

THE **sensor** report ISSUE 1/2022

WELCOME TO THE SENSOR REPORT, ISSUE 1, 2022

With this issue of *The Sensor Report*, we are looking forward to an exciting year, with opportunities to contribute and connect at live diabetes congresses, and to continue to provide you with clinical insights and commentary on how the FreeStyle Libre system is continuing to change diabetes. You will see in this issue that we also want to focus on a subject of continued interest and relevance – how laboratory measured HbA1c levels can be improved as a consequence of using the FreeStyle Libre system, and how this can be interpreted in the age of multiple digital metrics of diabetes health.

Managing and measuring HbA1c has been the gold-standard for assessing diabetes health and predicting the real risks for microvascular and macrovascular complications of diabetes. The emergence of sensor glucose metrics such as time in range (TIR), time below range (TBR), time above range (TAR), the glucose management indicator (GMI) and the coefficient of variation (CV), have helped redefine how we look at short-to-medium term glycemic health. Each of these parameters allow people with diabetes to make daily decisions about living better with diabetes. HbA1c on the other hand remains a critical measure of long-term glycemic control and is assuming a new relevance in conjunction with short-term glycemic measures such as GMI. Thus, reducing laboratory-tested HbA1c levels remains a central objective of good diabetes care.

In this issue of *The Sensor Report*, we will investigate the role of HbA1c in current diabetes clinical practice and provide the evidence that shows how using the FreeStyle Libre system is associated with reductions in HbA1c, both for children and adults with type 1 diabetes (T1DM) and also for adults with type 2 diabetes (T2DM). Importantly, the observed patterns of change in HbA1c in T1DM and T2DM after starting the FreeStyle Libre system show that flash glucose monitoring should be used in the same way to reduce long-term glucose exposure for children with T1DM and adults with T1DM or T2DM.



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featurestory

Flash glucose monitoring can be used in the same way by people with T1DM or T2DM to reduce long-term glucose exposure

A large proportion of people with T1DM or T2DM are not meeting recommended targets for glycemic control and are therefore at increased risk of diabetes-related complications such as nephropathy, retinopathy and neuropathy. The evidence that flash glucose monitoring can substantially reduce HbA1c for people with diabetes is now overwhelming, with consequent implications for reduced risk of microvascular or macrovascular disease.



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The use of flash glucose monitoring with the FreeStyle Libre system or traditional continuous glucose monitoring (CGM) systems by people with T1DM or T2DM is associated with lowered HbA1c, increased TIR and reduced TBR in hypoglycemia¹⁻³. A 2020 meta-analysis⁴ of 25 real-world studies demonstrated that flash glucose monitoring was associated with a mean reduction in laboratory-measured HbA1c of 0.56% (6.2 mmol/mol) amongst adults and 0.54% (5.9 mmol/mol) in children and adolescents. A longitudinal analysis showed that HbA1c fell significantly within the first 2-4 months of use and changes were sustained up to 12 months in adult subjects. An important outcome of this study was that no significant differences were detected between T1DM and T2DM, and regression analysis indicated that the greater the HbA1c immediately prior to starting flash glucose monitoring, the larger the reduction in HbA1c with continued use, independent of the type of diabetes.

The importance of implementing flash glucose monitoring in standard care is emphasized by data from national audits and diabetes registries that show that recommended targets for glycaemic control⁵⁻⁷ are not met by up to two-thirds of people with T1DM⁸ and 50% of people with T2DM⁹. The evidence that flash glucose monitoring or traditional CGM can substantially increase the attainment of HbA1c targets^{10,11} may help reduce the risks of long-term microvascular and macrovascular disease for people with T1DM¹² or T2DM¹³.

In a recently published and more-extensive meta-analysis of real-world data¹⁴, Evans and colleagues were able to include data from 75 studies in which using the FreeStyle Libre system was associated with reductions in HbA1c for 28,063 children and adults with T1DM, and 2415 adults with T2DM over periods from 1 to 24 months. This meta-analysis confirms that using the FreeStyle Libre system is associated with significant reductions in chronic hyperglycaemia, as measured by laboratory HbA1c. For adults these reductions are evident by 3 months after the introduction of flash glucose monitoring, with a fall in HbA1c of -0.53% (5.8 mmol/mol) in T1DM and by -0.45% (5.0 mmol/mol) in T2DM. These reductions are correlated with the starting HbA1c for FreeStyle Libre users. At the 4.5-7.5 month point, for every percentage point increase in mean starting HbA1c, adult users with T1DM will see an additional -0.49% (5.4 mmol/mol) reduction in HbA1c and users with T2DM will see an additional -0.35% (3.9 mmol/mol) fall. These improvements are shown to persist for up to 24 months in T1DM and at least up to 12 months in T2DM, although longer use of the FreeStyle Libre system has not been studied in T2DM.

