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ORIGINAL RESEARCH

Cost-Effectiveness of a Real-Time Continuous Glucose Monitoring System Versus Self-Monitoring of Blood Glucose in People with Type 2 Diabetes on Insulin Therapy in the UK

John J. Isitt · Stéphane Roze · Helen Sharland · Greg Cogswell · Hamza Alshannaq · Gregory J. Norman · Peter M. Lynch

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ABSTRACT

Introduction: Real-time continuous glucose monitoring (rt-CGM) involves the measurement and display of glucose concentrations, potentially improving glucose control among insulin-treated patients with type 2 diabetes (T2D). The present analysis aimed to conduct a cost-effectiveness analysis of rt-CGM versus self-monitoring of blood glucose (SMBG) based on a USA retrospective cohort study in insulin-treated people with T2D adapted to the UK.

Methods: Long-term costs and clinical outcomes were estimated using the CORE Diabetes Model, with clinical input data sourced from a retrospective cohort study. Patients were assumed to have a baseline glycated hemoglobin (HbA1c) of 8.3%. Patients using rt-CGM were assumed to have a 0.56% reduction in HbA1c based on the mean difference between groups after 12 months of follow-up. Reduced fingerstick testing when using rt-CGM was associated with a quality of life (QoL) benefit. The analysis was performed over a lifetime time horizon from a National Health Service (NHS) perspective, including only direct costs from published data. Future costs and clinical outcomes were discounted at 3.5% per annum. Extensive sensitivity analyses were performed.

Results: Projections showed that rt-CGM was associated with increased quality-adjusted life expectancy of 0.731 quality-adjusted life years (QALYs) and increased mean total lifetime costs of Great British pounds (GBP) 2694, and an incremental cost-effectiveness ratio of GBP 3684 per QALY compared with SMBG. Key drivers of outcomes included HbA1c reduction and reduced fingerstick testing QoL benefit.

Conclusions: Over patient lifetimes, rt-CGM was associated with improved clinical outcomes and is highly likely to be cost effective versus SMBG in people with T2D on insulin therapy in the UK.

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J. J. Isitt (✉)
Vyoo Agency, San Diego, CA, USA
e-mail: jisitt@vyoo-agency.com

S. Roze
Vyoo Agency, Lyon, France

H. Sharland
Ossian Health Economics and Communications, Basel, Switzerland

G. Cogswell · H. Alshannaq · G. J. Norman · P. M. Lynch
Dexcom, San Diego, CA, USA

H. Alshannaq
University of Cincinnati College of Medicine, Cincinnati, OH, USA

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Key Summary Points

Why carry out this study?

Real-time continuous glucose monitoring (rt-CGM) could potentially improve glucose control in patients with type 2 diabetes (T2D).

The present analysis aimed to conduct a cost-effectiveness analysis of rt-CGM in patients with T2D on insulin therapy compared with self-monitoring of blood glucose (SMBG) in a UK setting.

What was learned from the study?

Rt-CGM was associated with increased quality-adjusted life expectancy and increased mean total lifetime costs versus SMBG in people with T2D on insulin therapy.

In the UK, in patients with T2D on insulin therapy, rt-CGM is highly likely to be cost effective compared with SMBG.

INTRODUCTION

Type 2 diabetes (T2D) is characterized by an increase in insulin resistance followed by progressive loss of insulin secretion [1]. Over 3.4 million people in the UK have T2D, with 12.2 million estimated to be at risk of developing T2D [2]. In the UK, T2D was estimated to cost GBP 21.7 billion in 2010/2011, with GBP 8.8 billion attributable to direct costs and GBP 13.0 billion to indirect costs [3]. Eighty percent of the direct costs were associated with treating complications [3]. The cost of T2D is expected to increase to over GBP 15 billion by 2035/2036 [3]. The overall direct cost of T2D would be greatly reduced through reductions in diabetes-related complications.

Glycemic control for patients with T2D can reduce the onset and progression of complications [4]. This is especially important as one in three people with T2D have a microvascular complication at diagnosis [2]. When patients are unable to manage their glucose levels through antihyperglycemic medications alone insulin treatment, accompanied by glucose monitoring, can be used to lower glucose levels [4]. In England, approximately 20% of patients with T2D receive insulin treatment [5]. Current guidelines in the UK recommend a HbA1c target of 7.0% (53 mmol/mol) for patients on a drug associated with hypoglycemia [6]. Despite the recommendations, a retrospective cohort analysis of adults with T2D from a nationally representative sample in England showed that approximately 53% of patients had a HbA1c $\geq$ 7% [5].

