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FreeStyle Libre Flash Glucose Monitoring system for people with type 1 diabetes in the UK: a budget impact analysis

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ABSTRACT

Introduction This study aims to estimate the budget impact of increased uptake of the FreeStyle Libre Flash Glucose Monitoring system in people with type 1 diabetes mellitus (T1DM) in the UK.

Research design and methods A budget impact model was developed, applying real-world data collected in the Association of British Clinical Diabetologists (ABCD) FreeStyle Libre Nationwide Audit. Costs of diabetes glucose monitoring in a T1DM population (n=1790) using self-monitoring of blood glucose (SMBG) or the FreeStyle Libre system were compared with a scenario with increased use of the FreeStyle Libre system.

Results The ABCD audit demonstrates FreeStyle Libre system use reduces diabetes-related resource utilization. The cost analysis found that higher acquisition costs are offset by healthcare costs avoided (difference £168 per patient per year (PPPY)). Total costs were £1116 PPPY with FreeStyle Libre system compared with £948 PPPY with SMBG. In an average-sized UK local health economy, increasing FreeStyle Libre system uptake from 30% to 50% increased costs by 3.4% (£1 787 345–£1 847 618) and when increased to 70% increased by a further 3.3%.

Conclusion Increased uptake of the FreeStyle Libre system in the T1DM population marginally increases the cost to UK health economies and offers many system benefits.

Significance of this study

What is already known about this subject?

- ► The Association of British Clinical Diabetologists (ABCD) set up a nationwide audit to study the effect of the FreeStyle Libre system on glycemic control, hypoglycemia, diabetes-related distress, and resource utilization.
- ► The audit demonstrated the FreeStyle Libre system use is associated with significantly improved glycemic control, hypoglycemia awareness and reduction in hospital admission.

What are the new findings?

- ► This analysis quantifies the budget impact of widespread adoption of the FreeStyle Libre system in type 1 diabetes mellitus populations from a local UK health economy's perspective.
- ► Higher acquisition costs for FreeStyle Libre system are partially off-set by reduced healthcare utilization.
- ► In an average-sized local health economy in the UK, increasing the proportion of people with T1DM using the FreeStyle Libre system from 30% in year 1 to 70% over 3 years is expected to result in a 3.4% and 3.3% year-on-year increase in glucose monitoring and diabetes-related healthcare costs for this population.

How might these results change the focus of research or clinical practice?

- ► The results are relevant to current decision making for UK local health economy budget holders.
- ► Widespread adoption of the FreeStyle Libre system in T1DM populations offers many benefits and has a relatively small budget impact compared with the total cost of glucose management.

INTRODUCTION

Improved glycemic control, facilitated by effective blood glucose monitoring improves acute outcomes in type 1 diabetes mellitus (T1DM) by reducing the risk of hypoglycemia and severe hypoglycemic events (SHE),[1] as well as longer term outcomes such as slowing down disease progression of retinopathy, nephropathy and other diabetes endpoints.[2] Self-monitoring of blood glucose (SMBG), or 'finger-prick' testing, has been the standard of care for people with T1DM. However, the introduction of new technology is changing the standard approach to glucose monitoring.[3] Traditional continuous glucose monitoring (CGM) is demonstrated to improve glycemic control and is increasingly used in diabetes management.[4] However, high cost has limited widespread adoption, and therefore, traditional CGM is mainly recommended in the UK to adults with T1DM who have problematic hypoglycemia (National Institute for Health and Care Excellence (NICE)).[5]

The FreeStyle Libre system (Abbott Diabetes Care, Witney, Oxon, UK), a sensor-based glucose monitoring system, is convenient and easy to use and improves the frequency of glucose monitoring relative to SMBG.[6 7] Furthermore, it provides data on time in range, estimated glycated hemoglobin (HbA1c) and time below range as well as other measures. This enables informed discussion between people with diabetes and their clinicians about glucose management. The addition of digital communication tools (LibreView), helps clinicians risk-stratify patients, enabling clinicians to review glucose data in the cloud. This potentially minimizes the need for face-to-face contact with those considered to be lower risk through remote assessment.[8] In contrast to traditional CGM, the user must scan the sensor to access glucose data, the system does not have alarms, and has lower acquisition costs. It is indicated for measuring interstitial fluid glucose levels in people age 4 years and older with diabetes mellitus, including pregnant women and is designed to replace SMBG testing in the self-management of diabetes.

