Update on recent advances in technology in type 1 diabetes

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Abstract

Those living with type 1 diabetes (T1DM) require daily adjustments of exogenous insulin doses and frequent glucose monitoring to optimally manage their condition. Consequently, it is one of the most challenging long-term conditions to live with. Recent years have seen major progress in the management of T1DM, with minimally invasive glucose monitoring technology and glucose-responsive insulin delivery systems, also called hybrid closed-loop systems. This narrative review focuses on three key areas: continuous glucose monitoring (CGM), hybrid closed-loop (HCL) systems, and connected pen devices, sometimes known as smart pens. We describe features of commonly used devices in the UK NHS and summarise their key evidence base. Randomised controlled trials and real-world studies of CGM devices have shown improved haemoglobin A1c (HbA_{1c}) levels, improved sensor-based metrics such as higher time spent in the target glucose range, and reduced rates of hypoglycemia. HCL studies have similarly shown improved HbA_{1c} and other sensor-based glucose outcomes. Further recent innovations for insulin users include connected insulin pens, which allow the display and recording of insulin delivery information. In addition to glycaemic benefits, novel diabetes technology has been shown to improve quality of life and to give higher treatment satisfaction. Some disadvantages of technology include alarm burden, connectivity problems and premature device failure. To get the best from novel diabetes technology, appropriate training and education are required, specifically in identifying and dealing with critical system failures such as cannula failure and the risk of ketoacidosis. Recent recommendations from the National Institute of Health and Care Excellence (NICE) regarding HCL further underscore the growing significance of these advances in diabetes care.

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Introduction

Type 1 diabetes (T1DM) is a lifelong endocrine condition related to insulin deficiency caused by pancreatic beta-cell dysfunction.[1] People with T1DM need to be able to self-adjust their insulin dose to achieve normoglycaemia and minimise the risk of micro- and macrovascular complications. Glucose monitoring entails multiple glucose measurements per day to facilitate self-adjustment of insulin and is thus a key foundation of modern T1DM self-management.[2] The pain and inconvenience of conventional glucose monitoring through frequent finger-stick capillary blood testing however is, unsurprisingly, associated with lower quality of life, and poor treatment satisfaction and adherence.[3,4]

Advances in glucose monitoring

Capillary blood glucose meters were introduced into clinical practice in the late 1960s. For years, diabetes management consisted primarily of daily fingerstick testing, multiple daily insulin administrations, and handwritten diaries to record glucose levels. Current sensor-based glucose monitoring devices, first introduced in the 1990s, provide a minimally invasive method to measure interstitial fluid glucose levels in real time. Commercial externally worn devices use a subcutaneously implanted needle-type amperometric enzyme electrode: this measures interstitial glucose concentration by detecting changes in the electric current caused by the enzyme-catalysed oxidation of glucose into hydrogen peroxide.[5]

Since the introduction of the first continuous glucose monitoring (CGM) system by Medtronic in 1999, innovations in CGM have undergone a transformative change. Flash glucose monitoring, more specifically the Freestyle Libre System (FSL), was first introduced in 2014 in Europe. It consists of a 2-week, externally worn glucose sensor that displays present, 8-hour historic and trend glucose data when the user "scans" the sensor using nearfield communication via a Freestyle Libre reader or compatible mobile phone.[6,7] The first generation of FSL differs from real-time continuous glucose monitoring systems (RT-CGM) in that FSL does not continuously display or transmit sensor glucose information unless physically scanned by the user and does not provide low or high glucose alarms. The second generation FSL (Freestyle Libre 2), first released in Germany in 2018, incorporates a Bluetooth transmitter in addition to near-field communication, continuously sending data to activate low and high glucose threshold alerts on the Freestyle Libre 2 reader without needing to scan. However, the

user is still required to scan to visualise the actual glucose value, causing the alerts. In the UK, the Freestyle Libre 2 app was upgraded in August 2023 to display glucose data without having to scan the sensor. (Scanning is still required with the Libre 2 reader).[8]

