HbA₁c and hypoglycaemia outcomes for people with type 1 diabetes due to the introduction of a single-day structured education programme and flash glucose monitoring

GILLIAN L GARDEN¹,², DAVID W HUNT¹, KAREN MACKIE¹, BEVERLY TUTHILL¹, HELEN GRIFFITH¹, DAVID L RUSSELL-JONES¹,², ROSELLE A HERRING¹,²

Abstract
People with type 1 diabetes who met NHS England funding criteria attended an accredited, intensive one-day structured education programme and completed the online FreeStyle Libre Academy training module followed by a 30-minute healthcare professional face-to-face practical training session. HbA₁c, Gold hypoglycaemia score and Diabetes Distress Screening score were documented before commencement of the intervention and at 6 months. 213 people with type 1 diabetes (52% men; average age 48 years (range 18–87)) completed the 6-month intervention. Overall mean HbA₁c reduced by 6 mmol/mol (0.5%) from 62±14 mmol/mol (7.8%) to 56±12 mmol/mol (7.3%) (p<0.0001). Subgroup analysis of participants with a baseline HbA₁c ≥54 mmol/mol (7.1%) revealed a more dramatic reduction of 10 mmol/mol (0.9%) from 69±12 mmol/mol (8.5%) to 59±11 mmol/mol (7.6%). No deterioration was demonstrated for people with HbA₁c <54 mmol/mol (7.1%). 143 people (75%) reported a reduction in hypoglycaemia episodes and 162 (85%) reported a reduction in time spent in the hypoglycaemic range. There was significant improvement in the Gold score (p<0.0001) and Diabetes Distress Screening score (p=0.0001). Rates of hospital admissions, paramedic call-outs and third-party assistance were reduced. The combination of a one-day intensive structured education programme alongside flash glucose monitoring initiation provides a pragmatic, cost-effective and easily implemented intervention with positive clinical outcomes at 6 months.

Br J Diabetes 2021; 21:84-88

Key words: education, self-management, type 1 diabetes

Introduction
Type 1 diabetes is a complex medical condition and, despite advances in insulin delivery and therapy, many people do not achieve optimal glycaemic control and are at risk of hypoglycaemia and long-term diabetes-related complications. Changes in glucose monitoring have revolutionised care. Continuous glucose monitoring using interstitial glucose levels to aid self-management have shown improvements in hypoglycaemia and glycaemic control.¹,² However, funding restrictions in the UK have limited its use. Flash glucose monitoring (FGM) became available on the UK National Health Services drug tariff in 2017 for people with type 1 diabetes.³ FGM requires a sensor to be placed on a person’s arm which lasts up to 14 days to measure interstitial glucose levels. This provides an individual with a clearer awareness of glucose levels during the day and night, enhancing positive decision making. Early clinical trial data are very promising, with randomised controlled trials demonstrating a reduction in hypoglycaemia for people with type 1 diabetes.⁴ In addition, the largest real-world data from the UK nationwide study of FGM in people with type 1 diabetes have also recently published results demonstrating improvement in glycaemic control, hypoglycaemia awareness, reduced diabetes-related distress and reduced hospital admissions.⁵

NHS England (NHSE) have produced recommendations for Clinical Commissioning Groups (CCGs), which set out the criteria for people suitable for FGM including the need for education and follow-up. NHSE currently reimburses CCGs for each set of sensors prescribed for up to 20% of their population with type 1 diabetes – minus a proportion of cost savings from reduced requirement to fund test strips for this group.³

We present clinical outcomes combining initiation of FGM, attendance at an accredited 1-day structured education and formal 6-month review process for people with type 1 diabetes meeting NHSE criteria for FGM reimbursement. We have named the accredited 1-day (7-hour) structured education programme Cedric as it is held at the Centre for Endocrinology, Diabetes and Research centre.
Methods

Clinical pathway
People with type 1 diabetes from Guildford and Waverley CCG and neighbouring CCGs who met the NHSE criteria for FGM reimbursement from April 2018 onwards were included. Following collaboration with Guildford and Waverley CCG, a patient initiation pathway was agreed. This pathway was subsequently adopted by neighbouring CCGs and is shown in Appendix 1 (available online at www.bjd-abcd.com). Eligible individuals were informed of the pathway and a formal contract with personalised goals was set to be achieved during the 6-month trial. The contract was signed by the individual and medical professional and a copy was sent to their general practitioner (GP). Participants completed a 2-hour online FGM academy training module and were enrolled in the face-to-face structured education course. The structured education course lasted 7 hours and covered key self-management topics including what diabetes is, diabetes control and targets, carbohydrate counting and individual insulin adjustment, hypoglycaemia awareness, exercise and physical activity adjustments, illness and sick day rules in addition to annual diabetes review and complication awareness.

