Title: Majority of Time Outside of Target Glucose Range for Young Children with Type 1 Diabetes: a Continuous Glucose Monitor Study

Short Running Title: Time Outside Glucose Range in Youth with Type 1 Diabetes

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Novelty Statement:
What is already known:

- Traditional type 1 diabetes management in young children has focused on avoiding hypoglycemia even at the expense of hyperglycemia.
- There are limited glucose profile data available for very young children with type 1 diabetes.

What this study has found:

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- Very young children with type 1 diabetes spend the majority of the day outside of the target glucose range.

What are the clinical implications of this study:

- Given that both hypo- and hyperglycemia negatively impact pediatric neurocognitive development, strategies to increase time in target glucose range are needed.

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Abstract

Objectives: There are limited glucose profile data in very young children with type 1 diabetes. In this analysis we used masked, continuous glucose monitoring (CGM) data from youth 2 to < 8 years to assess associations between demographic and clinical characteristics and sensor glucose metrics.

Research Design/Methods: The analysis included 143 children across 14 sites in the United States enrolled in a separate clinical trial. Eligibility criteria: age 2-<8 years, type1 diabetes duration ≥3 months, no CGM use for past 30 days and hemoglobin A1c (HbA1c) 7.0-<10.0% (53-<86 mmol/mol). All wore masked CGM up to 14 days.

Results: On average, participants spent the majority (13 hours) of the day in a hyperglycemic range >10.0mmol/L and a median of about 1 hour/day in hypoglycemia (<3.9mmol/L). Participants with minority race/ethnicity and higher parent education levels had greater time in target range 3.9-10.0 mmol/L and less time in hyperglycemia. More time in hypoglycemia was associated with minority race/ethnicity and younger age at diagnosis. CGM metrics were similar in pump and injection users.

Conclusions: Given that both hypo- and hyperglycemia negatively impact neurocognitive development, strategies to increase time in target glucose range are needed.

Keywords: type 1 diabetes mellitus; youth; glucose; insulin infusion systems; parents

Background

Traditional type 1 diabetes management in young children has focused on avoiding hypoglycemia even at the expense of hyperglycemia. This approach has been based on data on adverse central nervous system (CNS) outcomes related to recurrent hypoglycemic seizure/coma [1-5] and parental fear of hypoglycemia in young children, especially at night[6]. There is increasing recognition that hyperglycemia also negatively impacts CNS structure and function in very young children [1, 7-11]**.**

Most pediatric studies examining glucose profiles using CGM have enrolled few, if any, very young children [12, 13] and have primarily used unmasked CGM (glucose values visible to patient/caregiver). Tansey and colleagues examined time in range using masked CGM in a cohort of 135 children with type 1 diabetes with a mean age of 7 years (range 4-10); however, that group used older generation CGM devices, enrolled a predominately non-Hispanic white cohort, and did not report on factors associated with time in range [14].

In this report, we used masked (glucose values not visible to patient) CGM data collected at baseline for a trial evaluating the benefits of CGM in a large cohort of children aged 2 to <8 years with type 1 diabetes in order to assess glucose profiles and identify demographic and clinical factors associated with time spent in glycemic ranges.

Research Design and Methods

The SENCE (Strategies to Encourage New CGM use in Early Childhood) study is a randomized clinical trial evaluating the efficacy and safety of CGM use in children aged 2 to <8 years with type 1 diabetes (ClinicalTrials.gov: NCT02912728). This report includes baseline data from participants enrolled at 14 pediatric endocrinology clinics in the T1D Exchange Clinic

Network in the US (Online Appendix). The protocol and consent forms were approved by a central Institutional Review Board (IRB) or local IRBs as required. Written informed consent was obtained from the parent/legal guardian prior to enrollment. Child assent also was obtained as applicable.

Children were eligible for the SENCE study if they met the following criteria: clinical diagnosis of type 1 diabetes for at least 3 months, age 2-<8 years, total daily insulin ≥0.3 units per kg of body weight per day, hemoglobin A1c (HbA1c) 53-<86 mmol/mol (7.0%-<10.0%) within 30 days prior to consent or at time of screening, use of either an insulin pump or multiple daily injections (MDI) of insulin, no use of real-time CGM in the 30 days prior to enrollment, and self-report or meter download of at least 3 fingerstick blood glucose checks per day.

Following enrollment, participants used masked (glucose values not visible) Dexcom G4 Platinum Professional CGM (Dexcom™ G4 Platinum CGM System® with the enhanced 505 software algorithm, Dexcom, Inc., San Diego, CA) for 14-21 days with daily calibrations of the sensor with a blood glucose meter per manufacturer's instructions. The Dexcom G4 CGM involves insertion of a subcutaneous sensor under the skin with an attached transmitter that sends a glucose reading every 5 minutes to a downloadable receiver; each sensor can be used for glucose readings for up to 7 days before a new insertion is needed. Only participants who wore the CGM sensor for at least 200 hours (equivalent to 8.3 days) and performed at least 3 blood glucose measurements with a home blood glucose meter (BGM) per day were included. Whole blood samples were collected for HbA1c following the successful completion of blinded CGM data collection. These samples were analyzed at the University of Minnesota Advanced Research and Diagnostics Laboratory using the Diabetes Control and Complications Trial standardized analyzer (Tosoh Automated Analyzer HLC-723G8).