In 2017, the FreeStyle Libre system was listed on the National Health Service (NHS) business services authority Drug Tariff for England and Wales, making it available to people with diabetes in the UK.[9] In 2020, it is being used by over 30% of the T1DM population in England (unpublished internal market report provided by IQVIA). The clinical and patient benefits of FreeStyle Libre system have been demonstrated in two meta-analyses, of clinical studies and real-world evidence,[10 11] two randomized controlled trials (RCTs) in a T1DM population (NCT02232698 (IMPACT))[6] and in T2DM populations (NCT02082184 (REPLACE))[7 12] as well as a single-arm study in younger people with diabetes (NCT02821117 (SELFY))[13] and several large real-world studies.[14–18]

The ABCD nationwide audit was set-up to assess the patterns of use of FreeStyle Libre system and to study its effect on glycemic control, hypoglycemia, diabetes-related distress, and hospital admissions due to hypoglycemia and hyperglycemia/diabetic ketoacidosis (DKA).[15] The study commenced in November 2017 and involved clinicians from 102 NHS hospitals in the UK for which they were asked to submit user data collected during routine clinical care. Data collected included baseline pre-Freestyle Libre system demographics, source of funding, previous structured diabetes education completion, HbA1c values from the previous 12 months, Gold score (to assess hypoglycemia awareness), severe hypoglycemia, paramedic callouts, and hospital admissions due to hypoglycemia, hyperglycemia, and DKA over the previous 12 months. The objective of the current study is to estimate the budget impact of more widespread adoption of the FreeStyle Libre system from a local health economy's perspective in the UK by applying the outcome data reported in the ABCD nationwide audit.

METHOD

Analytical methods

A budget impact model was developed in Microsoft Excel to calculate the net difference in costs per patient and total budget impact over a 3-year time horizon, comparing the FreeStyle Libre system to SMBG. Traditional CGM was excluded from the analysis because data on traditional CGM were not captured in the ABCD audit. Included in the analysis were the acquisition costs, costs associated with SHE, DKA events, and cost savings from a reduction in HbA1c. The change in resource utilization with the FreeStyle Libre system compared with SMBG was sourced from the ABCD nationwide audit, where the people included in the ABCD audit are a subgroup of all T1DM populations defined by the NHS funding criteria and those able to self-fund.[19] All costs are reported in 2019 Great British pounds. Unit costs were sourced from either 2018/2019 or 2019/2020 databases or 2019 list prices, therefore no cost inflation was applied. The budget impact analysis applied FreeStyle Libre system uptake assumptions to estimate total costs, multiplying uptake by the cost per person using the FreeStyle Libre system and SMBG.

Budget impact model inputs

The analysis considered a hypothetical population of 1790 people with T1DM, which represents the mean number of people with T1DM across all clinical commissioning groups, representing local health economies in England.[18] In the base-case, parameters for the rate of SHE events, DKA events and change in HbA1c for the FreeStyle Libre system and SMBG were sourced using the most up to date, previously unpublished, data from ABCD audit and are listed in table 1. For post-FreeStyle Libre system use, 7-month data were applied and prorated to estimate annual outcomes. While 7.5 months' follow-up data have been published on 3182 participants,[13] more recent, unpublished data in a larger cohort (n=4250) were applied. The global COVID-19 pandemic has limited the number of patients with 12-month follow-up data at the time of this publication due to the disruption to planned follow-ups.[8] The demographic characteristics of the 4250 participants with 7-month follow-up data are similar to the baseline data of participants without follow-up. The mean age of those with 7-month follow-up was 46.9 (±15.3), 50% were female and the mean pre-FreeStyle Libre HbA1c was 68.1 (±16.3) (mmol/mol). Further details are provided in the online supplemental table 1.