It was also agreed that their clinical and demographic data would be entered into the Association of British Clinical Diabetologists (ABCD) FreeStyle Libre Audit, which had Caldicott Guardian approval. At the end of the structured education course a 30-minute face-to-face practical training session on FGM was delivered by a diabetes specialist nurse. Individuals could email or arrange one-to-one telephone or face-to-face discussion over the 6-month period with a diabetes specialist as required and a formal follow-up consultation at approximately 6 months was offered during which the individual's progress was reviewed against the goals set in the contract. If the goals were met the participant was granted longer term continuation of FGM which was formally communicated back to their GP.

Demographic data, HbA1c and diabetes-specific data as per the ABCD FreeStyle Libre Audit Programme was collected at initiation and at the 6-month follow-up consultation. The primary outcome measure was HbA1c. Secondary outcomes included hyperglycaemia- or hypoglycaemia-related hospital admission, paramedic call-outs and third-party assistance, frequency of hypoglycaemic episodes, time spent in hypoglycaemic range, hypoglycaemic awareness assessed using Gold’s Score and quality of life indicators assessed using the Diabetes Distress Screening Scale 1 and 2. Both quantitative and qualitative data reviewing the intervention were also collected.

Statistical analysis of audit data
Anonymised Trust data were extracted from the ABCD FreeStyle Libre Nationwide Audit website (http://www.diabetologists-abcd.org.uk/n3/FreeStyle_Libre_Audit.htm) and entered onto a Microsoft Excel 2010 spreadsheet for analysis. Paired t-test analysis was undertaken for statistical significance.

Audit findings

Demographics
Between April 2018 and October 2019 a total of 213 adults with type 1 diabetes had completed the 6-month programme. This was 20% of people with type 1 diabetes who were known to our service during this time period. Of the population under our service for type 1 diabetes care, 1.0% are in the indices of multiple deprivation (IMD) most deprived category, 6.3% in the second most deprived, 13% in the third most deprived, 21.3% in the second least deprived and 53.6% in the least deprived category.

Of the 213 participants, 52% were men, the mean±SD age was 48±16.8 years and 72% were following a regime of multiple daily injections, 20% were using continuous subcutaneous insulin infusion and 8% were using another insulin regime. Mean±SD baseline HbA1c was 62±14 mmol/mol (7.8%). There were a number of overlapping indications for starting FGM including reduction in frequent hypoglycaemia, improvement in HbA1c and reduction or replacement of capillary monitoring.

HbA1c variability
The mean HbA1c fell from 62±14 mmol/mol (7.8%) to 56±12 mmol/mol (7.3%), showing a statistically significant reduction in mean HbA1c of 6 mmol/mol (0.5%) (p<0.0001). Subgroup analysis was conducted based upon baseline HbA1c into three categories: above target range (≥54 mmol/mol or 7.1%), in target range (44–53 mmol/mol or 6.2–7.0%) and below target range (≤43 mmol/mol or 6.1%). Of the 150 people with a baseline HbA1c above target, the mean±SD baseline HbA1c was 69±12 mmol/mol (8.5%), falling to a mean HbA1c of 59±11 mmol/mol (7.6%) at 6 months (p<0.0001). The two subgroups with a baseline HbA1c within the target range (n=50) and within the below target range (n=13) had no statistically significant change in HbA1c. Table 1 shows the mean change in HbA1c for all participants and for each subgroup. Figure 1 shows the pre-baseline and post-intervention HbA1c in a histogram and Figure 2 presents the change in individual HbA1c for each study participant.

Hospital admissions/paramedic call-out and third-party assistance
Not all study participants had baseline and post-intervention data for admissions to hospital, paramedic call-outs and events requiring third-party assistance. For each category, data were only included for analysis if participants had complete data. Of the entire cohort (n=213), 198 individuals had complete data coded for hospital admissions relating to hyper- or hypoglycaemia.