Importantly, this persistence at 24 months supports the contention that the reductions in HbA1c are due to the use of the FreeStyle Libre system rather than other confounding factors. For example, initiation of the flash

glucose monitoring can have been accompanied by device training or diabetes education, as well as more-focused time with healthcare professionals during the initiation process. However, the durability of the change in HbA1c at 12 and 24 months following initiation argues strongly that the fall in HbA1c is a consequence of using the FreeStyle Libre system for daily diabetes management.

The observed patterns of change in HbA1c in T1DM and T2DM across these 75 real-world studies are not different after starting the FreeStyle Libre system. This indicates that flash glucose monitoring can be used in the same way to reduce long-term glucose exposure for adults with either T1DM or T2DM. Both in T1DM and in T2DM, greater reductions in HbA1c are shown for users with higher starting baselines. The majority of the 2415 adults with T2DM reported in the meta-analysis by Evans and colleagues were reported to be on intensive insulin therapy. A recent publication indicates that adults with T2DM on non-insulin therapy may see a greater reduction by comparison to those on insulin therapy and with similar HbA1c levels at initiation¹⁵.

Together, the weight of accumulated evidence confirms beyond doubt that flash glucose monitoring with the FreeStyle Libre system can substantially reduce HbA1c for people with diabetes and therefore reduce their risk of microvascular or macrovascular disease. These benefits can be achieved in the same way for people with T1DM or T2DM, and for children as well as adults.

1. Bolinder J, et al. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. *Lancet* 2016;388
2. Haak T, et al. Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial. *Diabetes Ther*. 2017;8:55-73
3. Rose L, et al. Improving HbA1c Control in Type 1 or Type 2 Diabetes Using Flash Glucose Monitoring: A Retrospective Observational Analysis in Two German Centres. *Diabetes Ther*. 2021;12:363-372
4. Evans M, et al. The Impact of Flash Glucose Monitoring on Glycaemic Control as Measured by HbA1c: A Meta-analysis of Clinical Trials and Real-World Observational Studies. *Diabetes Ther*. 2020;11:83-95
5. DiMeglio LA, et al. ISPAD Clinical Practice Consensus Guidelines 2018: Glycemic control targets and glucose monitoring for children, adolescents, and young adults with diabetes. *Pediatr Diabetes*. 2018;19:105-114
6. American Diabetes Association. Standards of Medical Care in Diabetes—2021. 6. Glycemic Targets. *Diabetes Care* 2020;44:S73-84
7. Buse JB, et al. 2019 Update to: Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care* 2019;43:487-493
8. Hermann JM, et al. The Transatlantic HbA1c gap: differences in glycaemic control across the lifespan between people included in the US T1D Exchange Registry and those included in the German/Austrian DPV registry. *Diabetic Med*. 2020;37:848-855
9. Khunt K, et al. Achievement of guideline targets for blood pressure, lipid, and glycaemic control in type 2 diabetes: A meta-analysis. *Diabetes Res Clin Pract*. 2018;137:137-48
10. National Paediatric Diabetes Audit Annual Report 2019-2020: Care Processes and Outcomes. Available from: <https://www.hqip.org.uk/wp-content/uploads/2021/06/Ref.-261-NPDA-annual-core-Report-summary-FINAL.pdf>
11. Foster NC, et al. State of Type 1 Diabetes Management and Outcomes from the T1D Exchange in 2016-2018. *Diabetes Technol Ther*. 2019;21:66-72
12. DCCT study group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. *New Engl J Med*. 1993;329:977-986
13. UKPDS Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998;352:837-53
14. Evans M, et al. Reductions in HbA1c with flash glucose monitoring are sustained for up to 24 months: a meta analysis of 75 real-world observational studies. *Diabetes Ther*. 2022; in press
15. Wright EE, et al. Use of Flash Continuous Glucose Monitoring Is Associated With A1C Reduction in People With Type 2 Diabetes Treated With Basal Insulin or Noninsulin Therapy. *Diabetes Spectr*. 2021;34:184-9

Image is for illustrative purposes only. Not real patient or data.



