>
<tr><td rowspan="2">Equity</td><td>Impacts</td><td>Premature mortality in t1 diabetes is strongly associated with socioeconomic deprivation. Socioeconomic deprivation is also associated with lower rates of meeting HbA1c targets, attending structured education and accessing diabetes technology. Recent published Edinburgh data shows that current utilisation of HCL is strongly skewed to the most affluent even though interest in HCL is evenly distributed across deprivation quintiles. The numeracy and organisational skills required to achieve tight glucose control have historically represented a barrier to many people, whereas HCL offers a more accessible option to a wider spectrum of the diabetes population.

The redesign of the onboarding model undertaken by the Lothian Diabetes team has incorporated a flexibility in approach in order to better meet individual need, and widen access to those who previously would have been excluded due to for example disability.

Category 1: Approximately 535 individuals are currently on potential HCL pumps and it is expected that 80% of patients would like to move to HCL (approx. 428). This will increase the number of individuals on HCL but slightly worsen current inequalities resulting in 39% in all those with HCL being from the least deprived quintile and 6% of all those with HCL being from the most deprived quintile.

<table>
<tr><td>SIMD</td><td>Q1</td><td>Q2</td><td>Q3</td><td>Q4</td><td>Q5</td></tr>
<tr><td>CLS to 80% of Category 1</td><td>6%</td><td>19%</td><td>15%</td><td>21%</td><td>39%</td></tr>
<tr><td>T1 population</td><td>11%</td><td>21%</td><td>17%</td><td>20%</td><td>28%</td></tr>
</table>

Category 2: Those with highest HbA1c are in the lower SMID quintiles and therefore even if access to technology is equal across deprivation levels it will not reduce inequality. Whilst the referral criterion has widened to include a larger proportion of the population, it will be essential that the service monitors access and continues current programmes that have commenced to improve outcomes across all quintiles, levelling up and prioritising those with most need. This option will help to support equal access.</td></tr>
<tr><td>Risks</td><td>Referral bias is a challenge. Those patients that engage in regular clinic reviews are more likely to be referred. The service team understand that there is a need to access those that are disengaged through outreach, and other strategies. The Diabetes service is currently undertaking a programme of work to tackle inequalities through various methods including working with the third sector, collaboration with other boards and community partnerships. The service will need to continue to actively monitor equity across all quintiles and modify approaches as required.

In attempting to work within financial constraints and therefore choosing the most cost effective options to provide as many patients as possible with technology, only T:slim and Omnipod users will be on closed loop by this time next year (Libre 2). Medtronic users will not – this is a systematic inequality that is not of the patient's choosing – when they chose their pump there were not aware that NHSL future policy and market forces would mean they would not have access to HCL due to the cost of the CGM system that links with their chosen pump. Equally there are some Medtronic users that are on HCL as the CGM system came as part of the SG funded call off contract in 2022/3, and so there is another level of inequity in the system.</td></tr>
</table>

Staff experience	Impacts	Administratively an increase in technology use at scale will require robust mechanisms for financial and patient level information governance and management. The current Tech team will require additional administrative resource/ support to manage this effectively. Following the transition of the service onto TRAK earlier this year, and streamlining of processes, the service is fully scalable, with appropriate resource. Efficiencies identified within the clinical team this year, in both patient pathways and staffing mix, will allow an increase in Educator on-boarding alongside the national ANIA programme. As the numbers of patients increase, all clinical staff will have more regular interaction with this technology and therefore all staff knowledge will increase. Currently keeping on top of the technology is more difficult when there are fewer patients in the system seeing less staff, creating more of a niche clinical understanding for the few. It is expected that as patients are commenced on pump and CGM (HCL) there will be a reduction in the required follow up, allowing resource to be diverted to onboarding more patients. The model of care for T1 patients on long term HCL will change over time, to a more virtual Outpatient model, with some patients moving towards PIFU. Monitoring can be remote and support for the technology may move more to the technology companies. As T1 patients on technology require less regular clinical support from the clinical teams, the staff can focus on areas of current unmet need especially in the T2 population. The number of newly diagnosed type 2 patients is expected to increase, resulting on more pressure on secondary care, where clinical staffing levels are not expected to increase. Therefore, any long-term reduction in face to face clinical care in T1 diabetics will need to be directed at the type 2 population, which even now far exceeds the T1 numbers management by the Lothian Diabetes team. Inpatient care in an area of significant strain. The 2023 NaDIA audit has highlighted increasing levels of unmet need, with 20% of patients not getting seen by the Diabetes team. With numbers of patients in hospital with Diabetes increasing, and DKA events on the rise, the need for timeous access to specialised care is becoming even more essential.
	Risks	As the technology progresses, staff need to get kept up to date. Education will need to be ongoing for diabetes technology with regular opportunities to attend updates/technology education sessions to ensure that staff feel confident and able to deliver excellent diabetes care using the latest technology devices and data platforms. The most challenging time will be in the transition years, as more T1 patients are moved onto HCL, who will need more initial support, and the team work towards different models of care. This will require broad communication, especially with patients, to manage expectations and manage change. There are currently 2 patient systems in place for Diabetes – TRAK and SCI-Diabetes. Information is input into both systems. Most of the administration for technology is now on TRAK, with a small element on Excel. At scale, there will need over time for there to be an interface between TRAK and SCI-Diabetes (national system) – this is currently with the TRAK team as a new work request.
Environmental sustainability	Impacts	Reduction in footprint as many T1 patients will only require remote consultation possibly with a longer gap. There is also the possibility for some patients to move to PIFU.

	Risks	
Technical / compliance	Impacts	
	Risks	
With cognisance of the above impact and risk assessment, please indicate any specific considerations in relation to the impact on / risk to particular groups (note, impacts on patients and staff should be recorded in the table above):		
Other services within NHS Lothian	Acute USC services AE attendances	
Health Board (NHS Lothian)	Positive Reputational impact	
Partner organisations including IJBs	IJB fund Diabetes Care	
Scottish Government	Unachievable without more SG funding on a recurrent basis	
Other (please state)		
Please consider whether the impact / risk profile for any of the impact factors changes over time. Describe why this would happen and the extent of the change:		
Medium-term (2-5 years)	Changing the model of service to support HCL and focus on the developing T2 burden is more acute in this period. Financial modelling is challenging due to the nature of the tech markets	
Long-term (6-10 years)	Impacts on the t1 population in terms of outcomes T1 population medical care changed	

Extended (10+ years)	High reduction in Diabetes complications from t1 Diabetes

Part 3: Impact & Risk Assessment of Options - Summary

Please use this table to summarise the impact / risk of each option compared to baseline (status quo). Indicate whether, for each impact factor, the alternative option(s) increases, decreases, or offers no change from the baseline.

	Performance		Cost		Quality		Patient experience		Equity		Staff experience		Environmental sustainability	
↑↓	Impact	Risk	Impact	Risk	Impact	Risk	Impact	Risk	Impact	Risk	Impact	Risk	Impact	Risk
Option 1 – work within budget	↓	↑	↓	↓	↓	↑	↓	↑	↓	↑	↓	↑	↓	↑
Option 2 – Status Quo	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Option 3 – 50% within five years	↑	↓	↑	↑	↑	↓	↑	↓	↑	↓	↑	↓	↑	↓

Part 4: Specialist & Independent Assessment

This section will be completed by identified independent and specialist experts. It is used to add further information to the impact assessment and to validate the assessment made locally.

Which independent and specialist assessments are required to support decision-making in relation to this choice?

	Assessment required? Please provide a short rationale	Assessment assigned to:
Quality (clinical outcome / risk of harm)		
Performance		
Compliance		
Reputation		

Part 4: Specialist & Independent Assessment

This form should be completed for **each** specialist assessment (quality, performance, compliance, reputation). It should be used to provide any additional information to that collated by the service under the impact and risk assessment. It should also clearly state if it agrees / disagrees with the service's assessment or parts thereof.

Please make clear reference to any relevant documentation, literature or additional evidence to support the assessment.

Which independent and specialist assessments are required to support decision-making in relation to this choice?

This specialist assessment relates:

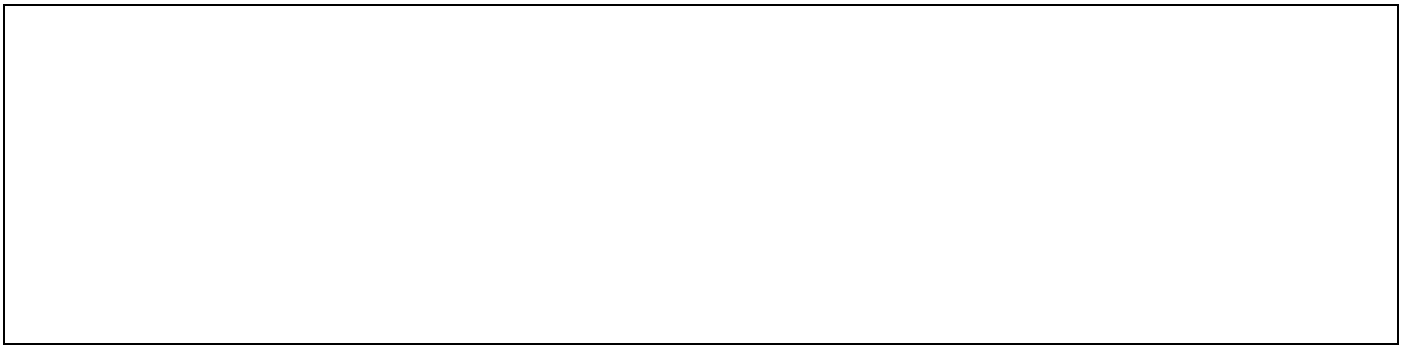
Quality	
Performance	
Compliance	
Reputation	

Please state whether there are any aspects of the service impact and risk assessment that require updating based on the specialist assessment:

Is there any additional evidence that requires to be considered as part of the impact and risk assessment? Please provide details:

On the basis of specialist assessment, do any of the options presented for review become unfeasible within the stated constraints? If so, please describe why:

On the basis of specialist assessment, do any of the options present an intolerable impact or risk to the organisation? If so, please describe why:



Part 5: Decision-Making
This form does not deliver an outcome in terms of the choice (options) presented. It collates the necessary information to inform decision-making. Judgement should be applied to the choice (options) as it is presented; and the decision-making forum should agree the outcome based on the organisation's impact and risk tolerance. The very nature of choices is that someone will be detrimented. The rationale for the decision-making should be clearly captured in the section below, including if further information or specialist input is required.
The preferred option in the choice is:
The rationale for this decision is:

5.

NHS LOTHIAN

Corporate Management Team
16th January 2024

Director of Strategic Planning
Chief Officer, East Lothian IJB

TYPE 1 DIABETES MELLITUS (T1DM)
STRATEGIC DIRECTION, FUTURE SERVICE MODEL & DIABETES TECHNOLOGIES
(WORKING DRAFT FOR PRESENTATION TO SPPC AND NHSL BOARD)

1 Purpose of the Report

1.1 The purpose of this report is to share a working draft of the paper that will be presented to the Strategy, Planning and Perofmrnace Committee (SPPC) in March and subsequently to the NHS Lothian Board in April on the strategic direction and future service model for Type 1 Diabetes Mellitus (T1DM) in Lothian, seeking guidance and input from members of the Corporate Management Team.

Any member wishing additional information should contact the Executive Lead in advance of the meeting.

2 Recommendations

CMT members are recommended to:

2.1 **Note** that much of the strategic context, policy context and benefits of diabetes technologies has been shared with CMT previously and that key points for discussion at the meeting are noted below

2.2 **Review** the current position of T1DM care in Lothian, including current performance in terms of technologies (para 3.30 – 3.33) and the financial position (para 3.41)

2.3 **Review** the options presented (table 8), anticipated impact on performance (table 9) and costs (table 10) and initial thoughts regarding prioritisation (para 3.46)

2.4 **Consider the next steps** in terms of Integrated Impact Assessment and developing this paper further, for SPPC and the Board

2.5 **Consider** NHS Lothian's approach to future non-recurring funding allocations for diabetes technologies (para 3.47)

3 Discussion of Key Issues

Background

3.1 T1DM is an incurable condition often diagnosed in childhood or early adulthood. T1DM affects approximately 8% of people with diabetes in the UK. In T1DM, the body attacks

the cells of the pancreas so that it is unable to make insulin. T1DM cannot currently be prevented.