The assessment of CGM accuracy is not standardised, which poses challenges for regulators, clinicians and users. The mean absolute relative difference (MARD) is the most commonly used measure. MARD is based on the comparison between paired measurements of a given CGM system and a reference method.[9] As measured by MARD, the accuracy of CGM devices has improved over time, reducing from 25% in 1990 to <10% in recent years. Kovatchev and colleagues, using simulation techniques, have calculated a minimal accuracy of a mean ARD of ≤10% for real-time CGM to reach sufficient safety when sensor glucose data are used for insulin dosing decisions.[10] Although MARD is widely used, there are several limitations to MARD. It is affected by study design, level of hypoglycemia, hyperglycaemia and glucose variability. Therefore, comparing MARD between studies should be done with caution. Additional sensor accuracy measures such as Clarke or Consensus error grids and precision Absolute Relative Difference (PARD) where two similar CGM systems are used as a reference, can be useful tools to assess CGM accuracy.[11]

Table 1 (adapted from https://www.diabetesspecialistnurseforumuk.co.uk/whats-new CGM Comparison chart from Diabetes Specialist Nurse Forum UK) summarises the key features of various CGM devices commonly used in the UK NHS.[12]

Evidence from clinical trials

Real-time CGM studies

The landmark JDRF multicentre randomised controlled trial (RCT) examined the benefits of using CGM using earlier generations of sensors (Dexcom Seven (Dexcom), the Minimed Paradigm System (Medtronic) or the Freestyle Navigator (Abbott Diabetes Care). In this study involving 322 people with T1DM with HbA_{1c} levels above 7.0% (53 mmol/mol), CGM led to improved HbA_{1c} levels for individuals over 25 years old. There was no improvement noted for those under 25, and this was linked with lower sensor use in this age group. In a secondary study, which included 129 people with HbA_{1c} levels below 7.0% (53 mmol/mol), CGM helped individuals maintain their target HbA_{1c} levels while reducing exposure to hypoglycaemia.[13]

The GOLD study was an open-label crossover RCT in 161 people with T1DM on multiple daily injections (MDI). The study compared the utility of Dexcom G4 CGM (Dexcom Inc. San Diego, US) with self-monitoring blood glucose (SMBG). The mean HbA_{1c} was 7.9% (63 mmol/mol) with CGM vs 8.3% (67 mmol/mol) with SMBG. The mean difference of −0.43% (4 mmol/mol) is thought to be a clinically meaningful reduction. There was only one severe hypoglycemia incident in the CGM group, compared to five such incidents in the SMBG group.[14]

The Diamond study was a parallel design multicentre trial in which 2:1 randomisation was used for 158 people with T1DM on MDI, for CGM Dexcom G4 (Dexcom Inc., San Diego, US) and conventional therapy. The improvement in HbA_{1c} was 1.1% (11.6 mmol/mol) at 12 weeks and 1.0% (10.6 mmol/mol) at

Table 1. Key features of continuous glucose monitoring devices (CGM) available in NHS.
(adapted from https://www.diabetesspecialistnurseforumuk.co.uk/ by DSN Forum UK CGM Comparison chart)[12]

	Freestyle Libre 2	Freestyle Libre 3	Dexcom One	Dexcom G6	Dexcom G7	Medtronic G4
Real-time CGM	Yes*	Yes	Yes	Yes	Yes	Yes
MARD	9.2	7.8	9.0	9.0	8.2	10.6
Sensor life	14 days	14 days	10 days	10 days	10 days + 12 hr grace period	7 days
Sensor warm-up time	60 mins	60 mins	120 mins	120 mins	30 mins	120 mins
Separate transmitter	No	No	Yes	Yes	No	Yes
Transmitter life	N/A	N/A	3 months	3 months	N/A	12 months
Smartphone app	LibreLink	Libre 3	Dexcom One	Dexcom G6	Dexcom G7	MiniMed
Reader available	Yes	No	Yes	Yes	Yes	No
High & low alarms	Yes	Yes	Yes	Yes	Yes	Yes
Predictive alarms	No	No	No	Yes	Yes	Yes
Pump compatibility	No	YpsoPump	No	Tandem T:slim DANA-i YpsoPump Omnipod 5	No	Medtronic 780G
Closed loop compatibility	No	Yes	No	Yes	No	Yes
Data share HCP	Libreview	Libreview	Clarity	Clarity	Clarity	CareLink
Data share friends/family app	Libre Linkup	Libre Linkup	N/A	Dexcom Follow	Dexcom Follow	CareLink Connect
Approved placement site	Upper arm	Upper arm	Abdomen, upper arm (buttocks in children)	Abdomen, upper arm (buttocks in children)	Abdomen, upper arm (buttocks in children)	Upper arm, abdomen