Statistical Analysis

Masked CGM data were used to calculate glucose metrics including percent time in range defined as 3.9-10.0 mmol/L, percent time below 3.9 mmol/L , percent time below 3.0 mmol/L, percent time above 10.0 mmol/L , percent time above 13.9 mmol/L , and coefficient of variation (CV, defined as standard deviation divided by the mean, to assess glucose variability) for each participant.[15, 16] Percent time in range 3.9-10.0 mmol/L and percent time below 3.0 mmol/L were also calculated separately for daytime (6am-<10pm) and nighttime (10pm-<6am) hours. For HbA1c, the central lab value was used where available; for 2 participants who were missing a central lab value, the local lab/point of care value (obtained on a DCCT standardized device) at screening was used.

The following demographic and clinical characteristics were assessed for associations with the above CGM glycemic metrics and with HbA1c: child age, sex, self-reported race/ethnicity, body mass index (BMI) percentile for age, age at diagnosis, type 1 diabetes duration, total daily insulin in units per kg, insulin delivery method (via an insulin pump or MDI), history of previous CGM use, average number of BGM checks per day, annual household income, highest level of parent education, and health insurance type. Race/ethnicity was evaluated as non-minority (non-Hispanic white) vs. minority (Hispanic, non-Hispanic black, and other) because the sample was not large enough to consider each of the minority races separately.

First, a univariable regression model was fit to assess the unadjusted association of each characteristic with each outcome. Then a multivariable linear regression model with stepwise selection of factors was fit for each glycemic outcome to determine the subset of factors associated with the outcome when considered together. A threshold of 0.20 was used to enter factors into the model and only factors with p-values <0.10 were retained. The stepwise selection

procedure was run before adjusting for multiple comparisons. For all models, multiple imputations based on fully conditional specification were used for missing data so that all participants were included. No formal statistical analyses to assess interactions were performed due to the small sample sizes in each combined category.

Analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC). Metrics that had a reasonably normal distribution were summarized using means ± SD. Skewed metrics were summarized using medians (interquartile range [IQR]) and were modeled using ranks. P-values were corrected for multiple comparisons using the adaptive Benjamini-Hochberg procedure to control the false discovery rate (FDR) with FDR value < 0.05 considered statistically significant [17-19]. All reported p-values are 2-sided.

Results

The cohort included 143 participants with a median of 305 (IQR 278, 352) masked CGM hours per participant collected over 14 to 21 days between February 2017 and August 2018. The median age of participants was 5.9 years (IQR 4.2, 7.3), 50% of participants were female and 68% non-Hispanic white. Thirty-five percent of the children were pump users. Only 12% of participants had ever used real-time CGM in the past. Participant demographic and clinical characteristics are shown in Table 1.

CGM-measured Time in Range and Hyperglycemia

Participants spent a mean 40% of time (9.6 hours per day) in target glucose range of 3.9-10.0 mmol/L and 55% of time (13.1 hours per day) above 10.0 mmol/L including 30% of time (7.3 hours per day) above 13.9 mmol/L (Figure 1a). Children with parents with lower education levels spent less time in range (p=0.014) and more time in hyperglycemia above both 10.0

mmol/L (p=0.014) and 13.9 mmol/L (p=0.014). Similarly, non-Hispanic white youth spent less time in range (p=0.031), more time above 10.0 mmol/L (p=0.014) and tended to have more time above 13.9 mmol/L (p=0.050). No other assessed factors, including pump use (vs. MDI), were significantly associated with these CGM metrics. (Table 2)

Participants spent a mean 40% of time in target glucose range of 3.9-10.0 mmol/Lduring both the daytime and nighttime. Children with parents with lower education levels spent less time in range during both daytime (p=0.020) and nighttime (p=0.020) hours. A lower age was associated with lower daytime time in range (p=0.021), but age was not associated with nighttime time in range. Minority race/ethnicity was associated with a higher nighttime time in range (p=0.031), but was not significantly associated with daytime time in range. No other factors were associated with time in range when considering daytime and nighttime hours separately. (Supplemental Table S1)

CGM-measured Hypoglycemia

Participants spent a median of 4.1% of time (59 minutes per day) in hypoglycemia below 3.9 mmol/L and 1.4% of time (20 minutes per day) below 3.0 mmol/L (Figure 1b). Pump use was not associated with less time spent in hypoglycemia. Younger age at diagnosis was significantly associated with more time spent in hypoglycemia both below 3.9 mmol/L (p=0.002) and below 3.0 mmol/L (p=0.005). Non-Hispanic white youth spent less time below 3.9 mmol/L than did other youth (median 3.4% vs. 6.7%, respectively, p=0.011). Time spent below 3.0 mmol/L also tended to be lower in non-Hispanic white youth (p=0.040). (Table 3)

Participants spent a median 1.1% of time below 3.0 mmol/L during the daytime and 1.4% of time below 3.0 mmol/L during the nighttime. Younger age at diagnosis was significantly associated with more time spent below 3.0 mmol/L during both the daytime (p=0.002) and

nighttime (p=0.030) hours. No other factors were associated with time below 3.0 mmol/L when considering daytime and nighttime hours separately. (Supplemental Table S2)

CGM-measured Glucose Variability

Overall, participants had highly variable glucose levels with a mean CV (SD/mean) of 44% ± 7%. No factors were significantly associated with glycemic variability. (Supplemental Table S3)

HbA1c

Overall participants had a mean HbA1c of 66±8 mmol/mol (8.2±0.7%). Mean HbA1c was 71 mmol/mol (8.6%) among participants with parent education of high school or less vs. 65 mmol/mol (8.1%) among those with parent education of some college or more (p=0.018). No other factors were associated with HbA1c. (Supplemental Table S4)

Discussion

We found that children 2-<8 years of age with type 1 diabetes not using CGM as part of daily diabetes management spent only a minority of the day in the glycemic target range of 3.9-10.0 mmol/L . Half of these children had glucose values over 10.0 mmol/L for at least 12 hours per day, as well as a substantial amount of time – median of almost one hour per day – in hypoglycemia. CGM metrics were similar in pump and MDI users.