FreeStyle Libre system significantly improves HbA1c in people with T2DM on a basal-bolus regimen



Image is for illustrative purposes only. Not real healthcare professional or patient.

This study from Italy investigated the impact of initiating the FreeStyle Libre system in comparison to self-monitoring of blood glucose (SMBG) for people with T2DM on basal-bolus insulin.

Sixteen hospitals included 322 individuals in the study (56.2% male, mean age 67.2 years). At baseline, HbA1c was $8.9 \pm 0.8\%$ (74 ± 9 mmol/mol). After 3–6 months, 234 complete cases (83 FreeStyle Libre and 151 SMBG users) demonstrated significantly reduced HbA1c for those using the FreeStyle Libre compared to SMBG ($0.3\% \pm 0.12$ [3 mmol/mol ± 1.3], $P=0.0112$).

The authors conclude a beneficial effect of glucose sensor monitoring technology on glucose control in T2DM and intensive insulin treatment. The authors were unable to identify the main cause for the significant change of HbA1c, as there was no difference in daily insulin doses or other glucose lowering medication between the two groups. They suggest insulin titration may have occurred without impacting upon overall total daily doses of insulin amongst the FreeStyle Libre group.

Bosi E et al. The use of flash glucose monitoring significantly improves glycaemic control in type 2 diabetes managed with basal bolus insulin therapy compared to self-monitoring of blood glucose: A prospective observational cohort study. *Diabetes Res Clin Pract.* 2022;183:109172. doi: 10.1016/j.diabres.2021.109172

US and Canadian study finds that HbA1c is reduced in people with T2DM on basal insulin with flash glucose monitoring

This retrospective real-world study and meta-analysis in the US and Canada aimed to assess the impact of FreeStyle Libre system use on HbA1c in adults with T2DM on basal insulin only.

In this group of people with T2DM not on intensive insulin therapy, HbA1c was recorded prior to initiating the FreeStyle Libre system, and 90 and 194 days after starting. The retrospective chart-review study observed a significant improvement in HbA1c 3–6 months after first use of the FreeStyle Libre system (from $9.4\% \pm 1.0\%$ to $8.0\% \pm 1.2\%$, $p<0.0001$).

The meta-analysis included a total of 234 medical records from 14 study sites in the USA ($n=8$) and Canada ($n=6$) from November 2017 to July 2020. HbA1c significantly decreased by $1.1\% \pm 0.14\%$, from baseline $9.2\% \pm 1.0\%$ to $8.1\% \pm 1.1\%$, ($p<0.0001$). The authors concluded that use of the FreeStyle Libre system was associated with reduced HbA1c in people with T2DM treated with basal insulin only.

Carlson AL et al. Flash glucose monitoring in type 2 diabetes managed with basal insulin in the USA: A retrospective real-world chart review study and meta-analysis. *BMJ Open Diabetes Res Care.* 2022; 10(1):e002590. doi: 10.1136/bmjdr-2021-002590

Real-world data supports the use of both flash glucose monitoring and traditional-CGM systems in people with T1DM

A retrospective, single-centre service evaluation of CGM and flash glucose monitoring was undertaken in a large UK teaching hospital.

The researchers aimed to evaluate the impact of flash glucose monitoring with the FreeStyle Libre system and traditional CGM systems on glycaemic outcomes in adults with T1DM under routine clinical care. They identified 789 adults with T1DM using either the FreeStyle Libre system ($n=591$) or Dexcom systems ($n=198$), and analysed time in range, time below range, time above range, coefficient of variation and glucose management index (GMI) for the past three months.

The study showed that under real-life conditions, the use of the FreeStyle Libre system or traditional CGM system is associated with significant improvements in HbA1c in those with baseline HbA1c values >59 mmol/mol (7.5%). Furthermore, they found that hypoglycaemic episodes were low; 65% of FreeStyle Libre system users and 74% of Dexcom users spent less than 4% of the time in hypoglycemia with glucose <3.9 mmol/L (70 mg/dL). These findings are consistent with similar studies, and they further added that in their cohort, males, as well as people living in areas of lower deprivation and people over 30 years of age achieved more time in range with the FreeStyle Libre system.