24 weeks with CGM vs 0.5% (5.3 mmol/mol) and 0.4% (4 mmol/mol) with conventional therapy. A mean difference of 0.6% (6.5 mmol/mol) was noted between the two groups at 24 weeks. Although both groups had similar incidences of severe hypoglycaemia incidents, time spent in the hypoglycaemia range was lower in the CGM group.[15]

Another RCT in 203 older adults (average age ≥60 years) with T1DM showed that median time with glucose <4 mmol/L (72 mg/dl) was reduced from 5.1% at baseline to 2.7% at six-month follow-up in the CGM group (difference of 1.9% between the two groups at six months), demonstrating the promise of CGM in reducing hypoglycaemia burden in this age group.[16]

Further, a parallel design RCT was conducted in 153 young adults (mean age 17 years) with T1DM. The study compared Dexcom 5 (Dexcom Inc. San Diego, US) CGM with SMBG over 26 weeks. The study showed a reduction in HbA_{1c} level from 8.9% (74 mmol/mol) to 8.5% (69 mmol/mol) in the CGM group, compared to no difference in HbA_{1c} level in the control group.[17] In a crossover RCT conducted in adolescents and young adults, Dexcom G6 CGM (Dexcom Inc. San Diego, US) was compared with SMBG. The study showed that eight weeks of CGM use improved time in range (TIR) by 11.1% (CGM 35.7% vs. SMBG 24.6%), reduced mean sensor glucose by 32.2 mg/dL (1.8 mmol/L) [219.7 mg/dL (12.2 mmol/L) with CGM, 251.9 mg/dL (14.0 mmol/L) with SMBG], and lowered HbA_{1c} levels by 0.76% (8 mmol/mol) compared to SMBG.[18]

CONCEPTT is a multicentre RCT in which women with T1DM who were either pregnant or planning pregnancy are assigned to RT-CGM and SMBG groups. In pregnant women, RT-CGM use showed improvement in HbA_{1c} levels by 0.19% (2 mmol/mol), an increase in TIR (68% RT-CGM vs 61% SMBG), and less time in hyperglycemia (27% RT-CGM vs 32% SMBG group). Neonatal health outcomes also improved in the CGM group. However, RT-CGM did not show the same benefits in women planning pregnancy.[19]

Intermittently scanned CGM studies

The IMPACT trial was a multicentre RCT including 239 people with well controlled (HbA_{1c} ≤7.5% [59 mmol/mol]) T1DM and intact awareness of hypoglycaemia. Intermittently scanned CGM (isCGM device) Freestyle Libre (Gen 1) was compared with SMBG. IsCGM use was associated with a 46% reduction in time spent in hypoglycaemia (<3.9 mmol/L or 70 mg/dl) at six months, without any change in total daily insulin dose. Treatment satisfaction was noted in the intervention group as compared to the control group.[20]

The FLASH-UK trial, a multicentre RCT of 156 people with T1DM, investigated the use of isCGM as an alternative to finger-prick testing in those with HbA_{1c} >7.5% (59 mmol/mol). The isCGM group experienced a reduction in baseline HbA_{1c} from 8.7% (72 mmol/mol to 7.9% (63 mmol/mol) at 24 weeks, with a 0.5% (5.3 mmol/mol) point difference between the two groups. The health-economic analysis of FLASH-UK revealed a small and statistically insignificant increase in Quality-Adjusted Life Years (QALY) during the trial, along with a short-term increase in costs. However, over the lifetime of a patient isCGM was projected to be cost-effective, particularly in those with high baseline HbA_{1c}, with an aggregate cost per QALY (ICER) of £4,445, which is within the NICE-recommended cost-effectiveness threshold of less than £20,000 per QALY.[21,22]

ALERT1 was a RCT in people with T1DM (already on isCGM), which compared RT-CGM with isCGM. It showed a reduction in self-reported hypoglycaemia worry and improvements in TIR (59.6% RT-CGM vs 51.9% isCGM) and HbA_{1c} (7.1% [54 mmol/mol] RT-CGM vs 7.4% [57 mmol/mol] isCGM) for the RT-CGM group. Though the investigators recommended the use of RT-CGM in the management of patients with T1DM, the study was not able to answer the question of whether those naive to CGM should start either RT-CGM or isCGM.[23]