During the 12-month period prior to the initial consultation, 23 hospital admissions were reported, equivalent to 11.5 admissions over a 6-month period. Admission rates for the 6-month post-intervention period reduced to four. Complete data were available for 194 participants regarding paramedic call-out...
events. Overall, 19 paramedic call-outs were reported for the 12 months prior to the intervention, equivalent to 9.5 over a 6-month period, compared with only two events in the 6 months after the intervention \( (p<0.0001) \). Similarly, episodes of hypoglycaemia requiring third party assistance \( (n=147) \) fell from 44 over the 12 months pre-intervention, equivalent to 22 episodes over a 6-month period, to a single event in the 6 months post-intervention \( (p<0.0001) \). Table 2 compares the baseline and post-intervention rates of hospital admission, paramedic call-outs and third-party assistance against the ABCD Nationwide Audit outcomes.

### Table 1 Mean±SD HbA1C pre-intervention and post-intervention and mean change in HbA1C for all patients and each subgroup

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline HbA1C (mmol/mol)</th>
<th>Post-intervention HbA1C (mmol/mol)</th>
<th>Change in mean HbA1C (mmol/mol)</th>
<th>Paired t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients ( (n=213) )</td>
<td>62.3±14.3</td>
<td>55.8±12.0</td>
<td>-6.5</td>
<td>( p&lt;0.0001^* )</td>
</tr>
<tr>
<td>Pre- HbA1C ≤43 ( (n=13) )</td>
<td>39.7±2.8</td>
<td>39.2±7.4</td>
<td>-0.5</td>
<td>( p=0.7384 )</td>
</tr>
<tr>
<td>Pre- HbA1C 44–53 ( (n=50) )</td>
<td>49.1±2.9</td>
<td>49.2±9.1</td>
<td>+0.1</td>
<td>( p=0.9285 )</td>
</tr>
<tr>
<td>Pre- HbA1C ≥54 ( (n=150) )</td>
<td>68.7±12.0</td>
<td>59.4±11.1</td>
<td>-9.3</td>
<td>( p&lt;0.0001^* )</td>
</tr>
</tbody>
</table>

### Table 2 Rate of hospital admission, paramedic call-outs and third-party assistance pre- and post-intervention

<table>
<thead>
<tr>
<th></th>
<th>Total pre-intervention (12 months)</th>
<th>Rate pre-intervention (6 months)</th>
<th>Total post-intervention (6 months)</th>
<th>Paired t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSCH data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total diabetes-related admissions ( (n=198) )</td>
<td>23</td>
<td>11.5</td>
<td>4</td>
<td>0.0872</td>
</tr>
<tr>
<td>Paramedic call-outs ( (n=194) )</td>
<td>19</td>
<td>9.5</td>
<td>2</td>
<td>0.0428*</td>
</tr>
<tr>
<td>Third-party assistance ( (n=147) )</td>
<td>44</td>
<td>22</td>
<td>1</td>
<td>0.0141*</td>
</tr>
<tr>
<td>ABCD FreeStyle Libre Nationwide Audit data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total diabetes-related admissions ( (n=1,978) )</td>
<td>389</td>
<td>194.5</td>
<td>131</td>
<td>N/A</td>
</tr>
<tr>
<td>for hyperglycaemia and DKA ( (n=1,940) )</td>
<td>275</td>
<td>123.5</td>
<td>38</td>
<td>N/A</td>
</tr>
<tr>
<td>for hypoglycaemia</td>
<td>1032</td>
<td>516</td>
<td>237</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| DKA, diabetic ketoacidosis; N/A, not available; RSCH, Royal Surrey County Hospital

Hypoglycaemic awareness and psychological impact

Individuals were asked to record their subjective hypoglycaemic awareness and the psychological impact of living with diabetes using two validated scales: the Gold Score and the Diabetes Distress Screening Scale (DDS). Participants reported a significant improvement in hypoglycaemic awareness, with the Gold Score changing from 1.8±0.1 to 1.4±0.9 \( (p<0.0001) \) and a significant reduction in distress caused by their diabetes with DDS1 changing from 2.5 to 2.0 and DDS2 from 2.7 to 2.2 \( (p<0.0001) \); see Figure 2.