A potential glucose management strategy for patients with T2D is through the use of real-time continuous glucose monitoring (rt-CGM), such as the Dexcom G6 rt-CGM device, which involves the measurement and display of glucose concentrations on a receiver or mobile device [7]. CGM devices are recommended by the American Diabetes Association and the American Association of Clinical Endocrinology for people with diabetes that are treated with insulin therapy [8, 9]. National Institute for Health and Care Excellence (NICE) guidelines recommend that patients with T2D and recurrent hypoglycemia or impaired hypoglycemia awareness be offered CGM [6]. Two randomized clinical trials in T2D patients treated with insulin showed patients using rt-CGM had significantly reduced HbA1c compared with patients using a traditional blood glucose meter for monitoring [10, 11]. A retrospective cohort study of insulin using patients with T2D from the Kaiser Healthcare Delivery System and Diabetes Registry compared patients that used rt-CGM to patients on self-monitoring of blood glucose (SMBG) [12]. The study showed that insulin-treated patients with T2D who used rt-CGM had significant improvements in HbA1c, as well as reductions in long-term diabetes related-complications, emergency department

visits, and hospitalizations for hypoglycemia compared with rt-CGM non-initiators [12].

Whilst rt-CGM is more commonly associated with the management of type 1 diabetes (T1D), the technologies have a place in the treatment of patients with T2D [13]. Current clinical evidence for the use of the technology in managing T2D focuses on patients receiving intensive insulin therapies, but rt-CGM has been shown to improve glycemic outcomes in patients with T2D on less intensive insulin therapy and in patients not on insulin treatment [11–13]. Through the use of rt-CGM, interstitial glucose levels can be continuously measured, and the current glucose level displayed (including direction and rate of change). Alarms and alerts are used to inform patients when glucose is exceeding or falling below specified thresholds, allowing patients to manage fluctuating glucose levels [14, 15].

The aim of the present study was to conduct a cost-effectiveness analysis of rt-CGM versus SMBG based on a large USA retrospective cohort study in people with T2D on insulin therapy adapted to the UK perspective.

METHODS

Model structure

The analysis was performed using the IQVIA CORE Diabetes Model (CDM; IQVIA, Basel, Switzerland). The CDM is a published and validated long-term model that can be used for T1D and T2D [16–18]. The model simulates the progression of diabetes and diabetes-related complications based on a series of interdependent submodels. Outcomes of the model include undiscounted life expectancy and quality-adjusted life expectancy, direct and indirect costs, and the incremental cost-effectiveness ratio (ICER) (Supplementary Material Table 1). Probabilistic sensitivity analyses are conducted utilizing second order Monte Carlo sampling [16]. To minimize uncertainty of the estimation of probabilities for acceptability and willingness-to-pay, we utilized second order Monte Carlo simulation based on 1000 bootstrap iterations, each based on a cohort of 1000 patients.

Simulation Cohort and Treatment Effects

The baseline cohort characteristics were sourced from a retrospective cohort study of insulin treated patients with T2D from the Kaiser Healthcare Delivery System and Diabetes Registry (Table 1) [12]. The cohort characteristics were computed using the weighted average of patients from each group (rt-CGM and SMBG). At baseline, all patients were receiving insulin treatment [including long acting, neutral protamin Hagedorn (NPH), rapid acting, short acting, and/or mixed insulin) [12]. Additional risk factors were sourced from published data [19–21]. The combined baseline cohort included 344 patients in the rt-CGM arm and 35,736 in the SMBG arm. The mean [standard deviation (SD)] age of the cohort was 64.5 (12.2) years, mean duration of diabetes was 15.8 (8.8) years, and mean HbA1c was 8.27% (1.60) (Table 1). HbA1c was reduced by 0.56% in the rt-CGM group based on the mean difference between groups after 12 months of follow-up (Supplementary Material Table 2) [12]. Hypo- and hyperglycemic event rates were sourced from the Kaiser retrospective cohort study [12]. Patients in the rt-CGM group were assumed to have a severe hypoglycemic event (SHE) rate of 0 events per 100 patient years, compared with 4 events per 100 patient years in the SMBG arm. Diabetic ketoacidosis events were assumed to occur in patients in the rt-CGM and SMBG groups at rates of 0 and 2.5 events per 100 patient years, respectively.