Evidence from real-world data

Findings from real-world data have been consistent with RCTs, with improvements in glycaemic control, user satisfaction and hypoglycaemia awareness. The Association of British Clinical Diabetologists (ABCD) conducted a multicentre service evaluation for over two years. It showed that, irrespective of duration of use, improvement in HbA_{1c} was evident (ranging from 0.37% [4 mmol/mol] to 0.55% [5.8 mmol/mol] improvement) in FSL users. There was further improvement in the GOLD score (hypoglycaemia awareness score) and DDS Score (reduction in diabetes distress) after FSL use.[24]

Another real-world observational study in 515 adults who used RT-CGM for at least two months showed improvements from baseline HbA_{1c} and hospitalisation from ketoacidosis, and a reduction in hypoglycaemia from 16% to 4%. Admission days, work absenteeism and quality of life improved significantly, with a reduction in the fear of hypoglycaemia with RT-CGM use.[25]

Collectively, these studies highlight the utility of CGM in improving HbA_{1c}, the time spent in the 'target glucose range' and the reduction in hypoglycaemia burden.

Advances in automated insulin delivery systems (hybrid closed loop)

Automated insulin delivery (AID) systems integrate insulin pumps with CGM devices using mathematical algorithms, allowing for glucose-responsive insulin delivery.[26] At present, the system continues to be classified as a hybrid system, as it requires user input of mealtime carbs and delivery of a meal bolus.[19]

Key features of these systems are shown in Table 2 (Adapted from https://www.diabetesspecialistnurseforumuk.co.uk/whats-new HCL comparison chart from Diabetes Specialist Nurse Forum UK).[27]

The commonly used AID systems in the UK NHS include:

1. Minimed 670G/780G (Medtronic) (Medtronic 670 G with Guardian 3 and Medtronic 780G with Guardian 4 sensor). Manufacturer: Medtronic; country of origin US
2. Tandem t:slim X2 Control IQ (T slim X2 pump with Dexcom G6 sensor). Manufacturer: Tandem Diabetes Care; country of origin: US
3. CamAPS FX system (DANA and Ypsomed pump with DexcomG6/Libre 3). Manufacturer: CamDiab Ltd (Cambridge, UK), and Ypsomed (Ypsomed AG Switzerland)

Table 2. Summary of salient features of hybrid closed-loop (AID systems available in NHS)
Adapted from HCL comparison table from DSN Forum UK (https://www.diabetesspecialistnurseforumuk.co.uk/whats-new)[27]

HCL system	Minimed	Tandem	CamAPS FX System		INsulet
Pump	Medtronic 780g	T-slim X2	DANA RS and DANA-i	mylife YpsoPump	Omnipod 5
Location of algorithm	Pump-integrated	Pump-integrated	App-based (Android)	App-based (Android)	Pod-integrated
Continuous glucose monitor (CGM)	Guardian 4	Dexcom G6	Dexcom G6	Dexcom G6, Freestyle Libre 3	Dexcom G6 Libre 2 plus *
Bolus delivery operation	Pump	Pump	Android smartphone	Android smartphone	Omnipod 5 Controller
Target glucose mmol/l (mg/dl)	5.5, 6.1 or 6.7 (99,110, or 120 mg/dl) default 5.5 (99 mg/dl)	6.25-8.9 (112-160 mg/dl) (uses range instead of target) Sleep: 6.25-6.7 (112-120 mg/dl)	Customisable from 4.4 to 11.1 (79-200 mg/dl) default 5.8 mmol/L (104 mg/dl)	Customisable from 4.4 to 11.1 (79-200 mg/dl) default 5.8 (104 mg/dl)	6.1, 6.7, 7.2, 7.8, or 8.3 [110,120,130,140,150 mg/dl]
Exercise mode target glucose	8.3 mmol/L (150 mg/dl)	7.8-8.9 mmol/L (140-160 mg/dl)	Ease-off mode can be used for exercise	Ease-off mode can be used for exercise	8.3 mmol/L (150 mg/dl)
Sleep mode target glucose	No	6.25-6.7 mmol/L (112-120 mg/dl)	Customisable glucose target can be adjusted overnight	Customisable glucose target can be adjusted overnight	Customisable glucose target can be adjusted overnight
Data share with HCPs	CareLink (Manual upload and automated via app)	Glooko (manual download needed)	Glooko (automated)	Glooko (automated)	Glooko (automated)
Maximum Pump capacity	300 units	300 units	300 units	160 units	200 units
Licensed in pregnancy	No	No	Yes	Yes	No
Age Range	7-80 years	6 years & over	1 years & over	1 years & over	2 years & over

