

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

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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. HbA_{1c}, 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 HbA_{1c} 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 HbA_{1c} ≥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 HbA_{1c} <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.

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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

(CEDAR). Cedric is formally accredited by the Quality Institute for Self Management Education and Training (QISMET) and was developed by the diabetes team at Royal Surrey NHS Foundation Trust. It is aimed at people in employment with limited time. It is held on a Friday to limit inconvenience and is designed to empower people with type 1 diabetes to manage their diabetes care and the associated emotional challenges.

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.⁶ 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.⁷ 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, HbA_{1c} 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 HbA_{1c}. 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)⁷ 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 HbA_{1c} was 62±14 mmol/mol (7.8%). There were a number of overlapping indications for starting FGM including reduction in frequent hypoglycaemia, improvement in HbA_{1c} and reduction or replacement of capillary monitoring.

HbA_{1c} variability

The mean HbA_{1c} fell from 62±14 mmol/mol (7.8%) to 56±12 mmol/mol (7.3%), showing a statistically significant reduction in mean HbA_{1c} of 6 mmol/mol (0.5%) ($p<0.0001$). Subgroup analysis was conducted based upon baseline HbA_{1c} 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 HbA_{1c} above target, the mean±SD baseline HbA_{1c} was 69±12 mmol/mol (8.5%), falling to a mean HbA_{1c} of 59±11 mmol/mol (7.6%) at 6 months ($p<0.0001$). The two subgroups with a baseline HbA_{1c} within the target range ($n=50$) and within the below target range ($n=13$) had no statistically significant change in HbA_{1c}. Table 1 shows the mean change in HbA_{1c} for all participants and for each subgroup. Figure 1 shows the pre-baseline and post-intervention HbA_{1c} in a histogram and Figure 2 presents the change in individual HbA_{1c} 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

Table 1 Mean±SD HbA_{1c} pre-intervention and post-intervention and mean change in HbA_{1c} for all patients and each subgroup

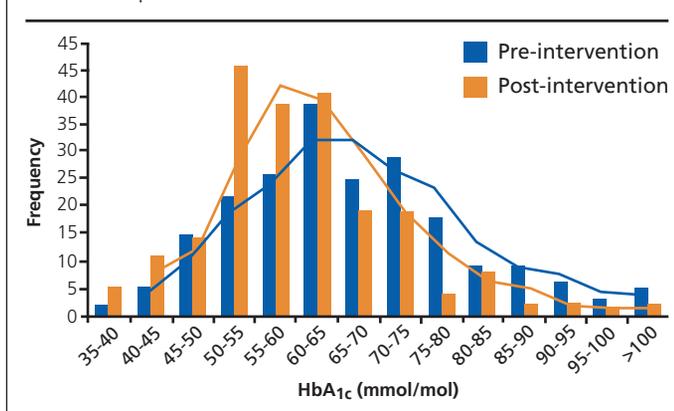
Group	Baseline HbA _{1c} (mmol/mol)	Post-intervention HbA _{1c} (mmol/mol)	Change in mean HbA _{1c} (mmol/mol)	Paired t-test
All patients (n=213)	62.3±14.3	55.8±12.0	-6.5	p<0.0001*
Pre- HbA _{1c} ≤43 (n=13)	39.7±2.8	39.2±7.4	-0.5	p=0.7384
Pre- HbA _{1c} 44–53 (n=50)	49.1±2.9	49.2±9.1	+0.1	P=0.9285
Pre- HbA _{1c} ≥54 (n=150)	68.7±12.0	59.4±11.1	-9.3	p<0.0001*

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

	Total pre-intervention (12 months)	Rate pre-intervention (6 months)	Total post-intervention (6 months)	Paired t-test
RSCH data				
Total diabetes-related admissions (n=198)	23	11.5	4	0.0872
Paramedic call-outs (n=194)	19	9.5	2	0.0428*
Third-party assistance (n=147)	44	22	1	0.0141*
ABCD FreeStyle Libre Nationwide Audit data (7 months)				
Total diabetes-related admissions (n=1,978 for hyperglycaemia and DKA/n=1,940 for hypoglycaemia)				
	389	194.5	131	N/A
Paramedic call-outs (n=1,952)	275	123.5	38	N/A
Third-party assistance (n=1,944)	1032	516	237	N/A

DKA, diabetic ketoacidosis; N/A, not available; RSCH, Royal Surrey County Hospital

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.