These data of children not currently using CGM are similar to those reported previously by Tansey et al in their cohort with type 1 diabetes with a mean age of 7 years (range 4-10) and a mean HbA1c of 63 mmol/mol (7.9%), 56% of whom were using insulin pumps[14]. Although 41% of their population used unmasked, real-time CGM, the children still spent >50% of time in hyperglycemia and 4.6% of time <3.9 mmol/L . That cohort also had substantial glucose

variability with a coefficient of variation for glucose values (43%) that was similar to that observed in our participants (44%).

Contrary to previous studies, we found differences in CGM profiles by race/ethnicity with non-Hispanic black or Hispanic children in this cohort spending more time in target range, less time in hyperglycemia, and more time in hypoglycemia than non-Hispanic white participants. Earlier research has generally reported higher HbA1c values, indicating higher mean glucose levels and less optimal glycemic control in racial/ethnic minority groups [20, 21]. On the other hand, children of parents with higher levels of education had greater time in range and lower HbA1c, which is in agreement with prior research [22, 23]. Higher parental education may be associated with more optimal recognition and fewer overcorrections of low glucose levels, as compared to families who may be challenged with basic understanding of management of hypoglycemia due to educational background. Alternatively, fear of hypoglycemia may be associated with overtreatment of low glucose levels.

We observed better glycemic control in minority youth despite minority families having lower parent education levels (23% minority parent with college degree vs. 51% in non-Hispanic white parents). Given our inclusion criteria, our cohort was composed of young children with type 1 diabetes who were not currently using CGM, very few of whom had any past experience with CGM (12%), raising the issue as to whether these families had easy access to CGM prior to enrollment in our study. Thus, the differences in association of ethnic and minority race and time in range compared to prior studies may be due to a larger population of relatively late CGM adopters even among non-Hispanic white children in our cohort compared with cohorts in other studies of CGM [1, 24]. Although this study had high representation of minority youth, the

minority families who chose to have their child with type 1 diabetes participate in the study may not be representative of other minority youth with type 1 diabetes in the US.

Intensive insulin therapy in children requires a complex orchestration of insulin dosing and diet while accounting for other variables such as physical activity and illness, which may help explain why the overwhelming majority of type 1 diabetes youth currently have suboptimal glycemic control and why only 17% of young children less than age 6 with type 1 diabetes achieve an HbA1c <58 mmol/mol (<7.5%) [25]. Further, overall underutilization and suboptimal utilization of advanced diabetes technologies (including insulin pumps, CGM, sensor-augmented pump therapy, and automated insulin delivery systems) in this age group remains [1, 25-28]. Given that both hypo- and hyperglycemia may negatively impact cognitive development in young children, further research and development of clinical strategies to successfully incorporate and sustain optimal use of new technologies that are readily employable by families and care providers are desperately needed.

Figure 1

Figure Legend: Time in ranges based upon glucose targets. Figure 1a boxplots show time in target range (3.9 to 10.0 mmol/L) and time in hyperglycemia (>10.0 and >13.9 mmol/L). Figure 1b shows time spent in hypoglycemia (<3.9 and <3.0 mmol/L). For both figures top and bottom of the boxes denote the 25th and 75th percentile, the line represents the median and the dot the mean. The whiskers represent the minimum and maximum after removing outliers.