*Currently Omnipod 5 with Libre 2 Plus is not available in the UK. However, it is anticipated to become available in the latter half of 2024.

and DANA (Advanced Therapeutics UK) (SOOIL, South Korea). Country of origin: UK, Switzerland and South Korea

4. Omnipod 5 (INSULET) (Omnipod 5 pump with Dexcom G6 and Libre 2 plus). Manufacturer: Insulet Corporation; country of origin: US. At present, Omnipod 5 with Libre 2 Plus is not available in the UK. However, it is anticipated that it may become available in the latter half of 2024.

In addition to commercially available AID systems, a category of open-source AID systems has gained global acceptance, embraced by a substantial user base. These technologies are the result of user-initiated advancements facilitated by a committed online community affected by diabetes. Real-world evidence consistently validates the safety and efficacy of open-source AID systems, highlighting notable improvements in glycaemic control and positive impacts on aspects such as quality of life, sleep quality and fear of hypoglycaemia.[28]

The CREATE trial, a recent RCT, has further confirmed the benefit of open-source systems when compared with sensor-augmented pumps. The average TIR has improved by 3 hours and 22 minutes in the open-source AID system.[29]

Evidence behind commercial systems

CamAPS Fx

The CamAPS Fx algorithm is available with two different pumps: DANA and Ypsomed insulin pump. When used with the DANA pump, only the Dexcom G6 sensor is compatible, while with the Ypsomed pump users have the option of choosing between Dexcom G6 or Libre 3 sensor. The University of Cambridge group in the UK has performed a large number of randomised clinical studies over the last 10 years, including studies in children and adolescents,[30] pregnant women,[31,32] and adults.[33]

In 2018, an RCT over a 12-week period involving 114 people with T1DM (both children and adults) found that HCL therapy with the CamAPS System increased the proportion of time spent within the target range (mean difference 10.8% points between the two groups), decreased HbA_{1c} levels (mean difference 0.31% or 3.3 mmol/mol), and shortened the duration of both low and high glucose concentrations.[33]

The AiDAPT Study, an RCT in pregnant women, found a higher percentage of time in the pregnancy-specific target glucose range (3.5-7.8 mmol/L or 63 mg/dl-140 mg/dl) (68.2% CamAPS group vs. 55.6% control group) and improvements in secondary outcomes, such as less time spent in hyperglycaemic states, more overnight time in the target range and lower HbA_{1c} levels, among the closed-loop group of 124 pregnant women.[32]

Medtronic 780G

The FLAIR study, a 12-week crossover trial with 113 people with T1DM aged 14-29, compared the Medtronic 670G and advanced hybrid closed-loop (AHCL) systems. The 670G group showed a 6.0% TIR improvement compared to baseline, while the AHCL

group exhibited a more significant 10% increase, indicating the superior impact of AHCL on glycaemic control.[34]

The ADAPT study was another RCT for patients with T1DM that compared AHCL with the combination of MDI and CGM. Mean HbA_{1c} levels were reduced by 1.54% (SD 0.73) in the AHCL group, from 9.0% (75 mmol/mol) to 7.3% (56 mmol/mol). In comparison, the mean HbA_{1c} levels were only reduced by 0.20% (SD 0.80) in the group receiving MDI plus isCGM, from 9.0% (75 mmol/mol) to 8.9% (74 mmol/mol). The model-based difference between the two groups was -1.42% (95% CI -1.74 to -1.10; p<0.0001).[35]

Tandem Control IQ

In 2019, an RCT was conducted on 168 individuals with T1DM. Among them, 112 were assigned to the closed-loop group (Control IQ system) and 56 to the control group (sensor-augmented pump). The participants' ages ranged from 14 to 71 years, and their initial HbA_{1c} levels varied from 5.4% (36 mmol/mol) to 10.6% (92 mmol/mol). Over a span of six months, the closed-loop group improved their time within the target glucose range by 11 percentage points compared to the control group.[36]