All unit costs applied in the model are reported in table 1. Acquisition costs for the FreeStyle Libre system were obtained from NHS tariff databases.[7] Unit costs for SMBG testing are the average of top 1o strips used in the UK calculated from IQVIA prescribing data (Internal market report provided by IQVIA). The number of tests strips per day with SMBG was sourced from IMPACT, a multicenter RCTs of the FreeStyle Libre in T1DM.[6] The cost of an ambulance callout and admission for SHE and

Table 1 Model parameters

	Input	OSWA range	Source
Clinical parameters			
SHE admissions (per year)			
Pre-FreeStyle Libre system	294		n=4250 ABCD audit
Prorated post-FreeStyle Libre system	149*		n=4250 87 events in 7 months of follow-up ABCD audit*
SMBG admissions per 100 person years	6.9	5.5, 8.3	Pre-FreeStyle Libre System events/n × 100
FreeStyle Libre System admission per 100 person years	3.5	2.8, 4.2	Prorated post-FreeStyle Libre system events/n × 100
SHE paramedic callouts (per year)			
Pre-FreeStyle Libre system	556		n=4250 ABCD audit
Prorated post-FreeStyle Libre system	99		n=4250 58 admissions in 7 months of follow-up ABCD audit
SMBG paramedic callouts per 100 person years	13.1	10.47, 15.70	Pre-FreeStyle Libre System events/n × 100
FreeStyle Libre paramedic callouts per 100 person years	2.3	1.87, 2.81	Prorated post-FreeStyle Libre system events/n × 100
DKA and hyperglycemic admissions (per year)			
Pre-FreeStyle Libre system	410		n=4250 ABCD audit
Prorated post-FreeStyle Libre system	133		n=4250 86 admissions in 7.5 months of follow-up ABCD audit
SMBG admissions per 100 person years	9.6	7.71, 11.58	Pre-FreeStyle Libre System events/n × 100
FreeStyle Libre system admissions per 1000 person years	5.4	4.28, 6.44	Prorated post-FreeStyle Libre system events/n × 100
HbA1c change after FreeStyle Libre system initiation			
Reduction in HbA1c (overall population)	0.5%	0.3%, 0.5%	ABCD audit
Reduction in HbA1c (>8.5% at baseline)	1.2%	1.0%, 1.4%	ABCD audit
Cost parameters			
FreeStyle Libre sensor unit cost	£35	£28, £42	NHS BSA Drug Tariff listing price[9]
FreeStyle Libre sensor lifetime (days)	14	11.2, 16.8	Manufacturer instructions
FreeStyle Libre additional SMBG tests per day	0.5	0.25, 0.329	IMPACT[6]
SMBG lancet unit cost	£0.04	£0.03, £0.05	IQVIA, average price of 10 units (data held by Abbott Diabetes Care Ltd)
SMBG test strip unit cost	£0.23	£0.18, £0.28	IQVIA, average price of 10 strips (data held by Abbott Diabetes Care Ltd)
SMBG tests per day	5.60	4.48, 6.72	IMPACT[6]
Cost of ambulance call out	£243	£194, £291	NHS reference costs 2018–2019 weighted average of ASS01/ASS02[20]
Cost of hypoglycemic admission	£2118	£1694, £2541	Weighted average of KB02J -G codes from 2019/2020 NHS tariff[21]

Continued

Table 1 Continued

	Input	OSWA range	Source
Cost of DKA admission†	£1843	£1474, £2211	Weighted average of KB01C-F codes from 2019/2020 NHS tariff†[21]
Annual cost diff per % HbA1c decrease			
HbA1c <7.5% at baseline	£33	£26, £40	Baxter *et al*[22]- derived by assuming linear relationship between 0.4% and 1%
HbA1c 7.5%– at baseline	£45	£36, £53	
HbA1c 8%–9% at baseline	£52	£41, £62	
HbA1c >9% at baseline	£92	£74, £110	

*Input reflects prorated events per year.
†The cost of DKA admission was estimated by using the cost of hyperglycemia admission as a proxy.
ABCD, Association of British Clinical Diabetologists; BSA, business services authority; DKA, diabetic ketoacidosis; HbA1c, glycated hemoglobin; NHS, National Health Service; OSWA, one-way sensitivity analysis; SHE, severe hypoglycemic events; SMBG, self-monitoring blood glucose.