Figure 1. Histogram showing pre-intervention and post-intervention HbA_{1c}

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 ± 0.12 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

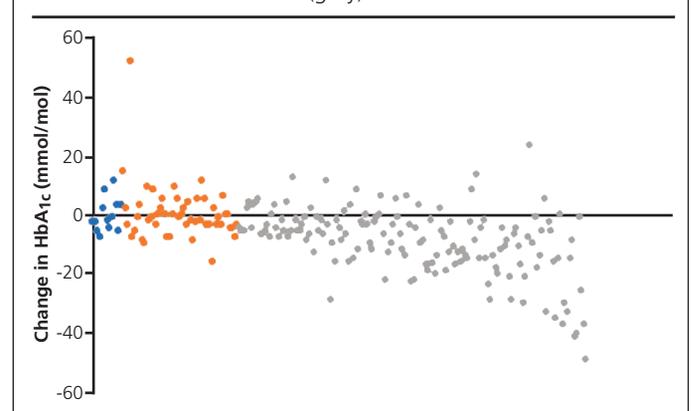
Figure 2. Scattergram showing the change in HbA_{1c} for each individual based on pre-intervention subgroup: pre- HbA_{1c} ≤43 mmol/mol (blue), pre- HbA_{1c} 44–53 mmol/mol (orange) and pre- HbA_{1c} ≥54 mmol/mol (grey)

Table 3 Comparison of study data outcomes with the ABCD Nationwide outcomes

	ABCD FreeStyle Libre Nationwide Audit data				RSCH (FGM + Cedric structured education)			
No of participants	3182				213			
Type 1 diabetes	3126 (98.2%)				213 (100%)			
Age (years)	39.5±19.6				48.0 ± 16.8)			
Gender (% female)	1688 (53%)				102 (48%)			
Completion of structured education	2002 (65%)				212 (100%)			
	Pre-intervention	Post-intervention	Change	P value	Pre-intervention	Post-intervention	Change	P value
Mean HbA _{1c} mmol/mol	69.8±18.2	62.3±18.5	-7.5	p<0.0001	62±14	56±12	-6	p<0.0001
Baseline HbA _{1c} ≤69.5 mmol/mol	57.7±7.7	56.2±17.4	-1.5	p<0.0001	47±4.8	46.9±9.8	-0.1	p>0.05
Baseline HbA _{1c} >69.5 mmol/mol	85.5±16.0	73.±15.8	-12.4	p<0.0001	81.2±10.8	66±13.1	-15.2	p<0.0001
Gold Score	2.7±1.9	2.4±1.7	-0.3	p<0.0001	1.8±1.2	1.4±0.9	-0.4	p<0.0001
DDS1	2.9	2.2		p<0.0001)	2.5	2.0		p<0.0001
DDS2	3.0	2.2		(p<0.0001)	2.7	2.2		(P<0.0001)

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.⁵ In order to make a direct comparison, HbA_{1c} has been re-analysed to be in line with the ABCD Nationwide HbA_{1c} subgroup analysis of ≥69.5 mmol/mol. The greatest impact on HbA_{1c} was seen with the higher baseline HbA_{1c} with a mean reduction of 15.2 mmol/mol compared with 12.4 mmol/mol in the ABCD FreeStyle Libre Nationwide Audit.⁵

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 HbA_{1c} in people with type 1 diabetes with a baseline HbA_{1c} ≥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 HbA_{1c} was seen in people who presented with a higher HbA_{1c} at baseline.

A number of studies have evidenced the positive association between structured education and enhanced diabetes knowledge, im-

proved self-care behaviour and better clinical outcomes measured by a decline in HbA_{1c} and improved quality of life.^{8,9} 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 HbA_{1c} of 1% at 6 months and no significant increase in severe hypoglycaemia.⁸ Structured education is now an integral part of the treatment of type 1 diabetes and is stipulated in current NICE guidance.¹⁰

It is difficult to ascertain the proportion of reduction in HbA_{1c} 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 HbA_{1c}, especially in those with a higher baseline HbA_{1c}, but not to the degree that we have demonstrated with the combined intervention.⁵ 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 HbA_{1c} prior to initiation of FGM. To date, randomised controlled trials of FGM alone have not demonstrated a reduction in HbA_{1c}, further supporting evidence that a combination of structured education and FGM is important.

In addition to a reduction in HbA_{1c}, 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.¹¹⁻¹⁴ 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.⁴

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.¹⁵ 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 accumulative benefits and provides a pragmatic, cost-effective and easily implemented intervention for people with type 1 diabetes with reduction in HbA_{1c} and significant improvement in hypoglycaemia, Gold Score and Diabetes Distress Screening Score at 6 months, especially for people who are not at target HbA_{1c}.

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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 (CAA). 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.