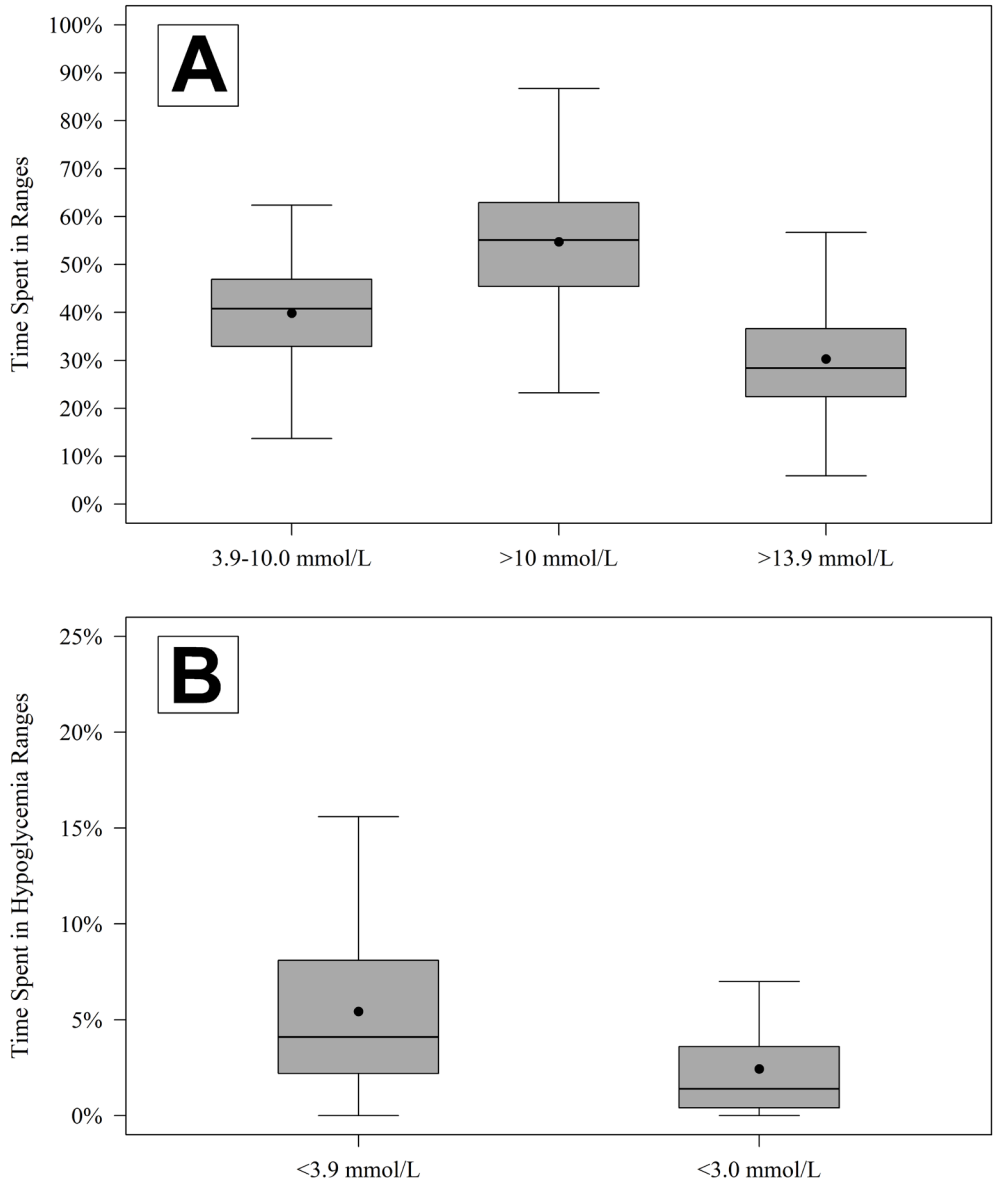

Table 1: Participant/Parent Characteristics

	Overall (N=143)[a]
Age (years)	
Median (Q1, Q3)	5.9 (4.2, 7.3)
Range	2.0 to 8.0
Sex: Female – *N (%)*	72 (50%)
Race/Ethnicity – *N (%)*	
Non-Hispanic white	95 (68%)
Non- Hispanic black	21 (15%)
Hispanic or Latino	16 (11%)
Asian	1 (<1%)
Other/More than One Race	7 (5%)
BMI Percentile – *Median (Q_1, Q_3)*	74 (53, 92)
BMI Category – *N (%)*	
Underweight (BMI percentile <5)	4 (3%)
Normal weight (5 ≤ BMI percentile <85)	90 (63%)
Overweight (85≤ BMI percentile <95)	25 (17%)
Obese (95≤ BMI percentile)	24 (17%)
Age at Diagnosis (years) – *Median (Q_1, Q_3)*	3.1 (1.8, 4.8)
Duration of Diabetes (years) – *Median (Q_1, Q_3)*	1.9 (0.7, 3.9)
HbA1c – *Mean ± SD*	
%	8.2 ± 0.7
mmol/mol	66 ± 8
Total Daily Insulin Units per Kg – *Median (Q_1, Q_3)*	0.7 (0.5, 0.8)
Insulin Pump Use – *N (%)*	50 (35%)
Prior CGM Use – *N (%)*	
In past, but not current	17 (12%)
Never	126 (88%)
≥1 Severe Hypoglycemic Event in the Past 12 Months[b] – *N (%)*	14 (10%)
≥1 DKA Event in the Past 12 Months[c] – *N (%)*	34 (24%)
Average BGM per day – *Median (Q_1, Q_3)*	6 (5, 7)
Annual Household Income – *N (%)*	
< $35,000	25 (19%)
$35,000 - <$75,000	54 (41%)
≥ $75,000	52 (40%)
Highest Level of Parent Education – *N (%)*	
High school or less	32 (24%)
Some college/Associates degree	47 (35%)
Bachelor's or higher	57 (42%)
Health Insurance – *N (%)*	
Private	87 (62%)
Medicaid/other	52 (37%)
None	2 (1%)

[a] Missing: Race/Ethnicity 3 (2%), Total Daily Insulin 1 (<1%), Income 12 (8%), Parent Education 7 (5%), Health Insurance 2 (1%). All other variables have no missing data.

[b]SH was defined as an event that required assistance from another person to administer carbohydrate, glucagon, or other resuscitative actions due to altered consciousness.
[c]DKA was defined as an episode when the participant had ketosis that necessitated treatment in a health care facility. DKA events in the past 12 months can include DKA at onset of type 1 diabetes for participants with disease duration <1 year.