Lee K et al. Real-world outcomes of glucose sensor use in type 1 diabetes-Findings from a large UK centre. *Biosensors (Basel).* 2021; 11(11):457. doi: 10.3390/bios11110457

Flash glucose monitoring improves HbA1c, decreases hypoglycemia and improves treatment satisfaction in people with T2DM on multiple daily injections

The aim of this prospective observational study was to evaluate the change in HbA1c and treatment satisfaction following the initiation of flash glucose monitoring in adults with T2DM in Saudi Arabia.

All participants (n=54) were managed with multiple daily injections of insulin and HbA1c was $\geq 7\%$ (53 mmol/mol) at baseline. Results showed a statistically significant improvement in HbA1c at 12 weeks, which fell by 0.44% (4.8 mmol/mol; $P < 0.001$) from 8.22% (66.3 mmol/mol) to 7.78% \pm (61.5 mmol/mol). Confirmed hypoglycemic episodes reduced from 4.43 episodes per month to 1.24 (-3.19, $p < 0.001$). Participants also performed significantly more scans per day and treatment satisfaction increased. The authors conclude that a larger multicentre study is warranted to inform future health policy for T2DM in Saudi Arabia.

Al Hayek A et al. The impact of flash glucose monitoring on markers of glycaemic control and patient satisfaction in type 2 diabetes. *Cureus*. 2021;13(6):e16007. doi: 10.7759/cureus.16007

CGM parameters of glycemic control should be considered alongside HbA1c

The aim of this prospective cohort study was to examine the relationship between HbA1c and use of CGM systems in a pediatric population.

Data were collected on time in range (TIR), time below range (TBR), coefficient of variation (CV), number of capillary blood glucose tests, and HbA1c, both before using the FreeStyle Libre system and after one year of use. A total of 191 pediatric patients with type 1 diabetes participated, and they were classified into five groups according to their HbA1c level after one year of using the FreeStyle Libre system.

The study found that although groups with HbA1c $< 6.5\%$ (48 mmol/mol) and HbA1c 6.5–7.0% (48–53 mmol/mol) had the highest TIR (62.2% and 50.5%, respectively), although these values were below optimal control ($> 70\%$) according to the International consensus on TIR. The authors conclude that CGM metrics, such as TIR, should be considered alongside HbA1c as parameters of good metabolic control. Long-term studies of these parameters and long-term complications are needed.

Porcel-Chacón R et al. Good metabolic control in children with type 1 diabetes mellitus: Does glycated hemoglobin correlate with interstitial glucose monitoring using FreeStyle Libre? *J Clin Med*. 2021 24;10(21):491

FreeStyle Libre system is a cost-effective alternative to SMBG in people with insulin-treated T2DM

This Swedish study compared the cost-effectiveness of using the FreeStyle Libre system compared with self-monitoring of blood glucose (SMBG) in insulin-treated T2DM.

Two cohorts of individuals were identified from the Swedish National Diabetes Register. The first cohort comprised those with HbA1c 8–9% (64–75 mmol/mol) and the second was individuals with HbA1c 9–12% (75–108 mmol/mol). Both cohorts saw a reduction in HbA1c after using the FreeStyle Libre system.

Analysis showed that, in those with HbA1c values of 8–9% (64–75 mmol/mol), the FreeStyle Libre provided additional life-years (0.03) and higher quality-adjusted life years (QALYs; 0.50) and total costs (SEK109,957), which resulted in an estimated incremental cost-utility ratio (ICUR) of SEK219,127 per QALY gained. For those with HbA1c values of 9–12% (75–108 mmol/mol), FreeStyle Libre system use resulted in higher life years (0.13), QALYs (0.57), and total costs (SEK82,170), generating an estimated ICUR of SEK144,412 per QALY gained. The authors concluded that for suboptimally controlled insulin-treated T2DM, the FreeStyle Libre system led to better health outcomes than SMBG over a lifetime.

