

## **Factors Predictive of Use and of Benefit from Continuous Glucose Monitoring in Type 1 Diabetes**

Running Title: Factors Predictive of CGM Use in Type 1 Diabetes

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\*The members of the writing committee and the full listing of the members of the study group are included at the end of the manuscript.

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*Objective:* To evaluate factors associated with successful use of continuous glucose monitoring (CGM) among participants with intensively-treated type 1 diabetes in the JDRF CGM Randomized Clinical Trial.

*Research Design and Methods:* The 232 participants randomized to the CGM group (165 with baseline HbA1c  $\geq 7.0\%$  and 67 with HbA1c  $< 7.0\%$ ) were asked to use CGM on a daily basis. The associations of baseline factors and early CGM use with CGM use  $\geq 6$  days/week in the sixth month and with change in HbA1c from baseline to 6 months were evaluated in regression models.

*Results:* The only baseline factors found to be associated with greater CGM use in month 6 were age  $\geq 25$  years ( $P < 0.001$ ) and more frequent self-reported pre-study blood glucose meter measurements per day ( $P < 0.001$ ). CGM use and the percentage of CGM glucose values between 71-180 mg/dL during the first month were predictive of CGM use in month 6 ( $P < 0.001$  and  $P = 0.002$ , respectively). More frequent CGM use was associated with a greater reduction in HbA1c from baseline to 6 months ( $P < 0.001$ ), a finding present in all age groups.

*Conclusions:* After 6 months, near-daily CGM use is more frequent in intensively-treated adults with type 1 diabetes than in children and adolescents, although in all age groups near-daily CGM use is associated with a similar reduction in HbA1c. Frequency of blood glucose meter monitoring and initial CGM use may help predict the likelihood of long-term CGM benefit in intensively treated patients with type 1 diabetes of all ages.

Despite recent advances in insulin delivery and home blood glucose monitoring, many individuals with type 1 diabetes (T1D) fail to achieve recommended HbA1c target levels (1; 2). Further, hypoglycemia is a problem for many patients with T1D (3) and can be a significant deterrent to achieving and maintaining tight glycemic control (4; 5). Thus, the introduction of real-time continuous glucose monitoring (CGM) systems was received with great interest as these devices may have the potential to increase the proportion of patients who are able to maintain target HbA1c values while simultaneously limiting their risk of severe hypoglycemia. The first real-time CGM device, the GlucoWatch Biographer (6), was difficult to use, in large part due to skin reaction and frequent skipping of glucose measurements that prevented patients from using it as a tool for day-to-day diabetes management. More recently, several new real-time CGM systems have been introduced that have improved accuracy, functionality, and user tolerance.

In a multi-center randomized controlled trial, our Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group evaluated the effectiveness of CGM compared with standard blood glucose monitoring in 451 adults and children with type 1 diabetes  $\geq 8$  years old, 322 of whom had baseline HbA1c  $\geq 7.0\%$  and 129 of whom had baseline HbA1c  $< 7.0\%$  (7). Among subjects with baseline HbA1c level  $\geq 7.0\%$ , we found that CGM substantially improved HbA1c levels during 6 months of follow up without increasing the frequency of hypoglycemia in adults  $\geq 25$  years of age. However, the efficacy of this device as a tool to help participants  $< 25$  years of age lower their HbA1c levels was much more limited (8). Among the subjects with baseline HbA1c  $< 7.0\%$ , we found that the CGM group had a reduction in

hypoglycemia on most measures compared with the control group and was able to maintain mean HbA1c levels at 6.4%; whereas, HbA1c increased in the control group (9).

The present analyses were conducted to determine which demographic, clinical, and psychosocial factors were associated with successful CGM use and HbA1c improvement in the 232 CGM group subjects.

## METHODS

The randomized trial protocol has been described in detail (7-9). This report includes the 6 month follow up of the 232 subjects in the CGM group, including both the  $\geq 7.0\%$  (n=165) and  $< 7.0\%$  (n=67) HbA1c cohorts. Major eligibility criteria for the trial included age  $\geq 8$  years, T1D for at least one year, use of either an insulin pump or at least 3 insulin injections per day, and HbA1c level  $< 10.0\%$ . Randomization was stratified in three age groups:  $\geq 25$ , 15 to 24, and 8 to 14 years old. Subjects in the CGM group were instructed to use the CGM device on a daily basis and were provided with written instructions on how to use the CGM data to make real-time insulin dose adjustments and on using computer software (for those with a home computer) to retrospectively review the glucose data to alter future insulin dosing (7; 10). Glucose data from the CGM devices were downloaded at each visit. A central laboratory-measured HbA1c level was obtained at baseline, 3 months, and 6 months at the University of Minnesota using the Tosoh A1c 2.2 Plus Glycohemoglobin Analyzer method (11).

**Statistical Methods:** The amount of CGM use was determined from the information downloaded from the CGM devices. CGM was considered to be used on a day when there was at least one sensor glucose value; on 85% of days with at least one glucose value, there were at least 12 hours of glucose values. Factors that were

evaluated for association with CGM use included baseline demographic and clinical characteristics as well as psychosocial factors that included total and subscale scores from the Hypoglycemia Fear Survey (12), Blood Glucose Monitoring System Rating Questionnaire (developed for the study), and Problem Area in Diabetes (PAID) Questionnaire (13; 14).

Logistic regression analyses were used to evaluate the association between baseline demographic and clinical factors (listed in table 1) and successful CGM use, which was defined as average use of 6.0 or more days per week during the sixth month of the trial. Baseline demographic and clinical factors were included in an initial model and then a backward elimination procedure was used to remove variables with a P-value >0.05. A forward selection process resulted in a similar model. Additional models evaluated the predictive value of CGM usage during the first month as well as CGM glucose indices of the percentage of glucose values between 71 and 180 mg/dL,  $\leq 70$  mg/dL, and  $>180$  mg/dL. The van der Waerden normal scores of the CGM usage were used in the models as a result of the skewed distribution of the data. A general linear model was used to evaluate demographic and clinical factors associated with a change in HbA1c from baseline to 6 months among subjects with a baseline HbA1c level  $\geq 7.0\%$ . The association between sensor use over the six months of the trial and change in HbA1c from baseline to 6 months also was evaluated with a general linear model.

Analyses were conducted using SAS version 9.1 (SAS Institute, Cary, NC). All P-values are 2-sided. For models 1 and 2 in table 1, missing values were imputed for covariates and an indicator for missing was added to the regression. One subject was missing sensor data for the first month due to a defective device that could not be downloaded and is excluded from table 2.

## RESULTS

The 232 subjects in the trial's CGM group ranged in age from 8 to 73 years; 86 (37%) being  $\geq 25$  years old, 72 (31%) 15 to 24 years old, and 74 (32%) 8 to 14 years old. Mean baseline HbA1c level was  $7.4\% \pm 0.9\%$ , with 165 (71%)  $\geq 7.0\%$  and 67 (29%)  $< 7.0\%$ . Insulin pump therapy was the treatment modality in 190 (82%) subjects, with the others being treated with multiple daily injections. The mean number of self-reported home blood glucose measurements per day was  $6.6 \pm 2.3$  measurements. Additional baseline characteristics have been reported previously (8; 9).

**Factors Associated with CGM Use:** CGM use averaged 6.0 or more days per week during month six of the study in 123 (53%) of the 232 subjects. As shown in table 1, CGM use averaging  $\geq 6.0$  days/week in study month 6 was associated with age (highest in adults,  $P < 0.001$  in a multivariate model) and frequency of self-reported prestudy daily blood glucose meter measurements ( $P < 0.001$ ). For the latter factor, the association was consistent across the three age groups (Appendix table 1, available at <http://care.diabetesjournals.org>, shows the factors in table 1 in three age groups). There was a trend toward baseline HbA1c  $< 7.0\%$  being associated with greater CGM use in an unadjusted model but not after adjusting for age and frequency of prestudy daily blood glucose meter measurements. Other variables associated with CGM use that were confounded by age included race/ethnicity, duration of diabetes, educational level, and household income. When we examined the psychosocial measures, we found that none of the total or subscale scores were significantly associated with CGM use.

As shown in table 2, CGM use during the first month of the trial was predictive of use in month 6 ( $P < 0.001$ , after adjusting for age and baseline frequency of daily blood

glucose measurements). Subjects who used the CGM device on at least 27 of the 28 days during the first month were more than 3 times more likely to be using the device  $\geq 6$  days/week in month 6 than were subjects who used the device fewer than 21 of the first 28 days. Results according to age group are shown in Appendix table 2.

In addition to the amount of use during the first month, a higher percentage of CGM glucose values between 71-180 mg/dL during month 1 was predictive of greater CGM use during month 6 ( $P=0.002$  adjusted for age, baseline frequency of daily blood glucose meter measurements, and sensor use during the first 4 weeks, table 2). In similar models, a lower percentage of glucose values  $>180$  in the first month was associated with greater use in month 6 ( $P=0.006$ ) but a lower percentage of glucose values  $\leq 70$  mg/dL was not ( $P=0.91$ ). The percentage of glucose values  $>180$  mg/dL was associated with baseline HbA1c ( $P<0.001$ ). The significant associations were still present after adjusting for the respective values obtained during blinded CGM use prior to randomization.

**Factors Associated with a Reduction in HbA1c:** In a multivariate model which included subjects with a baseline HbA1c level  $\geq 7.0\%$ , improvement in HbA1c from baseline to 6 months was associated with higher baseline HbA1c level ( $P<0.001$ ) and greater CGM use over the 6 months of the study ( $P<0.001$ , table 3). The spearman correlation between change in HbA1c from baseline to 6 months and average CGM use over the 6 months of the study was  $-0.46$  (Appendix Figure 1). None of the psychosocial measures were predictive of change in HbA1c. Age group was associated with the change in HbA1c in a multivariate analysis including baseline factors ( $P=0.004$ ) but after adjusting for the amount of CGM use, the association was no longer significant ( $P=0.70$ ). The main reason for this was that in all three age groups, greater CGM use was associated with

a similar reduction in HbA1c. As can be seen in figure 1, in each age group, subjects averaging at least 6 days per week of CGM use had substantially greater improvement in HbA1c compared with those who used CGM less often ( $P=0.02$  in  $\geq 25$  age group,  $P=0.002$  in 15 to 24 age group, and  $P<0.001$  in 8 to 14 age group).

## DISCUSSION

The goal of the JDRF CGM randomized clinical trial was to have the subjects use a CGM device every day and incorporate the real-time glucose information into their daily diabetes management in order to reduce the frequency of high and low glucose values. Before entering the study, the subjects were being intensively treated with either an insulin pump or multiple daily insulin injections and were performing frequent blood glucose monitoring (mean 6.6 measurements per day). We defined successful use of CGM as an average of 6 or more days per week to allow for the possibility of issues such as device inoperability, exhausted sensor supply, or other problems that might prevent daily use for a few days.

As reported previously, among subjects with baseline HbA1c  $\geq 7.0\%$ , nearly daily use after 6 months was strongly associated with age, with 83% of subjects  $\geq 25$  years sustaining CGM use  $\geq 6$  days/week compared with 30% of subjects 15 to 24 years and 50% of subjects 8 to 14 years (8). After adjusting for age, the only other baseline factor associated with successful use after 6 months was the frequency of self-reported pre-study daily blood glucose meter measurements. Subjects in all age groups who performed 6 or more meter measurements per day were more likely to use CGM on a near-daily basis than those who were monitoring fewer times a day. One possible explanation for this is that those subjects who were monitoring their blood

glucose frequently were utilizing these multiple glucose measurements to self-manage their diabetes and as a result could more readily incorporate information from CGM into their already intensive diabetes management. In addition, more frequent home blood glucose monitoring may be a marker for patients who are more engaged in their diabetes self-management and who are therefore more likely to be adherent to a daily CGM regimen as used in this trial.

Notably, none of our surveys geared to assess baseline psychosocial variables such as fear of hypoglycemia and perceived diabetes-associated burden were predictive of CGM use, suggesting that additional research is needed to identify salient patient beliefs and expectations regarding CGM use. We did not formally evaluate subject expectations for CGM at study entry and such an assessment might prove to be a predictor of sustained long-term use.

CGM use in the first month was very high, with more than 90% of subjects using CGM on at least 21 out of the first 28 days. Subjects who used the CGM device at least 27 of 28 days in the first month were more likely to sustain near-daily use through month 6 than those who used CGM less often. However, because of the overall high degree of use, the study had limited ability to evaluate whether CGM use in the first month could be used to predict the likelihood of long-term CGM use. This high degree of early use could reflect in part the fact that successful use of a blinded CGM device during a prerandomization run-in period was required for study entry.

A higher percentage of CGM glucose values in the range of 71 to 180 mg/dL during the first month (with fewer values above 180 mg/dL) were predictive of greater use in month 6 even after adjusting for the amount of CGM use. This could reflect the fact that those who observed the most benefit early in their usage of CGM were more likely to

recognize the advantages of sustained use of CGM. Conversely, individuals with more values above 180 mg/dL may have felt discouraged and therefore less inclined to use the device. Alternatively, frequent sensor values above 180 mg/dL may be a marker for persons less attentive or too busy to attend to diabetes management and the additional effort that CGM usage entails. Ongoing education and support may assist these patients in achieving equivalent CGM benefit.

We also analyzed benefit of CGM as measured by HbA1c in those whose baseline HbA1c was  $\geq 7.0\%$ . The amount of CGM use was strongly associated with change in HbA1c, similar to what was seen in other trials (15). In all three age groups, near-daily use of CGM was associated with similar improvements in HbA1c. In fact, the association between age and CGM use accounted for the association between age and change in HbA1c. Higher baseline HbA1c was associated with a greater HbA1c drop from baseline to 6 months but not greater CGM use. This likely is related to a floor effect in those who started with lower HbA1c levels. Less time with glucose values  $>180$  mg/dL during the first month was associated with greater CGM use in month 6.

Our results need to be interpreted within the context of the enrollment criteria for the study which required intensive diabetes management with an insulin pump or multiple daily injections, frequent home blood glucose monitoring, and successful completion of a run-in period of blinded CGM use. For such patients, our results have shown that long-term consistent CGM use is more frequent in adults than in children or adolescents, but a similar benefit on HbA1c is seen in patients of all ages who regularly use CGM. CGM use in the first month may help predict the likelihood of long-term benefit, and our results suggest that a trial of CGM use for several weeks may help predict long-term use and consequent benefit. Since

regular use of CGM is not observed in all patients with type 1 diabetes, particularly children and adolescents, further research is needed to better understand and overcome the barriers to daily CGM use.

#### **AUTHORSHIP**

The study was designed and conducted by the investigators, who collectively wrote the manuscript and vouch for the data. The investigators had complete autonomy to analyze and report the trial results. There were no agreements concerning confidentiality of the data between the Juvenile Diabetes Research Foundation, Inc. and the authors or their institutions. The

Jaeb Center for Health Research had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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**Table 1. Baseline Factors Predictive of Sensor Use ≥ 6 Days Per Week During Month Six of the Trial**

	N Overall (age groups <sup>‡</sup> )	% ≥ 6 days/wk in month 6 overall (age groups <sup>‡</sup> )	P-value <sup>§</sup>	Model 1*		Model 2 <sup>†</sup>	
				OR (95% CI)	P-value	OR (95% CI)	P-value
<b>Total</b>	232	53%					
<b>Age (years)</b>			<0.001/NA		<0.001		<0.001
8-<15	74	46%		1.00		1.00	
15-<25	72	29%		0.60 (0.28, 1.26)		0.60(0.29, 1.26)	
≥ 25	86	79%		5.35 (2.48, 11.53)		5.90 (2.78, 12.52)	
<b>Gender</b>			0.32/0.39				
Female	123 (37, 38, 48)	56% (57%, 29%, 77%)					
Male	109 (37, 34, 38)	50% (35%, 29%, 82%)					
<b>Race/Ethnicity</b>			0.02/0.37				
Non-White	19 (7, 12, 0)	26% (43%, 33%, 67%)					
White, Non-Hispanic	213 (67, 60, 86)	55% (46%, 32%, 79%)					
<b>Duration of Diabetes (years)<sup>  </sup></b>			<0.001/0.87				
< 5	48 (30, 15, 3)	42% (43%, 33%, 67%)					
5-<10	70 (35, 27, 8)	47% (49%, 30%, 100%)					
10-<20	61 (9, 30, 22)	44% (44%, 27%, 68%)					
≥20	53 (0, 0, 53)	81% (0%, 0%, 81%)					
<b>Baseline Insulin Modality</b>			0.006/0.06				
MDI	42 (10, 22, 10)	33% (30%, 23%, 60%)		1.00	0.45		
Pump	190	57%		1.20 (0.51, 2.84)			

	(64, 50, 76)	(48%, 32%, 82%)				
<b>Baseline HbA1c<sup>ll</sup></b>			0.002/0.10		0.28	
≥8.0%	63	38%		1.00		
	(27, 26, 10)	(44%, 23%, 60%)				
7.0%- <8.0%	102	53%		1.23 (0.57, 2.65)		
	(29, 31, 42)	(45%, 23%, 81%)				
<7.0%	67	67%		1.69 (0.72, 4.01)		
	(18, 15, 34)	(50%, 53%, 82%)				
<b>Severe Hypoglycemia in Last 6 Months</b>			0.39/0.64			
None	211	52%				
	(71, 65, 75)	(48%, 28%, 77%)				
≥1 episode	21	62%				
	(3, 7, 11)	(0%, 43%, 91%)				
<b>Self-reported Home Blood Glucose Meter Measurements Per Day<sup>ll, ¶</sup></b>			<0.001/0.002		0.005	0.002
3-5	68	28%		1.00		1.00
	(16, 31, 21)	(13%, 16%, 57%)				
6-8	104	61%		3.64 (1.69, 7.84)		4.00 (1.89, 8.47)
	(34, 26, 44)	(53%, 27%, 86%)				
≥ 9	31	68%		4.16 (1.45, 11.96)		4.82 (1.72, 13.55)
	(12, 4, 15)	(50%, 50%, 87%)				
<b>Education Level<sup>ll, #</sup></b>			0.04/0.40			
≤12	26	19%				
	(2, 22, 2)	(50%, 14%, 50%)				
Associate	23	57%				
	(8, 6, 9)	(38%, 50%, 78%)				
Bachelor	90	61%				
	(32, 21, 37)	(53%, 38%, 81%)				
Master	65	55%				
	(21, 14, 30)	(38%, 36%, 77%)				
Professional	28	50%				
	(11, 9, 8)	(45%, 22%, 88%)				

<b>Household Income</b> <sup>  ,**</sup>			0.04/0.26		
\$25,000 or less	16	25%			
	(2, 12, 2)	(50%, 17%, 50%)			
\$25,001 to \$50,000	27	48%			
	(3, 13, 11)	(67%, 46%, 45%)			
\$50,001 to \$100,000	74	65%			
	(24, 14, 36)	(58%, 43%, 78%)			
Over \$100,000	95	53%			
	(37, 24, 34)	(35%, 25%, 91%)			

\*The multivariate logistic regression model includes all variables having age-adjusted P-value < 0.20.

†Multivariate logistic regression model using backward selection keeping those variables with P-value < 0.05.

‡ Age groups are 8-14, 15-24 and ≥25 years.

§ P values are unadjusted/adjusted for age group

|| P-value obtained by treating as continuous variable. Education level and income category analyzed as ordinal variables.

¶ Collected on randomization form, as assessed by clinic personnel over the last 7 days. Question was added to CRF after study initialization and data were missing for 29 subjects in RT-CGM group.

# Education level is for parent/guardian for subjects <15 years old and for the subject for age ≥25 years. For subjects in the 15 to 24 age group, education level is that of the subject for 28, for the subject's spouse for 1, and the parent for 43.

\*\* 20 subjects did not provide household income data. In the 15 to 24 year age group, household income reflects the subject in 35 and parent in 37.

**Table 2: CGM Use and Sensor Glucose Values during First Month as Predictors of Month 6 CGM Use**

	N*	Sensor Use $\geq$ 6 days/week during month 6 N (%)	Odds Ratio (95% Confidence Interval)	P-value <sup>†</sup>
<b>Sensor Use during First 7 Days</b>				
0-5 <sup>‡</sup>	8	2 (25%)	1.00	0.14
6	19	7 (37%)	1.70 (0.23, 12.63)	
7	204	114 (56%)	3.13 (0.55, 17.71)	
<b>Sensor Use during First 14 Days</b>				
4-8	13	4 (31%)	1.00	0.03
9-11	14	4 (29%)	2.22 (0.34, 14.53)	
12-13	26	11 (42%)	2.83 (0.56, 14.26)	
14	178	104 (58%)	4.26 (1.08, 16.84)	
<b>Sensor Use during First 21 Days</b>				
7-13	14	3 (21%)	1.00	<0.001
14-17	13	6 (46%)	9.93 (1.48, 66.83)	
18-20	53	18 (34%)	3.35 (0.70, 16.05)	
21	151	96 (64%)	8.86 (2.03, 38.63)	
<b>Sensor Use during First 28 Days</b>				
7-20	20	4 (20%)	1.00	<0.001
21-23	19	7 (37%)	4.52 (0.90, 22.63)	
24-26	34	10 (29%)	2.43 (0.55, 10.72)	
27-28	158	102 (65%)	7.19 (2.04, 25.37)	
<b>Sensor Use during 15- 28 Days</b>				
0-10	28	7 (25%)	1.00	<0.001
11-13	57	19 (33%)	1.57 (0.50, 4.89)	
14	146	97 (66%)	4.80 (1.72, 13.37)	
<b>% of day 71-180 mg/dL during First Month<sup>§</sup></b>				
20-<55%	64	13 (20%)	1.00	0.002
55-<70%	94	56 (60%)	3.39 (1.50, 7.66)	
70-95%	73	54 (74%)	3.82 (1.52, 9.57)	
<b>% of day <math>\leq</math>70 mg/dL during First Month<sup>§</sup></b>				
5-31%	77	38 (49%)	1.00	0.91
2-<5%	77	43 (56%)	1.71 (0.79, 3.74)	
0-<2%	77	42 (55%)	1.43 (0.64, 3.19)	
<b>% of day &gt;180 mg/dL during First Month<sup>§</sup></b>				
40-79%	68	18 (26%)	1.00	0.006
25-<40%	86	50 (58%)	2.09 (0.95, 4.63)	
1-<25%	77	55 (71%)	2.42 (1.01, 5.85)	

\*N=231 One subject is missing sensor data for the first month due to a defective device that could not be downloaded.

<sup>†</sup>P-values are from logistic regression model treating CGM use as continuous variable, adjusting for age and baseline number of blood glucose meter measurements/day. Categories were created for presentation purposes.

<sup>‡</sup>One subject had zero use, 1 subject one day of use, 4 four days, and 2 five days.

<sup>§</sup>Logistic regression models adjusted for age and baseline number of blood glucose meter measurements/day and sensor use during first month.

**Table 3. Baseline Factors Predictive of Change in HbA1c from Baseline to 6 Months in Subjects with Baseline HbA1c  $\geq 7.0\%$** 

			Univariate Models	Model 1*	Model 2†
	N	Mean‡	P-value	P-value	P-value
<b>Total</b>	162	-0.35			
<b>Gender</b>			0.55		
Female	86	-0.32			
Male	76	-0.38			
<b>Age Group</b>			0.08	0.004	0.70
8-<15	56	-0.37			
15-<25	56	-0.18			
$\geq 25$	50	-0.50			
<b>Race/Ethnicity</b>			0.69		
White, Non-Hispanic	148	-0.35			
Non-White	14	-0.27			
<b>Baseline Insulin Modality</b>			0.51		
MDI	35	-0.27			
Pump	127	-0.37			
<b>Baseline HbA1c<sup>§</sup></b>			<0.001	<0.001	<0.001
7.0%- <7.5%	47	-0.11			
>7.5%-<8.0%	53	-0.36			
$\geq 8.0\%$	62	-0.52			
<b>Severe Hypoglycemia in last 6 months</b>			0.76		
None	149	-0.34			
$\geq 1$ episode	13	-0.41			
<b>Self-reported Home Blood Glucose per day<sup>§,  </sup></b>			0.27		
3-5	55	-0.16			
6-8	69	-0.36			
$\geq 9$	15	-0.34			
<b>Education Level of Primary Caregiver<sup>§,  </sup></b>			0.78		
$\leq 12$	20	-0.38			
Associate	19	-0.21			
Bachelor	58	-0.43			
Master	45	-0.32			
Professional	20	-0.26			
<b>Household Income<sup>§,#</sup></b>			0.89		
\$25,000 or less	13	-0.25			
\$25,001 to \$50,000	17	-0.47			
\$50,001 to \$100,000	49	-0.39			
Over \$100,000	67	-0.33			
<b>Number of Days per Week of Sensor Use during 6 months</b>			<0.001		<0.001
<4 days	18	+0.02			
4-<6 days	56	-0.10			
$\geq 6$ days	88	-0.58			

\*Includes all baseline variables with univariate P-value  $\leq 0.20$  (does not include sensor use).

† Includes all variables in Model 1 plus CGM use.

‡ Negative change denotes improvement and positive change is worsening.

§P-value obtained by treating as continuous variable. Education level and income category analyzed as ordinal variables.

|| Collected on randomization form, as assessed by clinic personnel over the last 7 days. Question was added to CRF after study initialization and data were missing for 29 subjects in RT-CGM group.

¶ Education level is for parent/guardian for subjects <15 years old and for the subject for age ≥25 years. For subjects in the 15 to 24 age group, education level is that of the subject for 28, for the subject's spouse for 1, and the parent for 43.

# 20 subjects did not provide household income data. In the 15 to 24 year age group, household income reflects the subject in 35 and parent in 37.

**Figure Legend**

**Figure 1.** Change in HbA1c from Baseline to 6 Months in Subjects with Baseline HbA1c >=7.0% According to Average Amount of CGM Use Over the 6-month Period.

The N's refer to the number of subjects in each CGM use category. The P-values are for the association between sensor use over the six months and change in HbA1c from baseline to 26 weeks, evaluated in a general linear model with sensor use as continuous variable adjusted for baseline HbA1c.