Table 2: CGM-measured Time in Range and Hyperglycemia

	N	% Time in Range 3.9-10.0 mmol/L			% Time above 10.0 mmol/L			% Time above 13.9 mmol/L		
		Mean ± SD	Univarible P-Value[a]	Multivariable P-Value[a,b]	Mean ± SD	Univariable P-Value[a]	Multivariable P-Value[a,b]	Mean ± SD	Univariable P-Value[a]	Multivariable P-Value[a,b]
Overall	143	40% ± 11%	-	-	55% ± 13%	-	-	30% ± 12%	-	-
Age[c]			0.124	0.059		0.470	-		0.079	0.068
<5 years	49	37% ± 12%			57% ± 15%			34% ± 15%		
≥5 years	94	41% ± 10%			54% ± 12%			28% ± 10%		
Sex			0.470	-		0.497	-		0.394	-
Women	72	39% ± 11%			56% ± 13%			32% ± 13%		
Men	71	41% ± 11%			53% ± 13%			29% ± 12%		
Race/Ethnicity			0.170	0.031		0.050	0.014		0.190	0.050
Non-minority	95	39% ± 10%			57% ± 12%			32% ± 12%		
Minority	45	42% ± 12%			50% ± 14%			27% ± 14%		
Annual Household Income			0.550	-		0.741	-		0.616	-
< $35,000	25	40% ± 9%			52% ± 12%			28% ± 10%		
$35,000 - <$75,000	54	37% ± 12%			58% ± 14%			33% ± 15%		
≥ $75,000	52	41% ± 10%			53% ± 12%			28% ± 11%		
Highest Level of Parent Education			0.024	0.014		0.043	0.014		0.030	0.014
High school or less	32	35% ± 11%			60% ± 13%			37% ± 14%		
Some college/Associates degree	47	40% ± 10%			55% ± 12%			30% ± 11%		
Bachelor's or higher	57	42% ± 11%			52% ± 14%			28% ± 12%		
Health Insurance			0.574	-		0.751	-		0.735	-
Not private/no insurance	54	39% ± 11%			55% ± 13%			31% ± 13%		
Private	87	41% ± 11%			54% ± 13%			30% ± 13%		
BMI Category[c]			0.800	-		0.809	-		0.729	-
Normal/Underweight	94	40% ± 10%			54% ± 13%			31% ± 12%		
Overweight	25	39% ± 12%			56% ± 15%			32% ± 15%		
Obese	24	41% ± 11%			55% ± 13%			28% ± 10%		
Type 1 Diabetes Duration[c]			0.738	-		0.607	-		0.557	-
<2 years	76	40% ± 12%			55% ± 14%			31% ± 14%		
≥2 years	67	40% ± 9%			54% ± 12%			30% ± 11%		

Age at Diagnosis[c]			0.190	-		0.741	-		0.455	-
<3 years	68	38% ± 10%			55% ± 13%			31% ± 13%		
≥3 years	75	41% ± 11%			54% ± 13%			29% ± 12%		
Insulin Delivery Method			0.839	-		0.989	-		0.659	-
Injections	93	40% ± 12%			55% ± 14%			31% ± 14%		
Pump	50	40% ± 9%			55% ± 11%			29% ± 10%		
Total Daily Insulin Units per Kg[c]			0.638	-		0.923	-		0.741	-
0.3-<0.7	77	40% ± 12%			55% ± 15%			30% ± 14%		
≥0.7	65	40% ± 8%			55% ± 11%			30% ± 10%		
Prior CGM use			0.587	0.234		0.716	-		0.735	-
Prior CGM use	17	38% ± 11%			56% ± 14%			31% ± 12%		
No prior CGM use	126	40% ± 11%			55% ± 13%			30% ± 13%		
Average BGM per day[c]			0.859	-		0.850	-		0.557	-
<6	62	39% ± 13%			55% ± 15%			31% ± 15%		
≥6	81	40% ± 9%			54% ± 12%			29% ± 11%		

[a] P-values have been adjusted for multiple comparisons using the adaptive Benjamini-Hochberg procedure to control the false discovery rate.

[b]P-values are only given for variables that were selected in the final model.

[c]Age, BMI percentile, type 1 diabetes duration, age at diagnosis, total daily insulin per kg, and BGM checks/day were entered in the models as continuous variables. Parent education and annual household income were considered ordinal with 7 and 5 levels, respectively. Categories for these variables are for display only.

Table 3: CGM-measured Hypoglycemia

	N	% Time 3.9 mmol/L			% Time 3.0 mmol/L		
		Median (Q1, Q3)	Univariable P-Value[a]	Multivariable P-Value[a,b]	Median (Q1, Q3)	Univariable P-Value[a]	Multivariable P-Value[a,b]
Overall	143	4.1% (2.2%, 8.1%)	-	-	1.4% (0.4%, 3.6%)	-	-
Age[c]			0.260	-		0.140	-
<5 years	49	4.5% (2.3%, 8.1%)			1.8% (0.5%, 3.6%)		
≥5 years	94	3.6% (2.1%, 7.1%)			1.2% (0.4%, 3.2%)		
Sex			0.578	-		0.789	-
Women	72	4.3% (1.9%, 7.5%)			1.5% (0.4%, 3.5%)		
Men	71	3.7% (2.3%, 8.1%)			1.4% (0.5%, 3.6%)		
Race/Ethnicity			0.011	0.011		0.019	0.040
Non-minority	95	3.4% (1.6%, 6.5%)			1.0% (0.4%, 2.4%)		
Minority	45	6.7% (2.9%, 10.2%)			3.1% (0.9%, 4.9%)		
Annual Household Income			0.223	-		0.080	-
< $35,000	25	4.5% (2.9%, 9.9%)			2.4% (1.0%, 4.9%)		
$35,000 - <$75,000	54	3.7% (1.3%, 7.4%)			1.3% (0.4%, 2.8%)		
≥ $75,000	52	3.4% (2.2%, 7.9%)			1.0% (0.4%, 3.4%)		
Highest Level of Parent Education			0.516	-		0.956	-
High school or less	32	3.9% (1.8%, 7.6%)			1.4% (0.4%, 3.9%)		
Some college/Associates degree	47	4.2% (2.4%, 7.4%)			1.4% (0.5%, 3.6%)		
Bachelor degree or higher	57	3.7% (2.2%, 8.6%)			1.2% (0.4%, 2.9%)		
Health Insurance			0.170	-		0.040	0.127
Not private/no insurance	54	5.6% (2.7%, 8.6%)			2.0% (0.9%, 3.9%)		
Private	87	3.4% (2.0%, 7.1%)			1.0% (0.4%, 2.8%)		
BMI Category[c]			0.815	-		0.806	-
Normal/Underweight	94	4.2% (2.4%, 8.6%)			1.4% (0.5%, 3.7%)		
Overweight	25	3.7% (1.6%, 7.1%)			1.6% (0.5%, 3.5%)		
Obese	24	3.7% (2.1%, 5.2%)			1.0% (0.4%, 1.8%)		
Type 1 Diabetes Duration[c]			0.074	-		0.170	-
<2 years	76	3.4% (1.4%, 7.5%)			1.1% (0.3%, 3.6%)		
≥2 years	67	4.2% (2.7%, 8.6%)			1.5% (0.7%, 3.6%)		
Age at Diagnosis[c]			0.002	0.002		0.002	0.005
<3 years	68	5.1% (3.3%, 8.7%)			1.9% (0.9%, 3.7%)		