3.2 Individuals with T1DM are dependent on insulin administered either as multiple daily injections or continuously via an insulin pump. Maintaining a near normal glucose level is extremely important as persistently high glucose levels are associated with a high risk of permanent eye, kidney and nerve damage as well as premature cardiovascular disease. Extreme elevations in blood glucose are associated with an acutely life-threatening state known as diabetic ketoacidosis. However, the ability to achieve near normal glucose is curtailed by the risk of low blood glucose (hypoglycaemia) which, at its most extreme, can result in coma, seizures and death.

3.3 Individuals with T1DM are supported to manage their condition by acute hospital services in Lothian. While adult Diabetes services are operationally managed within our Acute Services structure in Lothian, they are considered to be part of "set-aside" services. This means that the budget of these services is set aside for Integration Joint Boards (IJBs), and decisions about planning around these services and how budgets are deployed sit under the purview of IJBs. The paediatric Diabetes service is not a delegated or set aside service.

3.4 There is a separate budget for diabetes technology (insulin pumps, continuous glucose monitoring systems and associated staffing costs), which is agreed annually with IJBs. The Scottish Government periodically supplements this budget, with ring-fenced money for capital spend on diabetes technologies; the amount of money provided varies substantially from year to year.

3.5 In February 2022, CMT commissioned a multidisciplinary short life working group (SLWG) to review the model of care for T1DM in light of strategic drivers including health inequalities, finance, infrastructure, workforce and the emergence of new technologies.

3.6 The SLWG subsequently agreed a vision for T1DM services. It is anticipated that diabetes technologies would support realisation of this vision:

Figure 1: Vision for T1DM services

- NHS Lothian supports people to **live well** with Type 1 Diabetes
- Our clinical model for Type 1 Diabetes **is focussed on what is important to the individual**, and is designed to support **confident, effective self-management**
- People living with Type 1 Diabetes have **good glycaemic control, fewer people experience complications**, and more people can expect to live **a longer, healthier life** wth diabetes
- People living with Type 1 Diabetes can access **timely and effcive support** when they need it

Policy Context: Diabetes Technologies

3.7 Scottish Health Technologies Group (SHTG) Guidance issued in January 2022[1] recommends that Hybrid Closed Loops (HCL) "*should be available to people with T1DM who, under their current diabetes plan, continue to have suboptimal glycaemic control, a high risk of severe hypoglycaemic or impaired awareness of hypoglycaemia; or experience diabetes-related distress…which is likely to be improved by moving to a closed loop system."*

3.8 The Scottish Government (SG) Diabetes Improvement Plan 2021-26 supports appropriate and timely access to technologies to improve glycaemic control and quality of life for people living with T1DM. Progress is measured in terms of the proportion of people with T1DM with access to Flash Glucose Monitoring (FGM), insulin pump therapy (CSII), Continuous Glucose Monitoring (CGM), CGM during pregnancy and Hybrid Closed Loops (HCL) which link CGM and CSII, with a pending measure of those who are provided with technology within six months of referral. The plan also seeks to measure the proportion of people with T1DM in SIMD1 vs SIMD5 with access to diabetes technologies.

3.9 NICE[2] has published draft guidance which recommends that HCL should be available to people with T1DM who have an HbA1c >58 mmol/mol or disabling hypoglycaemia despite best possible management with at least one of an insulin pump, flash- or continuous glucose monitoring. The draft guidance also recommends that HCL be made available to children, young people and those with T1DM who are pregnant or planning to become pregnant. The draft guidance also reads that 'HCL systems are only recommended if the companies and NHS England agree a cost-effective price for the systems'. While NICE guidance applies only to England and Wales, it carries some influence over Scottish policy.

3.10 Diabetes Scotland have launched a public campaign in the Scottish Parliament in November 2023, entitled "Diabetes Tech Can't Wait". This campaign calls for 70% of people with T1DM to have access to HCL in Scotland by 2030 and aims to highlight disparity in access to technology across different Health Boards.

3.11 The current approach to funding new health technology in Scotland is different to the approach to funding new pharmaceutical medicines. It is SG policy that Health Boards are expected to fund new medicines approved by the Scottish Medicines Consortium. By contrast, there is no similar guarantee that new technologies supported by the SHTG are funded. This creates disparity. For example, GLP-1 agonist therapy for people with Type 2 Diabetes costs approximately £1000 per annum in Scotland. Providing patients meet the licensed ondications for this drug, there is no restriction on the number of people in NHS Lothian with T2 Diabetes who can receive this drug. By contrast, due to financial constraints, the number of people with T1 Diabetes who can access diabetes technologies is capped on an annual basis. GLP-1 agonist therapy is

[1] SHTG, *Closed loop systems and the artificial pancreas for the management of type 1 diabetes*, January 2022
[2] NICE, *Hybrid Closed Loop Systems for Managing Blood Glucose Levels in Type 1 Diabetes*, FINAL DRAFT, November 2023.

beneficial for people with Type 2 Diabetes but is not life-transforming. People with T1DM are being significantly disadvantaged because the therapeutic intervention that could transform their quality of life is a technology and not a medicine.

Strategic Context in Lothian

3.12 As outlined above, strategic planning and commissioning of diabetes services for adults is delegated to Integration Authorities (IJB). For Children and Young People up to their 18th birthday, this responsibility sits with NHS Lothian.

3.13 The Lothian Strategic Development Framework (LSDF), which is owned by NHSL and our four IJBs prioritises the prevention of disease and the use of new technologies in its principles and assumptions. These also note that the system will be resource-constrained, leading to the system needing to carefully consider the choices that it will need to make. The LSDF also explicitly prioritises the development of services for Children and Young People as an investment in prevention.

Benefits of Diabetes Technologies

3.14 Age at onset T1DM is an important determinant of survival, as well as all cardiovascular outcomes, with highest excess risk in women. For those diagnosed youngest, life expectancy is reduced by:17·7 life-years (14·5–20·4) for women / 14·2 life-years (12·1–18·2) for men. Achieving better glycaemic control is essential to reducing this risk.

Improved quality of care

3.15 HbA1c measures average blood glucose levels over the previous 2-3 months. If you have diabetes, an ideal HbA1c level is 48mmol/mol (6.5%) or below, according to Diabetes UK. HbA1c also correlates well to the risk of long-term complications. It is accepted that supporting patients to reduce their Hba1c level and increase their time in range (TIR) translates into improvements in “hard” outcomes over time, including a reduced risk of long-term complications including end-stage kidney disease, diabetic eye disease, lower limb amputation and cardiovascular disease

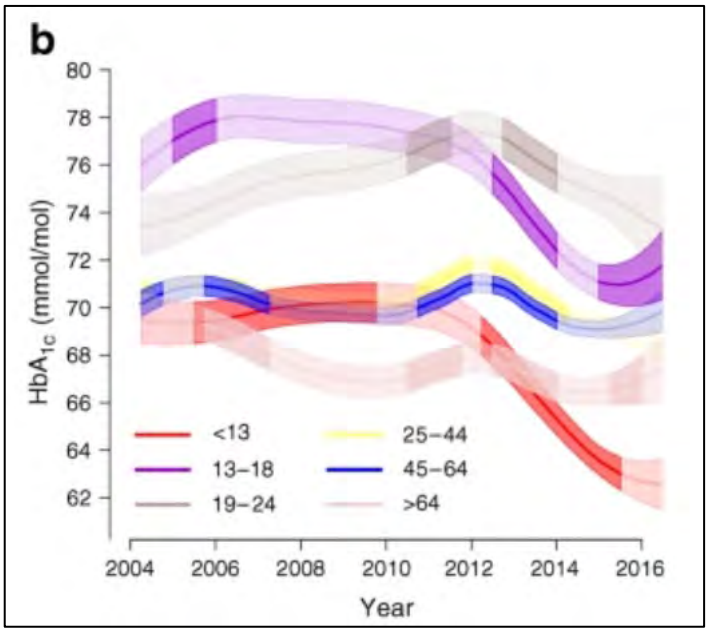
3.16 Research shows that Diabetes technologies including Insulin pumps and CGM, and the DAFNE structured education course all support patients to improve glycaemic control and HbA1c. A recent international comparison paper notes that technologies are associated with lower HbA1c. This was exemplified by the difference in adults meeting HbA1c targets between Scotland (24%) and Norway (41%), where CSII use was 12% and 31%, respectively, at the time of publication. [3]

3.17 A further analysis examining improvements in glycaemic control for those with T1DM in Scotland between 2004 and 2016, identifies a modest but important improvement in HbA1c between 2012 and 2016, most markedly in children and adolescents. The paper concludes that: *These changes coincided with national initiatives to reduce HbA1c including an expansion of pump therapy. However, in most people, overall glycaemic*

[3] International comparison of glycaemic control in people with type 1 diabetes: an update and extension

control remains far from target levels and further improvement is badly needed, particularly in those from more-deprived areas[4]*.* The figure below is taken from the publication and shows estimated HbA1c tragetories and 95% confidence interval for all individuals, stratified by age.

Figure 2: Estimated HbA1c trajectories, stratified by age



3.18 Diabetes technologies can reduce the frequency of mild and severe episodes of hypoglycaemia (thereby improving TIR), which also significantly improves quality of life. HCL has the biggest impact in terms of reduction in HbA1c, and also in improving quality of life. In a 'real-world' study performed by NHS England, the average improvement in HbA1c was 18 mmol/mol. Within NHS Lothian, almost twice as many people currently using HCL are meeting HbA1c targets, compared with those who are not. An audit of 45 patients within NHSL suggests that use of HCL improved time in range (TIR) for the cohort by 21% (from 40% to 61%) over a period of 2-3 months, and that those meeting the Hb1Ac target rose from 26% to 46%.

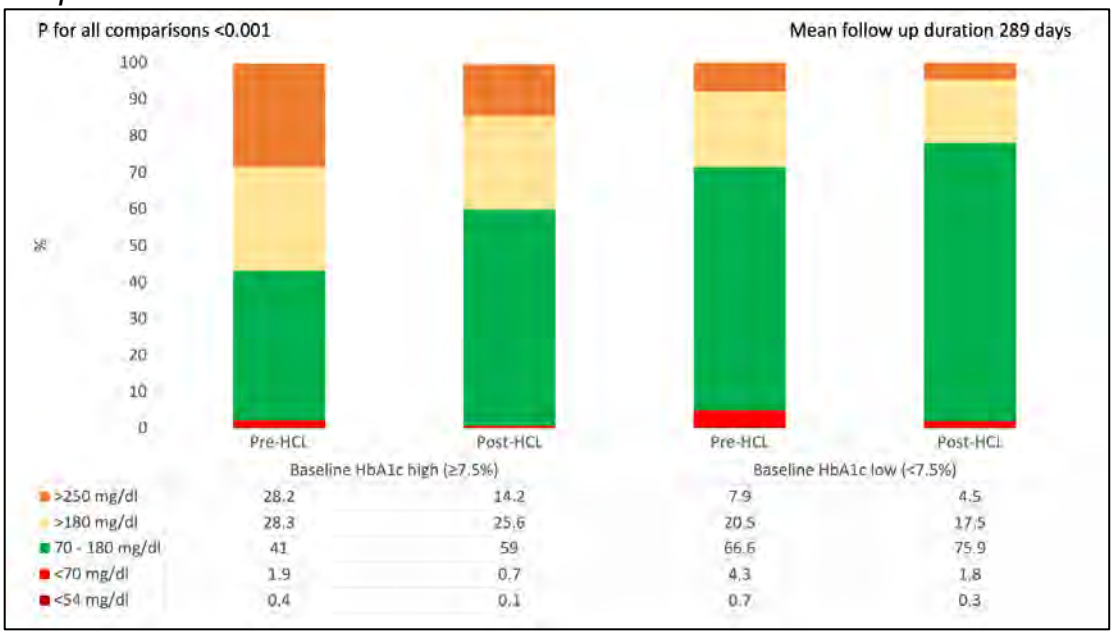
Table 2: Impact of switching from DASH pumps to Omnipod 5 Closed Loop in adults

n = 45	Omnipod DASH	During OP5	P
GMI (mmol/mol)	66 (58 – 72)	58 (58 – 66)	<0.001
Average glucose (mM)	11.3 (9.7 – 12.6)	9.6 (8.6 – 11.0)	<0.001
Time <3.0mM (%)	0.2 (0.6)	0.0 (0.2)	0.015
Time 3.0 – 3.8 mM (%)	1.7 (1.7)	1.0 (1.3)	0.002
Time below range (%)	1.9 (2.2)	1.1 (1.4)	<0.001
Time in range (%)	40 (31 – 57)	61 (48 – 73)	<0.001
Time above range (%)	58 (41 – 67)	38 (25 – 52)	<0.001
Time 10.1 – 13.9 mM (%)	29 (25 – 33)	25 (20 – 32)	0.003
Time >13.9mM (%)	27 (16 – 34)	10 (3 – 21)	<0.001
CV glucose (%)	36.9 (33.8 – 41.9)	31.8 (29.5 – 36.0)	<0.001
Meeting TIR >70% target	11%	31%	0.007