Jendle J et al. Cost-effectiveness of the FreeStyle Libre® System versus blood glucose self-monitoring in individuals with type 2 diabetes on insulin treatment in Sweden. *Diabetes Ther*. 2021;12(12):3137-3152. doi: 10.1007/s13300-021-01172-1



Image for illustrative purposes only. Not real patient.

CGM parameters can help individualise treatment in people with insulin-treated T2DM

This study investigated glucose variations associated with HbA1c in people with T2DM treated with insulin.

Data from a 2-week period were extracted from the Diabetes and Lifestyle Cohort Twente (DIALECT)-2 study (n=79). The researchers investigated the differences in time in range (TIR), time below range (TBR) and time above range between different HbA1c levels (low= ≤7.0% [53 mmol/mol]; intermediate= >7.0–7.8% [54–62 mmol/mol]; high= ≥7.9% [≥63 mmol/mol]), and looked for differences in glucose variability. They also evaluated the frequency, duration, and start time of the hypoglycemic and hyperglycemic episodes.

An important finding was that patients in the low HbA1c category did not have a higher TIR than those in the intermediate category, and there were no differences in glucose variability between these two groups. It was also noted that nocturnal TBR episodes occurred across all HbA1c categories, which accounted for 61% of patients during the study period. Interestingly, the frequency of nocturnal TBR episodes was not lower in patients with the higher HbA1c values, compared with low or intermediate HbA1c values. The authors conclude that, in order to allow individualised glycaemic control, CGM parameters should be used alongside HbA1c measures.

den Braber N et al. Glucose regulation beyond HbA1c in type 2 diabetes treated with insulin: Real-world evidence from the DIALECT-2 cohort. *Diabetes Care*. 2021; 44(10):2238–44. doi: 10.2337/dc20-2241

Flash glucose monitoring is useful in lowering HbA1c in people with insulin-treated T2DM

This Canadian retrospective real-world study assessed whether starting flash glucose monitoring led to a change in HbA1c in basal insulin-treated adults with T2DM.

Medical records were reviewed in people with a diagnosis of T2DM for at least one year and who had been using the FreeStyle Libre system for at least 3 months. HbA1c levels were recorded prior to device use and then again 3–6 months after starting the device. Data showed that HbA1c significantly decreased by $0.8\% \pm 1.1$ ($P < 0.0001$) from baseline (8.9% [74 mmol/mol]) to 3–6 months (8.1% [65 mmol/mol]). The authors conclude that this study further supports the use of flash glucose monitoring management in T2DM treated with basal insulin only.

Elliott T et al. The impact of flash glucose monitoring on glycated hemoglobin in type 2 diabetes managed with basal insulin in Canada: A retrospective real-world chart review study. *Diab Vasc Dis Res*. 2021; 18(4):14791641211021374. doi: 10.1177/14791641211021374

Number of daily sensor scan rates associated with better HbA1c levels in children using the FreeStyle Libre system

An assessment of the relationship between daily FreeStyle Libre sensor scan rates and changes in both HbA1c and time spent in hypoglycaemia in children.

A total of 145 children (mean age 11 years), who were naïve to the FreeStyle Libre system, had their HbA1c assessed at baseline, 1, 3, and 6 months after starting to use the FreeStyle Libre system, along with other glucose metrics. The study found that HbA1c was higher at lower scan rates, and decreased as scan rate increased to between 15–20 scans. Interestingly, HbA1c values then began to increase with greater than 20 scans per day. The authors speculate that this may reflect psycho-emotional exhaustion for children seeking positive results in the short term by raising their number of scans without consequent action.

A further important observation was that there was a significant correlation between daily scan rates and the change in three measures of hypoglycaemia over the 6-month study period. Reductions in hypoglycaemia were evident in subjects with higher daily scan rates. The authors suggest that further study is required to identify which children and young people with T1DM are most likely to benefit from use of the FreeStyle Libre system.

Leiva-Gea I et al. Metabolic control of the FreeStyle Libre System in the pediatric population with type 1 diabetes dependent on sensor adherence. *J Clin Med*. 2022; 11(2):286. doi: 10.3390/jcm11020286

1. For children aged 4–12, a caregiver at least 18 years old is responsible for supervising, managing, and assisting them in using the FreeStyle Libre system and interpreting its readings.
2. Image is for illustrative purposes only. Not real patient.



Real-world data from Israel shows increased scan rates with the FreeStyle Libre system is associated with increased time in range and decreased hypoglycemia

This study from Israel aimed to determine whether more frequent scanning with the FreeStyle Libre system is associated with better glycemic control.

The researchers extracted anonymous data from 131,639 separate sensors, comprising 152 million individual glucose readings for users in Israel. Mean daily scan rates ranged from 4.1 scans/day (lowest 10%) to 38.7 scans/day (highest 10%). Time in range (TIR) data showed 70% TIR for the highest scanning group, compared with 56.9%, in the lowest scanning group ($P < 0.001$). The authors found a similar pattern for estimated A1c; patients in the lowest scan-rate group had an eA1c of 7.6% and the highest scan-rate group had an eA1c of 6.7% ($P < 0.001$).

A similar pattern was seen for hyperglycaemia (>180 mg/dL), which decreased with more frequent scanning (from 37.2% to 23.6%). Median %TBR <54 mg/dL rose from 0.95% to 1.23% as scan rates increase from 4.1 to 11.1 scans/day. Thereafter, fell to 0.87% at 18 scans/day. This study defines important benchmark levels for %TIR amongst people with diabetes in Israel, using the FreeStyle Libre system.

Eldor R et al. Flash glucose monitoring in Israel: understanding real-world associations between self-monitoring frequency and metrics of glycemic control. *Endocr Pract.* 2022; S1530-891X(22)00045-3. doi: 10.1016/j.eprac.2022.02.004

FreeStyle Libre 2 system can improve diabetes self-management and glycemic control in young people with T1DM using insulin pumps

This prospective single-centre cohort study included 47 children and young people with T1DM (aged 13–21 years) who had relied previously on checking their glucose levels using self-monitored blood glucose (SMBG) fingerprick tests.

All 47 insulin pump users were introduced to the FreeStyle Libre 2 system and given the appropriate education. All glycemic data were collected at baseline and then again at 12 weeks. Participants also completed the 16-item Diabetes Self-Management Questionnaire (DSMQ) at baseline and 12 weeks.

Baseline glucose monitoring frequency was 2.4 times per day with SMBG, but this increased to 5.8 glucose scans per day after 12 weeks of FreeStyle Libre 2 system, in line with clinical guidelines. There were also significant improvements on all relevant glycemic metrics, and in the diabetes self-management subdomain of glucose management. Furthermore, compared with baseline, three DSMQ items ('check blood sugar levels with care and attention', 'take diabetes medication as prescribed' and 'record blood sugar levels regularly') showed an improvement at 12 weeks after initiating the FreeStyle Libre 2 system.

Al Hayek AA et al. Effectiveness of the FreeStyle Libre 2 flash glucose monitoring system on diabetes self-management practices and glycemic parameters among patients with type 1 diabetes using insulin pump. *Diabetes Metab Syndr.* 2021; 15(5):102265. doi: 10.1016/j.dsx.2021.102265

breakingnews

FLASH-UK RCT in people with T1DM using the Freestyle Libre 2 system investigates HbA1c over 12 weeks and 24 weeks compared to SMBG

In their introduction to this study, the investigators of the FLASH-UK randomised controlled trial (RCT) note the lack of RCT data to assess the efficacy of the system, an economic evaluation of the relative costs and benefits of the system, or an assessment of patient acceptability.¹ Therefore, the investigators set out to establish whether use of flash glucose monitoring would affect glycaemic control in adults with type 1 diabetes (T1DM).

The FLASH-UK multi-centre, open-label, two arm, parallel, study is the first RCT of the FreeStyle Libre 2 system in people with T1DM. The primary aim of the study was to evaluate the impact of FreeStyle Libre 2 use over 6 months in this population to improve HbA1c compared with self-monitoring of blood glucose

(SMBG). Secondary outcomes included sensor-based metrics such as time in ranges, insulin dose changes, adverse events and user reported psychosocial measures. The user experience of the FreeStyle Libre 2 system and cost effectiveness were also explored.¹

The FLASH-UK RCT was conducted in primary and secondary care sites and included 156 individuals aged 16 years or more, with T1DM treated by either multiple daily insulin injections or insulin pump therapy, and with an HbA1c 7.5%–11% (59 to 97 mmol/mol). Study participants were randomised 1:1 to either the intervention or control arm and their glycaemic management was reviewed at 4, 12 and 24 weeks.¹

Preliminary results from the FLASH-UK study, indicating significant statistical

and clinical improvements in measures of glycemia amongst the FreeStyle Libre 2 group, with increased user-reported treatment satisfaction and cost-effectiveness data, were shared at the 15th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD), April 2022 in Barcelona, Spain by the Principal Investigator Dr Leelarathna, (Manchester Diabetes Centre and University of Manchester, UK), and Dr Emma Wilmot (University Hospitals of Derby and Burton NHS Foundation Trust, UK).