Additional real-world data from Breton and colleagues confirmed results consistent with the RCT, with a 10-12% improvement in TIR using the Control IQ system.[37]

Omnipod 5 system

Omnipod 5 (Insulet) is a tubeless HCL system recently approved for use in the UK. No RCT of this system has been published. However, a single-arm before and after study suggested the safety and effectiveness of the system. Following a conventional treatment phase, 112 children and 129 adults used this system, resulting in an improvement in HbA_{1c} levels (0.71% or 7.8 mmol/mol in children, 0.38% or 4.2 mmol/mol in adults) and an improvement in TIR by 15.6 ± 11.5% in children and 9.3 ± 11.8% in adults. Overall, the device was well tolerated and it improved glucose management.[38]

Evidence for HCL from the NHS

A real-world observational study, led by ABCD DTN (Diabetes Technology Network UK) and funded by NHS England (NHS England closed-loop pilot),[39] investigated the use of the HCL system in a cohort of 570 patients with diabetes with HbA_{1c} >8.5% (69 mmol/mol). The findings demonstrated an improvement in HbA_{1c} levels by 1.7% (18 mmol/mol, p<0.0001), along with an increase in TIR from 34.2% to 61.9%. The proportion of individuals with HbA_{1c} levels of 7.5% (58 mmol/mol) or lower rose from 0% to 39.4% (p < 0.0001). 94.7% of the participants reported a positive impact on their quality of life, indicating the potential of HCL systems to transform diabetes management.[40]

Connected pen technology

In the realm of diabetes management, connected pens and button devices have emerged as innovative tools that cater to patients requiring MDI. These devices employ Bluetooth, or near-field communication technology, to record insulin dosages and the timing of injections, offering convenience and improved data tracking for individuals with diabetes.[41]

An observational study from 2019 examined the use of a Bluetooth-enabled pen device by 75 people with MDI. The study revealed that a significant proportion of participants missed their bolus and basal insulin doses when using these devices, and this was found to be strongly linked to suboptimal glycaemic control. These findings highlight the significance of monitoring and resolution of adherence concerns in the management of diabetes to enhance overall glycaemic control.[42]

The usefulness of one connected pen device (Insulclock connected cap device) was shown by a RCT of 55 people with T1DM (26 active on the device vs. 29 masked). Those in the active group experienced a 5.2% increase in TIR vs. -0.8% in the masked group. The active group further showed lower average glucose levels, less time above the target range, and a higher on-time insulin dosage rate.[43]

This connected pen technology holds immense potential for simplifying insulin administration and data tracking, benefiting individuals with diabetes who rely on MDI. Nevertheless, the research emphasises the need for continuing investigation and user enlightenment to maximise the advantages offered by these ground-breaking instruments.

Non-glycaemic benefits, patient-reported outcomes and disadvantages of novel diabetes technology

Many studies evaluating diabetes technology also include the assessment of diabetes-related patient-reported outcomes (PROMs), with a focus on outcomes related to treatment satisfaction, hypoglycaemia burden and diabetes distress. However, findings from these studies have shown inconsistencies and depend on factors such as study type and the characteristics of the study population.[44]

Diabetes technology offers several benefits, such as glycaemic control, helping remove the burden of disease from the user and providing comprehensive data for healthcare providers to make more informed treatment decisions. It also comes with disadvantages. Commonly observed drawbacks include information overload, alarm fatigue (users being frequently bothered by alarms, whether real or false), the constant presence of sensors on the body, and the potential for skin irritation.[45]

Our understanding of the impact of HCL therapy on retinopathy outcomes remains limited. A 2021 NHS pilot study examined the effects of HCL on retinopathy outcomes in individuals with T1DM and an HbA_{1c} ≥8.5% (69 mmol/mol). The study, encompassing a nine-month follow-up of 62 participants, identified a 12.5% retinopathy progression rate, highlighting the imperative need for continuous vigilance to discern and address potential risks.[46]

Users require better education to fully understand and utilise these systems. In cases of system failure, patients should be aware of sick day rules, monitor blood ketones, and manage blood glucose levels while administering insulin doses.