[4] Glycaemic control trends in people with type 1 diabetes in Scotland 2004–2016 | Diabetologia (springer.com)

3.19 In addition, a recent observational study of 254 adults following conversion from CSII to HCL in a secondary care setting saw HbA1c fall by 0.64% (7 mmol/mol) (p <0.001, mean follow up 467 days). For those HbA1c over 58mmol/mol, the fall in HbA1c was 0.91% (10mmol/mol) (p <0.001). The figure below illustrates the results.

Figure 3: Impact of conversion from CSII to HCL



3.20 Within paediatric services, readmission data demonstrates that those utilising with technologies are less likely to be admitted with an episode of Diabetic Ketoacidosis that those continuing with multiple daily injections:

Table 4: Paediatric Readmission Data

Year	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
Known patients in DKA	12	7	13	11	3	10	3
Illness	16	22	22	19	4	10	16
Illness with hypo	1	3	3	2	2	5	1
Hypoglycaemia	7	1	2	0	2	3	0
Hypo Seizure	0	3	2	2	1	2	0
Total Admissions	36	36	42	34	12	28	20

Table 5: Management regimen for known patients in DKA readmitted

Year	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
CSII with HCL	0	0	0	0	0	0	1
CSII without HCL	2	0	3	2	3	1	2
Multiple Daily Injections	10	7	10	8	0	9	0
Total	12	7	13	11	3	10	3

Improved patient experience

3.21 Clearly, the daily regime for management of T1DM places a mental, social, and physical burden on patients. A key attraction of the technologies discussed herein is that they have well-described benefits to mental health and general wellbeing. This is noted in both the SHTG and NICE assessments. Diabetes services in Lothian have received multiple positive testimonials from those who are using closed loop systems,

with many reporting that they have found the technology “life-changing” or “game-changing”, giving then increase confidence, improved quality of life and better sleep: *“With closed loop, my control has remained optimal and I spend a LOT less time thinking about diabetes…The improvement in my quality of life has been significant and should not be underestimated”.* The “Tech Can’t Wait” report from Diabetes Scotland also demonstrates positive impacts as a result of technologies including CSII, CGM and HCL in terms of improved blood sugar management, reduced risk of complications, impact on mental wellbeing and quality of life. This suggests that the more technology we can distribute, the better patient experience is likely to be.

Staff Experience

3.22 The adult Diabetes service experience significant challenges in terms of capacity and demand. Pressures include meeting increasing demand for antenatal care, supporting inpatients with Diabetes, and upskilling the staff caring for them to avoid iatrogenic DKA, managing demand to the telephone helpline and delivering planned return appointments. Work is ongoing to manage these challenges.The service estimates that increasing distribution of diabetes technologies could allow staff time to be diverted to support these areas of pressure.

Environmental Sustainability

3.23 If more people are supported to access diabetes technologies, there will likely be greater opportunity for remote access to monitoring data, online appointments and online support, resulting in a likely reduction in health miles.

Cost effectiveness

3.24 Future savings as a result of investment in diabetes technologies are currently speculative. For example: In 2010/11, the cost of T1DM complications to the NHS in the UK was estimated to be £719m. Extrapolating to the NHSL catchment population gives an annual figure of £9.8m. It is anticipated that increased use of HCL would result in a substantial reduction in diabetes complications and the costs associated with their management in the longer term. It could be anticipated that this would be linked to the proportion of those with T1DM who have access to HCL and the range of improvement in glycaemic control achieved.

3.25 The NICE and SHTG assessments suggest HCL is likely to be cost-effective but requires a reduction in the current cost of technology, which is currently being negotiated by NHS England with technology companies. There is, therefore, not currently a strongly-evidenced financial case for increasing access to these technologies. However NICE concluded that because quality of life is not well captured in cost-effectiveness models, it is almost certainly underestimated and that would particularly be the case in people with tight glycaemic control who often have a high mental burden.

3.26 Clinical and cost effectiveness is likely to be greatest in

- Women with T1DM planning pregnancy and who are pregnant
- in children and young people
- people with HbA1c>75 mmol/mol.

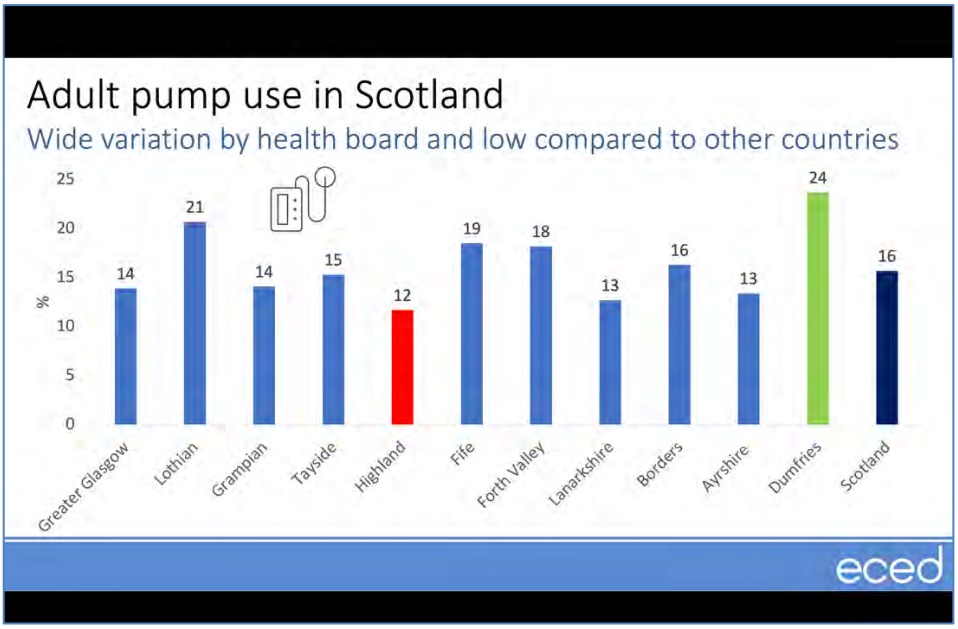
T1DM in Lothian

3.27 In Lothian, approximately 5,623 people live with T1DM, including 5,118 adults and 505 children. There are approximately 56 new diagnoses in children and young people aged 0-16 each year (although 83 children were diagnosed in 2022), and 124 new diagnoses in adults per year on average, based on the last four years. Every year, around 53 young people transition into the adult service. This means we can anticipate around 200 new diagnoses per annum in Lothian.

3.28 Both paediatric and adult diabetes services operate a waiting list for diabetes technologies. In paediatarics, pumps are offered to all those with T1DM three months post-diagnosis at the fifth clinic visit. If the patient wishes to progress they are added to the waiting list, with those aged 17 or over added to the adult waiting list. In adult services, patients who meet the current criteria for access can be added to the waiting list. It is acknowledged that some of those eligible may not have been referred, either due to referral/selection bias or because limited availability of diabetes technologies devalues referral. Some eligible patients will decline referral as they do not wish to use technology, for a variety of reasons.

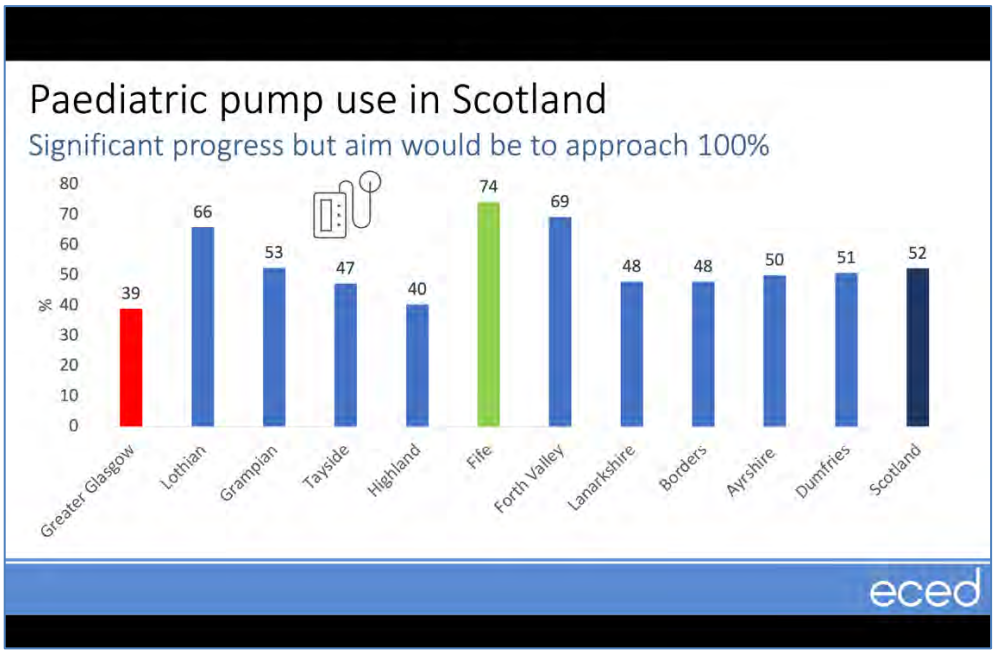
3.29 Approximately 21% of adults with T1DM in Lothian have access to insulin pump therapy, and 66% of children. Our position comparable to other Health Boards within Scotland is shown in the graphs below.

Figure 4: Adult pump use in Scotland



Source: SCI Diabetes, November 2023

Figure 5: Paediatric pump use in Scotland



Source: SCI Diabetes, November 2023

3.30 In terms of CGM, >75% of adults in Lothian have access to Freestyle Libre 2 or Dexcom One CGM, and a further 8% have an interoperable CGM (ie CGM which connects to a pump). This means that over 80% of adults are on some form of CGM. The remaining 17% have opted not to use the technology, or have not attended a clinic since March 2018. Virtually all children with T1DM have access to CGM, prescribed by their GP.

3.31 Levels of HCL provision can be estimated using the proportion of patients on pumps and CGM. There is marked variation in the current level of HCL in Scotland. For adults, NHS Lothian currently has the fourth lowest level of HCL provision in Scotland, with lower levels of provision only in Tayside, Western Isles, and Borders. NHS Forth Valley & Dunfries and Galloway have seen a substantial expansion in HCL provision over the last two years. The table below shows that in these Health Boards there has been a significant increase in the proportion of people with HbA1c <58mmol/mol and a significant decrease in the proportion of people with HbA1c > 75mmol/mol. By contrast, these metrics have seen only a small improvement in NHS Lothian, where HCL expansion has been modest.