≥3 years	75	2.9% (1.3%, 7.1%)			0.9% (0.3%, 3.1%)		
Insulin Delivery Method			0.570	-		0.738	-
Injections	93	4.2% (2.2%, 8.1%)			1.4% (0.5%, 3.6%)		
Pump	50	3.9% (2.3%, 7.4%)			1.4% (0.4%, 3.2%)		
Total Daily Insulin Units per Kg[c]			0.040	0.072		0.040	0.080
0.3-<0.7	77	3.8% (1.4%, 8.1%)			1.1% (0.5%, 3.6%)		
≥0.7	65	4.2% (2.6%, 7.4%)			1.7% (0.4%, 3.6%)		
Prior CGM use			0.605	-		0.474	-
Prior CGM use	17	4.4% (2.5%, 7.4%)			2.4% (0.7%, 3.5%)		
No prior CGM use	126	3.9% (2.1%, 8.1%)			1.4% (0.4%, 3.6%)		
Average BGM per day[c]			0.666	-		0.839	-
<6	62	3.9% (1.7%, 7.1%)			1.2% (0.4%, 3.1%)		
≥6	81	4.1% (2.5%, 8.1%)			1.4% (0.5%, 3.6%)		

[a] P-values have been adjusted for multiple comparisons using the adaptive Benjamini-Hochberg procedure to control the false discovery rate.

[b]P-values are only given for variables that were selected in the final model.

[c]Age, BMI percentile, type 1 diabetes duration, age at diagnosis, total daily insulin per kg, and BGM checks/day were entered in the models as continuous variables. Parent education and annual household income were considered ordinal with 7 and 5 levels, respectively. Categories for these variables are for display only.

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Appendix 1.

A listing of the SENCE sites with participating principal investigators (PI), co-investigators (I), primary coordinator (PC) and coordinators (C) is included below:

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Supplemental Table S1: CGM-measured Time in Range by Daytime (6am-<10pm) and Nighttime (10pm-<6am)

	N	Daytime % Time in Range 3.9-10.0 mmol/L			Nighttime % Time in Range 3.9-10.0 mmol/L		
		Mean ± SD	Univariable P-Value[a]	Multivariable P-Value[a,b]	Mean ± SD	Univariable P-Value[a]	Multivariable P-Value[a,b]
Overall	143	40% (12%)	-	-	40% (14%)	-	-
Age[c]			0.050	0.021		0.616	-
<5 years	49	36% (13%)			39% (16%)		
≥5 years	94	42% (10%)			40% (14%)		
Sex			0.264	0.143		0.825	-
Female	72	38% (12%)			39% (14%)		
Male	71	42% (11%)			40% (15%)		
Race/Ethnicity			0.443	0.128		0.147	0.031
Non-minority	95	39% (11%)			38% (14%)		
Minority	45	42% (12%)			43% (15%)		
Annual Household Income			0.557	-		0.594	-
< $35,000	25	40% (10%)			41% (14%)		
$35,000 - <$75,000	54	39% (12%)			35% (15%)		
≥ $75,000	52	41% (12%)			42% (13%)		
Highest Level of Parent Education			0.050	0.020		0.079	0.020
High school or less	32	34% (11%)			35% (15%)		
Some college/Associates degree	47	40% (10%)			39% (14%)		
Bachelor's or higher	57	42% (13%)			43% (14%)		
Health Insurance			0.557	-		0.741	-
Not private/no insurance	54	39% (11%)			39% (15%)		
Private	87	41% (12%)			40% (14%)		
BMI Category[c]			0.813	-		0.851	-
Normal/Underweight	94	40% (11%)			40% (15%)		
Overweight	25	40% (12%)			36% (14%)		
Obese	24	42% (12%)			40% (14%)		
Type 1 Diabetes Duration[c]			0.459	-		0.550	-
<2 years	76	39% (13%)			42% (16%)		
≥2 years	67	41% (10%)			37% (12%)		
Age at Diagnosis[c]			0.451	-		0.162	0.170
<3 years	68	39% (11%)			38% (14%)		
≥3 years	75	41% (12%)			41% (15%)		
Insulin Delivery Method			0.557	-		0.143	0.169

Injections	93	39% (12%)			41% (16%)		
Pump	50	41% (10%)			36% (11%)		
Total Daily Insulin Units per Kg[c]			0.795	-		0.498	-
0.3-<0.7	77	40% (13%)			40% (16%)		
≥0.7	65	40% (9%)			39% (12%)		
Prior CGM use			0.616	0.169		0.616	-
Prior CGM use	17	38% (10%)			37% (14%)		
No prior CGM use	126	40% (12%)			40% (15%)		
Average BGM per day[c]			0.616	-		0.616	-
<6	62	39% (13%)			40% (16%)		
≥6	81	41% (10%)			39% (14%)		

[a] P-values have been adjusted for multiple comparisons using the adaptive Benjamini-Hochberg procedure to control the false discovery rate.

[b]P-values are only given for variables that were selected in the final model.