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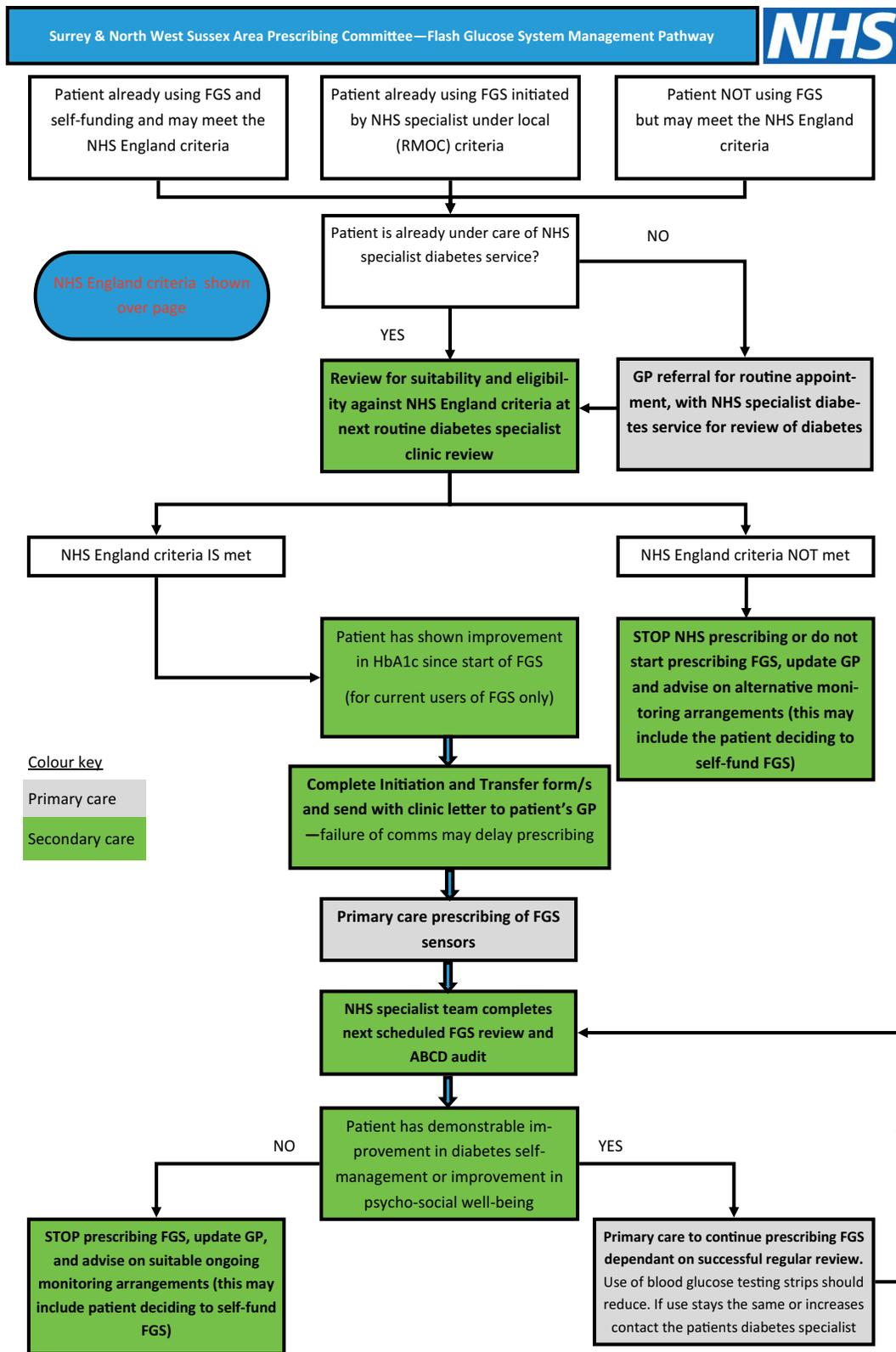


Key messages

- Structured education and flash glucose monitoring individually have benefits to self-management for people with type 1 diabetes
- The combination of a one-day intensive structured education programme alongside the initiation of flash glucose monitoring provides a pragmatic cost-effective intervention for people with type 1 diabetes with reduction in HbA_{1c} at 6 months

- glycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. *Lancet* 2018;**391**(10128):1367–7. [https://doi.org/10.1016/S0140-6736\(18\)30297-6](https://doi.org/10.1016/S0140-6736(18)30297-6)
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Appendix 1. Surrey and North West Sussex Area Prescribing Committee – FGM pathway



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: