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Real-Time Continuous Glucose Monitoring Among Participants in the T1D Exchange Clinic Registry

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OBJECTIVE

To assess the frequency of continuous glucose monitoring (CGM) device use, factors associated with its use, and the relationship of CGM with diabetes outcomes (HbA_{1c}, severe hypoglycemia [SH], and diabetic ketoacidosis [DKA]).

RESEARCH DESIGN AND METHODS

Survey questions related to CGM device use 1 year after enrollment in the T1D Exchange clinic registry were completed by 17,317 participants. Participants were defined as CGM users if they indicated using real-time CGM during the prior 30 days.

RESULTS

Nine percent of participants used CGM (6% of children <13 years old, 4% of adolescents 13 to <18 years, 6% of young adults 18 to <26 years, and 21% of adults ≥26 years). CGM use was more likely with higher education, higher household income, private health insurance, longer duration of diabetes, and use of insulin pump ($P < 0.01$ all factors). CGM use was associated with lower HbA_{1c} in children (8.3% vs. 8.6%, $P < 0.001$) and adults (7.7% vs. 7.9%, $P < 0.001$). In adults, more frequent use of CGM (≥6 days/week) was associated with lower mean HbA_{1c}. Only 27% of users downloaded data from their device at least once per month, and ≤15% of users reported downloading their device at least weekly. Among participants who used CGM at baseline, 41% had discontinued within 1 year.

CONCLUSIONS

CGM use is uncommon but associated with lower HbA_{1c} in some age-groups, especially when used more frequently. Factors associated with discontinuation and infrequent use of retrospective analysis of CGM data should be considered in developing next-generation devices and education on CGM use.

Real-time continuous glucose monitoring (CGM) has the potential to aid patients and providers in both the daily management of blood glucose levels and retrospective review of glucose patterns. Multicenter randomized controlled trials and meta-analyses have shown that CGM is associated with improved glycemic control, achievement or maintenance of target glycated hemoglobin (HbA_{1c}) levels, and reduction of severe hypoglycemia (SH) events in adults (1–7). For children in the JDRF-sponsored multicenter trial, which randomized patients to CGM or self-monitoring of blood glucose (SMBG), there was a larger percentage of subjects 8–14 years old using CGM who achieved at least a 10% decrease in HbA_{1c} and a target HbA_{1c} <7%, compared with children using SMBG (6). Some studies have shown that near-daily (as opposed to

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occasional) use of CGM is associated with better glycemic control, as measured by HbA_{1c} (5,8), leading to a practice guideline recommending CGM for adults who are able to use it at least 6 days a week (9). In clinical trials of CGM versus SMBG use in children, those who used near-daily CGM had a greater reduction in HbA_{1c} (−0.3 to −0.8%) and a greater percentage of blood glucose values in target range compared with those who used it less frequently (10–12). Other studies in children have reported reduced time spent in hypoglycemia with near-daily use (reviewed in 11), but such frequent use is more difficult to achieve in pediatric patients. In addition, subjects and their caregivers who participated in randomized CGM trials have reported high satisfaction and no negative impact on quality of life with CGM (12,13). Although these potential benefits of CGM are known, the actual rates of CGM device use and clinical outcomes of use in real-world clinical settings have not been well studied and few large studies have investigated the specific factors that influence CGM use outside of controlled trials.

The T1D Exchange Clinic Network (14) registry database provides the opportunity to understand the characteristics of CGM device use in a large clinic-based population. In this study, we report the frequency of CGM device use and the demographic and clinical factors associated with its use in this clinic-based cohort. We also investigated the relationship of CGM with diabetes outcomes including HbA_{1c}, SH events, and diabetic ketoacidosis (DKA). Finally, data were obtained regarding the attributes of CGM that participants identified as the most useful and most challenging, as well as why CGM is tried but discontinued. Understanding the factors that influence use of CGM in this registry can help optimize the use of this technology in clinical diabetes care.

RESEARCH DESIGN AND METHODS

The T1D Exchange clinic registry of individuals with type 1 diabetes commenced enrollment in September 2010 (14). Each clinic received approval from an institutional review board. Informed consent was obtained according to institutional review board requirements from adult participants and parents/guardians of minors; assent from minors was obtained as required. Data were collected for the registry's central

database from the participant's medical record and by having the participant or parent complete a comprehensive questionnaire, as previously described (14). One year after enrollment, data were collected again from the participant's medical record, and the participant or parent/guardian of the participant (for minors) completed another comprehensive questionnaire. This report includes data on 17,317 participants from 66 sites who completed survey questions related to CGM device use 1 year after enrollment in the registry.

Information pertaining to use of a CGM device was obtained from the participant or, for children, from the parent/guardian. Participants were defined as CGM users if they indicated using real-time CGM during the prior 30 days on the 1-year survey. CGM users were asked about frequency of CGM use in the prior 30 days, duration of CGM use, frequency of CGM data download, change in frequency of blood glucose checks when wearing the CGM device, and the real-time and retrospective features of CGM that they found useful. Registry participants also were queried as to whether they had been using CGM regularly (at least once a month) but if use was discontinued completely in the past year and, if yes, the reasons for discontinuation. Demographic data on sex, race/ethnicity, household income, health insurance status, and education (parent's highest education level if participant was <18 years old) were obtained. Participants were asked about occurrences of SH with seizure or loss of consciousness and DKA resulting in overnight hospitalization in the prior 3 months. Information about age, duration of diabetes, insulin delivery method (pump or injections), HbA_{1c}, and presence of diabetes-related complications was collected from medical chart review. The most proximal HbA_{1c} value to the date of administration of the participant survey (most recent HbA_{1c}) obtained between 6 months prior to and 1 month after the 1-year office visit was used for analysis.

Statistical Methods

Demographic and clinical characteristics of registry participants using CGM and participants not using CGM at the 1-year data collection were compared using the Wilcoxon rank sum test for continuous

variables and χ^2 tests for categorical variables (Mantel-Haenszel statistics were used for ordered categories). For accounting for differences in results expected across age-groups, all analyses, apart from descriptions of usefulness of CGM features and reasons for discontinuation of CGM, were stratified by age: <13 years old ("children"), 13 to <18 years old ("adolescents"), 18 to <26 years old ("young adults"), and ≥ 26 years old ("adults"). Linear regression models were used to examine the association between CGM use and most recent HbA_{1c} in each age-group, and logistic regression models were used to examine the association between CGM use and the occurrence of one or more SH events and the occurrence of one or more DKA events. Similar statistical methods were used to examine the association of frequency of CGM use during the past month and these outcomes.

All regression models (linear and logistic) included adjustment for the following demographic and clinical characteristics: sex, race/ethnicity, education level, annual household income, health insurance status, diabetes duration, and insulin delivery method (pump/injection). Tests of significance were reported from models using continuous or ordinal variables, and odds ratios (ORs) with 95% CIs and adjusted means were reported from models using categorical variables (average frequency of CGM device use per week during the past month was used to calculate categories for frequency of CGM device use [<4 days, 4 to <6 days, and ≥ 6 days]).

Data analyses used SAS software, version 9.3 (2011; SAS Institute, Cary, NC). All *P* values are two-sided. In view of the multiple comparisons and large sample size, only *P* values <0.01 were considered significant.

RESULTS

Participant and Clinical Characteristics Associated With CGM Use

The 17,317 participants ranged in age from 1 to 92 years; 51% were female, 84% were non-Hispanic white, and 59% were using an insulin pump. Additional characteristics of the cohort are shown in Table 1. Among the 17,317 participants, 1,613 (9%) reported using CGM, with 51% using a Medtronic Guardian or

Table 1—Participant characteristics by age

	<13 years old			13 to <18 years old			18 to <26 years old			≥26 years old		
	CGM user	CGM nonuser	P	CGM user	CGM nonuser	P	CGM user	CGM nonuser	P	CGM user	CGM nonuser	P
N	278	4,749		179	4,676		157	2,612		999	3,667	
Sex: female, n (%) ^{a,b}	143 (51)	2,274 (48)	0.25	92 (51)	2,277 (49)	0.48	92 (59)	1,293 (50)	0.03	566 (57)	2,020 (55)	0.38
Race/ethnicity, n (%) ^{a,b}			<0.001			0.31			0.18			0.03
White non-Hispanic	249 (91)	3,772 (80)		150 (84)	3,691 (79)		136 (87)	2,163 (83)		936 (94)	3,358 (92)	
Black non-Hispanic	3 (1)	261 (6)		9 (5)	259 (6)		3 (2)	107 (4)		17 (2)	113 (3)	
Hispanic or Latino	17 (6)	426 (9)		16 (9)	492 (11)		9 (6)	236 (9)		19 (2)	107 (3)	
Other	9 (3)	281 (6)		4 (2)	231 (5)		9 (6)	106 (4)		27 (3)	89 (2)	
Education level, n (%) ^{a,c}			<0.001			<0.001			N/A			<0.001
≤High school/GED	60 (22)	2,008 (43)		44 (25)	2,114 (47)		N/A	N/A		160 (21)	1,228 (34)	
Associate's or bachelor's	99 (36)	1,565 (33)		57 (33)	1,320 (29)		N/A	N/A		319 (41)	1,554 (43)	
Master's, professional, doctorate	113 (42)	1,099 (24)		72 (42)	1,058 (24)		N/A	N/A		298 (38)	831 (23)	
Household income (USD), n (%) ^a			<0.001			<0.001			0.32			<0.001
<35,000	13 (6)	765 (19)		9 (7)	648 (19)		23 (21)	456 (27)		54 (6)	634 (21)	
35,000 to <75,000	59 (27)	1,135 (29)		18 (15)	891 (26)		28 (25)	458 (27)		221 (26)	979 (32)	
≥75,000	150 (68)	2,042 (52)		94 (78)	1,835 (54)		59 (54)	772 (46)		583 (68)	1,418 (47)	
Insurance status, n (%) ^b			<0.001			0.001			0.001			<0.001
Private insurance	246 (90)	2,927 (74)		146 (87)	3,179 (74)		130 (91)	1,722 (78)		887 (90)	2,784 (78)	
Other insurance	27 (10)	1,020 (26)		21 (13)	1,063 (25)		12 (8)	447 (20)		97 (10)	710 (20)	
No insurance	0	16 (<1)		1 (<1)	31 (<1)		1 (<1)	43 (2)		2 (<1)	88 (2)	
Duration of type 1 diabetes (years) ^a			0.004			0.001			0.02			0.009
Median (25th, 75th percentile)	4 (2, 6)	3 (1, 5)		7 (4, 11)	6 (3, 9)		11 (7, 14)	9.5 (6, 14)		25 (16, 35)	24 (15, 34)	
n (%)												
<1	3 (1)	164 (3)		4 (2)	74 (2)		1 (<1)	10 (<1)		1 (<1)	10 (<1)	
1 to <10	262 (94)	4,452 (94)		123 (72)	3,513 (75)		65 (41)	1,296 (50)		113 (11)	540 (15)	
10 to <20	13 (5)	133 (3)		52 (26)	1,089 (23)		85 (54)	1,223 (47)		218 (22)	854 (23)	
20 to <50							6 (4)	83 (3)		624 (62)	2,093 (57)	
≥50 years										43 (4)	170 (5)	
Insulin delivery method, n (%) ^{a,b}			<0.001			<0.001			<0.001			<0.001
Pump	240 (88)	2,740 (58)		155 (89)	2,558 (55)		25 (16)	1,383 (54)		828 (84)	2,073 (57)	
Injections	34 (12)	1,961 (42)		19 (11)	2,063 (45)		131 (84)	1,202 (46)		162 (16)	1,545 (43)	

^aTwo transmitters in cohort; 9 missing race/ethnicity; 1,122 missing education level; 3,870 missing annual household income; 1,037 missing insurance status; 195 were excluded from insulin delivery method, since they were reported using both pump and injections. ^bP value from Wilcoxon rank sum test. Ordinal income and education variables were analyzed using Mantel-Haenszel statistics. ^cP value from χ^2 test. ^dHighest education level of participant or parent (if <18 years old). Not reported for participants 18 to <26 years old, since it was not an accurate representation of socioeconomic status for this age-group.