Table 6: Current HCL provision in Scotland (estimated)

Health Board	Current HCL Provision	HbA1c <58 2021	HbA1c <58 2023	Change	HbA1c > 75 2021	HbA1c >75 2023	Change
Forth Valley	17.20%	29.0%	33.0%	4.0%	31.7%	27.6%	-4.10%
Dumfries and Galloway	15.00%	27.5%	32.8%	5.3%	28.6%	24.4%	-4.20%
Fife	13.50%	26.3%	33.2%	6.9%	31.5%	28.0%	-3.50%
Lothian	7.40%	32.6%	34.5%	1.9%	24.1%	23.9%	-0.20%
Borders	3.00%	33.0%	30.7%	-2.3%	24.2%	29.6%	5.40%

3.32 It is anticipated that Freestyle Libre 2 CGM will become interoperable with Omnipod 5 and Tandem T:slim pumps in 2024. This interoperability will see the proportion of patients with HCL increase, as all those with compatible pumps transition to HCL. It is difficult to estimate exactly when this might happen for all pump users but it is anticipated that as pumps are replaced with pumps that are interoperable with Libre 2, that people with T1DM will transition to HCL. Further, it is anticipated that Freestyle Libre 3 will become interoperable with Ypso pumps later in the year. It should be noted that Freestyle Libre 3 is not yet available on the Lothian Prescribing Formulary.

Equalities in Lothian

3.33 The Diabetes Scotland "Tech Can't Wait" report highlights the potential for inequality in access to diabetes technologies, noting cases where people have needed to advocate strongly for themselves in order to access technology or have been refused access to technologies because their blood sugars are "too good", or "not good enough" or because their needs are "too complex". Data from our own services suggests that distribution of Hybrid Closed Loop and loopable pumps to those living in the most deprived areas is less than expected in Lothian, and that people living in deprived areas have less access to technology to support them in diabetes management. Data also shows that men represent 54.9% of the adult population with T1DM and 67.6% of all current HCL users. This suggests that women have less access to technologies to support them to manage their diabetes. Interestingly, recent survey work suggests that neither SIMD quintile or sex had any impact on interest in using HCL in Lothian.

3.34 While increasing distribution of diabetes technologies in line with the current waiting list will improve existing inequalities to some extent, inequality of access will likely continue. Those with the highest HbA1c stand to benefit the most from technology with respect to HbA1c lowering, and therefore reduction in complications. People from the most deprived quintiles 1 and 2 in Lothian currently account for 32% of the population but represent 46% of all patients with HbA1c over 75mmol who do yet not have access to a pump.

3.35 79.7% of all adults from the most deprived quintile do not yet have any technology and are not on the waiting list, compared to 62.2% of all adults from the least deprived quintile who do not yet have any technology and are not on the waiting list.
This inequality will continue if the current waiting list is used to allocate pumps over the next 5 years.

Technology costs in Lothian

3.36 The majority of patients with T1DM in Lothian are offered Freestyle Libre 2 CGM. Freestyle Libre 2 is prescribed within primary care, and can also be prescribed for patients with T2DM . The rolling twelve-month spend on Freestyle Libre 2 to June 2023 was £4.6m. Freestyle Libre 2 was prescribed to a total of 6,211 patients, so the assumed cost per patient is approximately £749. It should be noted that an increasing number of patients with Type 2 Diabetes are prescribed Freestyle Libre 2.

3.37 As noted above, it is anticipated that Freestyle Libre 2 will become compatible with Omnipod and Tandem T:slim pumps within 2024, and so it is likely that few patients will require alternative CGM, funded from the diabetes technologies budget. The exception may be pregnany women, as there is published evidence recommending the use of Dexcom CGM during pregnancy. The number is likely to be small, as some women already using Freeestyle Libre 2 may prefer to continue with their existing device.

3.38 Diabetes services in NHS Lothian have taken proactive steps to move away from the most expensive HCL systems in favour of lower cost alternatives, to ensure that available funding can be utilised to delivery therapy to the greatest number of people with T1DM. The annual cost of delivering HCL to an individual will drop significantly as we seek to move away from Medtronic pumps with Guardian CGM to Omnipod and T:Slim, as shown in the table below.

Table 7: Cost per patient of HCL options:

				Consumable Cost		
Pump	Compatible CGM	Initial Kit Cost	Annual Cost	Diabetes Technology Budget	Prescribing Budget	Total Cost
Medtronic	Guardian	£,3240	£810	£4,548	£0	£5,358
Tandem T:slim	Libre 2 (Anticipated)	£3,300	£825	£1,720	£749	£3,294
Omnipod	Libre 2	£0	£0	£3,353	£749	£4,102
YPSO	Libre 3*	£2,340	£585	£1,714	TBC	TBC

**It should be noted that Libre 3 CGM has not yet been approved to the East Region Prescribing Formulary. As such, it is not yet clear where these costs would sit.*

3.39 Diabetes services are also committed to reviewing potential cost savings through bio-similar insulin use, through the MCN Prescribing sub-group.

3.40 During 2023/24, the budget available for diabetes technologies totalled £5.4m. However, the recurring budget available is actually only £2.8m. The projected year-end position for technologies across adults and paediatrics is an overspend position of £1.35m.

<u>Options for Diabetes Technologies</u>

3.41 In autumn 2023, the T1DM short life working group outlined three options for diabetes technology in Lothian going forward using the Difficult Choices framework, which requires consideration of policy context, strategic context, performance, cost, quality, patient experience, equity, staff experience and environmental sustainability.

3.42 Initially, the group included as Option 1 “Working within current budgets to deliver Diabetes technologies. However, this option was subsequently ruled out, as it would require both cessation of insulin pump distribution, and withdrawal of Diabetes technologies/reversion to Multiple Daily Injections of Insulin (MDI) for a significant number of patients. This was not felt to be a viable option.

3.43 A revised Option 1, which seeks to maintain all existing patients on technologies but curtail any further distribution of technologies, is included here as the status quo.

Table 8: Options for diabetes technologies in Lothian

Option 1 (Revised)	Maintain all existing patients on technologies but curtail any further distribution (Status Quo)	• Replacement pumps & consumables will continue to be provided to all those currently using diabetes tech • No new diabetes technology will be provided • CGM (beyond Freestyle Libre 2) for pregnant women will be limited to 12 months – currently 45 per annum *NB It should be noted that this option assumes that the total number of devices for T1DM will remain steady. It should be noted that some people with T1DM may move into or out of the area and we assume that this number will balance out.*
Option 2a	Continue at current levels of technology distribution	• Total Lothian tech distribution = 226 devices • Continue to distribute 56 pumps per annum within children's servies. • Continue to distribute circa 12 CGM per annum to pregnant women. • Remaining devices to be distributed to adult WL • Continue with all replacements, as they become due • All new and replacement pumps will be Omnipod 5, Tandem T:Slim or Ypso
Option 2b	Slightly increase levels of technology distribution, with the aim of clearing the backlog of children waiting, and increasing distribution to adults within existing staffing.	• Total Lothian tech distribution = 288 devices per annum • 88 devices per annum to be distributed within children's services, with a view to clearing the waiting list by year 4 • Continue to distribute circa 12 CGM per annum to pregnan women • Remaining devices to be distributed to adult WL • Continue with all replacements as they become due • All new and replacement pumps will be Omnipod 5, Tandem T:Slim or Ypso
Option 3	Increasing technologies distribution to achieve 50% of adults and 100% of children living with T1DM have access to a Hybrid Closed Loop within five years	• Total Lothian tech distribution = 376 devices per annum • 76 devices per annum to be distributed within children's services, with a view to clearing the waiting list • 300 pumps to be distributed to adult WL • Continue with all replacements as they become due • All new and replacement pumps will be Omnipod 5, Tandem T:Slim or Ypso

3.44 The impact of the each option, in terms of cost and performance, are set out in the tables below. Performance figures have been estimated, using the following assumptions:

- 56 new diagnoses per annum within children's services
- 53 transitions per annum, at the overall rate of pump use within paediatrics
- Number of adults living with T1DM remains steady at 5118 – transitions + new diagnoses = deaths
- Deaths are at the overall rate of pump use within adult services

Table 9: Estimated impact of options in terms of performance

Option 1

	Year									
	One		Two		Three		Four		Five	
	Adults	Paeds	Adults	Paeds	Adults	Paeds	Adults	Paeds	Adults	Paeds
Proportion of those with T1DM with access to CSII	21.4%	58.7%	21.3%	52.3%	21%	46.5%	20.9%	41.4%	20.6%	36.9%
Proportion of those with T1DM with access to CGM	83%	100%	83%	100%	83%	100%	83%	100%	83%	100%
Proportion of those with T1DM with access to HCL									20.6%	36.9%
Provided with tech within six months of referral	0	0	0	0	0	0	0	0	0	0
Proportion in SIMD1 vs SIMD5 with access to tech										

Option 2a

	Year									
	One		Two		Three		Four		Five	
	Adults	Paeds	Adults	Paeds	Adults	Paeds	Adults	Paeds	Adults	Paeds
Proportion of those with T1DM with access to CSII	24.5%	66%	27.3%	66%	30.1%	66%	32.8%	66%	35.4%	66%
Proportion of those with T1DM with access to CGM	83%	100%	83%	100%	83%	100%	83%	100%	83%	100%
Proportion of those with T1DM with access to HCL									35.4%	66%
Provided with tech within six months of referral										
Proportion in SIMD1 vs SIMD5 with access to tech										

Option 2b

	Year									
	One		*Two*		*Three*		*Four*		*Five*	
	Adults	*Paeds*	*Adults*	*Paeds*	*Adults*	*Paeds*	*Adults*	*Paeds*	*Adults*	*Paeds*
Proportion of those with T1DM with access to CSII	*25.1%*	*76%*	*28.7%*	*85%*	*32.3%*	*93%*	*35.8%*	*100%*	*39.8%*	*100%*
Proportion of those with T1DM with access to CGM	*83%*	*100%*	*83%*	*100%*	*83%*	*100%*	*83%*	*100%*	*83%*	*100%*
Proportion of those with T1DM with access to HCL									*39.8%*	*100%*
Provided with tech within six months of referral								*100%*		*100%*
Proportion in SIMD1 vs SIMD5 with access to tech										

Option 3

	Year									
	One		*Two*		*Three*		*Four*		*Five*	
	Adults	*Paeds*	*Adults*	*Paeds*	*Adults*	*Paeds*	*Adults*	*Paeds*	*Adults*	*Paeds*
Proportion of those with T1DM with access to CSII	*27.1%*	*76%*	*32.6%*	*85%*	*38.1%*	*93%*	*41.4%*	*100%*	*47.7%*	*100%*
Proportion of those with T1DM with access to CGM	*83%*	*100%*	*83%*	*100%*	*83%*	*100%*	*83%*	*100%*	*83%*	*100%*
Proportion of those with T1DM with access to HCL									*54%*	*100%*
Provided with tech within six months of referral								*100%*		*100%*
Proportion in SIMD1 vs SIMD5 with access to tech										

Table 10: Impact of options in terms of cost

	Year									
	One*		Two		Three		Four		Five	
	Adults	Paeds	Adults	Paeds	Adults	Paeds	Adults	Paeds	Adults	Paeds
	£m	**£m**	**£m**	**£m**	**£m**	**£m**	**£m**	**£m**	**£m**	**£m**
Option 1 Estimated Costs	£3.777	£1.580	£4.186	£1.465	£4.182	£1.308	£4.106	£1.296	tbc	tbc
Option 1 Projected Variance against Budget	-£2.285	-£0.262	-£2.695	-£0.147	-£2.691	£0.010	-£2.615	£0.022	tbc	tbc
Option 2a Estimated Costs	£4.219	£1.795	£5.070	£1.605	£5.508	£1.406	£5.874	£1.426	tbc	tbc
Option 2a Projected Variance against Budget	-£2.727	-£0.477	-£3.579	-£0.287	-£4.017	-£0.088	-£4.382	-£0.108	tbc	tbc
Option 2b Estimated Costs	tbc	tbc	tbc	tbc	tbc	tbc	tbc	tbc	tbc	tbc
Option 2b Projected Variance against Budget	tbc	tbc	tbc	tbc	tbc	tbc	tbc	tbc	tbc	tbc
Option 3 Estimated Costs	£4.499	£1.847	£5.765	£1.777	£6.619	£1.627	£7.400	£1.594	tbc	tbc
Option 3 Projected Variance against Budget	-£3.007	-£0.529	-£4.274	-£0.459	-£5.127	-£0.309	-£5.909	-£0.276	tbc	tbc