[c]Age, BMI percentile, type 1 diabetes duration, age at diagnosis, total daily insulin per kg, and BGM checks/day were entered in the models as continuous variables. Parent education and annual household income were considered ordinal with 7 and 5 levels, respectively. Categories for these variables are for display only.

Supplemental Table S2: CGM-measured Time <54 mg/dL by Daytime (6am-<10pm) and Nighttime (10pm-<6am)

	N	Daytime % Time <3.0 mmol/L			Nighttime % Time <3.0 mmol/L		
		Median (Q1, Q3)	Univariable P-Value[a]	Multivariable P-Value[a,b]	Median (Q1, Q3)	Univariable P-Value[a]	Multivariable P-Value[a,b]
Overall	143	1.1% (0.4%, 2.7%)	-	-	1.4% (0.2%, 4.4%)	-	-
Age[c]			0.132	-		0.354	-
<5 years	49	1.5% (0.4%, 4.0%)			1.7% (0.6%, 4.7%)		
≥5 years	94	1.0% (0.4%, 2.3%)			0.9% (0.2%, 4.3%)		
Sex			0.613	-		0.919	-
Female	72	1.1% (0.3%, 2.6%)			1.4% (0.2%, 4.4%)		
Male	71	1.2% (0.4%, 3.2%)			1.5% (0.2%, 5.0%)		
Race/Ethnicity			0.108	0.116		0.056	0.056
Non-minority	95	0.9% (0.4%, 2.3%)			0.9% (0.1%, 3.4%)		
Minority	45	1.9% (0.5%, 3.9%)			2.6% (0.6%, 6.1%)		
Annual Household Income			0.207	-		0.456	-
< $35,000	25	2.6% (1.6%, 3.9%)			1.6% (0.0%, 10.1%)		
$35,000 - <$75,000	54	0.8% (0.3%, 2.1%)			1.4% (0.2%, 2.9%)		
≥ $75,000	52	0.9% (0.4%, 2.4%)			1.3% (0.3%, 4.6%)		
Highest Level of Parent Education			0.620	-		0.859	-
High school or less	32	1.3% (0.2%, 2.4%)			1.6% (0.1%, 5.7%)		
Some college/Associates degree	47	1.6% (0.4%, 3.3%)			1.4% (0.2%, 3.6%)		
Bachelor's or higher	57	0.9% (0.4%, 2.3%)			1.4% (0.2%, 4.4%)		
Health Insurance			0.132	-		0.305	-
Not private/no insurance	54	1.8% (0.6%, 3.7%)			2.2% (0.4%, 5.4%)		
Private	87	0.9% (0.4%, 2.1%)			0.8% (0.2%, 4.4%)		
BMI Category[c]			0.931	-		0.926	-
Normal/Underweight	94	1.1% (0.4%, 3.1%)			1.5% (0.3%, 5.4%)		
Overweight	25	1.4% (0.4%, 3.5%)			1.6% (0.2%, 4.4%)		
Obese	24	0.8% (0.2%, 2.4%)			0.7% (0.0%, 2.1%)		
Type 1 Diabetes Duration[c]			0.307	-		0.305	-
<2 years	76	1.0% (0.2%, 2.7%)			1.0% (0.1%, 3.6%)		
≥2 years	67	1.3% (0.6%, 2.7%)			1.5% (0.3%, 5.0%)		
Age at Diagnosis[c]			0.002	0.002		0.018	0.030
<3 years	68	1.5% (0.7%, 3.4%)			2.2% (0.8%, 5.6%)		

≥3 years	75	0.7% (0.2%, 2.3%)			0.6% (0.0%, 2.9%)		
Insulin Delivery Method			0.620	-		0.929	-
Injections	93	1.1% (0.4%, 3.1%)			1.4% (0.2%, 4.2%)		
Pump	50	1.3% (0.5%, 2.3%)			1.5% (0.2%, 4.7%)		
Total Daily Insulin Units per Kg[c]			0.173	-		0.126	0.225
0.3-<0.7	77	1.1% (0.4%, 2.6%)			1.4% (0.2%, 3.6%)		
≥0.7	65	1.2% (0.4%, 2.8%)			1.4% (0.2%, 5.4%)		
Prior CGM use			0.573	-		0.377	-
Prior CGM use	17	1.3% (0.6%, 2.6%)			2.1% (0.8%, 5.5%)		
No prior CGM use	126	1.1% (0.4%, 2.7%)			1.4% (0.2%, 4.1%)		
Average BGM per day[c]			0.959	-		0.664	-
<6	62	1.0% (0.2%, 2.6%)			1.3% (0.1%, 5.0%)		
≥6	81	1.3% (0.4%, 2.8%)			1.4% (0.4%, 4.1%)		

[a] P-values have been adjusted for multiple comparisons using the adaptive Benjamini-Hochberg procedure to control the false discovery rate.

[b] P-values are only given for variables that were selected in the final model.

[c]Age, BMI percentile, type 1 diabetes duration, age at diagnosis, total daily insulin per kg, and BGM checks/day were entered in the models as continuous variables. Parent education and annual household income were considered ordinal with 7 and 5 levels, respectively. Categories for these variables are for display only.