A significant challenge to the sustainable use of AID systems is ensuring user acceptance and helping individuals to integrate these technologies into their daily lives, addressing the various challenges that come with long-term use.[19]

NICE guidance

In 2022, the National Institute for Health and Care Excellence (NICE) updated its guidance on glucose monitoring for people with T1DM. They recommended providing either flash or continuous glucose monitoring to all people with T1DM.[47]

The NICE technology appraisal (TA 943) published in December 2023 advocates HCL systems as an efficacious method for regulating blood glucose levels. This recommendation extends to children, young people, and women who are either attempting conception or are pregnant. Furthermore, it is recommended for adults with T1DM exhibiting an HbA_{1c} of 58 mmol/mol (7.5%) or higher, or those encountering severe hypoglycemia despite optimal management with continuous subcutaneous insulin infusion (CSII), RT-CGM or isCGM. These recommendations signify a substantial progression in the treatment of diabetes, heralding a notable improvement in managing the condition.[48]

Despite the publication of the NICE TA around HCL therapy, significant challenges exist in terms of implementation. In England, only 15% of people living with T1DM are using an insulin pump. It is not clear how each area will prioritise the implementation and it is likely that significant expansion of the workforce may also be required for full implementation of the guidance.

There is currently no dedicated NICE guidance on the use of connected pen devices, necessitating a future review of the evidence for efficacy and cost-effectiveness in the NHS. Pen devices have a potential role, particularly for those who may not be suitable candidates for conventional insulin pumps or HCL.

Evolution of health care professional role in response to recent technological innovations

As the use of technology increases in T1DM, health care professionals (HCPs) and educators will need to understand the role and suitability of these technologies in addressing the different clinical and personal needs of individuals, whilst discussing the benefits and limitations to ensure that appropriate expectations are met. HCPs providing AID therapy will also need to ensure that specific education and clinical guidance on managing glycaemia during periods of illness or exercise are provided to users of this system, to ensure their safe and effective use. Ultimately, HCPs can be advocates on behalf of people living with diabetes, to ensure wider and equitable access to technology, especially in underserved populations.

Future landscape for diabetes technology

Further progress to improve the performance and usability of closed-loop (CL) systems is underway. Examples of these are highlighted below:

Conventional single-hormone or insulin-only CL systems still carry a residual risk of hypoglycaemia due to the limitations of subcutaneous insulin action. Dual-hormone CL using glucagon as an adjuvant has the potential to further reduce this risk. An example of a dual-hormone system awaiting full regulatory approval is the iLET CL system, also known as the "Bionic Pancreas".

Ongoing trials of the Bihormonal Pancreas AID system by Beta Bionics,[49,50] promise a more comprehensive approach to blood glucose regulation and enhanced responsiveness to mitigate hypoglycaemic events.

CGM usability and performance are other factors directly impacting CL users' experience and outcome. Currently, minimally invasive subcutaneous CGM devices are key components of CL systems, with acceptable accuracy and wearability. However, research into the development of novel CGM sensors that may enhance CL use and reduce device burden is ongoing. An implantable CGM sensor, Senseonics (Senseonics Holdings Inc, NYSE America) has been approved for use as a standalone CGM device, but it is no longer available in the UK at present. Research into non-invasive CGM sensors which uses technology such as radio-frequency identification (RFID) shows promise.[51] However, further clinical studies are needed to demonstrate acceptable accuracy and safety.

Access to greater interoperability and choice of different CL components (i.e. the ability to use different CGM sensors and insulin within a CL system) is another important factor in enhancing the usability and acceptance of CL therapy. The CamAPS FX CL system adopts a modular approach, allowing users to have a choice of more than one CGM and insulin pump device which are compatible for use with the algorithm. This approach underscores the potential for further advancements in CL use, enhancing customization and user choice.

Key message

- CGM and HCL systems enhance glycaemic control and quality of life in type 1 diabetes.
- Connected insulin pens are potential alternatives for those unsuitable for insulin pumps or hybrid closed-loop systems.
- Successful use of diabetes technology requires proper education and troubleshooting skills.

Conclusion

There have been tremendous advances in diabetes technology in the last couple of decades, with novel glucose sensors and automated insulin delivery showing increased accuracy, convenience, improved glycaemic control and better quality of life for individuals with diabetes.

To unlock the full potential of these technologies for enhanced diabetes management, continuous research, effective user education and treatment tailored to each

patient's specific needs are required. With these cutting-edge tools at our disposal, the future of diabetes treatment holds significant promise.

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