We will have all the results from this exciting study in the next issue of the *Sensor Report* once the data results of this exciting RCT are formally published.

1. Wilmot EG, et al. Flash glucose monitoring with the FreeStyle Libre 2 compared with self-monitoring of blood glucose in suboptimally controlled type 1 diabetes: the FLASH-UK randomised controlled trial protocol. *BMJ Open.* 2021 Jul 14;11(7):e050713. doi: 10.1136/bmjopen-2021-050713

A practical approach to person-centred education on the functionality of CGM devices: The use of optional alarms

This interesting practical guide provides advice to healthcare professionals (HCPs) on counselling people with diabetes on the use of optional alarms, which are a feature of the FreeStyle Libre 2 and FreeStyle Libre 3 systems.

Although glucose alarms can improve TIR for the person with diabetes, many patients are reluctant to switch to the FreeStyle Libre 2 system because there is an assumption that the alarms are a mandatory feature. This is not the case, but it is often not known that these alarms can be disabled.

The authors stress the importance of educating individual people with diabetes about their options when using the FreeStyle Libre 2 system. The authors helpfully detail a 5-step practical approach to educating the patient to make the right choice for them. Some patients may be attracted to the system because of the alarm capabilities, but others may be more comfortable without the alarms. As part of patient-centred care, diabetes HCPs should be able to offer advice regarding the functionality of the glucose alarms, as well as how to disable them.

Miller E, et al. Just because you can, doesn't mean you should... now. A practical approach to counselling persons with diabetes on use of optional CGM alarms. *Diabetes Technol Ther*. 2021; 23(S3):S66-S71. doi: 10.1089/dia.2021.0192

Association of Children's Diabetes Clinicians offer practical support on starting CGM use in children and young people

Written by professionals aligned to the Association of Children's Diabetes Clinicians (ACDC), this practical guide offers advice on how to use CGM in children and young people (CYP).

The aim is to help clinicians identify which CYP may be most likely to benefit and how the technology may be implemented in order to maximise the clinical benefits. The article was published in addition to the 2017 guidelines developed by the ACDC, to reflect the significant advances in CGM technology that has happened since that time.

The article details many practical points to consider and highlights that careful patient profiling and training is important to maximise the clinical benefit. The authors emphasize that both traditional CGM and FreeStyle Libre systems support improvements in HbA1c and reduce hypoglycaemia. Furthermore, they acknowledge that diabetes related distress can be reduced by the use of CGM systems, especially as part of hybrid closed loop therapy. Although CGM technologies may not be appropriate for all CYP, the ACDC authors conclude that they provide a valuable diabetes management tool for many families.

Soni A et al. A practical approach to continuous glucose monitoring (rtCGM) and FreeStyle Libre systems (isCGM) in children and young people with type 1 diabetes. *Diabetes Res Clin Pract*. 2022;184:109196. doi: 10.1016/j.diabres.2022.109196

Opinion from diabetes leaders highlights how differences between GMI and HbA1c may be used to benefit glucose management

This paper sets out to show that differences between laboratory-measured HbA1c and GMI should be expected, and that understanding this difference can be a valuable part of adjusting diabetes therapy.

Since an HbA1c test result is typically reviewed every 3 months or less, even an on-target HbA1c reading can mask the risk of hypoglycaemia or extreme glucose fluctuations. On the other hand, GMI is based on short-term average glucose values, rather than long-term glucose exposure, and is not influenced by non-glycemic factors, such as the glycation rate of blood cells.

The authors argue that understanding the factors that cause differences between HbA1c and GMI is an important clinical skill by which short-term glucose control, as indicated by the GMI, can be mapped and compared with the longer-term HbA1c metric. Where GMI is significantly lower than HbA1c, the risk of hypoglycemia with treatment intensification is greater than when GMI is the same or higher than HbA1c. Understanding the relationship between GMI and HbA1c can assist in individualising care for the diabetes patient.

Gomez-Peralta F et al. Understanding the clinical implications of differences between glucose management indicator and glycated haemoglobin. *Diabetes Obes Metab*. 2022 Jan 4. doi: 10.1111/dom.14638

did you know...

Essential CME on GMI as a glucometric can be accessed at: www.diabetes-symposium.org/gmi

Study confirms that GMI and HbA1c are not identical in children and young people with T1DM

Previous research has indicated a marked discordance between HbA1c and GMI in adults, and this paper reports on a study comparing these two metrics in a large cohort of children and young people with T1DM.

HbA1c and CGM data were collected for 12 weeks in 805 patients. The cohort was stratified by type of CGM, insulin therapy, gender, age and puberty. The results showed that the discordance between the two metrics, calculated over the 12-week sampling period, was <0.1% in only 25% of patients, while 33.9% and 9.2% of subjects had an absolute difference $\geq 0.5\%$ and $\geq 1.0\%$, respectively.

Since a third of the participants in this study had significant discordance between HbA1c and GMI, the authors suggest that the size of this difference, and whether GMI is lower or higher than HbA1c, should be considered by diabetes healthcare professionals when comparing the two metrics.

Piona C et al. Evaluation of HbA1c and glucose management indicator discordance in a population of children and adolescents with type 1 diabetes. *Pediatr Diabetes*. 2022; 23(1):84-89. doi: 10.1111/pedi.13299

People with poor glycemic control and those who test infrequently can benefit more from flash glucose monitoring

This prospective observational study from Croatia looked at the effectiveness of implementing the FreeStyle Libre system in a real-life clinical setting, with particular interest on the effect of initial education.

The study involved 425 people with T1DM who were followed up for 3–12 months. They all received education over 5 days when starting the FreeStyle Libre system. There was a significant decrease in HbA1c values across the whole sample at 3 months ($P < 0.001$). The authors note that the change in HbA1c values across the cohort was driven mainly by an improvement in a subgroup of patients with HbA1c $> 7\%$ (53 mmol/mol) in the first 3 months (reduction from 8.22% [66 mmol/mol] to 7.68% [61 mmol/mol]; $P < 0.0001$).

Notably, in subjects who were previously performing fingerprick tests < 5 times per day, HbA1c levels decreased at both 3 months and 6 months ($P < 0.05$ and $P < 0.001$, respectively). The authors suggest that these improvements were driven by the consequences of more glucose scanning each day. They conclude that those with poor glycemic control and those that test less-frequently using SMBG can benefit the most from the FreeStyle Libre system.

Caneci Varzic S et al. Assessment of FreeStyle Libre flash glucose monitoring system implementation in real life clinical setting: A prospective observational study. *Diagnostics (Basel)*. 2021; 11(2):305. doi: 10.3390/diagnostics11020305

Canadian analysis points to the opportunity to change the organization and delivery of care using the FreeStyle Libre system

This paper reports on the wider value of flash glucose monitoring from the perspectives of people living with diabetes, healthcare providers and healthcare policy stakeholders.

Literature searches on the impact of the FreeStyle Libre system in diabetes were analyzed in the context of the outcomes of three healthcare attitudes surveys among people with diabetes and diabetes healthcare professionals in Canada. These combined approaches reveal that the proven benefits of the FreeStyle Libre system on limiting hypoglycemia, lowering HbA1c, optimizing metrics of glucose control and reducing hospital admissions, are accompanied by improvements in patients' quality of life, work productivity, and savings to the health system.

The authors conclude that the FreeStyle Libre system has created an opportunity to change the organization and delivery of care in Canada. This was demonstrated during COVID-19 restrictions on access to standard care in Canada, thus generating system-wide benefits in addition to those accrued by patients and HCPs. This can include telemedicine with remote monitoring systems that create the opportunity for simultaneous review of glucose data with HCPs and shared decision-making, thus encouraging adherence with treatment.

Glennie JL, et al. Sensor-Based Technology: Bringing Value to People with Diabetes and the Healthcare System in an Evolving World. *Clinicoecon Outcomes Res*. 2022;14:75-90. doi:10.2147/CEOR.S346736



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