**please note year 1 is financial year 2024/25*

	Year					
Overal Projected Overspend against Budget	*One**	*Two*	*Three*	*Four*	*Five*	
	£m	***£m***	***£m***	***£m***	***£m***	
Option 1	*-£2.548*	*-£2.842*	*-£2.681*	*-£2.593*	*tbc*	*tbc*
Option 2a	*-£3.205*	*-£3.865*	*-£4.105*	*-£4.491*	*tbc*	*tbc*
Option 2b					*tbc*	*tbc*
Option 3	*-£3.536*	*-£4.733*	*-£5.436*	*-£6.184*	*tbc*	*tbc*

3.45 It is noted that, given current financial constraints, it is unlikely to be affordable to pursue Option 3. In the interests of pragmatism, consideration has been given below to the choices that could be made within Option 2 to address current inequalities and maximise the benefits of technologies across the whole system. Within the adult service, it has been suggested that a proportion of available pumps (circa 40%) be reserved for those with high HbA1c, consistently over 70mmol/mol, a small number to be reserved for pregnancy planning and remaining tech to be distributed to the routine waiting list. It is anticipated that this would lead to a more balanced distribution of technologies across the SIMD quintiles, although the extent is not yet fully understood. Option 2B includes an additional complement of technologies to clear the waiting list backlog within paediatrics by Year 4, with a view to being able to offer technologies to all those aged 0-16 within six months of diagnosis, within five years.

Future non-recurring funding allocations

3.46 It should be noted that it is possible that NHS Lothian will receive further non-recurring funding allocations for diabetes technologies from SG in future. Consideration should be given to how these allocations might best be utilised, given that funding is usually provided for the initial cost of a pump plus one year's consumables. If additional technologies were purchased, a recurrent source of funding would need to be identified.

4 Key Risks

4.1 The key risks associated with this paper have been explored within the discussion, and pertain to quality of care, patient experience, equalities, staff experience, finance and environmental sustainability.

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5 Risk Register

5.1 The most significant impact on the risk register would relate to the risk to financial balance. NHSL currently has a more than £100m structural deficit which it manages year-to-year, and is projecting a deficit at the end of the 23-24 financial year. The current overspend on the technology budget is included in this paper, and the position is likely to decline.

5.2 SHTG and NICE guidance suggest that there is the potential for wider adoption of technologies to lead to cost avoidance with a reduction in complications for individuals. However, there is also a noted challenge with the cost of technologies, and a need for a national agreement on the cost of these technologies.

5.3 The service has been clear that no resource could be reallocated from within its current operations, so this would not be a source of mitigation.

6 Impact on Inequality, Including Health Inequalities

6.1 As outlined previously, there are significant inequalities in access to diabetes technology currently, and in outcomes. It is anticipated that an Inequalities Impact Assessment would be beneficial, to determine the best way forward within the preferred option, prior to SPPC.

7 Duty to Inform, Engage and Consult People who use our Services

7.1 The Short Life Workiing Group includes representation from the patient organisation Diabetes Scotland, and from patient representatives in order to engage with those living with T1DM in developing the new clinical model and implementation plan.

7.2 Diabetes Scotland gathers feedback from people with experience of using closed loop systems and those seeking access to the technology on a regular basis and collate and share the results of that work.

7.3 Both the adult and paediatric service have undertaken surveys, and gathered feedback from their patient populations which has been used to support the development of the options outlined.

7.4 Moving forward, the challenges are significant. Clear communication about the challenges we face is likely to be required.

8 Resource Implications

8.1 The resource implications associated with implementing future diabetes technology options are outlined in this paper.

8.2 These future resource implications should be seen in the context of the current NHS Lothian financial plan projections for 2024/25, which following the Scottish Goverment budget announcement in December 2023 projects a signicfcnat and unprecedented financial gap for NHS Lothian and IJB partners.

Rebecca Miller
Head of Strategy Development
12th January 2024
rebecca.miller@nhslothian.scot.nhs.uk

Contributors:

Louise Bath
Shona Binning
Julie Bladen
Colin Briggs
Claire Flanagan
Fraser Gibb
Lois Marshall
Mike Porteous
Stuart Ritchie
Mark Strachan

Appendix 1 – Glossary of terms

These definitions have been informed by the website of Diabetes Scotland.

CGM	**Continuous Glucose Monitoring** Continuous glucose monitors let you check your sugar levels without having to prick your fingers. You wear a small sensor on your body day and night that reads your sugar levels so you can see the information on your mobile, or other device. A Continuous Glucose Monitor transmits those readings via Bluetooth to a device or a mobile phone. Continuous Glucose Monitors can "talk" to an insulin pump, to become a hybrid closed loop.
CSII	**Continuous Subcutaneous Insulin Infusion** or insulin pump therapy. An insulin pump is a small electronic device that releases the regular insulin your body needs through the day and night — so you don't need to do insulin injections. An insulin pump can either be "tethered" or a "patch pump". **Tethered pumps** attach to your body and a small tube connects to your cannula. A **patch pump** sits directly on your skin and works by using a remote.
FGM	**Flash Glucose Monitoring** Flash glucose monitors let you check your sugar levels without you having to prick your fingers. You wear a small sensor on your body day and night that reads your sugar levels so you can see the information on your mobile, or other device. Readings are only given when you wave or scan your device over the sensor.
Freestyle Libre 2	**Freestyle Libre 2** is a type of glucose monitor. It originally provided flash glucose monitoring. A software upgrade earlier in 2023 means that Freestyle Libre 2 can now be used as a Continuous Glucose Monitor, with glucose levels transmitted by Bluetooth.
HCL	**Hybrid Closed Loop System** A closed loop system consists of a continuous glucose monitor and an insulin pump that talk to each other, via a computer programme on a smartphone or within the insulin pump. Hybrid Closed Loops are systems that are regulated and available to buy.
Omnipod 5	**Omnipod 5** is a type of "path" insulin pump. It can be integrated with a Dexcom 6 Continuous Glucose Monitor to become a hybrid closed loop.

	It is anticipated that the Omnipod 5 will also be become “loopable” with Freestyle Libre 2 early in 2024.

SBAR – Technology support for patients with Type 1 Diabetes Mellitus

NHS Lothian Executive Leadership Team, 6th February 2024

Situation

Type 1 diabetes mellitus (T1DM) is an incurable congenital condition affecting the control of blood sugar. Technological support has advanced significantly over the last 15 years and can now significantly improve Hb1AC control while simultaneously lessening the psychological burden on patients and families.

A working group has been examining the case for expansion of access to this technology and has formulated multiple options. The conclusion to this work has coincided with the Scottish Budget of 19th December 2023 and the impact on the NHSL budget, which has led to a default position of not making any further investment in this technology as it is unaffordable.

Background

There are approximately 5600 people in the Lothians with a diagnosis of T1DM. Approximately 500 of these are under the age of 16, with a further 510 between their 16th and 24th birthdays.

Technology to support patients with T1DM broadly falls into two parts – a "pump" which can automatically alter the input of insulin for a patient, depending on blood sugar readings, and a glucose monitor which takes those readings. A flash glucose monitor (FGM) takes readings at intervals, while a continuous glucose monitor (CGM) takes these 24/7. Both send information to either a smart device like a phone or to the pump itself.

Currently, about 67% of children with T1DM have a pump, with roughly 21% of all adults having one. Approximately 41% of young adults have a pump. Advances in technology mean that almost all patients with T1DM either have a CGM or will have one by the end of the 2024 calendar year.

The planning and commissioning of services for children with T1DM sits with NHS Lothian. For adults, it sits with the four Integration Authorities (IJBs)

A working group co-chaired by the Director of Strategic Planning and the Chief Officer of East Lothian IJB has been building an evidence base, examining options to maximise resources, and forecasting resource requirements. The output from this work has been discussed at Strategic CMT twice (October 2023 and January 2024). A range of options from "maintain status quo" to "major expansion over 5 years" have been modelled but all have been unaffordable, given the relatively small budget for these technologies and the consumables for them. NHSL has benefitted from both internal investment (dating from 2010) and Scottish Government investment, but the latter has tended to focus on pumps and not on the consumables to support them.

The evidence base for these technologies is a solid one, with both the Scottish Health Technologies Group (SHTG) and, in England, the Institute for Health and Care Excellence (NICE) recommending these as an appropriate treatment tool.

Both, however, note that the evidence base is at least in part based on the long-term preventative effects and the reduction in psychological burden. They both note that there is a less strong evidence base for adults, and that the preference would be to ensure that children and young people, and women with T1DM who are either pregnant or trying to become so, should be given pumps whenever possible.

The combined T1DM technologies budget is projected to be overspent by c. £2.6m in 2023-24, and c. £2.8m in 2024-25.

There are significant waiting lists in both the adult and children's services, with approximately 150 pumps per year having previously been made available for adults and 50 for children.

NHSL needs to save £133m in the 2024-25 financial year.

Assessment

The evidence for distribution is strongest for children and young people (and pregnant women), so logically that would be the most appropriate place to start any further expansion. Over time, these children obviously graduate into an "adult cohort" but should present fewer costs to the health system with fewer complications.

The *Lothian Strategic Development Framework* prioritises both "new, innovative technologies, such as insulin pumps" and states that "investment in Children's Services is the ultimate in prevention", and these combined provide a policy direction reinforcement for the evidential basis.

CMT has identified its support for this technology but has noted that it does not have the financial resources to continue to rapidly expand the number of patients with pumps.

There are further technological advances which make the costs of consumables, in particular, likely to reduce over the next 3-5 years, which may provide opportunities to utilise resources differently.

There are approximately 100 children on the waiting list for pumps and there is clear evidence that NHSL's investment has delivered improvement in control and avoiding complications. 100 new pumps in each of the next two years is projected to meet all new diagnoses and all but eradicate the waiting list.

Should NHSL wish to make inroads in the 16-24 cohort it could seek to fund a further 25 pumps per annum specifically for this cohort.

Recommendation

NHSL should adopt a refashioned programme for T1DM technology which, for the next two years, seeks to prioritise children and young people before their 25th birthday, and pregnant women. This would seek to significantly reduce the waiting list and establish a stable level of provision for children, matching the reasonably steady number of diagnoses per annum. This time period would also see reductions in costs associated with consumables.

Approximately 100 pumps per annum for the 2024-25 and 2025-26 financial years would cost c. £195k in 24-25 and £280k in 2025-26. Should NHSL wish to increase the distribution to young people in the 16-24 cohort it could consider funding an additional 25 pumps per annum. This would be estimated to cost an additional £50k in 24-25 and c. £75k in 2025-26. This programme would require the paediatric and adult services to work together as no further staffing resource could be funded.

The target for the rate of provision for children would be 90% by the close of the 2025-26 financial year, with a growth to c. 50% in the young adult cohort if the second option were selected.

This position would be reviewed no later than September 2025 in order to consider where resources could be best deployed in subsequent years.

Colin Briggs, Director of Strategic Planning, 2nd February 2024

NHS LOTHIAN

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Strategy Planning and Performance Committee
20th March 2024

Director of Strategic Planning
Chief Officer, East Lothian Integration Joint Board

TECHNOLOGY SUPPORT FOR PATIENTS WITH TYPE 1 DIABETES MELLITUS

1 Purpose of the Report

1.1 The purpose of this report is to recommend that the committee notes the position regarding T1DM technologies and supports the proposed way forward over the next two years.