Supplemental Table S3: CGM-measured Glucose Variability

	N	Coefficient of Variation (%)		
		Mean ± SD	Univariable P-Value[a]	Multivariable P-Value[a,b]
Overall	143	44% ± 7%	-	-
Age[c]			0.557	-
<5 years	49	44% ± 8%		
≥5 years	94	44% ± 7%		
Sex			0.720	-
Female	72	44% ± 7%		
Male	71	44% ± 7%		
Race/Ethnicity			0.070	0.070
Non-minority	95	43% ± 7%		
Minority	45	46% ± 8%		
Annual Household Income			0.170	-
< $35,000	25	47% ± 8%		
$35,000 - <$75,000	54	43% ± 7%		
≥ $75,000	52	44% ± 7%		
Highest Level of Parent Education			0.716	-
High school or less	32	43% ± 8%		
Some college/Associates degree	47	44% ± 7%		
Bachelor's or higher	57	44% ± 7%		
Health Insurance			0.650	-
Not private/no insurance	54	45% ± 7%		
Private	87	44% ± 7%		
BMI Category[c]			0.587	-
Normal/Underweight	94	45% ± 7%		
Overweight	25	44% ± 7%		
Obese	24	42% ± 5%		
Type 1 Diabetes Duration[c]			0.459	-
<2 years	76	43% ± 8%		
≥2 years	67	45% ± 6%		
Age at Diagnosis[c]			0.070	0.144
<3 years	68	45% ± 7%		

≥3 years	75	43% ± 7%		
Insulin Delivery Method			0.692	-
Injections	93	44% ± 7%		
Pump	50	44% ± 7%		
Total Daily Insulin Units per Kg[c]			0.099	0.143
0.3-<0.7	77	44% ± 7%		
≥0.7	65	44% ± 7%		
Prior CGM use			0.741	-
Prior CGM use	17	44% ± 8%		
No prior CGM use	126	44% ± 7%		
Average BGM per day[c]			0.557	-
<6	62	44% ± 8%		
≥6	81	44% ± 6%		

[a] P-values have been adjusted for multiple comparisons using the adaptive Benjamini-Hochberg procedure to control the false discovery rate.

[b] P-values are only given for variables that were selected in the final model.

[c]Age, BMI percentile, type 1 diabetes duration, age at diagnosis, total daily insulin per kg, and BGM checks/day were entered in the models as continuous variables. Parent education and annual household income were considered ordinal with 7 and 5 levels, respectively. Categories for these variables are for display only.

Supplemental Table S4: HbA1c

	N	HbA1c (%)		
		Mean ± SD	Univariable P-Value[a]	Multivariable P-Value[a,b]
Overall - % (mmol/mol)	143	8.2 ± 0.7 (66±7.7)	-	-
Age[c] - % (mmol/mol)			0.494	-
<5 years	49	8.3 ± 0.9 (67±9.8)		
≥5 years	94	8.1 ± 0.7 (65±7.7)		
Sex - % (mmol/mol)			0.679	-
Female	72	8.2 ± 0.7 (66±7.7)		
Male	71	8.2 ± 0.8 (66±8.7)		
Race/Ethnicity - % (mmol/mol)			0.434	0.138
Non-minority	95	8.3 ± 0.7 (67±7.7)		
Minority	45	8.1 ± 0.8 (65±8.7)		
Annual Household Income - % (mmol/mol)			0.338	-
< $35,000	25	8.4 ± 0.9 (68±9.8)		
$35,000 - <$75,000	54	8.3 ± 0.7 (67±7.7)		
≥ $75,000	52	8.1 ± 0.7 (65±7.7)		
Highest Level of Parent Education- % (mmol/mol)			0.037	0.018
High school or less	32	8.6 ± 0.8 (70±8.7)		
Some college/Associates degree	47	8.1 ± 0.7 (65±7.7)		

Bachelor's or higher	57	8.1 ± 0.7 (65±7.7)		
Health Insurance- % (mmol/mol)			0.476	-
Not private/no insurance	54	8.3 ± 0.8 (67±8.7)		
Private	87	8.1 ± 0.7 (65±7.7)		
BMI Category[c] - % (mmol/mol)			0.677	-
Normal/Underweight	94	8.2 ± 0.8 (66±8.7)		
Overweight	25	8.2 ± 0.8 (66±8.7)		
Obese	24	8.1 ± 0.6 (65±6.6)		
Type 1 Diabetes Duration[c]- % (mmol/mol)			0.921	-
<2 years	76	8.2 ± 0.8 (66±8.7)		
≥2 years	67	8.2 ± 0.7 (66±7.7)		
Age at Diagnosis[c] - % (mmol/mol)			0.476	-
<3 years	68	8.3 ± 0.8 (67±8.7)		
≥3 years	75	8.1 ± 0.7 (65±7.7)		
Insulin Delivery Method - % (mmol/mol)			0.765	-
Injections	93	8.2 ± 0.8 (66±8.7)		
Pump	50	8.2 ± 0.7 (66±7.7)		
Total Daily Insulin Units per Kg[c] - % (mmol/mol)			0.679	-
0.3-<0.7	77	8.2 ± 0.8 (66±8.7)		

≥0.7	65	8.2 ± 0.6 (66±6.6)		
Prior CGM use - % (mmol/mol)			0.654	-
Prior CGM use	17	8.1 ± 0.7 (65±7.7)		
No prior CGM use	126	8.2 ± 0.8 (66±8.7)		
Average BGM per day[c] - % (mmol/mol)			0.476	-
<6	62	8.2 ± 0.7 (66±7.7)		
≥6	81	8.2 ± 0.8 (66±8.7)		

[a] P-values have been adjusted for multiple comparisons using the adaptive Benjamini-Hochberg procedure to control the false discovery rate.

[b] P-values are only given for variables that were selected in the final model.

[c]Age, BMI percentile, type 1 diabetes duration, age at diagnosis, total daily insulin per kg, and BGM checks/day were entered in the models as continuous variables. Parent education and annual household income were considered ordinal with 7 and 5 levels, respectively. Categories for these variables are for display only.