Costs and Utilities

The present analysis included only direct medical costs and were sourced from published sources and inflated to 2021 GBP utilizing the UK consumer price index (Table 2) [22–39]. The annual cost of Dexcom rt-CGM varies dramatically across the UK, from GBP 900 to GBP 1600. The present analysis utilized the median annual treatment cost of GBP 1250 for rt-CGM in the UK. which includes 36 sensors, four

Table 1 Baseline characteristics of simulation cohort

	Mean (SD)			References
	rt-CGM (n = 344)	SMBG (n = 35,736)	Combined cohort (n = 36,080)	
Patient demographics				
Age, years	59.1 (14.5)	64.6 (12.1)	64.5 (12.2)	[12]
Male, %	52.9	50.4	50.5	[12]
Duration of diabetes, years	17.1 (11.1)	15.8 (8.8)	15.8 (8.8)	[12]
Risk factors				
HbA1c, %	8.20 (1.5)	8.27 (1.6)	8.27 (1.6)	[12]
HbA1c, mmol/mol	70	70	70	[12]
BMI, kg/m^2	30.0 (6.6)	33.4 (7.5)	33.4 (7.5)	[12]
eGFR, mL/min/1.73 m^2			72.8 (26.6)	[12]
Systolic blood pressure, mmHg			130.7 (15.7)	[12]
Diastolic blood pressure, mmHg			69.5 (11.2)	[12]
Total cholesterol, mg/dL			156.5 (43.1)	[12]
High-density lipoprotein cholesterol, mg/dL			44.6 (12.2)	[12]
Low-density lipoprotein cholesterol, mg/dL			81.4 (33.3)	[12]
Triglycerides, mg/dL			170.6 (136.7)	[12]
Heart rate, beats/min			72 (12)	[19]
Smoking status, %			5.9	[12]
Racial/ethnic group				
White European, %			55.7	[12]
African American, %			10.5	[12]
Hispanic, %			14.3	[12]
Asian/Pacific Islander, %			19.5	[12]
Cardiovascular disease				
Angina pectoris, %			11.6	[12]
Myocardial infarction, %			5.1	[12]
Congestive heart failure, %			14,1	[12]
Stroke, %			3.7	[12]
Peripheral vascular disease, %			14.6	[12]
Renal disease				

Table 1 continued

	Mean (SD)			References
	rt-CGM (n = 344)	SMBG (n = 35,736)	Combined cohort (n = 36,080)	
Microalbuminuria, %			54.7	[12]
Gross proteinuria, %			10.1	[12]
ESRD, %			2.2	[12]
Retinopathy				
Background diabetic retinopathy, %			31.3	[20]
Proliferative diabetic retinopathy, %			9.2	[12]
Foot ulcer				
Peripheral neuropathy, %			44.7	[12]
Healed ulcer, %			10	[12]
Amputation, %			3.3	[12]
Other eye complications				
Macular edema, %			9.0	[21]
Cataract, %			11.0	[21]

BMI body mass index, *ESRD* end-stage renal disease, *HbA1c* glycated hemoglobin, *rt-CGM* real-time continuous glucose monitoring, *SD* standard deviation, *SMBG* self-monitoring of blood glucose

transmitters, and a receiver [40]. SMBG costs were based on patients testing 3.8 times per day, as observed in the DIAMOND trial, and the mean annual cost of SMBG was GBP 401.81 (Supplementary Material Table 3).

Quality of life utilities and disutilities associated with diabetes-related complications were sourced from Beaudet et al. [41, 42] The baseline utility associated with T2D without complications was 0.785 (Table 3) [43]. An annual QoL benefit of avoiding finger sticks was applied to the rt-CGM arm. The utility benefit of 0.03 was taken from Matza et al., and patients in the SMBG arm were assumed to have no corresponding QoL utility benefit [44].

Time Horizon, Perspective, and Discount Rate

The analysis only included direct costs and were performed from a UK NHS perspective. The time horizon used in the analyses was set to the remaining lifetime of the patients (30 years). A discount rate of 3.5% was applied to economic and clinical outcomes as recommended in NICE guidelines [45].

Sensitivity Analyses

A series of one-way sensitivity analyses (SA) were performed to determine key drivers of outcomes. SA were performed around the QoL benefit associated with rt-CGM, including applying a utility associated with reduced fear of hypoglycemia (FoH). The FoH utility was based on the Hypoglycemia Fear Survey (HFS) from the DIAMOND trial [46], which was mapped to the EQ-5D by utilizing a study from Currie et al. [47] Therefore, the rt-CGM group was associated with a FoH utility of 0.02536. The FoH utility is additive to the finger stick avoidance utility of 0.03, resulting in a total

Table 2 Direct costs associated with diabetes-related complications

Event	Costs, GBP	References
Myocardial infarction, year of event	7261	[22]
Myocardial infarction, subsequent years	1313	[22]
Angina, each year	3548	[23]
Congestive heart failure, year of onset	1172	[22]
Congestive heart failure, subsequent year	3602	[22]
Stroke, year of event	1677	[22]
Stroke, subsequent years	1280	[22]
Stroke death within 30 days	4500	[22]
Peripheral vascular disease, year of onset	2036	[23]
Hemodialysis, each year	44,999	[23]
Peritoneal dialysis, year of onset	24,747	[23]
Renal transplant, year of event	26,591	[23]
Renal transplant, subsequent years	8642	[23]
Laser treatment	151	[24]
Severe vision loss/blindness, year of onset	6904	[25]
Cataract extraction	2849	[23]
Cataract treatment, subsequent year	482	[23]
Neuropathy, each year	381	[26]
Standard uninfected ulcer	920	[27, 28]
Infected foot ulcer	3051	[29]
Gangrene treatment	6098	[29]
Healed ulcer with/without history of amputation	296	[29]
Amputation, year of event	5547	[23]
Amputation, prosthesis	2106	[23]
Severe hypoglycemic event requiring medical assistance	1544	[30]
Severe hyperglycemia (DKA)	2239	[31]
Aspirin, annual cost	11.74	[32]
Statins (20 mg), annual cost	12.17	[33]
Angiotensin converting enzyme inhibitor (ramipril 5 mg), annual cost	14.73	[34]
Screening for retinopathy	31.98	[35]
Screening for microalbuminuria	16.00	[36, 37]
Screening for gross proteinuria	15.94	[36, 38]

DKA diabetic ketoacidosis, *GBP* Great British pounds
Cost were inflated to 2021 GBP using the UK consumer price index [39]

utility benefit of 0.05536 for the rt-CGM group in the SA.

Additional SA related to the intervention effect on HbA1c, SMBG tests per day, time horizon (with and without changes to the mean age of cohort), discounting of future costs and clinical effects, Dexcom rt-CGM treatment costs, and baseline cohort were performed. SA were performed wherein the intervention effect on HbA1c was increased or decreased by 30%. SA were conducted where patients using SMBG were assumed to use one, two, three, or four SMBG tests per day. The effect of changes to the time horizon on model outcomes was explored through analyses where a time horizon of 10, 15, or 20 years was applied, and through analyses where the mean cohort age was reduced to 30, 40, or 50 years over a lifetime horizon, respectively. A SA was performed with a discount rate of 1.5% (compared with a base case of 3.5%). Two SA were conducted to explore projected cost effectiveness using a UK cohort. In one analysis only the UK ethnic distribution reported in the T2D management guidelines were applied, and in another all baseline risk

Table 3 Health state utilities and disutilities

Event/state	Utility/ disutility	References
T2D, no complication	0.785 ± 0.11	[43]
Angina disutility, year of event	−0.09 ± 0.01	[41]
Congestive heart failure disutility, year of event	−0.108 ± 0.01	[41]
Myocardial infarction disutility, year of event	−0.055 ± 0.01	[41]
Stroke disutility, year of event	−0.164 ± 0.01	[41]
Peripheral vascular disease disutility, year of event	−0.061 ± 0.01	[41]
Gross proteinuria disutility, year of event	−0.048 ± 0.01	[41]
Hemodialysis disutility, year of event	−0.164 ± 0.03	[41]
Peritoneal dialysis disutility, year of event	−0.204 ± 0.03	[41]
Kidney transplant disutility, year of event	−0.023 ± 0.12	[41]
Background diabetic retinopathy disutility, year of event	−0.04 ± 0.02	[41]
Proliferative diabetic retinopathy disutility, year of event	−0.07 ± 0.02	[41]
Cataract disutility, year of event	−0.016 ± 0.02	[41]
Macular edema disutility, year of event	−0.04 ± 0.02	[41]
Severe vision loss/ blindness disutility, year of event	−0.074 ± 0.01	[41]
Neuropathy disutility, year of event	−0.084 ± 0.01	[41]
Active foot ulcer disutility, year of event	−0.17 ± 0.01	[41]
Amputation disutility, year of event	−0.28 ± 0.01	[41]
Diurnal severe hypoglycemia event (SHE1 and SHE2) requiring any third party medical assistance	−0.047 ± 0.014	[42]
Nocturnal severe hypoglycemia event (SHE1 and SHE2) requiring any third party medical assistance	−0.051 ± 0.014	[42]

factors from the guideline, and the proportion of patients managed for various chronic and recurrent conditions, were applied to the population [6]. Finally, the effect of the annual treatment cost of the Dexcom rt-CGM system was also explored in a SA in which the acquisition cost was increased or decreased by 20% or 30%.

The economic evaluation is reported in accordance with the "Mt Hood Checklist for Modelling Transparency," the "Impact Inventory from the 2nd Panel on Cost-effectiveness in Health and Medicine," and the "ISPOR Consolidated Health Economic Evaluations Reporting Standards (CHEERS) II Good Reporting Practices Task Force" 2022. Full checklists can be found in the Supplementary Material.

RESULTS

Base Case Analysis

In the base case analysis, rt-CGM was associated with an increased quality adjusted life expectancy of 0.731 quality-adjusted life years (QALYs) compared with SMBG. Mean total lifetime costs associated with rt-CGM and SMBG were GBP 79,866 and GBP 77,172,

Table 4 Base case results

	rt-CGM	SMBG	Difference
Cost, GBP	79,866	77,172	+2694
Treatment costs	14,691	4631	+10,060
Management costs	672	657	+15
Cardiovascular complications	13,898	13,929	–31
Renal complications	33,696	39,619	–5923
Ulcer/amputation/neuropathy complications	6496	6663	–168
Opthalmic complications	10,414	10,903	–490
Severe hypoglycemia	0	715	–715
Diabetic ketoacidosis	0	54	–54
Quality-adjusted life expectancy, QALY	7.897	7.166	+0.731
ICER, GBP per QALY gained		3684	
Probability of being cost effective with a WTP threshold of GBP 20,000 (%)		70.8	
Probability of being cost saving (%)		38.7	

GBP Great British pounds, *ICER* incremental cost-effectiveness ratio, *QALY* quality-adjusted life year, *rt-CGM* real-time continuous glucose monitoring, *SMBG* self-monitoring of blood glucose, *WTP* willingness-to-pay

respectively. Whilst rt-CGM was associated with an incremental cost of GBP 2694 versus SMBG, using rt-CGM was associated with reduction in costs related to both chronic and acute diabetes-related complications. The ICER of rt-CGM versus SMBG was GBP 3684 per QALY gained (Table 4). The probability of rt-CGM being cost effective versus SMBG at a willingness-to-pay threshold of GBP 20,000 per QALY gained was approximately 70.8%, whilst the probability of being cost saving was estimated at 38.7%.

Sensitivity Analyses

SA showed that the findings were sensitive to changes around rt-CGM cost, QoL benefit associated with rt-CGM, number of SMBG per day, time horizon, changes in baseline mean age (with corresponding changes in time horizon), and baseline cohort (Table 5). SA on annual rt-CGM cost were conducted with current Dexcom discounted costs in the UK. Increasing the annual cost of rt-CGM by 20% or 30% increased the ICER relative to the base case to GBP 7701 and GBP 9709 per QALY gained, respectively However, a 20% or 30% reduction in rt-CGM cost both resulted in a dominant ICER over SMBG increasing the likelihood of rt-CGM being more effective and cost-saving (–20%: 46% probability of being cost saving and 75.6% of being cost effective; –30%: 49.3% probability of being cost saving and 78% probability of being cost effective). Testing specific annual rt-CGM costs of GBP 1600 resulted in an incremental cost of rt-CGM versus SMBG of GBP 6807, resulting in an ICER of GBP 9308 (probability of being cost saving 31.3% and probability of being cost effective 60.9%). Testing the lowest annual rt-CGM cost in the UK of GBP 900, resulted in an incremental cost of rt-CGM versus SMBG of –1419, resulting in rt-CGM becoming a dominant management strategy over SMBG (probability of being cost saving 48.9% and probability of being cost effective 77.8%).

Decreasing the QoL benefit associated with rt-CGM to 0 resulted in an ICER nearly double that of the base case, GBP 7112 per QALY gained, whilst decreasing or increasing the utility benefit by 50% lead to ICERs of GBP 4853 and GBP 2968 per QALY gained, respectively. Addition of a utility benefit associated with reduced FoH to the base case utility benefit for rt-CGM resulted in a 1.029 incremental QALY and an ICER of GBP 2617 per QALY gained. Increasing the effect of rt-CGM on HbA1c by 30% decreased the ICER to GBP 1102 per QALY gained, and decreasing the effect of rt-CGM on HbA1c by 30% increased the ICER to GBP 6671 per QALY gained. The ICER ranged from GBP 8349 per QALY gained to GBP 3350 per QALY gained in SA where the number of SMBG

Table 5 Sensitivity analyses results

Analysis	Cost, GBP			Quality-adjusted life expectancy, QALYs			ICER, GBP per QALY gained
	rt-CGM	SMBG	Difference	rt-CGM	SMBG	Difference	
Base case	79,866	77,172	+2694	7.897	7.166	+0.731	3684
Dexcom rt-CGM GBP 1600	83,979	77,172	6807	7.897	7.166	0.731	9308
Dexcom rt-CGM GBP 900	75,753	77.172	−1419	7.897	7.166	0.731	Dominant
Dexcom rt-CGM cost + 20% (GBP 1500)	82,804	77,172	5532	7.897	7.166	0.731	7701
Dexcom rt-CGM cost + 30% (GBP 1625)	82,273	77,172	7101	7.897	7.166	0.731	9709
Dexcom rt-CGM cost −20% (GBP 1000	76,928	77,172	−244	7.897	7.166	0.731	Dominant
Dexcom rt-CGM cost -30% (875)	75,459	77,172	−1713	7.897	7.166	0.731	Dominant
rt-CGM utility benefit 0%	79,866	77,172	+2694	7.544	7.166	+0.379	7112
rt-CGM utility benefit −50%	79,866	77,172	+2694	7.721	7.166	+0.555	4853
rt-CGM utility benefit + 50%	79,866	77,172	+2694	8.073	7.166	+0.907	2968
rt-CGM utility benefit + FoH	79,866	77,172	+2694	8.195	7.166	+1.029	2617
rt-CGM HbA1c −30%	81,643	77,172	+4471	7.836	7.166	+0.670	6671
rt-CGM HbA1c +30%	78,039	77,172	+867	7.953	7.166	+0.787	1102
One SMBG/day	79,866	73,760	+6106	7.897	7.166	+0.731	8349
Two SMBG/day	79,866	74,978	+4888	7.897	7.166	+0.731	6683
Three SMBG/day	79,866	76,197	+3669	7.897	7.166	+0.731	5017
Four SMBG/day	79,866	77,416	+2450	7.897	7.166	+0.731	3350
Time horizon 10 years	34,581	31,093	+3488	4.988	4.610	+0.378	9232
Time horizon 15 years	49,682	46,254	+3428	6.315	5.801	+0.514	6672
Time horizon 20 years	62,337	59,379	+2958	7.136	6.519	+ 0.617	4794
Baseline mean age 30 years, lifetime horizon	280,648	291,986	−11,338	13.711	12.537	+1.174	Dominant
Baseline mean age 40 years, lifetime horizon	204,341	210,215	−5874	12.180	11.096	+1.084	Dominant
Baseline mean age 50 years, lifetime horizon	141,036	142,751	−1715	10.442	9.489	+0.953	Dominant
Discount rate 1.5%	104,459	101,859	+2600	9.588	8.662	+0.926	2808
NG28 UK ethnic distribution	75,309	72,110	+3199	7.826	7.111	+0.715	4474

Table 5 continued

Analysis	Cost, GBP			Quality-adjusted life expectancy, QALYs			ICER, GBP per QALY gained
	rt-CGM	SMBG	Difference	rt-CGM	SMBG	Difference	
All NG28 baseline risk factors (UK cohort)	47,125	42,578	+4546	8.490	7.741	+0.749	6069

FoH fear of hypoglycemia, *GBP* Great British pounds, *HbA1c* glycated hemoglobin, *ICER* incremental cost-effectiveness ratio, *QALY* quality-adjusted life year, *rt-CGM* real-time continuous glucose monitoring, *SMBG* self-monitoring of blood glucose

per day in the SMBG arm were assumed to be between one and four, respectively.

When the time horizon was reduced to 20 years, the ICER increased to GBP 4794 per QALY gained, and increased to GBP 6672 per QALY gained and GBP 9232 per QALY gained when the time horizons were set to 15 and 10 years, respectively. As in the base case, shorter time horizons remained highly cost effective for rt-CGM. SA were performed wherein the baseline mean age was reduced and adjusting the lifetime horizon of the analysis to estimate the effect of starting rt-CGM earlier in the patients' treatment path. Reduction of the baseline cohort mean age to 50 years led to reduced incremental costs of GBP –1714 and increased incremental QALYs to 0.953, and rt-CGM now dominant over SMBG. Reducing the baseline cohort mean age to 40 years further decreased incremental costs to GBP –5873 and increased incremental QALYs to 1.084 with rt-CGM dominant over SMBG. Similarly, with a baseline cohort mean age of 30 years, the incremental cost of rt-CGM versus SMBG was decreased to GBP –11,338 and incremental QALYs increased to 1.174, resulting in rt-CGM being dominant over SMBG. Applying a discount rate of 1.5% to future costs and clinical outcomes resulted in an ICER of GBP 2808 per QALY gained. Applying only the UK ethnic distribution increased the ICER associated with rt-CGM to GBP 4474 per QALY gained versus SMBG, whilst when all baseline risk factors and the proportion of patients managed for various chronic condition were taken from a UK population, the ICER increased to GBP 6069 per QALY gained.

This article is based on previously conducted studies and does not contain any studies with human participants or animals performed by any of the authors.

DISCUSSION

Overall, the base-case analysis suggests that rt-CGM is highly cost effective compared with SMBG in patients with T2D on insulin therapy in the UK. Rt-CGM was associated with an ICER of GBP 3684 per QALY gained. Based on a willingness-to-pay threshold of GBP 20,000, the probability of rt-CGM being cost-effective versus SMBG was 70.8%, and the probability of rt-CGM being cost saving was 38.7%. These findings were robust under a wide range of plausible assumptions around key input parameters.

The results of the SA indicated that the cost effectiveness of the rt-CGM system is sensitive to changes in assumptions around the annual cost of rt-CGM, QoL benefit associated with rt-CGM, number of SMBG per day, time horizon, changes in baseline mean age with a lifetime horizon, and baseline cohort. Multiple SA around the annual cost of rt-CGM showed that reducing the annual cost to GBP 1000 or lower resulted in rt-CGM being dominant, whilst increasing the cost to GBP 1600 increased the ICER to GBP 9308 per QALY gained. The use of a FoH utility resulted in one of the largest QALY benefits in the SA. The HFS score was taken from the DIAMOND trial and applied in SA, and,

whilst there is difficulty in quantifying FoH and its effect on QoL, FoH is still present in people with T2D and should be taken into account in a manner similar to that of other impacts on QoL (e.g., complications) [46, 48], In addition, FoH has been shown to impact glycemic control, diabetes biomarkers, and health outcomes through the maintaining of higher levels of blood glucose to avoid SHE, thereby also affecting patient behavior and daily decision making [49–51]. Therefore, the QALY benefit presented in the base case analysis may be a conservative projection as the base case analysis did not take into account any QoL benefit associated with a reduced FoH. In SA with time horizons of 10, 15, and 20 years (ICERs GBP per QALY gained: 9232, 6672, and 4794 respectively), analyses demonstrated that for patient subgroups that potentially start rt-CGM later in their treatment path (owing to policy change or aging populations), rt-CGM is still cost-effective. In SA where mean age of the cohort was decreased to 50, 40, and 30 years, rt-CGM dominates SMBG as a result of increased QALY benefits and reduced incremental costs over longer time horizons. The age of T2D diagnosis has recently shown to be decreasing [52]. Therefore, modeling of the potential benefits of rt-CGM in younger populations is useful and the present analysis shows that rt-CGM is more likely to be more cost effective and cost saving when rt-CGM is started earlier in patients' treatment path. Our modeling shows that the earlier T2D patients can use rt-CGM, the greater the quality-of-life benefit is gained (T2D patients with mean age of 30 years: 1.174 QALYs gained). Younger populations may benefit from earlier intervention and more years monitoring glucose levels with rt-CGM, and potentially experience less risk of diabetes-related complications associated with uncontrolled glycemia. In SA where either a UK ethnic distribution or all baseline risk factors of the UK cohort was applied, the ICER associated with rt-CGM increased, but remained cost effective [6]. The use of the non-UK cohort in the base case analysis was considered preferable as treatment effects were derived from the same cohort, but differences in real-world populations can lead to differences in outcomes. These SA show that the differences in projected outcomes are likely minimal and reflect the minimal differences observed between the Kaiser T2D cohort versus the NG28 UK T2D cohort.

The analyses only included direct costs and did not capture any potential reductions in indirect costs due to lost productivity. With the indirect cost of T2D estimated to be GBP 13.0 billion in 2010/2011 and expected to rise to GBP 20.5 billion by 2035/2036, the indirect cost of T2D is substantial, especially as the direct costs of T2D are projected to rise to GBP 15.1 billion [3]. Of the indirect costs, informal care accounted for the largest proportion of the costs at 38%, followed by 32% due to mortality, 23% attributable to presenteeism, and 7% due to sickness. Hypoglycemia, including non-severe hypoglycemic events (NSHE), can have a considerable impact on productivity. A survey of people with T1D or T2D in the UK found that a NSHE during or outside of working hours often resulted in individuals missing work, demonstrating that hypoglycemia is detrimental to productivity [53]. Therefore, this analysis may underestimate the potential economic benefits of rt-CGM because the UK NHS perspective does not consider work productivity loss.

The primary baseline patient characteristics and treatment effects used in this analysis were based on a retrospective cohort study from the Kaiser Healthcare Delivery System and Diabetes Registry [12]. The strengths of this study are that propensity scores and overlap weighting were utilized to adjust for treatment allocation between groups, providing balanced baseline characteristics thereby improving acceptability for cost-effectiveness analysis and adjusting for confounding factors that may have influenced the decision to initiate rt-CGM. As a result of overlap weighting, the distribution of the expected likelihood of initiating rt-CGM (based on propensity scores) was similar between patients who used rt-CGM and those who did not. The real-world study included 36,080 patients with T2D during 2014–2019 but does contain some limitations reported in the primary publication that could affect the present analysis. Advances in rt-CGM technology could not be captured over the study period, such as predictive low glucose alerts and no calibration

requirements. The inclusion of older rt-CGM technology may have led to more conservative results in the current analysis. Additionally, the study was not limited to Dexcom devices, and therefore the HbA1c benefit cannot be directly attributed to the Dexcom devices [12]. Owing to the newer features of the Dexcom G6 device, such as the Urgent Low Soon Alert that allows patients to potentially avoid a hypoglycemic event, it is likely that a cohort of patients using the Dexcom G6 device would match the 0.56% HbA1c decrease from the retrospective study, and potentially would experience further decreases in HbA1c [12, 54]. A recent randomized clinical trial of the Dexcom G6 device in people with T2D reported a decrease in HbA1c of 1.1% compared with 0.6% in patients using a traditional blood glucose meter [11]. The follow-up study of discontinuance of rt-CGM also demonstrated the importance of T2D patients on insulin to remain on rt-CGM, as rt-CGM patients that discontinued treatment lost significant glycemic control [55]. Discontinuation of rt-CGM use was not factored into the present modeling analysis, despite the likelihood of some patients choosing to discontinue in real-world practice. The lack of data on rt-CGM discontinuation specific to a population of people with T2D would have resulted in likely inaccurate projections of usage rates, reducing the relevance of present analysis. Additionally, despite patients expressing negative opinions towards alarms, opinions towards rt-CGM have been seen to be positive [56]. The time required from staff for both patient education and the reviewing of results was not applied in the modeling analysis owing to the highly variable nature of the requirement and the lack of an available micro-costing study to accurately provide such costs. Additionally, owing to the lifetime time horizon used in the analysis, it is likely that the costs associated with patient education at the start of the time period would not have a significant impact on projected outcomes. Finally, the case mix of patients using rt-CGM may differ from other settings with different prescribing patterns and guidelines. We acknowledge this limitation in the current study, however, with the paucity of UK real-world evidence in T2D patients on insulin, our study provides a large robust cost-effectiveness analysis of T2D patients on insulin using rt-CGM adapted to the NHS perspective.

Recent NICE guidelines for the management of T2D patients on insulin therapy recommend limited access to rt-CGM in high-risk groups and imposed financial restrictions based on rt-CGM acquisition costs [6]. However, NICE guidelines for the management of T2D were published before the present analysis and did not take into account the new economic evidence showing rt-CGM to be cost effective, and likely cost saving, in T2D populations on insulin.

CONCLUSIONS

Long-term cost-effectiveness analysis of rt-CGM versus SMBG in patients with T2D on insulin therapy in the UK suggests that using rt-CGM improves QoL and is a cost-effective T2D management option compared with SMBG based on a willingness to pay threshold of GBP 20,000.

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