1.2 Any member wishing additional information should contact the Executive Lead in advance of the meeting.

2 Recommendations

2.1 Note the current position regarding T1DM technologies in Lothian (Para 3.1-3.12)

2.2 Support the proposal to provide 100 additional insulin pumps per annum in 2024/25 and 2025/26

2.3 Agree that adult and paediatric services should work together to agree appropriate distribution of the 100 pumps per year (Para 3.26)

2.4 Note and accept the risks associated with this proposal

3 Discussion of Key Issues

Background

3.1 Type 1 Diabetes Mellitus (T1DM) is an incurable condition affecting the control of blood sugar often diagnosed in childhood or early adulthood. In T1DM, the body attacks the cells of the pancreas so that it is unable to make insulin. T1DM cannot currently be prevented.

3.2 Individuals with T1DM are dependent on insulin administered either as multiple daily injections or continuously via an insulin pump. Maintaining a near normal glucose level is extremely important to prevent complications including eye, kidney and nerve damage.

3.3 Technology to support patients with T1DM broadly falls into two parts – an insulin "pump" which alter the rate of input of insulin for a patient, depending on blood sugar readings, and a glucose monitor which takes those readings. A flash glucose monitor (FGM) takes readings at intervals, while a continuous glucose monitor (CGM) takes these 24/7. Increasingly, where the CGM and insulin pump are interoperable, the two pieces of technology can be linked to create a Closed Loop, such that the insulin pump automatically amends the rate of insulin input according to the readings taken by the CGM.

T1DM in Lothian

3.4 The planning and commissioning of services for children with T1DM sits with NHS Lothian. For adults, it sits with the four Integration Authorities (IJBs).

3.5 In Lothian, approximately 5,600 people live with T1DM. Approximately 500 of these are under the age of 16, with a further 510 between their 16th and 24th birthdays.

Evidence base for T1DM technologies

3.6 The evidence base for diabetes technologies including closed loop systems is a solid one, with both the Scottish Health Technologies Group (SHTG) and, in England, the Institute for Health and Care Excellence (NICE) recommending these as an appropriate treatment tool.

3.7 Both, however, note that the evidence base is at least in part based on the long-term preventative effects and the reduction in psychological burden. They both note that there is a less strong evidence base for adults, and that the preference would be to ensure that children and young people, and women with T1DM who are either pregnant or trying to become so, should be given pumps whenever possible.

3.8 The Lothian Strategic Development Framework prioritises both “new, innovative technologies, such as insulin pumps” and states that “investment in Children’s Services is the ultimate in prevention”, and these combined provide a policy direction reinforcement for the evidential basis.

T1DM Technologies in Lothian

3.9 Currently, about 67% of children with T1DM have a pump, with roughly 21% of all adults having one. Approximately 41% of young adults have a pump. Advances in technology mean that almost all patients with T1DM either have a CGM or will have one by the end of the 2024 calendar year, including over 80% of adults and virtually all children.

3.10 There are approximately 100 children on the waiting list for pumps and there is clear evidence that NHSL’s investment has delivered improvement in control and avoiding complications. Within paediatric services, readmission data demonstrates that those utilising with technologies are less likely to be admitted with an episode of Diabetic Ketoacidosis that those continuing with multiple daily injections.

3.11 A working group co-chaired by the Director of Strategic Planning and the Chief Officer of East Lothian IJB has been building an evidence base, examining options to maximise resources, and forecasting resource requirements. The output from this work has been discussed twice at Strategic CMT. A range of options from “maintain status quo” to “major expansion over 5 years” have been modelled. CMT has identified its support for this technology but has noted that it does not have the financial resources to continue to rapidly expand the number of patients with pumps. To date, NHSL has benefitted from both internal investment (dating from 2010) and Scottish Government investment, although the latter has tended to focus on pumps and not on the consumables to support them. There are further technological advances which make the costs of consumables, in particular, likely to reduce over the next 3-5 years, which may provide opportunities to utilise resources differently.

3.12 In February 2024, following consideration of the attached SBAR (Appendix I) ELT agreed that 100 new insulin pumps per year would be provided targeted at children and pregnant women. It was expected that this would lead us to have no waiting list for children and over 90% of children having a pump by 31st March 2026.

Equalities and Children's Rights Impact Assessment

3.13 An ECRIA was carried out on February 21st and February 28th 2024, in line with our legal responsibilities under Equality and Fairer Scotland duties and to consider whether the proposal could have an impact on children's rights. For the purposes of the ECRIA, it was assumed that of the 100 pumps, 90 would be allocated to children aged under 16, and ten would be reserved for pregnant people with T1DM.

3.14 The ECRIA did not identify any unlawful discrimination but did note some disadvantages that groups of people might experience. During the process of the ECRIA, additional information also came to light.

Pregnancy

3.15 There is a strong evidence base for utilising diabetes technologies during pregnancy. At the last review, there were approximately 30 pregnancies per annum in people with T1DM in Lothian. Historically, people failing to meet pregnancy HbA1c targets (<48mmol/mol) despite intervention including intensive education and preconception planning were offered an insulin pump. It is not known how many people per year this equates to but it has been noted that 22% of patients were using insulin pumps during pregnancy.

3.16 When Hybrid Closed Loop (HCL) became available recently, this option was extended to those with HbA1c above 75mmol/mol as a priority (numbering approximately 10 per annum), with existing pump criteria honoured for those not meeting pregnancy HbA1c targets.

3.17 The ECRIA specifically considered offering technologies only to those pregnant women/women planning a pregnancy with HbA1c over 75mmol/mol. This would reduce the disadvantages experienced by those who are pregnant with very high HbA1c. It is anticipated that this could reduce ICU admissions and support those who are breastfeeding and/or acting as the primary caregiver to younger children. It was noted that those with HbA1c 48-74mmol/mol will be disadvantaged.

3.18 It has since been noted that, in the studies that showed a clear evidence-based benefit of diabetes technologies in pregnancy, the mean HbA1c was 60mmol/mol in early pregnancy. It is likely that a significant cohort of women and babies could benefit if we were able to extend diabetes technologies to a larger group.

3.19 The ten pregnant people with HbA1c over 75mmol/mol may require both an insulin pump and a specific Continuous Glucose Monitor (CGM) recommended for use during pregnancy (a total of up to 20 items of diabetes technology) unless they choose to maintain their existing Libre 2 CGM. Most adults already have Libre 2 CGM, which it is anticipated will be able to link with some insulin pumps to provide a HCL during 2024.

Children under 2 years of age

3.20 Following the ECRIA, it has been noted that children with T1DM under 2 years old would require a specific CGM, as Libre 2 is not licensed for under 2s. The number of children under 2 diagnosed with T1DM has been one or none in each of the last three years, although 6 children under 2 were diagnosed in 2020. It is anticipated that the 100 items of diabetes technology available per annum will need to include CGM for these children.

Children/Young People aged 16 and 17

3.21 At present, those diagnosed with T1DM at age 16 or 17 who wish to use an insulin pump are added to the adult diabetes technology waiting list. This is due to the current length of the paediatric waiting list, as these people would likely transition to the adult service before they reached the top of the paediatric waiting list. Pump starts for those aged 16 and 17, however, are usually managed within paediatrics.

3.22 Prioritising those aged under 16 would have a positive impact on those diagnosed youngest and reduce the disadvantages experienced by these people. During the ECRIA, it was noted that the rights of those children aged 15,16 and 17 could be limited by the proposal to prioritise those aged under 16 and on the paediatric waiting list, and it was proposed that consideration be given to prioritising those aged 16 and 17 for a pump.

3.23 It has since been noted that operating a hybrid transition service for those aged 14 to 18, whereby those aged under 16 can be offered a pump, and those aged 16 and 17 cannot, would be challenging.

3.24 There are currently 102 people on the paediatric technology waiting list, and 12 people aged between 16 and 17.99 on the adult technology waiting list. There are approximately 56 diagnoses per annum of people aged under 16, and a further three young people aged 16 or 17. Prioritising these young people would increase the time it would take to establish a stable position within the paediatric service.

Adults with T1DM at risk of death due to severe hypoglycaemia

3.25 It has been noted that there are a number of adults with Type 1 Diabetes each year who are identified as at severe risk of death due to hypoglycaemia. To date, these adults would be prioritised for technology, and number approximately 10-20 per annum. This was discussed during the ECRIA, and it was recommended that 10-20 devices per annum be prioritised for this group.

Summary of impact on distribution

3.26 Each of the issues discussed above could impact how the agreed 100 insulin pumps per annum are distributed. In some cases, some of the insulin pumps may need to be converted to specific CGM. This was discussed at Strategic CMT on 12th March, and it was recommended that adult and paediatric service leadership teams work together to determine how the available resource can best be utilised, with their decision informed by the LSDF, the parameters of the available budget and the outputs of the ECRIA.

Potential external investment

3.27 Periodically, NHS Lothian receives offers of additional technology or investment from industry partners and/or from Scottish Government. Given the long revenue tail associated with any additional investment in diabetes technologies, consideration should be given as to whether these offers could be used to offset the cost of planned new technology starts or for replacement kit.

3.28 It is understood that colleagues within the Scottish Government Clinical Priorities team are seeking additional investment in diabetes technology nationally, with a view to supporting sustainable investment in increased technologies.

4 Key Risks

4.1 This proposal will have a significant impact on the waiting time for diabetes technologies for adults. There are currently almost 800 adults on the technology waiting list and this number is expected to increase. Technology waiting times for adults can be anticipated to extend beyond 10 years.

4.2 Following final agreement regarding the distribution of diabetes technologies, the proposal will need to be communicated sensitively, particularly to those currently on the adult waiting list for technologies as well as to members of the Managed Clinical Network (MCN), staff members and the wider diabetes community. A draft communication has been developed by the adult diabetes team and will be shared with the Communications team for advice and input.

4.3 Various evidence, including testimonials from those using closed loop systems in Lothian and the positive impacts of technologies recorded in the Diabetes Scotland “Tech Can’t Wait” report, demonstrate that the more technology we can distribute, the better patient experience is likely to be. Those waiting for technologies may require additional support. The adult diabetes services is giving consideration to how staff time released as a result of reduced adult pump starts might be utilised in future.

4.4 The proposal will increase the overspend within the T1DM technologies budget. This will need to be mitigated elsewhere to support overall achievement of financial balance across NHS Lothian.

5 Risk Register

5.1 There is a risk to financial balance as the combined T1DM technologies budget is projected to be overspent by c. £2.6m in 2023-24, and the proposal requires additional investment of c. £195k in 24-25 and £280k in 2025-26.

6 Impact on Inequality, Including Health Inequalities

6.1 As discussed, an impact assessment was carried out on 21st and 28th February 2024. This paper is primarily concerned with the main findings of the impact assessment and potential changes to the distribution of the proposed 100 insulin pumps per annum. A copy of the impact assessment report is attached at Appendix II.

6.2 It is not possible to address existing inequalities in the distribution of diabetes technologies.

6.3 The impact assessment identified a number of other actions that could be taken, to mitigate the potential negative impacts of the proposal:

- Identify care experienced people with T1DM and put in place appropriate support.
- Take mitigating actions to support those experiencing socio-economic disadvantage.
- Explore how we can best utilise staff resources, to better support those currently using technologies to optimise HbA1c, focussing on equalities groups that face the most barriers.
- Explore potential to develop the adult diabetes service team and redesign the service to better meet the needs of all those living with T1DM.
- Review attendance at structured education sessions, identify barriers to attendance and identify actions to reduce inequalities.
- Identify the ethnicity of the T1DM population and identify actions to address any inequalities.
- Identify the ethnicity and SIMD of pregnant people with T1DM, to understand whether people from different backgrounds have more or less access to diabetes technologies.

7 Duty to Inform, Engage and Consult People who use our Services

7.1 The Working Group co-chaired by the Director of Strategic Planning and the Chief Officer of East Lothian IJB includes representation from the patient organisation Diabetes Scotland, and from a patient representative in order to engage with those living with T1DM. Both Diabetes Scotland and the patient representative have been kept informed and involved in ongoing discussions regarding investment in diabetes technologies.