**Figure 1.** Histogram showing pre-intervention and post-intervention HbA1C

**Figure 2.** Scattergram showing the change in HbA1C for each individual based on pre-intervention subgroup: pre- HbA1C ≤43 mmol/mol (blue), pre- HbA1C 44–53 mmol/mol (orange) and pre- HbA1C ≥54 mmol/mol (grey)
Table 3 Comparison of study data outcomes with the ABCD Nationwide outcomes

<table>
<thead>
<tr>
<th>No of participants</th>
<th>ABCD FreeStyle Libre Nationwide Audit data</th>
<th>RSCH (FGM + Cedric structured education)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1 diabetes</td>
<td>3126 (98.2%)</td>
<td>213</td>
</tr>
<tr>
<td>Age (years)</td>
<td>39.5±19.6</td>
<td>48.0 ± 16.8</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>1688 (53%)</td>
<td>102 (48%)</td>
</tr>
<tr>
<td>Completion of structured education</td>
<td>2002 (65%)</td>
<td>212 (100%)</td>
</tr>
<tr>
<td>Mean HbA1c mmol/mol</td>
<td>Pre-intervention 69.8±18.2</td>
<td>Post-intervention 62.3±18.5</td>
</tr>
<tr>
<td>Baseline HbA1c ≥69.5 mmol/mol</td>
<td>57.7±7.7</td>
<td>65±13</td>
</tr>
<tr>
<td>Baseline HbA1c &gt;69.5 mmol/mol</td>
<td>85.5±16.0</td>
<td>73±15.8</td>
</tr>
<tr>
<td>Gold Score</td>
<td>2.7±1.9</td>
<td>2.4±1.7</td>
</tr>
<tr>
<td>DDS1</td>
<td>2.9</td>
<td>2.2</td>
</tr>
<tr>
<td>DDS2</td>
<td>3.0</td>
<td>2.2</td>
</tr>
</tbody>
</table>

DDS, Diabetes Distress Screening score; FGM, flash glucose monitoring; RSCH, Royal Surrey County Hospital.

Table 3 for numerical data. Seventy-five percent of participants (n=143) reported an increase in hypoglycaemic detection and 85% (n=162) reported a reduction in the time spent in the hypoglycaemic range following intervention.

Overall, qualitative feedback on the Cedric structured education course in combination with a 6-month trial of FGM was overwhelmingly positive. Individuals valued all aspects of the face-to-face structured education course, but particularly the opportunity to work through scenarios in small groups and find solutions to problems with other people who share the same diagnosis and challenges managing their diabetes.

Comparison with ABCD FreeStyle Libre Nationwide Audit data

Table 3 shows a comparison of the results of this study with the ABCD FreeStyle Libre Nationwide Audit outcomes. In order to make a direct comparison, HbA1c has been re-analysed to be in line with the ABCD Nationwide HbA1c subgroup analysis of ≥69.5 mmol/mol. The greatest impact on HbA1c was seen with the higher baseline HbA1c with a mean reduction of 15.2 mmol/mol compared with 12.4 mmol/mol in the ABCD FreeStyle Libre Nationwide Audit.

Discussion

We present data which show that the combination of an accredited single-day structured education programme alongside a 6-month trial of FGM is an effective intervention in improving HbA1c in people with type 1 diabetes with a baseline HbA1c ≥54 mmol/mol (7.1%). In addition, there was a significant reduction in the number of hypoglycaemia episodes and a reduction in the time spent in the hypoglycaemic range. The greatest improvement in HbA1c was seen in people who presented with a higher HbA1c at baseline.

A number of studies have evidenced the positive association between structured education and enhanced diabetes knowledge, improved self-care behaviour and better clinical outcomes measured by a decline in HbA1c and improved quality of life. The Dose Adjustment for Normal Eating (DAFNE) programme was the first structured education course to show a modest benefit in glycaemic control with a reduction in HbA1c of 1% at 6 months and no significant increase in severe hypoglycaemia. Structured education is now an integral part of the treatment of type 1 diabetes and is stipulated in current NICE guidance.

It is difficult to ascertain the proportion of reduction in HbA1c that can be attributed to the structured education programme and that resulting from the use of the FGM system, but it is highly probable that the combination of the two intervention modalities resulted in an accumulative effect. The large observational ABCD FreeStyle Libre study showed a similar trend of a significant reduction in HbA1c, especially in those with a higher baseline HbA1c, but not to the degree that we have demonstrated with the combined intervention. Only 65% of participants in the national observational audit had completed a structured education course at some point in their diagnosis. Therefore, the additional benefit seen in this study is likely to be secondary to attendance at type 1 structured education, especially for people with higher HbA1c prior to initiation of FGM. To date, randomised controlled trials of FGM alone have not demonstrated a reduction in HbA1c, further supporting evidence that a combination of structured education and FGM is important.

