



Flash Continuous Glucose Monitoring: A Summary Review of Recent Real-World Evidence

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Optimizing glycemic control remains a shared challenge for clinicians and their patients with diabetes. Flash continuous glucose monitoring (CGM) provides immediate information about an individual's current and projected glucose level, allowing users to respond promptly to mitigate or prevent pending hypoglycemia or hyperglycemia. Large randomized controlled trials (RCTs) have demonstrated the glycemic benefits of flash CGM use in both type 1 and type 2 diabetes. However, whereas RCTs are mostly focused on the efficacy of this technology in defined circumstances, real-world studies can assess its effectiveness in wider clinical settings. This review assesses the most recent real-world studies demonstrating the effectiveness of flash CGM use to improve clinical outcomes and health care resource utilization in populations with diabetes.

During the past 5 years, increasing numbers of people with type 1 or type 2 diabetes have integrated continuous glucose monitoring (CGM) into their diabetes self-management regimens. Unlike traditional blood glucose meters, CGM systems provide immediate information about the concentration and the direction and rate of change of interstitial glucose. This information enables patients to intervene promptly to prevent or reduce acute hypoglycemia or hyperglycemia.

Flash CGM is among the most recent CGM technologies. Currently, the FreeStyle Libre 14-day system (Abbott Diabetes Care) and FreeStyle Libre 2 are the only flash CGM systems available, and these systems are being adopted rapidly. Large randomized controlled trials (RCTs) have confirmed the glycemic benefits of flash CGM use in people with type 1 diabetes (1,2) and those with type 2 diabetes (3–6). However, because RCTs are mostly focused on measures of efficacy in defined circumstances, real-world studies can usefully assess the effectiveness of flash CGM in wider clinical settings.

Although adoption of flash CGM continues to expand within endocrinology and diabetes specialty practices, primary care providers may be less familiar with this technology and how it can benefit patients with diabetes. This review assesses recent real-world studies demonstrating the impact of flash CGM use on clinical outcomes and health care resource utilization in both type 1 and type 2 diabetes populations.

Rationale for Intensive Interventions to Improve Glycemic Control

The International Diabetes Federation estimated the global prevalence of diabetes in 2019 to be 9.3% (463 million people), and this proportion is expected to rise to 10.2% (578 million people) by 2030 (7), with associated annual costs of ~\$2.25 trillion (7). This figure includes \$1.5 trillion in direct costs and \$730 billion in indirect costs (e.g., absenteeism and societal costs) resulting from uncontrolled diabetes (7).

Therefore, preventing or reducing the severity of acute and long-term diabetes complications through patient-centered care remains a primary goal of diabetes management, and maintaining optimal glycemic control is central to achieving this goal (8,9). Although improvements in glycemic control should always be a priority, it is also important to strike a balance among the clinical benefits of new diabetes technologies, the initial and ongoing costs associated with their use, and the long-term gains for health and well-being.

Lowering A1C Levels Reduces Health Care Costs

Many studies have demonstrated that lower A1C levels result in lower health care resource utilization and associated costs (10–14). In a recent U.K. analysis using the IMS Core Diabetes Model, the per-person cost reductions

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TABLE 1 Cost Reductions per Person for an A1C Reduction From Baseline by 0.4% (4.4 mmol/mol) in U.K. Adults With Diabetes (12)

Baseline A1C	5 Years	10 Years	15 Years	20 Years	25 Years
<i>Adults with type 1 diabetes</i>					
<7.5%	£66 (\$87)	£271 (\$359)	£719 (\$953)	£1,379 (\$1,828)	£2,057 (\$2,726)
7.5–8.0%	£89 (\$118)	£358 (\$474)	£901 (\$1,194)	£1,713 (\$2,270)	£2,621 (\$3,473)
>8.0–9.0%	£103 (\$137)	£494 (\$655)	£1,224 (\$1,622)	£2,138 (\$2,833)	£2,831 (\$3,752)
>9.0%	£184 (\$244)	£808 (\$1,071)	£1,880 (\$2,491)	£3,147 (\$4,171)	£4,136 (\$5,481)
<i>Adults with type 2 diabetes</i>					
<7.5%	£83 (\$110)	£317 (\$420)	£682 (\$904)	£1,280 (\$1,429)	£1,280 (\$1,696)
7.5–8.0%	£132 (\$175)	£449 (\$595)	£995 (\$1,319)	£1,510 (\$2,001)	£1,678 (\$2,224)
>8.0–9.0%	£138 (\$183)	£607 (\$804)	£1,366 (\$1,820)	£1,999 (\$2,649)	£2,223 (\$2,946)
>9.0%	£105 (\$139)	£662 (\$877)	£1,274 (\$1,688)	£1,591 (\$2,108)	£1,559 (\$2,065)

Costs are based on a 1.32 USD (\$) to GBP (£) calculation.

that could be achieved over time were calculated based on a 0.4% (4.4 mmol/mol) reduction from baseline A1C (12). As shown in Table 1, the cost savings are most notable for individuals with the highest baseline A1C levels.

Reducing the Incidence and Severity of Hypoglycemia Reduces Health Care Costs

The global HAT (Hypoglycemia Assessment Tool) study, a 6-month retrospective and 4-week prospective investigation of 27,585 insulin-treated patients (type 1 diabetes, $n = 8,022$; type 2 diabetes, $n = 19,563$) in 24 countries noted the costs of inadequate glycemic control (15). During the prospective period, 83% of patients with type 1 diabetes and 46.5% of those with type 2 diabetes reported hypoglycemia, resulting in increased blood glucose monitoring, a marked increase in contact with health care providers, and increased hospitalizations. Significant indirect costs were incurred during the prospective period, with lost work time averaging 2.0 days for patients with type 1 diabetes and 1.8 days for those with type 2 diabetes. Other studies have had similar findings (15). Importantly, any level of hypoglycemia confers substantial indirect costs on employers as well as on individuals with diabetes because of increased work days lost (16–18).

Glycemic and Economic Benefits of Flash CGM Use in Real-World Studies

Although well-designed RCTs provide high levels of evidence, there is growing recognition for the complementary relationship between RCTs and real-world

prospective and retrospective observational studies. An increasing number of payers and regulators now request that pharmaceutical and medical device companies provide real-world evidence alongside RCT findings when evaluating the safety and effectiveness of new drugs and medical devices (19–22).

Large RCTs have clearly established that use of flash CGM improves glycemic control, reduces hypoglycemia, and achieves higher treatment satisfaction scores among individuals with type 1 diabetes (1,2) or type 2 diabetes (4,5) who are treated with intensive insulin therapy. Now real-world studies are investigating the use of flash CGM within different clinical settings and diverse diabetes populations.

Recent Study Results

As presented in Table 2, results from recently published prospective, observational studies closely align with glycemic benefits reported in earlier RCTs and also demonstrate the value of flash CGM use on cost outcomes and quality of life (QoL) measures (23–31). While these studies confirm significant reductions in A1C (23–25,32) and hypoglycemia (23,24) within large populations with type 1 or type 2 diabetes, they also provide strong evidence linking metabolic outcomes of flash CGM use to reductions in health care resource utilization. For example, one prospective, observational study assessed the impact of flash CGM in an unselected real-world cohort of 1,913 adults with type 1 diabetes (23). Over the 12-month study period, admissions for severe hypoglycemia and/or diabetic ketoacidosis (DKA) decreased from 3.3 to 2.2%

TABLE 2 Summary of Recently Published Real-World, Prospective, Observational Studies

Published Report	Design/Intervention	Outcome Measures	Findings
Charleer et al., 2020 (23)	<ul style="list-style-type: none"> 12-month, prospective, observational, multicenter, cohort study (Belgium) 1,913 adults with type 1 diabetes Use of flash CGM 	<ul style="list-style-type: none"> Hospitalization with DKA and/or severe hypoglycemia Hypoglycemia Absenteeism QoL 	<ul style="list-style-type: none"> Hospitalizations decreased from 3.3 to 2.2% ($P = 0.031$). Severe hypoglycemic events decreased from 14.6 to 7.8% ($P < 0.0001$). Hypoglycemic comas decreased from 2.7 to 1.1% ($P = 0.001$). Fewer people were absent from work (2.9 vs. 5.8%). Questionnaire-derived measures of treatment satisfaction improved.
Fokkert et al., 2019 (24)	<ul style="list-style-type: none"> 12-month, prospective nationwide registry (the Netherlands) 1,365 adults with type 1 diabetes (77%), type 2 diabetes (16%), or other diabetes (7%) Use of flash CGM 	<ul style="list-style-type: none"> A1C Hypoglycemia Diabetes-related hospitalizations Absenteeism QoL 	<ul style="list-style-type: none"> A1C decreased from 64.1 to 60.1 mmol/mol (difference of -4 [95% CI -6 to 3] mmol/mol; $P < 0.001$). In participants with a baseline A1C > 70 mmol/mol, the A1C decrease was -9 (95% CI -12 to 5) mmol/mol. The proportion of participants who reported hypoglycemia decreased from 93.5 to 91.0% ($P < 0.05$). The diabetes-related hospital admission rate (per year) decreased from 13.7 to 4.7% ($P < 0.05$). Absenteeism (per 6 months) decreased from 18.5 to 7.7% ($P < 0.05$). Questionnaire-derived measures of QoL improved.
Kröger et al., 2020 (32)	<ul style="list-style-type: none"> European pragmatic, parallel retrospective, noninterventional chart review study 363 adults with type 2 diabetes Use of flash CGM over 3–6 months 	<ul style="list-style-type: none"> A1C 	<ul style="list-style-type: none"> Mean (\pm SD) A1C levels were reduced by 9.6 ± 8.8 mmol/mol ($0.9 \pm 0.8\%$, $P < 0.0001$) in Austria, 8.9 ± 12.5 mmol/mol ($0.8\% \pm 1.1\%$, $P < 0.0001$) in France, and 10.1 ± 12.2 mmol/mol ($0.9\% \pm 1.1\%$, $P < 0.0001$) in Germany compared with levels recorded up to 90 days before starting use of the device. No significant differences were detected for age, sex, BMI, or duration of insulin use.
Tyndall et al., 2019 (25)	<ul style="list-style-type: none"> 8-month, prospective observational study (United Kingdom) 900 adults with type 1 diabetes Use of flash CGM SMBG comparator group ($n = 518$) 	<ul style="list-style-type: none"> A1C Hypoglycemia Hospitalization QoL 	<ul style="list-style-type: none"> A1C levels decreased by 0.6% ($P < 0.001$) among participants with a baseline A1C $\geq 7.5\%$; there was no change in the comparator group. The percentage of participants who achieved an A1C $< 7.5\%$ increased from 34.2 to 50.9% ($P < 0.001$). More symptomatic (OR 1.9, $P < 0.001$) and asymptomatic (OR 1.4, $P < 0.001$) hypoglycemia was reported with flash CGM. Hospitalizations for DKA were reduced ($P = 0.043$) with flash CGM. Participants experienced less regimen-related and emotional distress, but more patients had elevated anxiety and depression with flash CGM use.
Paris et al., 2018 (26)	<ul style="list-style-type: none"> 12-month, observational study (Belgium) 120 adults with type 1 diabetes Use of flash CGM 	<ul style="list-style-type: none"> A1C Scanning frequency Hypoglycemia 	<ul style="list-style-type: none"> A1C levels decreased from 8.51 to 8.16% ($P < 0.0001$) among participants with baseline A1C $> 7.5\%$. Number of daily scans was negatively correlated with decreased A1C. Number of hypoglycemic events (< 70 mg/dL) increased from 16.9 to 22.9 events per month ($P < 0.05$). No severe hypoglycemic events were reported. Less fear of hypoglycemia was reported.

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TABLE 2 Summary of Recently Published Real-World, Prospective, Observational Studies (continued)

Published Report	Design/Intervention	Outcome Measures	Findings
Messaoui et al., 2019 (27)	<ul style="list-style-type: none"> 12-month, prospective, observational study (Belgium) 335 children/adolescents (10.9–16.3 years of age) with type 1 diabetes Use of flash CGM 	<ul style="list-style-type: none"> Hypoglycemia Hypoglycemia change Use of SMBG A1C Acceptance Adverse events 	<ul style="list-style-type: none"> Proportion of flash CGM continuers who experienced a severe hypoglycemic event decreased by 86% ($P = 0.037$); no change was seen in the SMBG group. SMBG use decreased during use of flash CGM from 4.3 to 0 tests per day; SMBG use did not change in the SMBG group. No significant changes in A1C occurred with either flash CGM or SMBG monitoring. A total of 278 participants (83.2%) switched from SMBG to flash CGM, 234 participants were still using their device at end of the follow-up period, and 44 (15.8%) reverted to SMBG after a median use of 5.3 months. Discontinuers reported more frequent occurrence of adverse events than continuers, including premature loss of sensor (31.8 vs. 12.4%), skin reactions (18.2 vs. 2.6%), and local pain (6.8 vs. 0%) (all $P < 0.001$). Discontinuation of flash CGM was associated with longer duration of diabetes and higher baseline A1C level.
Pintus et al., 2019 (28)	<ul style="list-style-type: none"> 12-month, prospective study (UK) 52 children (4 months to 17 years of age) with type 1 diabetes Use of flash CGM with education/support from health care professionals 	<ul style="list-style-type: none"> A1C QoL 	<ul style="list-style-type: none"> Improvements were seen in A1C post-flash CGM compared with values at 12 ($P < 0.04$), 6 ($P < 0.04$), and 3 months ($P = 0.012$) pre-flash CGM use. Questionnaire-derived measures of QoL improved ($P = 0.014$), diabetes symptoms decreased ($P = 0.018$), and treatment barriers were reduced ($P = 0.035$).
Al Hayek et al., 2019 (29)	<ul style="list-style-type: none"> 12-week, prospective study (Saudi Arabia) 33 adolescents/young adults (14–21 years of age) with type 1 diabetes Use of flash CGM 	<ul style="list-style-type: none"> Well-being 	<ul style="list-style-type: none"> Questionnaire-derived measures of well-being improved: mean (\pm SD) DTSQ score increased from 14.4 ± 6.5 to 32.1 ± 1.8 ($P < 0.001$), and percentage score for the WHO-5 Well-Being Index increased from 45.1% at baseline to 93.6% ($P < 0.001$).

DTSQ, Diabetes Treatment Satisfaction Questionnaire; OR, odds ratio.

($P = 0.031$), and fewer individuals reported severe hypoglycemic events (7.8 vs. 14.6%, $P < 0.0001$) or experienced hypoglycemic coma (1.1 vs. 2.7%, $P = 0.001$). Although measures of general and diabetes-specific QoL were relatively high at baseline and remained stable throughout the study, treatment satisfaction was increased by study end. Moreover, fewer subjects were absent from work (2.9 vs. 5.8%, $P < 0.0001$), a metric that is often not reported in RCTs and provides an informative indicator of economic benefit.

Similarly, an analysis of a Dutch registry assessed the impact of flash CGM use among 1,365 individuals with diabetes (77% with type 1 diabetes, 16% with type 2 diabetes, and 7% with other types of diabetes) (24). After 12 months of flash CGM use, A1C decreased from 8.0 to 7.4%, with the greatest reductions occurring among participants with a baseline A1C $> 8.6\%$. The percentage

of patients experiencing any hypoglycemic event decreased from 93.5 to 91.0% ($P < 0.05$), and the number of diabetes-related hospital admissions decreased from 144 before baseline to 22 at 12 months ($P < 0.001$). Additionally, flash CGM users reported reduced diabetes burden with the SF-12 (12-item Short Form, v. 2) survey, EQ-5D-3 L (EuroQol 5-Dimension, three-level version) instrument, and DVN-PROM (Diabetes Vereniging Nederland Patient-Reported Outcomes Measure) questionnaire. The majority of study participants reported fewer hypoglycemic events (77%), less severe hypoglycemia (78%), more frequent insulin dose adjustments (80%), better understanding of their glucose fluctuations (95%), and less worry about their diabetes among housemates and family members (62%). Moreover, 81.7% felt no inhibitions about measuring their glucose in the presence of strangers, which was consistent with an

increased frequency of sensor scanning. Also, in addition to the cost savings associated with reduced hospitalizations, there were fewer absences from work (7.8 vs. 18.55%, $P < 0.001$).

While findings from these real-world studies further support the metabolic benefits associated with flash CGM use reported in RCTs, the reductions in hospitalizations (23–25,33) and in absenteeism (23,24) also demonstrate the immediate and substantial economic benefits of flash CGM use within populations with type 1 or type 2 diabetes. The improvements observed in treatment satisfaction (23,29), levels of hypoglycemia fear (26,29), sense of well-being (29), and other health-related measures (23–25,28,29) additionally support patient-reported outcomes described in RCTs (1,5).

Additional Emerging Real-World Evidence

As use of flash CGM technology continues to grow, large national and commercial database studies are being investigated to discern the impact of flash CGM on both A1C and acute diabetes-related events (Table 3). Two recent analyses showed significant reductions in all-cause hospitalizations and diabetes-related events among adults with either type 1 or type 2 diabetes who acquired flash CGM.

Analysis of a French national reimbursement claims database identified 74,158 adults with diabetes (type 1: $n = 33,203$, type 2: $n = 40,955$) who initiated flash CGM during the last 6 months of 2017 (34). Over the next 12 months, yearly hospitalization rates for DKA and acute hyperglycemia were reduced by 52% among patients with type 1 diabetes and by 47% for those with type 2 diabetes. The reduced rates were most evident for people with very low or very high adherence to self-monitoring of blood glucose (SMBG).

Significant reductions in acute diabetes-related adverse events (ADEs) and all-cause hospitalizations (ACH) were noted among 1,244 adults with type 2 diabetes treated with rapid- or short-acting insulin who acquired flash CGM (35). At 6 months post-acquisition, ADE rates decreased from 0.158 to 0.077 events/patient-year (hazard ratio [HR] 0.49 [95% CI 0.34–0.69], $P < 0.001$). Hospitalizations also decreased from 0.345 to 0.247 events/patient-year (HR 0.72 [95% CI 0.58–0.88], $P = 0.002$). These findings equate to numbers needed to treat of 12 and 10 for 1 year to avoid one ADE or 1 ACH, respectively.

Strong evidence for the clinical and economic benefits associated with use of flash CGM has also emerged from studies of individuals treated less intensively with insulin

or noninsulin therapy (30,31,33). In addition to significant reductions in ADEs and hospitalization rates (33), there were substantial and sustained reductions in A1C among adults with type 2 diabetes treated with long-acting insulin or noninsulin therapies (30). For those not treated with insulin, the reductions in A1C were similar to what would be expected from adding insulin glargine (36). Further studies (34,37) have established that there is no correlation between previous frequency of daily blood glucose monitoring and ADEs.

These findings challenge the view that CGM should be made available only to patients who are treated with intensive insulin therapy and who have a documented history of frequent blood glucose monitoring. This perception may have reduced the coverage of CGM offered by some commercial and public insurers. For example, the Centers for Medicare & Medicaid Services currently limit coverage to patients who administer three or more insulin injections per day (or use an insulin pump) and perform four or more glucose tests per day.

Summary

Many individuals with diabetes experience poor glycemic control (38,39), which puts them at increased risk for acute adverse glycemic events (40,41) and the long-term development of microvascular and macrovascular disease (42–44). In addition to its clinical consequences, uncontrolled diabetes is driving an inordinate economic burden on private payers and national health care systems (7).

Numerous studies have shown that optimizing A1C levels and reducing the incidence of severe hypoglycemia and DKA can significantly lower health care costs (10–14,45–47). However, achieving optimal diabetes control necessitates expanded adoption of diabetes medications and technologies that are effective, safe, and feasible in real-world clinical settings.

Flash CGM provides immediate information about an individual's current and projected glucose level using rate-of-change arrows, which allows users to respond promptly to mitigate or prevent pending hypoglycemia or hyperglycemia. Findings from large RCTs and prospective, observational studies have shown that use of flash CGM is associated with improved overall glycemic control (23–26,28), reductions in hypoglycemia (23–25), fewer diabetes-related hospitalizations (23–25,33), decreased absenteeism (23,24), and improvements in treatment satisfaction (23,29) and measures of well-being (23,25,28,29). These outcomes indicate both clinical and economic benefits, and use of flash CGM can enable these

TABLE 3 Summary of Emerging Real-World Evidence

Published Reports	Design/Intervention	Outcome Measures	Findings
<i>A1C reductions</i>			
Miller et al., 2020 (30)	<ul style="list-style-type: none"> 6- and 12-month retrospective, observational analyses using medical/pharmacy claims database and Quest laboratory A1C values (United States) 6- and 12-month: 774 and 207 adults, respectively, with type 2 diabetes treated with long-acting insulin or premixed insulin ($n = 277$ and 87, respectively) or noninsulin therapy ($n = 497$ and 120, respectively) Acquisition of flash CGM 	<ul style="list-style-type: none"> A1C 	<ul style="list-style-type: none"> A1C decreased by -0.8% ($P < 0.0001$) in the 6-month cohort: long-acting insulin by -0.6% ($P < 0.0001$), noninsulin by -0.9% ($P < 0.0001$). A1C decreased by -0.6% ($P < 0.0001$) in the 12-month cohort: long-acting insulin by -0.5% ($P = 0.0014$), noninsulin by -0.7% ($P < 0.0001$).
Wright et al., 2020 (31)	<ul style="list-style-type: none"> 12-month, retrospective, observational study using IBM Explorys, a U.S. EHR database 1,183 adults with type 2 diabetes using long-acting insulin or premixed insulin ($n = 378$) or noninsulin ($n = 805$) therapy 12-month, retrospective, observational study using IBM Explorys, a U.S. EHR database 	<ul style="list-style-type: none"> A1C 	<ul style="list-style-type: none"> A1C decreased by -1.38% (from 10.16 to 8.78%, $P < 0.0001$) at 6 months post-flash CGM acquisition. Greatest reductions of A1C were seen in participants with highest baseline A1C levels.
Eeg-Olofsson et al., 2020 (48)	<ul style="list-style-type: none"> 12-month, retrospective, observational study using Swedish National Diabetes Register 538 adults with type 1 or type 2 diabetes Flash CGM use 	<ul style="list-style-type: none"> A1C 	<ul style="list-style-type: none"> A1C decreased by -0.52% ($P < 0.0001$) at 12 months.
<i>Reductions in events/hospitalizations</i>			
Hirsch et al., 2020 (37)	<ul style="list-style-type: none"> 12-month, retrospective, observational study using IBM MarketScan Commercial Claims and Medicare Supplemental databases 12,521 adults with type 1 or type 2 diabetes Acquisition of flash CGM 	<ul style="list-style-type: none"> Acute ADEs for hypoglycemia or hyperglycemia 	<ul style="list-style-type: none"> ADE decreased from 0.245 to 0.132 events/patient-year (HR: 0.54 [95% CI 0.49-0.59], $P < 0.001$). Similar reductions in ADE were seen in participants with a history of performing four or more or less than four glucose tests per day.
Bergental et al., 2020 (35)	<ul style="list-style-type: none"> 12-month, retrospective, observational study using IBM MarketScan Commercial Claims and Medicare Supplemental databases 1,244 adults with type 2 diabetes Acquisition of flash CGM 	<ul style="list-style-type: none"> Acute ADEs for hypoglycemia or hyperglycemia ACH 	<ul style="list-style-type: none"> ADEs decreased from 0.158 to 0.077 events/patient-year (HR: 0.49 [95% CI 0.34-0.69], $P < 0.001$). ACH decreased from 0.345 to 0.247 events/patient-year (HR: 0.72 [95% CI 0.58-0.88], $P = 0.002$).
Miller et al., 2020 (33)	<ul style="list-style-type: none"> 12-month, retrospective, observational study using IBM MarketScan Commercial Claims and Medicare Supplemental databases 7,167 adults with type 2 diabetes treated with long-acting insulin or noninsulin therapy Acquisition of flash CGM 	<ul style="list-style-type: none"> Acute ADEs Hospitalization or outpatient emergency for hypoglycemia or hyperglycemia 	<ul style="list-style-type: none"> ADEs decreased at 6 months post-acquisition of flash CGM from 0.071 to 0.052 events/patient-year (HR: 0.70 [95% CI 0.57-0.85], $P < 0.001$). Hospitalizations decreased from 0.180 to 0.161 events/patient-year (HR: 0.87 [95% CI 0.78-0.98], $P = 0.025$).
Roussel et al., 2020 (34)	<ul style="list-style-type: none"> 12-month, retrospective, observational study using the French nationwide reimbursement claims database 33,203 individuals with type 1 diabetes and 40,955 individuals with type 2 diabetes Flash CGM use for 12 months 	<ul style="list-style-type: none"> Hospitalizations for DKA 	<ul style="list-style-type: none"> DKA hospitalizations decreased by 52% in participants with type 1 diabetes and by 47% in those with type 2 diabetes.

EHR, electronic health record; IBM, International Business Machines.

outcomes regardless of therapy and previous blood glucose monitoring frequency (30,31,33,34,37).

Given the growing global prevalence of diabetes and its associated costs, there is an opportunity to take advantage of flash CGM to facilitate improvements in metabolic control and patient QoL while reducing the projected costs of diabetes care.

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AUTHOR CONTRIBUTIONS

C.J.B. and J.R.G. wrote, reviewed, and approved the manuscript for submission. C.J.B. is the guarantor of this work and takes responsibility for the integrity of the data and the accuracy of the content.

REFERENCES

1. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. *Lancet* 2016;388:2254–2263
2. Oskarsson P, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R, Bolinder J. Impact of flash glucose monitoring on hypoglycaemia in adults with type 1 diabetes managed with multiple daily injection therapy: a pre-specified subgroup analysis of the IMPACT randomised controlled trial. *Diabetologia* 2018;61:539–550
3. Evans M, Welsh Z, Ells S, Seibold A. The impact of flash glucose monitoring on glycaemic control as measured by HbA1c: a meta-analysis of clinical trials and real-world observational studies. *Diabetes Ther* 2020;11:83–95
4. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Use of flash glucose-sensing technology for 12 months as a replacement for blood glucose monitoring in insulin-treated type 2 diabetes. *Diabetes Ther* 2017;8:573–586
5. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Flash glucose-sensing technology as a replacement for blood glucose monitoring for the management of insulin-treated type 2 diabetes: a multicenter, open-label randomized controlled trial. *Diabetes Ther* 2017; 8:55–73

6. Yaron M, Roitman E, Aharon-Hananel G, et al. Effect of flash glucose monitoring technology on glycemic control and treatment satisfaction in patients with type 2 diabetes. *Diabetes Care* 2019;42:1178–1184
7. Bommer C, Sagalova V, Heesemann E, et al. Global economic burden of diabetes in adults: projections from 2015 to 2030. *Diabetes Care* 2018;41:963–970
8. Davies MJ, D'Alessio DA, Fradkin J, et al. Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetologia* 2018; 61:2461–2498
9. National Institute for Health and Care Excellence. Type 1 diabetes in adults: diagnosis and management. Available from <https://www.nice.org.uk/guidance/ng17>. Accessed 1 July 2019
10. Fitch K, Pyenson BS, Iwasaki K. Medical claim cost impact of improved diabetes control for medicare and commercially insured patients with type 2 diabetes. *J Manag Care Pharm* 2013;19: 609–620, 620a–620d
11. Bansal M, Shah M, Reilly B, Willman S, Gill M, Kaufman FR. Impact of reducing glycated hemoglobin on healthcare costs among a population with uncontrolled diabetes. *Appl Health Econ Health Policy* 2018;16:675–684
12. Baxter M, Hudson R, Mahon J, et al. Estimating the impact of better management of glycaemic control in adults with type 1 and type 2 diabetes on the number of clinical complications and the associated financial benefit. *Diabet Med* 2016;33:1575–1581
13. Gilmer TP, O'Connor PJ, Rush WA, et al. Predictors of health care costs in adults with diabetes. *Diabetes Care* 2005;28:59–64
14. Juarez D, Goo R, Tokumaru S, Sentell T, Davis J, Mau M. Association between sustained glycated hemoglobin control and healthcare costs. *Am J Pharm Benefits* 2013;5:59–64
15. Aronson R, Galstyan G, Goldfracht M, Al Sifri S, Elliott L, Khunti K. Direct and indirect health economic impact of hypoglycaemia in a global population of patients with insulin-treated diabetes. *Diabetes Res Clin Pract* 2018;138:35–43
16. Pawaskar M, Iglay K, Witt EA, Engel SS, Rajpathak S. Impact of the severity of hypoglycemia on health-related quality of life, productivity, resource use, and costs among US patients with type 2 diabetes. *J Diabetes Complications* 2018;32:451–457
17. Brod M, Christensen T, Thomsen TL, Bushnell DM. The impact of non-severe hypoglycemic events on work productivity and diabetes management. *Value Health* 2011;14:665–671
18. Giorda CB, Rossi MC, Ozzello O, et al.; HYPOS-1 Study Group of AMD. Healthcare resource use, direct and indirect costs of hypoglycemia in type 1 and type 2 diabetes, and nationwide projections: results of the HYPOS-1 study. *Nutr Metab Cardiovasc Dis* 2017;27:209–216
19. Khosla S, White R, Medina J, et al. Real world evidence (RWE): a disruptive innovation or the quiet evolution of medical evidence generation? *F1000 Res* 2018;7:111
20. U.S. Food and Drug Administration. Use of real-world evidence to support regulatory decision-making for medical devices. Available from <https://www.fda.gov/media/99447/download>. Accessed 30 March 2019

21. Resnic FS, Matheny ME. Medical devices in the real world. *N Engl J Med* 2018;378:595–597
22. Katkade VB, Sanders KN, Zou KH. Real world data: an opportunity to supplement existing evidence for the use of long-established medicines in health care decision making. *J Multidiscip Healthc* 2018;11:295–304
23. Charleer S, De Block C, Van Huffel L, et al. Quality of life and glucose control after 1 year of nationwide reimbursement of intermittently scanned continuous glucose monitoring in adults living with type 1 diabetes (FUTURE): a prospective observational real-world cohort study. *Diabetes Care* 2020;43:389–397
24. Fokkert M, van Dijk P, Edens M, et al. Improved well-being and decreased disease burden after 1-year use of flash glucose monitoring (FLARE-NL4). *BMJ Open Diabetes Res Care* 2019;7:e000809
25. Tyndall V, Stimson RH, Zammit NN, et al. Marked improvement in HbA_{1c} following commencement of flash glucose monitoring in people with type 1 diabetes. *Diabetologia* 2019;62:1349–1356
26. Paris I, Henry C, Pirard F, Gérard A-C, Colin IM. The new FreeStyle Libre flash glucose monitoring system improves the glycaemic control in a cohort of people with type 1 diabetes followed in real-life conditions over a period of one year. *Endocrinol Diabetes Metab* 2018;1:e00023
27. Messaaoui A, Tenoutasse S, Crenier L. Flash glucose monitoring accepted in daily life of children and adolescents with type 1 diabetes and reduction of severe hypoglycemia in real-life use. *Diabetes Technol Ther* 2019;21:329–335
28. Pintus D, Ng SM. FreeStyle Libre flash glucose monitoring improves patient quality of life measures in children with type 1 diabetes mellitus (T1DM) with appropriate provision of education and support by healthcare professionals. *Diabetes Metab Syndr* 2019;13:2923–2926
29. Al Hayek AA, Al Dawish MA. The potential impact of the FreeStyle Libre flash glucose monitoring system on mental well-being and treatment satisfaction in patients with type 1 diabetes: a prospective study. *Diabetes Ther* 2019;10:1239–1248
30. Miller E, Brandner L, Wright E. HbA_{1c} reduction after initiation of the FreeStyle Libre system in type 2 diabetes patients on long-acting insulin or non-insulin therapy [Abstract]. *Diabetes* 2020;69(Suppl. 1):84-LB
31. Wright E, Kerr MSD, Reyes I, Nabutovsky Y, Miller E. HbA_{1c} reduction associated with a FreeStyle Libre system in people with type 2 diabetes not on bolus insulin therapy [Abstract]. *Diabetes* 2020;69(Suppl. 1):78-LB-P
32. Kröger J, Fasching P, Hanaire H. Three European retrospective real-world chart review studies to determine the effectiveness of flash glucose monitoring on HbA_{1c} in adults with type 2 diabetes. *Diabetes Ther* 2020;11:279–291
33. Miller E, Kerr MSD, Roberts GJ, Souto D, Nabutovsky Y, Wright E. FreeStyle Libre system use associated with reduction in acute diabetes events and all-cause hospitalizations in patients with type 2 diabetes without bolus insulin [Abstract]. *Diabetes* 2020;69(Suppl. 1):85-LB
34. Roussel R, Bruno Guerci B, Vicaut E, et al. Dramatic drop in ketoacidosis rate after FreeStyle Libre system initiation in type 1 and type 2 diabetes in France, especially in people with low self-monitoring of blood glucose (SMBG): a nationwide study [Abstract]. *Diabetes* 2020;69(Suppl. 1):68-OR
35. Bergenstal RM, Kerr MSD, Gregory J, et al. FreeStyle Libre system use is associated with reduction in inpatient and outpatient emergency acute diabetes events and all-cause hospitalizations in patients with type 2 diabetes [Abstract]. *Diabetes* 2020;69(Suppl. 1):69-OR
36. Sanofi. Lantus [prescribing information]. Available from <https://products.sanofi.us/Lantus/Lantus.html#section-15.1>. Accessed 25 June 2020
37. Hirsch IB, Kerr MSD, Roberts GJ, et al. Utilization of continuous glucose monitors is associated with reduction in inpatient and outpatient emergency acute diabetes events regardless of prior blood test strip usage [Abstract]. *Diabetes* 2020;69(Suppl. 1):875-P
38. Carls G, Huynh J, Tuttle E, Yee J, Edelman SV. Achievement of glycated hemoglobin goals in the US remains unchanged through 2014. *Diabetes Ther* 2017;8:863–873
39. Brath H, Paldánus PM, Bader G, Kolaczynski WM, Nilsson PM. Differences in glycemic control across world regions: a post-hoc analysis in patients with type 2 diabetes mellitus on dual antidiabetes drug therapy. *Nutr Diabetes* 2016;6:e217
40. Monnier L, Colette C, Wojtuszczyk A, et al. Toward defining the threshold between low and high glucose variability in diabetes. *Diabetes Care* 2017;40:832–838
41. Qu Y, Jacober SJ, Zhang Q, Wolka LL, DeVries JH. Rate of hypoglycemia in insulin-treated patients with type 2 diabetes can be predicted from glycemic variability data. *Diabetes Technol Ther* 2012;14:1008–1012
42. Diabetes Control and Complications Trial Research Group. The relationship of glycemic exposure (HbA_{1c}) to the risk of development and progression of retinopathy in the Diabetes Control and Complications Trial. *Diabetes* 1995;44:968–983
43. Lind M, Pivodic A, Svensson A-M, Ólafsdóttir AF, Wedel H, Ludvigsson J. HbA_{1c} level as a risk factor for retinopathy and nephropathy in children and adults with type 1 diabetes: Swedish population based cohort study. *BMJ* 2019;366:l4894
44. Sherwani SI, Khan HA, Ekhzaimy A, Masood A, Sakharkar MK. Significance of HbA_{1c} test in diagnosis and prognosis of diabetic patients. *Biomark Insights* 2016;11:95–104
45. Liu J, Wang R, Ganz ML, Paprocki Y, Schneider D, Weatherall J. The burden of severe hypoglycemia in type 1 diabetes. *Curr Med Res Opin* 2018;34:171–177
46. Liu J, Wang R, Ganz ML, Paprocki Y, Schneider D, Weatherall J. The burden of severe hypoglycemia in type 2 diabetes. *Curr Med Res Opin* 2018;34:179–186
47. Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project (HCUP). Available from <https://www.ahrq.gov/research/data/hcup/index.html>. Accessed 1 February 2020
48. Eeg-Olofsson K, Svensson A-M, Franzén S, Ismail HA, Levrat-Guillen F. Sustainable HbA_{1c} decrease at 12 months for adults with type 1 and type 2 diabetes using the FreeStyle Libre system: a study within the National Diabetes Register in Sweden [Abstract]. *Diabetes* 2020;69(Suppl. 1):74-LB-P