7.2 As noted above, it is anticipated that specific communications with those on the adult waiting list, members of the MCN, staff and the wider diabetes community will be required.

8 Resource Implications

8.1 Approximately 100 pumps per annum for the 2024-25 and 2025-26 financial years would cost c. £195k in 24-25 and £280k in 2025-26.

Rebecca Miller
Head of Strategy Development
13th March 2024
rebecca.miller@nhslothian.scot.nhs.uk

List of Appendices

Appendix 1: SBAR: Technology Support for Patients with Type 1 Diabetes Mellitus
Appendix 2: ECRIA Report: Type 1 Diabetes Technology

APPENDIX 1

SBAR – Technology support for patients with Type 1 Diabetes Mellitus

NHS Lothian Executive Leadership Team, 6th February 2024

Situation

Type 1 diabetes mellitus (T1DM) is an incurable congenital condition affecting the control of blood sugar. Technological support has advanced significantly over the last 15 years and can now significantly improve Hb1AC control while simultaneously lessening the psychological burden on patients and families.

A working group has been examining the case for expansion of access to this technology and has formulated multiple options. The conclusion to this work has coincided with the Scottish Budget of 19th December 2023 and the impact on the NHSL budget, which has led to a default position of not making any further investment in this technology as it is unaffordable.

Background

There are approximately 5600 people in the Lothians with a diagnosis of T1DM. Approximately 500 of these are under the age of 16, with a further 510 between their 16th and 24th birthdays.

Technology to support patients with T1DM broadly falls into two parts – a "pump" which can automatically alter the input of insulin for a patient, depending on blood sugar readings, and a glucose monitor which takes those readings. A flash glucose monitor (FGM) takes readings at intervals, while a continuous glucose monitor (CGM) takes these 24/7. Both send information to either a smart device like a phone or to the pump itself.

Currently, about 67% of children with T1DM have a pump, with roughly 21% of all adults having one. Approximately 41% of young adults have a pump. Advances in technology mean that almost all patients with T1DM either have a CGM or will have one by the end of the 2024 calendar year.

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The combined T1DM technologies budget is projected to be overspent by c. £2.6m in 2023-24, and c. £2.8m in 2024-25. There are significant waiting lists in both the adult and children's services, with approximately 150 pumps per year having previously been made available for adults and 50 for children.

NHSL needs to save £133m in the 2024-25 financial year.

Assessment

The evidence for distribution is strongest for children and young people (and pregnant women), so logically that would be the most appropriate place to start any further expansion. Over time, these children obviously graduate into an "adult cohort" but should present fewer costs to the health system with fewer complications.

The *Lothian Strategic Development Framework* prioritises both "new, innovative technologies, such as insulin pumps" and states that "investment in Children's Services is the ultimate in prevention", and these combined provide a policy direction reinforcement for the evidential basis.

CMT has identified its support for this technology but has noted that it does not have the financial resources to continue to rapidly expand the number of patients with pumps.

There are further technological advances which make the costs of consumables, in particular, likely to reduce over the next 3-5 years, which may provide opportunities to utilise resources differently.

There are approximately 100 children on the waiting list for pumps and there is clear evidence that NHSL's investment has delivered improvement in control and avoiding complications. 100 new pumps in each of the next two years is projected to meet all new diagnoses and all but eradicate the waiting list.

Should NHSL wish to make inroads in the 16-24 cohort it could seek to fund a further 25 pumps per annum specifically for this cohort.

Recommendation

NHSL should adopt a refashioned programme for T1DM technology which, for the next two years, seeks to prioritise children and young people before their 25th birthday, and pregnant women. This would seek to significantly reduce the waiting list and establish a stable level of provision for children, matching the reasonably steady number of diagnoses per annum. This time period would also see reductions in costs associated with consumables.

Approximately 100 pumps per annum for the 2024-25 and 2025-26 financial years would cost c. £195k in 24-25 and £280k in 2025-26. Should NHSL wish to increase the distribution to young people in the 16-24 cohort it could consider funding an additional 25 pumps per annum. This would be estimated to cost an additional £50k in 24-25 and c. £75k in 2025-26. This programme would require the paediatric and adult services to work together as no further staffing resource could be funded.

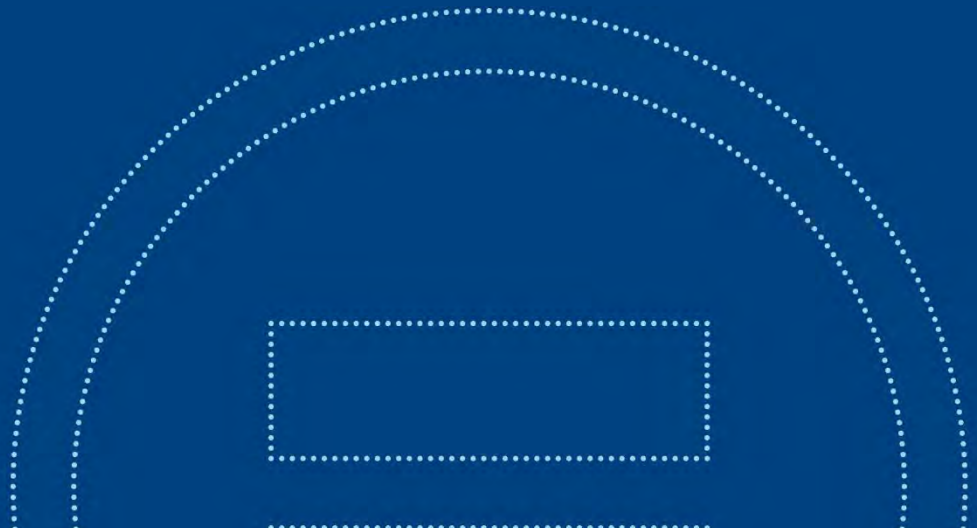
The target for the rate of provision for children would be 90% by the close of the 2025-26 financial year, with a growth to c. 50% in the young adult cohort if the second option were selected.

Following the discussion at ELT it was agreed that the 100 pumps each year targeted at children and pregnant women was the agreed position. This position would be reviewed no later than September 2024 in order to consider whether there should be an expansion for young people and beyond.

Colin Briggs, Director of Strategic Planning, 2nd February 2024 revised 13th February

Equality. Fairer Scotland. Children's Rights. Impact Assessment Report

NHS Lothian Type 1 Diabetes Technology for adults and children



Contents

Description Guidance pages 4-7

Title of proposed work and name of contracted organisation (if applicable)

Supporting those with Type 1 Diabetes in Lothian to live well with Diabetes, through distribution of technologies.

Purpose/ objective of proposal

The proposal seeks to determine how best to distribute a limited number of diabetes technology devices during 2024/25 and 2025/26, to maximise the impact of those technologies and with due consideration of the Public Sector Equality Duty. It is anticipated that 100 devices will be available per year. An initial proposal to prioritise all children and young people up to the age of 16 and pregnant women with HbA1c over 75 ml/mmol has been considered.

Who will be affected by this proposal

Adults with Type 1 Diabetes

Children with Type 1 Diabetes and their carers and family

NHS Lothian Adults and Children Diabetes Teams

Reported written by (job title)

Lois Marshall – Outpatients Strategic Programme Manager

Rebecca Miller – Head of Strategy Development

Report authorised by (and date)

PLEASE NOTE

Once your proposal has been agreed and signed off, send the completed Impact Assessment Report to impactassessments@nhslothian.scot.nhs.uk for publication on NHS Lothian website. Also use this email address to provide feedback or suggestions for ways to improve the impact assessment process.

Evidence Guidance pages 8-9 & 18-22

Evidence used:

List the evidence you used, including if you involved people with relevant protected characteristics and lived experience.

- Research – from Scotland, the UK, and further afield
- Data from NHS Lothian – taken from SCI Diabetes and other reports
- Alliance and Diabetes Scotland reports including people with lived experience.
- NICE recommendations
- SIGN guidelines
- People with lived experience who attended the ECRIA workshop.

Summary of findings:

Include evidence about relevant population demographics, different health and/ or employment inequalities, people's different needs and how to meet them, barriers and how to address them, inclusion/ participation in the service, diversity in employment and any complaints and feedback.

See Evidence brief – Appendix 1

Impact on equality & socio-economic disadvantage Guidance p10-16

Negative impacts

Using the evidence you have collected, explain if your proposal could be discriminatory or put a group of people at a disadvantage. Some work will be broad and affect everyone working for us or using our services, but some may only affect specific groups of people. Say 'not relevant' or 'no known relevance' if your proposal does not affect a group.

Relevant group	Could your work result in unlawful discrimination?	Could your work put people at a disadvantage/ make their lives worse?
People in different age groups	No	The proposal could disadvantage adults aged over 16 who it is felt are at high risk of death if they are not supplied with a pump. It is estimated that there are 10-20 people per annum in this situation. Young people (aged 16 and over) with higher HbA1c, who don't yet have a pump could be disadvantaged as the risk of complications is higher in those who have poor glycaemic control for longer, and those diagnosed youngest. There is also some evidence young adults are at higher risk of DKA, and evidence from the Children's service has shown a reduction in DKA admissions for those on Hybrid Closed Loop systems (pump linked with CGM) The proposal could disadvantage children aged 15 who turn 16 before they receive a pump.
Disabled people	No	There may be existing inequalities in access to diabetes technologies for disabled people in Lothian, including where

Relevant group	Could your work result in unlawful discrimination?	Could your work put people at a disadvantage/ make their lives worse?
		individuals are unable to use devices independently and safely due to illness or disability and available support arrangements. There may be inequalities in access to being put on the Waiting List for technology. This proposal will not address these inequalities
Trans and non-binary people	No	No known relevance
People who are pregnant or on maternity leave	No - people will not be discriminated against because they are pregnant or on maternity leave.	Under the current proposal, those who are pregnant with HbA1c >75ml/mmol would be provided with technologies as a clinical priority either as part of pre-pregnancy planning or early in their pregnancy. They will retain this post-pregnancy. Pregnant people with HbA1c 48-75, who do not have a pump will not be provided with a pump, it is anticipated that less that 10% of pregnant people will have HbA1c of 48 at the point of conception and approximately 40-50% will have a pump. So pregnant people without a pump with an HbA1c in this range will be disadvantaged compared to those with the highest HbA1c >75ml/mmol.
People from different ethnic backgrounds	No	No evidence from Lothian currently available. Based on national evidence in England it may be that both children and adults from some ethnic groups may be disadvantaged in their access to technology. If we do not provide support including interpretation, we could disadvantage those from different ethnic minority backgrounds.

Relevant group	Could your work result in unlawful discrimination?	Could your work put people at a disadvantage/ make their lives worse?
		This proposal will not address these inequalities.
People with religious or protected beliefs	No	No known relevance
Men and women	No - men will not be discriminated against because they are men.	It was noted that a higher proportion of women with T1DM than men with T1DM were currently using diabetes technologies. It is anticipated that this pattern will continue as the priority based on the evidence will be on providing technologies to those women (and non-binary people and trans men) who are pregnant and maintaining technologies for these people post-pregnancy. This would put men, older women, and women who do not plan pregnancy, or become pregnant, at a disadvantage as the priority will be for pregnant women.
People who are heterosexual, lesbian, gay or bisexual	No	No known relevance
People who are married or in a civil partnership [only in employment situations]	No	No known relevance

Relevant group	Could your work result in unlawful discrimination?	Could your work put people at a disadvantage/ make their lives worse?
Care experienced people	This box should not be completed because there is no legal protection from discrimination on basis of care experience.	Care experienced people aged 16 and over will experience disadvantage as they will not have access to technologies, although this is primarily linked to age. The statutory guidance on corporate parenting duties highlights that a corporate parent's duties apply equally to all care leavers, up until their 26th birthday. NHS Lothian is a corporate parent. Care experienced young people aged 16-25 will be disadvantaged as they experience poorer health outcomes compared to the general T1 population.
People experiencing health inequalities caused by socio-economic disadvantage	This box should not be completed because there is no legal protection from discrimination on basis of socio-economic disadvantage.	Under the proposal, we would not be able to address existing inequalities in access to technologies for people experiencing socio-economic disadvantage.
People experiencing employment inequalities caused by socio-economic disadvantage	This box should not be completed because there is no legal protection from discrimination in employment on basis of socio-economic disadvantage.	No known relevance
Carers	This box should not be completed because there is no legal protection from discrimination on basis of caring responsibilities.	No known relevance

Positive impact

Using the evidence you have collected, explain if and how your proposal could have a positive impact on reducing inequalities facing different groups. Some work will be broad and affect everyone working for us or using our services, but some may only affect specific groups of people. If this is the case, say 'not relevant' or 'no known relevance' if your proposal does not affect a group.

Relevant group	**Can your work advance equality of opportunity?** [reduce disadvantage, meet needs, increase participation]	**Can your work foster good relations?** [reduce prejudice + increase tolerance]
People in different age groups	Potential to reduce the disadvantages experienced by children and young people up to age 16 with T1DM, and those diagnosed youngest.	No known relevance
Disabled people	No known relevance	No known relevance
Trans and non-binary people	No known relevance	No known relevance
People who are pregnant or on maternity leave	Reduce disadvantages experienced by those who are pregnant with high HbA1c >75. Anticipate this could also reduce neonatal ICU admissions, and support those who are breastfeeding and/or acting as primary caregiver to very young children.	No known relevance
People from different ethnic backgrounds	No known relevance	No known relevance
People with religious or protected beliefs	No known relevance	No known relevance
Men or women	No known relevance	No known relevance

Relevant group	Can your work advance equality of opportunity? [reduce disadvantage, meet needs, increase participation]	Can your work foster good relations? [reduce prejudice + increase tolerance]
People who are heterosexual, lesbian, gay or bisexual	No known relevance	No known relevance
Care experienced people	No known relevance	No known relevance
People who experience health inequalities caused by socio-economic disadvantage	No known relevance	No known relevance
People who experience employment inequalities caused by socio-economic disadavantage	No known relevance	No known relevance
Carers	No known relevance	No known relevance

Impact on UNCRC rights Guidance pages 17, 21-22

Confirm whether your proposal affects children and young people (yes or no).

YES

If yes, using the evidence you have collected explain how your proposal could impact Children's Rights. Not all UNCRC rights may apply to your proposal. If this is the case, simply say 'Not relevant' or 'no known relevance'. If your proposal does not affect children and young people do not complete this section.

The UN Convention on the Rights of the Child (UNCRC) applies to everyone under the age of 18.

UNCRC right	How will your work limit or restrict this right?	How will your work progress this right?	Are any groups of children particularly impacted
3 - the best interests of the child shall be a primary consideration	This proposal will limit this right for children aged 15, 16,17 as it is in their best interests to have access to technologies to support their diabetes management.	This proposal will progress this right for children aged up to 15 It is in the best interests of the child to reduce the waiting time for technology	Children aged 15 (if they turn 16 before they can receive a pump) and aged 16 & 17
4. making rights real			
5 – family guidance as children develop	n/a	n/a	n/a

UNCRC right	How will your work limit or restrict this right?	How will your work progress this right?	Are any groups of children particularly impacted
6 – to live and the survival and development of the child will be ensured to the maximum extent possible	This proposal will limit this right for children aged 15, 16,17 as they will not have access to technologies to support their diabetes management, which support this to the maximum extent possible (over MDI)	This proposal will progress this right for all children up to the age of 15	Children aged 15 (if they turn 16 before they can receive a pump) and aged 16 & 17
7 – name and nationality	N/A	N/A	N/A
8 – identity	N/A	N/A	N/A
9 – keeping families together	N/A	N/A	N/A
10 - contact with parents across countries	N/A	N/A	N/A
11 – protection from kidnapping	N/A	N/A	N/A

UNCRC right	How will your work limit or restrict this right?	How will your work progress this right?	Are any groups of children particularly impacted
12 – respect for children's views	N/A	N/A	N/A
13 – sharing thoughts freely	N/A	N/A	N/A
14 – freedom of thought and religion	N/A	N/A	N/A
15 –freedom of association and peaceful assembly	N/A	N/A	N/A
16 – protection of privacy	N/A	N/A	N/A
17 – access to information	N/A	N/A	N/A

UNCRC right	How will your work limit or restrict this right?	How will your work progress this right?	Are any groups of children particularly impacted
18 – responsibility of parents	N/A	N/A	N/A
19 – protection from violence	N/A	N/A	N/A
20 – children without families	N/A	N/A	N/A
21 – children who are adopted	N/A	N/A	N/A
22 – refugee children	N/A	N/A	N/A
23 – disabled children	N/A	N/A	N/A

UNCRC right	How will your work limit or restrict this right?	How will your work progress this right?	Are any groups of children particularly impacted
24 – enjoyment of the highest attainable standard of health	This proposal will limit/restrict this right for children aged 15 up to 18 years.	Technology, and access to Hybrid Closed loop technology supports children with type 1 diabetes to the highest attainable standard of health. This proposal will progress this right for all children up to the age of 15	Children aged 15 (if they turn 16 before they can receive a pump) and aged 16 & 17
25 – review of a child's placement	N/A	N/A	N/A
26 – social and economic help	N/A	N/A	N/A
27 – food, clothing and safe home	N/A	N/A	N/A
28 – access to education	It will limit this right for children aged 15/16 until they turn 18. Children with higher Hba1c levels miss more school and perform worse in exams. Technology supports young people to lower their Hba1c levels.	This proposal will progress this right for all children up to the age of 15	Children aged 15 (if they turn 16 before they can receive a pump) and aged 16 & 17

UNCRC right	How will your work limit or restrict this right?	How will your work progress this right?	Are any groups of children particularly impacted
29 – aims of education	N/A	N/A	N/A
30 – minority culture, language and religion	N/A	N/A	N/A
31 – rest, play, culture, arts	It will limit this right for children aged 15/16 until they turn 18. These children will not have access to technology which can support them with better sleep/rest and may enable them to participate in wider opportunities	It will progress this right for children aged up to 15 years. Having a technology can support children with better sleep, and more opportunities for play and to foster independence	Children aged 15 (if they turn 16 before they can receive a pump) and aged 16 & 17
32 – protection from harmful work	N/A	N/A	N/A
33 – protection from harmful drugs	N/A	N/A	N/A
34 – protection from sexual abuse	N/A	N/A	N/A

UNCRC right	How will your work limit or restrict this right?	How will your work progress this right?	Are any groups of children particularly impacted
35 – prevention of sale and trafficking	N/A	N/A	N/A
36 – protection from exploitation	N/A	N/A	N/A
37 – children in detention	N/A	N/A	N/A
38 – protection in war	N/A	N/A	N/A
39 – recovery and reintegration	N/A	N/A	N/A

Making a difference

Guidance pages 11 & 15

What changes will you make to your proposal based on the results of this impact assessment?

Changes	What difference this will make
Prioritise 10-20 devices per annum for adults who may otherwise be at high risk of death (agree clinical criteria for this)	This will remove the disadvantage for adults aged over 16 who it is felt are at high risk of death if they are not supplied with a pump.
Consider prioritisation of devices for children aged 16 and 17 to support and progress the relevant children's rights as outlined in the UNCRC. This group average approximately 10 young people a year.	If this is progressed this will remove the disadvantage for children aged 16 and 17, and progress the relevant children's rights.
Identify the full population of care experienced young people aged 16 – 25 (currently 24 have been identified) Identify and put in place appropriate support, linking with relevant staff. Identify those who do not have a pump and consider prioritisation	This will allow us to identify the care experienced population, understand their current outcomes and care, and put in place changes to reduce inequalities in health outcomes for care experienced young people.
We will need to take mitigating actions to support people experiencing socio-economic disadvantage, as we know they are more likely to have high HbA1c and less access to technology. We need to • Review pilot work in Wester Hailes to inform these actions • Review whether those living in the most deprived areas have access to Libre 2 CGM, and how access to this can be improved, and implement changes required. • Review whether those living in the most deprived areas have access to structured education, and put in place actions to address any inequalities	This will allow us to reduce the inequalities facing people experiencing socio-economic disadvantage by -understanding barriers to accessing health care, what works to reduce these and rolling out pilot projects to support this where required. -understanding barriers to accessing and effectively using CGM and putting in place changes in the service to address these -understanding barriers to accessing structured education, and putting in place changes to address these.

Changes	What difference this will make
• Undertake meaningful public engagement with BME and disabled people in most deprived areas of Lothian, with a focus on working age men and women, to understand barriers to effective diabetes care and suitable solutions (linking with wider engagement work underway led by Equalities Lead)	-understanding barriers to BME populations in these communities accessing care and identifying what changes to the service could help to address these.
Given that pump starts will be fewer than expected, explore how we can best utilise staff resources, to better support those currently using technologies to optimise HbA1c. Focussing on equalities groups who face the most barriers to this.	Reduce the inequalities in Hba1c seen in different equality groups including young people up to 25, and SIMD
Explore potential to develop the team and redesign the service to better meet the needs of all those living with T1DM. (There may be potential to do this with the E&HR team) including considering expansion of Wester Hailes pilot project and possibility of a youth work approach/youth worker	Reduce the inequalities in Hba1c seen in different equality groups including young people up to 25, and SIMD
Review attendance at structured education sessions, including by equalities groups and SIMD, and identify barriers and inequalities in access. Identify actions to reduce any inequalities	This will allow us to identify and then reduce inequalities in access to structured education
Undertake work to identify the ethnicity of the type 1 child and adult diabetes population, use this to identify whether people from different ethnic backgrounds have more/less access to diabetes technologies, and identify actions to address inequalities. Identify in advance any interpretation support required for children and families	This will allow us to identify any inequalities in access to care and diabetes technologies by ethnicity

Changes	What difference this will make
Undertake work to identify the ethnicity and SIMD of pregnant adult women, and those planning pregnancy.	Use this to identify whether people from different ethnic backgrounds, and different SIMD have more/less access to diabetes technologies and any disadvantages that they face

Sharing with decision-makers

Guidance page 23

Explain how you will make sure the results of your impact assessment will be taken into account by decision-makers before a final decision is taken.

The results of the impact assessment will be shared with the NHS Lothian Strategic Planning and Performance Committee in March 2024 to support their decision making around options for Type 1 diabetes technology.

Monitoring the impact

Guidance page 24

How will you monitor the actual impact of this piece of work on equality, socio-economic disadvantage or children's rights?

Performance Indicator for equality, socio-economic disadvantage and children's rights.	What impact are you measuring
Proportion of children under 16 from each SIMD quintile and each ethnic group with access to a pump	Impact on identifying and addressing inequalities by ethnicity and SIMD and on progressing children's rights.

Proportion of children under 18 from each SIMD quintile and each ethnic group with access to a pump	Impact on identifying and addressing inequalities by ethnicity and SIMD and on progressing children's rights.
Proportion of pregnant women, from each SIMD quintile and each ethnic group, with hba1c over 75, with access to a pump	Impact on identifying and addressing inequalities by ethnicity, SIMD, and pregnancy.
Proportion of pregnant women, from each SIMD quintile, and each ethnic group, with HbA1c from 48-75, with access to a pump	Impact on identifying and addressing inequalities by ethnicity, SIMD, and pregnancy.
Proportion of children and adults from each SIMD quintile who have are able to achieve different Hba1c levels	Impact on identifying and addressing inequalities by SIMD.
Proportion of adults from each SIMD quintile and each ethnic group who have accessed structured education	Impact on identifying and addressing inequalities by SIMD and ethnicity.
Proportion of adults from each SIMD quintile and each ethnic group who do, and do not, have access to a CGM	Impact on identifying and addressing inequalities by SIMD.
Number of care experienced young adults and proportion of care experienced children and young adults with access to a pump.	Impact on identifying and addressing inequalities by care experience