DKA events were sourced from the NHS reference cost and tariff data collection for 2018/2019, respectively.[20 21]

The cost associated with each incremental reduction in HbA1c was sourced from a study that estimated the costs associated with microvascular and macrovascular complications with different HbA1c levels using the diabetes CORE model. It reports the cost avoided from a UK payer perspective in 5-year periods,[22] stratified by baseline HbA1c. The costs for the first 5-year period reported were annualized to a 1-year basis.

The budget impact analysis evaluates a scenario where the FreeStyle Libre system would replace a proportion of SMBG use in T1DM adults within 3 years from the perspective of a UK local health economy (using hypothetical population size of 1790). In year 1, 30% of the T1DM population are assumed to use the FreeStyle Libre system and the remaining 70% use SMBG, reflecting estimated trends in 2020.[23] In years 2 and 3, uptake of the FreeStyle Libre system is assumed to increase to 50% and 70% respectively, with the remaining population using SMBG.

Sensitivity analysis

One-way sensitivity analysis was performed on all model parameters to investigate the sensitivity of the cost-effectiveness model result to variations in each of the parameter values. Where CIs were not appropriate, we varied the parameters by ±25% (refer to table 1).

In addition, threshold analysis varied the number SMBG tests per day to consider a low estimate of four tests per day and identify the SMBG test rate per day rate required to achieve cost-neutrality.

Subgroup analysis

The results from the ABCD nationwide audit found that the reduction in HbA1c was greater among people with a higher baseline HbA1c. The impact of this was considered in a subgroup analysis comparing the FreeStyle Libre system with SMBG reporting the cost-per patient treated in people with T1DM with higher baseline HbA1c.

RESULTS

Per patient cost analysis

In all years, the FreeStyle Libre system is marginally more expensive than SMBG when testing 5.6 time per day because higher acquisition costs are partly offset by cost savings from reduced resource utilization (table 2).

Budget impact analysis: FreeStyle Libre system versus SMBG

In an average local health economy (hypothetical population size of 1790), the net budget impact of increasing the proportion of people with T1DM using the FreeStyle Libre system from 30% in year 1% to 50% and 70% in year 2 and 3, respectively, is illustrated in table 3. In year 1, the total cost was £1 787 345 increasing to £1 847 618 and £1 907 890 in years 2 and 3, respectively, representing 3.4% and 3.3% year-on-year increase.

Sensitivity analysis

In the incremental cost per patient sensitivity analysis (online supplemental figure 1) and sensitivity analysis, it was found that the model was most sensitive to the number of SMBG tests per day and costs of the test strips.

Applying a low estimate of four tests per day, increased the difference in cost per patient per year with the

Table 2 Per patient cost analysis

	FreeStyle Libre system	SMBG
Acquisition costs	£937	£552
Healthcare resource use costs*	£200	£396
Costs avoided due to HbA1c	–£21	–
Annual total	£1116	£948
Annual difference		£168

*Includes paramedic call outs and hospital admissions for severe hypoglycemic, DKA and hyperglycemic events.
DKA, diabetic ketoacidosis; HbA1c, glycated hemoglobin; SMBG, self-monitoring blood glucose.

Table 3 Budget impact

Budget impact analysis of increasing FreeStyle Libre System uptake			
	Year 1	**Year 2**	**Year 3**
FreeStyle Libre System Costs	£599 490	£1 847 618	£1 907 890
Cost of acquisition	£502 959	£838 265	£1 173 570
Healthcare resource use costs*	£107 593	£179 593	£251 050
Cost offset due to improved HbA1c	−£11 062	−£18 437	−£25 812
SMBG costs	£1 187 856	£1 847 618	£1 907 890
Cost of acquisition	£691 506	£493 933	£296 360
Cost of SHE/DKA and hyperglycemia events	£496 350	£354 536	£212 721
Total cost for local health economy	£1 787 345	£1 847 618	£1 907 890
Cost increase relative to year 1 per T1DM person	–	£33.67	£67.34

*Includes paramedic call outs and hospital admissions for severe hypoglycemic, DKA and hyperglycemic events.
DKA, diabetic ketoacidosis; HbA1c, glycated hemoglobin; SHE, severe hypoglycemic events; SMBG, self-monitoring blood glucose; T1DM, type 1 diabetes mellitus.

FreeStyle Libre System compared with SMBG is, to £326 compared with £163 in the base-case. Cost neutrality with SMBG would be achieved when carrying out 7.3 tests per day.

Subgroup analysis

The results of the subgroup analysis in people with higher baseline HbA1c are reported in online supplemental table 2. Among those with a high HbA1c baseline (>8.5%), the costs savings from reduced HbA1c with the FreeStyle Libre system are projected to be greater relative to the overall population. The difference in cost per patient per year with the FreeStyle Libre system compared with SMBG is £73, compared with £163 in the overall population. Threshold analysis of the number of tests per day in the high HbA1c group shows that cost neutrality with SMBG would be achieved when carrying out approximately 6.5 tests per day.

DISCUSSION

This budget impact analysis is the first to apply UK data collected in a real-world setting to estimate the impact of widespread adoption of the FreeStyle Libre system from an NHS budget holder's perspective. The results are therefore relevant to current decision making for UK local budget holders.

The ABCD nationwide audit demonstrates that the FreeStyle Libre system use is associated with improved outcomes, resulting in reduced diabetes-related resource utilization in T1 DM populations in the real world. This finding is consistent with other real-world studies that report reduced hospitalizations,[16 17 24–26] improved HbA1c[16 18] or improved quality of life or well-being[14 16–18] associated with FreeStyle Libre system. Applying these data in a budget impact analysis, it was found that higher acquisition costs are partially offset by healthcare costs avoided. In an average-sized local English health economy (population size of 1790 T1DM), increasing FreeStyle Libre system uptake from 30% in year 1 to 50% in year 2 increased costs by 3.4%. Similarly increasing the FreeStyle Libre system uptake to 70% in year 3 increased the budget by a further 3.3%.

This increase in costs is associated with patient and healthcare system benefits including improved glucose monitoring, reduced hospital admissions and improved quality of life. FreeStyle Libre system use is associated with improved quality of life as reported in a time trade-off study,[20] which reported a mean difference in health states of 0.03 (±0.053) between sensor-based (flash glucose monitoring) and conventional monitoring. This gain is assumed to reflect the greater convenience as well as intangible benefits of empowering patients to monitor and self-manage their glucose levels compared with SMBG. In addition, further quality of life improvements with FreeStyle Libre system compared with SMBG alone are expected, due to reduced risk of SHE[27] and DKA events[28] and improved HbA1c.[29] Other benefits of FreeStyle Libre system not captured in this analysis include access to glucose management indicators that can be used as a substitute for quarterly HbA1c blood tests, further reducing system costs as well as the function to facilitate remote consultation and monitoring of people with diabetes. This feature has been particularly beneficial during the global COVID-19 pandemic.[30–32]

The findings of this analysis should be considered in the context of the following limitations. As with all budget impact analyses, there is uncertainty in the assumptions applied to project future uptake of the new intervention. The only RCT that has evaluated FreeStyle Libre system use in T1DM (IMPACT)[6] did not observe statistically significant differences in HbA1c reduction, and thus the effects observed in real world settings cannot be definitively said to be a result of FreeStyle Libre system use. However, the primary outcome of IMPACT[6] was to measure change in hypoglycemia, and this study only recruited people with a baseline HbA1c of 7.5% and under, therefore a change in HbA1c was not expected. The ABCD audit demonstrated that people with T1DM with baseline HbA1c of over 8.5% had a mean reduction in HbA1c of 1.2% compared with 0.5% in the overall T1DM population. This is consistent with other real world studies, demonstrating improved HbA1c pre and post starting FreeStyle Libre system.[10 11]

An assumption implicit in this cost analysis is that the change in resource utilization reported in the ABCD audit is transferrable to all T1DM populations that may switch to the FreeStyle Libre system in the future. However, the people included in the ABCD audit are a subgroup of all T1DM populations defined by the NHS funding criteria and those able to self-fund.[19] These criteria, which include high testing frequency or hypoglycemia unawareness, may influence baseline characteristics and therefore resource utilization. However, although this has the potential to bias the analysis, it is not clear in which direction. The substantial reduction in HbA1c seen in the earliest cohort enrolled in the ABCD audit may be partly influenced by a 'regression to the mean' effect, as the HbA1c level at baseline was 8.3%. Unpublished data provided by a national specialty advisor for diabetes with NHS England suggests that these data are reasonably representative because at the time of this analysis, approximately 40% of people with T1DM living in the UK were using the FreeStyle Libre system. If later adopters have lower baseline HbA1c, similar to those recruited to IMPACT,[6] they may not experience the same decrease in HbA1c or reduction in hospital events. Similarly, the baseline rate of DKA events and SHEs requiring hospital admissions was found to be between 5% and 10%. These rates may be high compared with the total T1DM population because people with a history of hospital admission for diabetes related events were prioritized for starting FreeStyle Libre system. Nonetheless, these rates are comparable with other real-world studies. The UK hypoglycemia study[33] reported 1.1 and 3.2 episodes of SHE per person-year among people with T1DM for less than 5 years and between 5 and 15 years, respectively, and Heller *et al*[34] reported that 5% of SHE in T1DM populations resulted in hospital stay.

Furthermore, 7-month data were prorated to estimate the annual outcomes post-FreeStyle Libre system use to capture outcomes from a larger sample. This was not expected to introduce a seasonal bias because recruitment was ongoing, and therefore, people were started and followed up at difference times of the year. Furthermore, comparison of the data applied in this analysis with 7-month data extracted at a different time point[15] show similar trends.

There is also uncertainty regarding the attribution of a cost reduction to change in HbA1c because healthcare costs were not directly measured in the ABCD audit. The cost reduction assumption was sourced from a prior cost-effectiveness analysis[23] using the previously validated CORE diabetes economic model in a UK context and therefore carries with it the uncertainty associated with that model. Furthermore, the cohort modelled in this modelling study may differ from the ABCD audit participants considered in this cost analysis. However, the cost attributed to a 1% reduction in HbA1c reported in Baxter *et al*[19] was stratified by baseline HbA1c and matched to the baseline rate in the participants in the ABCD audit. The costs for the first 5-year period reported were annualized to a 1-year basis. If the 5-year costs were weighted towards year 5 more than year 1, this assumption would have overestimated the short-term (1 year) impact. However, this potential cost-saving would be expected to be realized over the medium term (5 years).

The effect of uncertainty in our analysis was explored in one-way sensitivity analysis and threshold analysis that concluded that the results were most sensitive to the cost and number per day of SMBG tests in the SMBG arm. A range of plausible hypothetical uptake scenarios were therefore considered, including applying conservative scenarios for SMBG tests per. Furthermore, subgroup analysis found that the potential costs avoided with the FreeStyle Libre system may be higher among those with a higher baseline HbA1c. The difference in cost per patient were even lower in this group compared with the overall population.

This analysis did not compare the FreeStyle Libre system to traditional CGM or conduct cost utility analysis. The aqusition cost of FreeStyle Libre system of £937 per patient per year (PPPY) applied in this analysis are considerably lower than the acquisition cost of Dexcom G6 (£1850 PPPY) applied in recent cost utility analysis of traditional CGM conducted from a UK payer perspective.[13] While the original FreeStyle Libre system differs from traditional CGM because it does not have alarms, the FreeStyle Libre 2 system, the next-generation device, was launched in late 2020 and has the added benefit of optional alarms. This therefore has the potential to provide similar functionality as other traditional CGMs in respect to triggering a patient response when glucose levels go too low or too high.

Conclusion

Widespread adoption of FreeStyle Libre system in T1DM populations offers many benefits and has a relatively small budget impact compared with the total cost of glucose management to health economies in the UK. People with T1DM and healthcare systems stand to benefit from the improved glycemic control, reduced diabetes related distress, reduced hospital admissions and the opportunity of virtual reviews that this easy to use monitoring solution provides.

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