Paradigm, 48% a Dexcom SEVEN PLUS, and 1% an Abbott FreeStyle Navigator device. By age-subgroups, CGM was used by 6% of children <13 years old (278 of 5,027), 4% of adolescents 13 to <18 years old (179 of 4,855), 6% of young adults 18 to <26 years old (157 of 2,769), and 21% of adults \geq 26 years old (999 of 4,666) (Table 1). Across all age-groups, except for household income in 18 to <26 year olds, CGM use was more likely in participants with higher education level, higher household income, private health insurance, longer duration of diabetes, and use of an insulin pump ($P < 0.01$ for each factor) (Table 1). Among children <13 years of age, CGM was more frequent in non-Hispanic whites than other races/ethnicities ($P < 0.001$), but this was not seen in older age-groups.

Description of CGM Use

The median reported duration of CGM use in the prior 30 days was 27 days (interquartile range 15–30) in children, 23 days (interquartile range 10–30) in adolescents, 21 days (interquartile range 7–30) in young adults, and 29 days (interquartile range 20–30) in adults (Supplementary Table 1). Frequency of CGM use was \geq 6 days per week in 55% of children, 45% of adolescents, 37% of young adults, and 60% of adults (Supplementary Table 1).

Relationship of CGM Use With Diabetes Outcomes

HbA_{1c}

Mean HbA_{1c} (\pm SD) for the entire cohort was $8.2\% \pm 1.5\%$ (66 ± 7 mmol/mol). Adjusted mean HbA_{1c} was lower in CGM users versus nonusers in children (8.3% vs. 8.6%, $P < 0.001$) and adults (7.7% vs. 7.9%, $P < 0.001$) but was not different in adolescents (9.0% vs. 9.0%, $P = 0.76$) or young adults (8.4% vs. 8.5%, $P = 0.33$) (Fig. 1A). In adults \geq 26 years old, more frequent use of CGM was associated with lower adjusted mean HbA_{1c} in those using it \geq 6 days a week (7.0% vs. 7.3% when using it 4 to <6 days a week and 7.3% when using it <4 days a week, adjusted $P < 0.001$) (Fig. 1B). This relationship was suggested but less prominent in the other age-groups (adjusted $P = 0.21$ for children, $P = 0.05$ for adolescents, and $P = 0.88$ for young adults).

SH and DKA

The frequencies of one or more SH events in the past 3 months were similar

between participants using CGM and participants not using CGM (Table 2). The frequency of one or more SH event in the prior 3 months was not associated with frequency of CGM use (Supplementary Table 2).

There was a trend toward decreased frequency of DKA events in the past 3 months in all ages, particularly in children who used CGM compared with children not using CGM (unadjusted OR 0.4 [95% CI 0.2, 0.8]). However, this trend toward decreased DKA frequency did not reach statistical significance after adjustment (adjusted OR 0.6 [0.3, 1.2]) (Table 2). With regard to frequency of CGM use, unadjusted point estimates and ORs suggested a trend toward decreased DKA events in children and adolescents who wore their CGM device more often (\geq 4 days/week), though this was not statistically significant or maintained after adjustment (Supplementary Table 2).

Use of CGM Data and Features

Only 27% of participants reported downloading data from their CGM device at least once per month. Even fewer participants reported downloading CGM data to a computer at least once a week (\leq 15% in each age-group), and many indicated never downloading CGM data (24%, 36%, 45%, and 42% of children, adolescents, young adults, and adults, respectively) (Supplementary Table 2).

When asked about change in frequency of blood glucose checks when wearing CGM, \sim 50% of users in each age-group reported checking their blood glucose less often or much less often (51%, 46%, 61%, and 53% of children, adolescents, young adults, and adults, respectively) (Supplementary Table 2). Smaller percentages of participants reported either checking their blood glucose more often (10%, 12%, 16%, and 20%) or no change in frequency of checking (38%, 42%, 23%, and 27%) in the four age-groups, respectively (Supplementary Table 2).

Participants were asked about the usefulness of specific features of CGM and, in general, reported that the real-time features of CGM were more useful than the retrospective features (Fig. 2). The most helpful feature was reported to be the arrows showing the direction of glucose change (92% indicated helpful), while the least helpful feature was reported to be the retrospective analysis

of glucose data to change the types or amount of food eaten (only 46% found this feature helpful, and 28% indicated that it was not helpful).

Discontinuation of CGM

Of the 1,662 participants reporting CGM use at enrollment into the registry, 675 (41%) reported discontinuing CGM use at the 1-year data collection. Among the 727 participants who indicated stopping CGM use (which includes 675 who were using CGM at enrollment but discontinued use by 1 year and 52 who started CGM after enrollment but discontinued use by 1 year), the top reason for stopping CGM was discomfort when wearing the CGM (42% [Supplementary Table 3]). Other reasons included problems inserting the CGM sensor (33%), problems with the adhesive holding the sensor on the skin (30%), problems with the CGM working properly (28%), too many alarms (27%), concerns about accuracy of CGM data (25%), interference with sports and activities (18%), and skin reactions from the CGM sensor (18%).

CONCLUSIONS

Real-time CGM has been widely available for use by people with type 1 diabetes for almost a decade (15), and has been shown to improve outcomes, particularly when used on a near-daily basis. However, our study shows that only a small proportion of patients with type 1 diabetes are using CGM in clinical practice, especially in children, adolescents, and adults <26 years old. CGM use was more likely in participants with higher education level, higher household income, private insurance, longer duration of diabetes, and use of an insulin pump. From our study, it is unclear how much these differences in use are due to provider prescription differences among patients of different ages and socioeconomic groups, and how much they are due to the patient factors themselves, such as having private or public insurance. CGM devices are not reimbursed by Medicare (16); lack of insurance coverage for CGM has been suggested as a barrier to adoption (17), which may have contributed to our observed differences.

Given the knowledge that these differences in characteristics between CGM users and nonusers exist, it is notable that even after adjusting for these

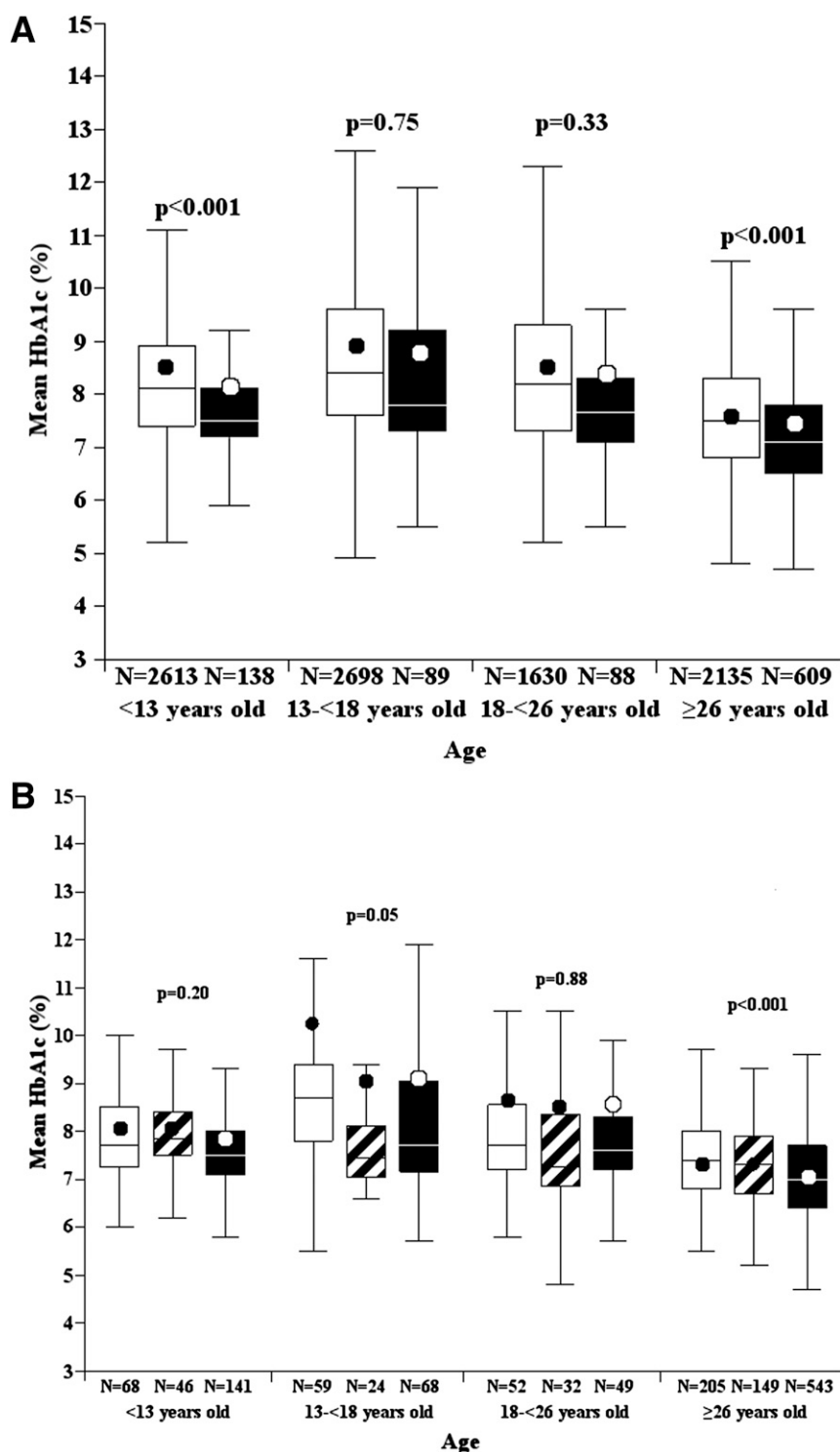


Figure 1—A: Mean HbA_{1c} vs. CGM use. White box, CGM nonusers (black line indicates median; the black dot indicates adjusted mean). Black box, CGM users (white line indicates median; the white dot indicates adjusted mean). P values and adjusted means from a linear regression model adjusted for sex, race/ethnicity, annual income, insurance status, education level, and diabetes duration. B: Mean HbA_{1c} by frequency of CGM use. White box, CGM use <4 days per week (the black line indicates median; the black dot indicates adjusted mean). White and black striped box, CGM use 4 to <6 days per week (black line indicates median; black dot indicates adjusted mean). Black box, CGM use ≥6 days per week (white line indicates median; white dot indicates adjusted mean). P values and adjusted means from a linear regression model of frequency of continuous CGM use vs. HbA_{1c} adjusted for sex, race/ethnicity, annual income, insurance status, education level, and diabetes duration.

factors there was an association between CGM use and lower HbA_{1c} in children and adults, although not in 13 to <26 year olds. We acknowledge that

the cross-sectional nature of our study does not preclude the possibility that those with lower HbA_{1c} were more likely to initiate CGM, but our findings

are in agreement with results from controlled trials showing improved glycaemic control in CGM intervention groups (1–3,6).

A unique feature of our study is the characterization of how patients with type 1 diabetes use CGM and the information from the monitoring device. More frequent use was associated with lower HbA_{1c} levels in adults >26 years old, with a similar trend in younger participants. This is a reassuring finding, given the guidelines recommending near-daily use of CGM in order to improve glycemic control (9,11). Regarding retrospective data review, studies have shown mixed results of blinded real-time CGM with retrospective review by the physician (reviewed in 10), but to our knowledge, no clinical studies have investigated whether patient retrospective self-review of data is associated with improved outcomes. However, it is recognized that reviewing data downloaded from the CGM device may assist in adjusting the insulin regimen and can help patients understand how food content and exercise influence their blood glucose levels (10). Although 53% of all participants downloaded their CGM data for retrospective review at least a few times a year, only 27% did this monthly and <15% of participants in each age-group did this at least weekly, while 38% never downloaded CGM data at all. Taken together, these findings suggest that most patients who use CGM may not be receiving the full benefit of CGM technology either by not using it often enough or by not regularly downloading and retrospectively reviewing data from their device to adjust their insulin regimens. This is further emphasized by our findings that real-time features of CGM were more useful to users than were retrospective features. Further research should focus on investigating the clinical importance of patient retrospective data review and ways to improve the usability of the retrospective features of CGM. In addition, educational interventions should teach patients how to use retrospective analysis to understand and adjust their insulin regimens, dietary habits, and daily activities to improve diabetes self-management.

Our study also shows that discontinuation of CGM use is common, with 41% of participants who reported use at enrollment reporting discontinuation within 1 year. The most common reasons for discontinuation included problems or discomfort with wearing the device or

Table 2—Frequency of one or more SH or one or more DKA event by age

Age (years)	N	% with event	One or more SH event in past 3 months				One or more DKA event in past 3 months					
			Unadjusted OR ^a (95% CI)	Unadjusted P ^a	Adjusted OR ^b (95% CI)	Adjusted P ^b	Unadjusted OR ^a (95% CI)	Unadjusted P ^a	Adjusted OR ^b (95% CI)	Adjusted P ^b		
<13	CGM nonuser	4,748	6	1.0	0.32	1.0	0.99	7	1.0	0.01	1.0	0.13
	CGM user	278	4	0.7 (0.4, 1.3)		1.0 (0.5, 1.9)		3	0.4 (0.2, 0.8)		0.6 (0.3, 1.2)	
13 to <18	CGM nonuser	4,676	8	1.0	0.51	1.0	0.15	10	1.0	0.69	1.0	0.49
	CGM user	179	9	1.2 (0.7, 2.0)		1.5 (0.9, 2.7)		9	0.9 (0.5, 1.5)		1.2 (0.7, 2.2)	
18 to <26	CGM nonuser	2,612	8	1.0	0.55	1.0	0.16	8	1.0	0.06	1.0	0.33
	CGM user	157	10	1.2 (0.7, 2.1)		1.7 (0.8, 3.4)		4	0.5 (0.2, 1.0)		0.6 (0.2, 1.8)	
≥26	CGM nonuser	3,667	11	1.0	0.83	1.0	0.04	3	1.0	0.09	1.0	0.23
	CGM user	999	11	1.0 (0.8, 1.2)		1.3 (1.0, 1.7)		2	0.7 (0.4, 1.1)		1.4 (0.8, 2.3)	

^aP value and OR from a logistic regression model without adjustment for other variables. ^bP value and OR from a logistic regression model adjusting for sex, race/ethnicity, education level, annual household income, insurance status, duration of diabetes, HbA_{1c}, and insulin delivery method.

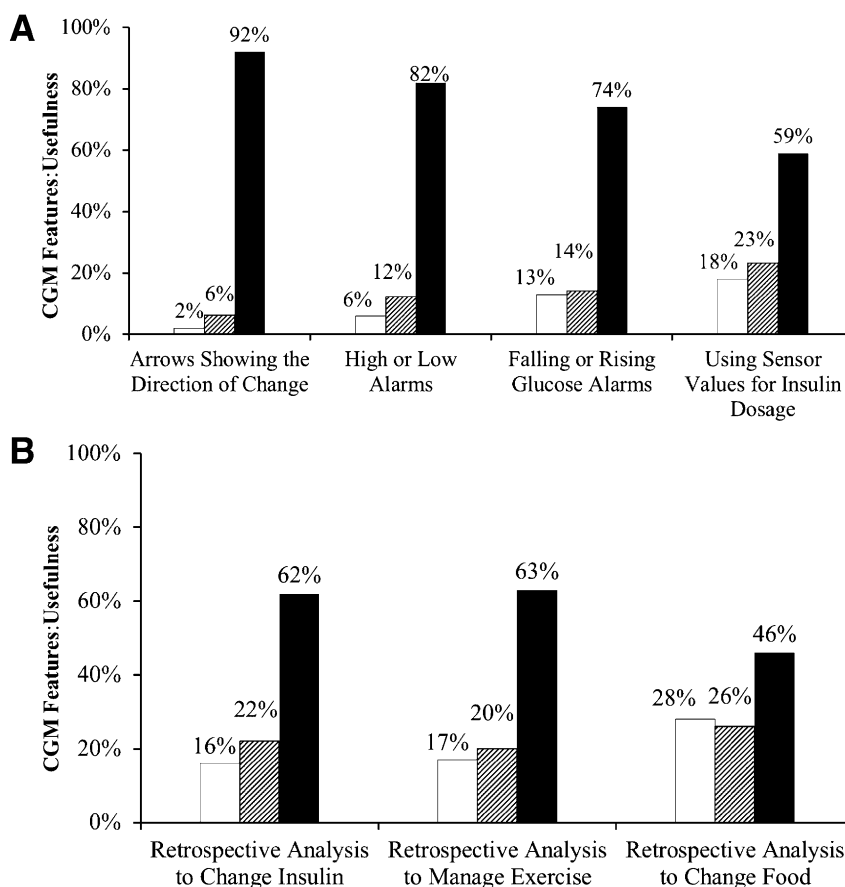


Figure 2—A: Usefulness of real-time CGM features. Solid white bar, not helpful. White and black striped bar, somewhat helpful. Solid black bar, helpful. B: Usefulness of retrospective CGM features. Solid white bar, not helpful. White and black striped bar, somewhat helpful. Solid black bar, helpful.

technical problems with the device, which are problems that might be solved by continued hardware development. However, 25% of those who discontinued use were concerned with the accuracy of the CGM data, an obstacle that may be overcome with further improvements in CGM technology. The participants in our study were using older generations of CGM devices, and some of the reported problems may be alleviated with newer-generation devices (e.g., Dexcom G4 Platinum and Medtronic Enlite). In all cases, better education about expectations for CGM use at the time of initiation may help patients tolerate these common problems.

Similar to prior studies, it is surprising to find that use of CGM is not associated with lower rates of SH in this study. However, this finding may be influenced by the cross-sectional nature of this study, which limits conclusions about causality between CGM use and outcomes. Our inability to detect a difference between frequency of SH in CGM users and nonusers is likely confounded by the fact that SH itself, along with nocturnal hypoglycemia

and hypoglycemia unawareness, is often an indication for use of CGM, as recommended by the American Diabetes Association (18). Regarding other limitations, we also acknowledge that our findings may not apply to those using more advanced CGM devices either currently or in the future. In addition, we relied on data for CGM use from participant self-report, which is subject to bias. It is possible that participants overreported use and/or frequency of use. However, if this occurred, it is likely to be independent of some of our outcomes of interest, such as HbA_{1c}. Finally, this registry is clinic based and not population based, which might affect the generalizability of the findings. However, a lack of representativeness is not likely to affect our findings of factors associated with CGM use or the association of CGM use with diabetes outcomes in patients similar to those in the study.

In summary, CGM use is currently relatively uncommon in clinical practice, despite evidence showing association with improved outcomes. While the majority of patients who use CGM find it

helpful, many do not use it regularly or use the retrospective features, and a large percentage discontinue use of the device. Future efforts should be made at improving CGM technology and features to address common obstacles and in educating and supporting users and potential users about the usefulness of all features and how to troubleshoot common pitfalls. Finally, special attention should be paid to patients with lower socioeconomic status and lack of private insurance, who may encounter more barriers to CGM access but may stand to benefit from this technology.

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