In addition to a reduction in HbA1c, there was a significant reduction in episodes of hypoglycaemia and a significant improvement in hypoglycaemic awareness. Structured education can influence lifestyle factors including carbohydrate to insulin ratios, carbohydrate counting and managing glucose levels during periods of physical activity or illness. Several education programmes have shown a positive impact on severe hypoglycaemia at 6 months. FGM can complement structured education skills as it enables recognition of a glucose trend which provides a greater sense of control for people with diabetes.
enabling early identification and prevention of hypoglycaemia or hyperglycaemia. Subjective factors such as satisfaction with treatment measured by the Diabetes Treatment Satisfaction Questionnaire and awareness of reduced hypoglycaemia have also been demonstrated with FGM, further supporting the positive psychological impact. A limitation of many structured education courses for type 1 diabetes is the duration of the programmes. The DAFNE programme, which is delivered over five consecutive days, is costly, time-intensive and often impractical for young working people to attend, which may be why widespread uptake across the UK has proved challenging. The National Diabetes Audit of 2016–17 found that, in 2015, only 41.3% of people who were newly diagnosed with type 1 diabetes were offered structured education within 12 months of diagnosis, and only 3.3% attended. In addition, the staffing levels required to deliver such a time-demanding course by qualified healthcare professionals must also be considered in a pressurised NHS and shortage of diabetes specialist nurses. It was these factors that incentivised the development of Cedric as an intensive single-day education programme. It is evidence-based, flexible to the needs of the individual and has a specific aim and learning objectives, all which support self-management attitudes, beliefs, knowledge and skills for the learner.

Conclusion

Structured education and FGM individually have benefits to self-management for people with type 1 diabetes. This study is the first to show that the combination of an accredited 1-day intensive structured education programme alongside FGM initiation has an cumulative benefits and provides a pragmatic, cost-effective and easily implemented intervention for people with type 1 diabetes with reduction in HbA1c and significant improvement in hypoglycaemia, Gold Score and Diabetes Distress Screening Score at 6 months, especially for people who are not at target HbA1c.

Acknowledgements: We are very grateful to Guildford and Wa-Verly Clinical Commissioning Group for supporting clinical pathway development and enabling early adoption of monitoring technology for this patient group.

Conflict of interest: DLR-J has received research funding or advisory board or lecture fee honoraria from AstraZeneca, Novo Nordisk, Sanofi, Lilly, Merck Sharp & Dohme and Janssen. He is contracted as an independent advisor to the UK Civil Aviation Authority (CAAs). RH has received research funding or advisory board or lecture fee honoraria from AstraZeneca, Novo Nordisk, Sanofi, Lilly, Merck Sharp & Dohme, and Janssen. GLG, DWH, KM, BT & HG have nothing to declare.

Funding: None.

References

Appendix 1. Surrey and North West Sussex Area Prescribing Committee – FGM pathway

Surrey & North West Sussex Area Prescribing Committee — Flash Glucose System Management Pathway

Patient already using FGS and self-funding and may meet the NHS England criteria

Patient already using FGS initiated by NHS specialist under local (RMOC) criteria

Patient NOT using FGS but may meet the NHS England criteria

NO

YES

Review for suitability and eligibility against NHS England criteria at next routine diabetes specialist clinic review

GP referral for routine appointment, with NHS specialist diabetes service for review of diabetes

NHS England criteria shown over page

NHS England criteria IS met

NHS England criteria NOT met

Patient is already under care of NHS specialist diabetes service?

Primary care prescribing of FGS sensors

Primary care prescribing of FGS sensors

NHS specialist team completes next scheduled FGS review and ABCD audit

Patient has shown improvement in HbA1c since start of FGS (for current users of FGS only)

Complete Initiation and Transfer form/s and send with clinic letter to patient’s GP — failure of comms may delay prescribing

STOP NHS prescribing or do not start prescribing FGS, update GP and advise on alternative monitoring arrangements (this may include the patient deciding to self-fund FGS)

Patient has demonstrable improvement in diabetes self-management or improvement in psycho-social well-being

Primary care to continue prescribing FGS dependant on successful regular review. Use of blood glucose testing strips should reduce. If use stays the same or increases contact the patient’s diabetes specialist

STOP prescribing FGS, update GP, and advise on suitable ongoing monitoring arrangements (this may include patient deciding to self-fund FGS)

No Colour key

Primary care

Secondary care

Crawley CCG│East Surrey CCG│Horsham & Mid Sussex CCG│Guildford & Waverley CCG│North West Surrey CCG│Surrey Downs CCG

Version 1 approved by Surrey and North West Sussex Area Prescribing Committee

Date: Expires: Review: