



Psychological Characteristics and Goals of Caregivers Choosing Continuous Glucose Monitoring for Children With Type 1 Diabetes

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BACKGROUND | Continuous glucose monitoring (CGM) can improve glycemic outcomes in pediatric type 1 diabetes management. However, its impact on the psychosocial functioning of caregivers is less well described. The objectives of this pilot study were to explore caregiver reasons for adding CGM to their child’s type 1 diabetes management, parental psychosocial function before initiating CGM, and the relationship between the two.

METHODS | Thirty-two families with a child with type 1 diabetes from Rainbow Babies and Children’s Hospital diabetes clinics who were initiating CGM were recruited over 3 months. Before CGM initiation, the caregivers completed the Fear of Hypoglycemia Scale, State-Trait Anxiety Inventory, Problem Areas in Diabetes Scale, and a questionnaire assessing their primary reason for starting CGM. Participant characteristics and questionnaire results were summarized with descriptive statistics. Participants were grouped by reason for starting CGM, and results were compared among groups using ANOVA and reporting the global *F* test.

RESULTS | Fifty percent of respondents indicated that they were starting CGM to optimize glycemic control. The majority of parents (71.8%) expressed worry about helplessness during a hypoglycemic episode. There were no statistically significant differences in patient characteristics or questionnaire results between groups. Forty-three percent of participating families started using CGM during the study’s 8-month follow-up period. The main reason (64%) for not starting CGM was not having the chance to start the process of obtaining a CGM system. There were no statistically significant differences between children who did and did not start CGM.

CONCLUSION | Caregivers have different reasons for starting CGM for their child with type 1 diabetes. Further studies are needed to understand whether these reasons are related to differences in psychosocial functioning. Despite interest in starting CGM, there remain barriers to implementation.

Continuous glucose monitoring (CGM) systems, first approved by the U.S. Food and Drug Administration for use in patients with diabetes in 1999, are small wearable devices that track glucose levels continuously in real time, alerting the patient and/or caregiver about changes in the interstitial glucose. CGM helps patients and/or caregivers make more informed treatment decisions with the aim of increasing time in range (TIR), defined as the percentage of time spent with glucose levels between 70 and 180 mg/dL. Maximizing TIR results in less time spent in the hyperglycemic and hypoglycemic glucose ranges. There is accumulating evidence that the addition of CGM to a person’s diabetes management plan can lower A1C, decrease glucose variability,

increase TIR, and reduce hypoglycemia (1). Laffel et al. (2) conducted a randomized clinical trial in youths 14–24 years of age with type 1 diabetes comparing use of the Dexcom G5 CGM system to standard blood glucose monitoring (BGM) and demonstrated a statistically significant improvement in glycemic control over 26 weeks. In a recent randomized clinical trial conducted by the SENCE (Strategies to Enhance New CGM Use in Early Childhood) Study Group, there was significant improvement in three important glycemic indices: time spent in hypoglycemia, number of severe hypoglycemic episodes, and glucose variability. There was subsequent improvement in parents’ psychosocial functioning among families using CGM (3).

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Evidence for improved psychological outcomes with the use of CGM has been mixed and often based on studies using older CGM systems. For example, Halford et al. (4) in 2010 used a questionnaire in a cross-sectional study and demonstrated that adults with type 1 diabetes who used CGM therapy for any length of time (1 month to 2.5 years) as part of their diabetes self-management plan had improved quality of life (QOL), reduced fear of hypoglycemia (FOH), and increased patient empowerment. In a 2012 study in youths with type 1 diabetes, their parents, and adults with type 1 diabetes, Markowitz et al. (5) reported that youths using CGM and their parents reported more negative affect around BGM than those in the BGM group. The youth CGM group also reported more trait anxiety (how people experience anxiety in stressful situations) than the youth BGM group, whereas the adult CGM group reported less state anxiety (the transient reaction to the stressful situation) and trait anxiety than the adult BGM group. Parents in both CGM and BGM groups reported more FOH than youths in both groups. Parent-proxy report of depression in the youth CGM group was significantly higher than that reported by parents of youths using BGM. Similarly, a 2006 randomized clinical trial by the DirecNet (Diabetes Research in Children Network) Study Group (6) found that youths with type 1 diabetes who were randomized to 6 months of either traditional BGM or CGM reported no difference in diabetes treatment adherence, diabetes-specific QOL, or diabetes-related anxiety at baseline and at the end of the study. Landau et al. (7) in 2014 used actigraphy to explore the impact of CGM on parental quality of sleep. The sleep diary showed a greater number of awakening episodes, an increase in the number of wake bouts, and increased total wake time during CGM use compared with the period before CGM use. They concluded that CGM use appeared to affect actual parental sleep continuity somewhat negatively. Different adverse outcomes were reported by Ramchandani et al. (8), who used a questionnaire designed to assess real-life use of and issues surrounding CGM. The authors surveyed 58 subjects with type 1 diabetes (mean age 15.0 ± 4.8 years, mean diabetes duration 5.7 ± 3.8 years) and found that occasional users described CGM as annoying, a hassle, and interfering with their lives. However, a randomized clinical trial in 2018 conducted by the CITY (CGM Intervention in Teens and Young Adults with T1D) Study Group (2) reported significantly higher satisfaction with CGM compared with BGM after 26 weeks. The CITY group postulated that this improvement was secondary to improvement in CGM technology with subsequent reduced burden of CGM implementation. Finally, a recent study by Sinisterra et al. (9) found that children who used CGM experienced fewer sleep disturbances than those who did not. However, parents of children who

used CGM experienced worsening quality of sleep secondary to a higher frequency of nighttime BGM.

Although research studies performed to date have not shown consistent improvement in psychological outcomes with the use of CGM, parents may choose to add CGM to their child's type 1 diabetes management in hopes of optimizing glycemic control (lowering A1C), reducing the frequency of BGM, reducing FOH, and improving QOL. It is also plausible that parents with different levels of underlying anxiety, FOH, and diabetes burden would have different reasons for adding CGM to their child's diabetes management. Having a better understanding of the relationships among these outcomes may have a significant impact on successful adoption of CGM and other diabetes-related technology in children and families with type 1 diabetes (10).

Thus, the objectives of this pilot study were to describe caregiver-identified reasons for adding CGM to their child's type 1 diabetes management; to describe caregivers' anxiety levels, FOH, and diabetes burden before initiating CGM; and to explore the relationship between reasons for initiating CGM and psychosocial functioning.

Research Design and Methods

After obtaining institutional review board approval, all caregivers of children aged 2–15 years with type 1 diabetes duration ≥ 6 months who were on either multiple daily injection or insulin pump therapy and were initiating the Dexcom CGM system as part of routine clinical care were invited to participate. Families were identified by medical providers in the outpatient pediatric diabetes clinics at University Hospitals' Rainbow Babies and Children's Hospital in Cleveland, OH, between August and November 2018 and referred to the study team. Caregivers were excluded if they did not speak English (questionnaires were not available in other languages), if their child had used CGM in the past 3 months, or if their child had another condition that affected glycemic control (e.g., use of steroids or gastrointestinal disorders).

A chart review was performed to obtain each child's age, sex, date of type 1 diabetes diagnosis, BGM frequency, A1C, and prior CGM use. Race/ethnicity and insurance type were not extracted from charts; however, 39% of the patients with type 1 diabetes at the center are covered by Medicaid, 61% have commercial insurance, 80% are Caucasian, 15% are African American, and 5% are other races/ethnicities.

Parents completed three validated questionnaires to measure anxiety, FOH, and diabetes burden at baseline, before initiation of their child's CGM. In addition, they answered an investigator-designed questionnaire assessing their primary

reason for adding CGM to their child's type 1 diabetes management. Caregivers were given the choice of improving glyce-mic control, decreasing the frequency of BGM, reducing FOH, or improving QOL. If the child had not started CGM within 6 months of enrollment or had started it but then stopped with no plans to resume, parents answered an additional question-naire to verify reasons for not starting CGM.

Measures

Validated self-report questionnaires were used to assess the psychosocial health of adult caregivers. To assess non-diabe-tes-specific parental anxiety, the State-Trait Anxiety Inven-tory (STAI) survey (11) was completed. Two diabetes-specific measures were used as well, including the Hypoglycemia Fear Survey for Parents of Young Children (HFS-PYC) (12) and the Problem Areas in Diabetes-Parent Revised (PAID-PR) survey (13).

STAI

State anxiety is defined as unpleasant emotional arousal in the face of dangers, whereas trait anxiety indicates the indi-vidual differences in the tendency to respond with state anx-ity in threatening situations (14). The STAI is validated in adults and consists of two 20-item subscales that measure current feelings (state) and longstanding quality of anxiety (trait). Higher scores indicate greater anxiety. A score >45 was used to categorize caregivers as having anxiety (15).

HFS-PYC

The HFS-PYC is validated in parents of children with type 1 diabetes. It is a 26-item measure of FOH that includes a 16-item worry subscale and a 10-item behavior subscale. Three main factors were identified and were scored separately: worry about FOH, worry about helplessness in case of hypoglycemia, and worry about the social consequences of hypoglycemia. Parents scoring too high or too low on each item (i.e., score >19 or <11 on worry about helplessness in case of low blood glucose, score >13 or <3 on worry about the social consequen-ces of low blood glucose, and score >8 or <2 on behaviors to maintain high blood glucose) is considered a risk factor for not achieving optimal glyce-mic control, as it reflects either increased or extremely low FOH (16).

PAID-PR

The PAID-PR is validated in parents of children with type 1 diabetes. It is an 18-item measure to assess burden related to having a child with type 1 diabetes. A higher score indi-cates greater burden. A cut point of 56 was used to identify

families in need of additional medical or psychological sup-port to improve biomedical and psychosocial outcomes (17).

Data Analysis

Because this was a pilot study, a formal power calculation was not performed. Participant characteristics and question-naire results were analyzed descriptively and comparatively. Continuous variables are described using medians and ranges. Nominal data are described with frequencies and percentages.

Primary comparative analyses were done among groups formed based on parents' primary reason for adding CGM to their child's type 1 diabetes management. ANOVA methods were used to compare continuous baseline scores. The overall significance levels of group membership are reported (global F test). Post hoc pairwise tests were carried out in some cases (e.g., to compare A1C and diabetes duration between two of the groups). A Fisher exact test was used to compare nominal variables among groups. Additionally, those who used CGM and those who did not were compared using Wilcoxon rank sum tests for continuous variables and χ^2 analysis for nomi-nal variables.

All analyses were carried out using SAS, version 9.4, sta-tistical software (SAS Institute, Cary, NC). The level of sig-nificance was set at $P < 0.05$.

Results

During the 3-month enrollment period, 32 families expressed interest in adding CGM to their child's diabetes management. All 32 families agreed to participate, signed informed consent/assent, and completed baseline questionnaires. Families inter-ested in adding CGM to their child's diabetes management during that time period were all noted to be English speaking, and none were excluded for language.

Families were followed until CGM was initiated or for 8 months, whichever came first (range 3–8 months). Four families were lost to follow-up, and we could not determine whether CGM was initiated. The median age of caregivers ($n = 22$) was 38.5 years, and 24 of the 28 (86%) were female. Ten parents left the age question and four left the sex ques-tion blank on the questionnaire. The children had a median age of 10.1 years (range 2.3–15.8 years), a median diabetes duration of 4.2 years (range 0.5–14.7 years), and a median A1C of 8.8% (range 6.3–13.7%), and 60% were male (Table 1). The most common reason for caregivers wanting to add CGM to their child's diabetes management was to improve glyce-mic control (16 of 32 [50%]). Six parents (18%) wanted to

TABLE 1 Baseline Characteristics and Questionnaire Results Overall and by Reason for Starting CGM

	Overall (N = 32)	Less FOH (n = 5)	Less BGM (n = 5)	Better Glycemic Control (n = 16)	Better QOL (n = 6)	P
<i>Demographic characteristics</i>						
Age, years	10.1 (2.3–15.8)	11.1 (4.4–12.4)	13.8 (6.7–13.9)	11.1 (2.3–15.8)	9.3 (5.4–12.7)	0.91
Male sex	20 (62.5)	3 (60)	3 (60)	12 (75)	2 (33.3)	0.35
Diabetes duration, years	4.2 (0.5–14.7)	8.4 (0.5–12.4)	7.1 (0.5–13.8)	3.5 (0.5–14.7)	2.8 (0.8–8.3)	0.58
A1C, %	8.8 (6.3–13.7)	8.2 (6.9–12.2)	8.1 (6.3–12.9)	9.5 (6.5–13.7)	7.5 (6.7–12.7)	0.60
Number of BG checks/day	4.5 (1.7–8.5)	4.8 (2.6–5.0)	5.0 (4.0–6.8)	3.7 (1.7–7.6)	5.0 (4.0–8.5)	0.20
<i>HFS-PSY</i>						
Maintain high BG	8.0 (4.0–20.0)	12.0 (5.0–14.0)	8.0 (4.0–15.0)	8.0 (4.0–20.0)	9.0 (4.0–18.0)	0.97
% <2	0	0	0	0	0	
% >8	46.8	80	40	50	50	
Helplessness about low BG	28.5 (11.0–55.0)	30.0 (19.0–42.0)	27.0 (11.0–32.0)	29.0 (12.0–55.0)	22.0 (16.0–41.0)	0.63
% <11	0	0	0	0	0	
% >19	71.8	80	60	75	66.6	
Social concerns about low BG	9.5 (5.0–25.0)	13.0 (5.0–16.0)	8.0 (5.0–14.0)	11.0 (5.0–25.0)	7.0 (6.0–17.0)	0.57
% <3	0	0	0	0	0	
% >13	25	20	20	25	33.3	
<i>PAID-PR</i>						
PAID score	50.6 (0.0–90.2)	47.0 (30.5–75.0)	61.1 (0.0–72.0)	53.5 (13.7–76.3)	39.6 (6.9–90.2)	0.81
% >56	37.5	40	60	31.2	33.3	
<i>STAI</i>						
State	37.5 (20.0–68.0)	43.0 (21.0–63.0)	29.0 (21.0–51.0)	40.0 (20.0–68.0)	35.5 (20.0–50.0)	0.57
% >45	31.2	60	20	25	33.3	0.83
Trait	36.5 (21.0–55.0)	43.0 (24.0–53.0)	33.0 (22.0–51.0)	36.5 (22.0–55.0)	38.5 (21.0–49.0)	
% >45	28.1	60	20	25	16.6	

Continuous variables are described with medians and ranges, and nominal variables with frequencies and percentages. For each questionnaire, the percentage of participants with an elevated score was determined using established ranges from the literature. Global *F* test, ANOVA, or Fisher exact test was used as appropriate. BG, blood glucose.

improve QOL, five (~16%) wanted to reduce BGM, and five (~16%) wanted to decrease FOH.

The majority of parents (71.8%) expressed worry on the HFS-PYC about helplessness during a hypoglycemic episode, although only ~46% reported possible behavioral changes to avoid hypoglycemia by maintaining high blood glucose levels. The median state anxiety and trait anxiety scores (37.5 and 36.5, respectively) were below the clinical cut point. However, 31.2% of caregivers had a state anxiety score above the cut point, and 28.1% had trait anxiety score above the cut point (Figure 1). Similarly, although the median score for the PAID-PR (50.6) did not fall above the cut point that would suggest significant stress or burden related to caring for a child with type 1 diabetes, the PAID-PR score was above the clinical cut point in 37.5% of caregivers (Figure 2).

Caregivers were divided into groups based on their reason for adding CGM to their child’s diabetes management, and the questionnaire results were compared across groups (Table 1). There were no statistically significant differences in demographic characteristics or questionnaire scores among the

different groups based on the global *F* test. However, the group of caregivers who wanted to start CGM to achieve improved glycemic control had children with a nominally higher median baseline A1C (9.5% [range 6.5–13.7%]) compared with the group of caregivers who wanted to add CGM to improve QOL (7.5% [range 6.7–12.7%]). Caregivers who wanted to add CGM to decrease FOH had children with a median diabetes duration of 8.4 years (range 0.5–12.4 years). However, caregivers who wanted to attain better QOL by adding CGM had children with a median diabetes duration of 2.8 years (range 0.8–8.3 years). Sixty percent of the caregivers who wanted to add CGM to decrease FOH had an elevated STAI score >45 (Figure 1). In addition, 60% of the caregivers who wanted to add CGM to reduce BGM had an elevated score (>56) on the PAID-PR, indicating higher diabetes burden (Figure 2).

Follow-Up Results

Among the 28 families followed for up to 8 months, only half of the children (*n* = 14) started using CGM during the follow-

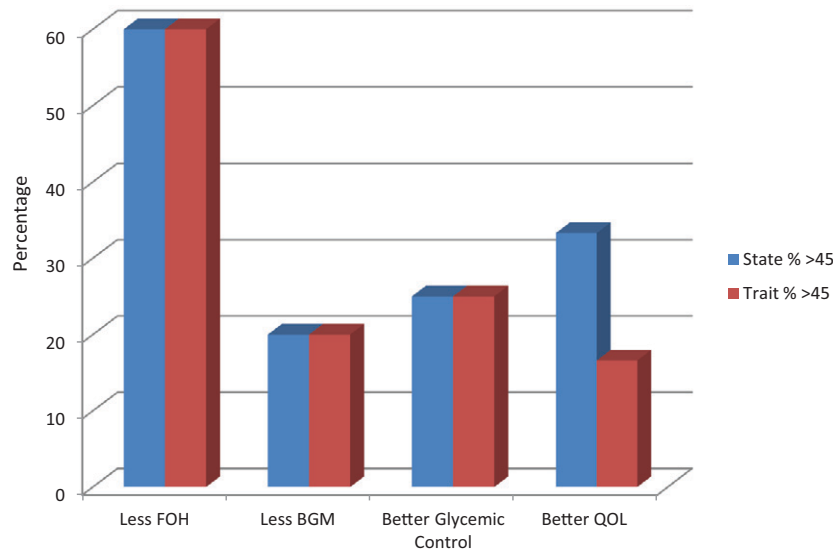


FIGURE 1 STAI results. Percentage of caregivers with state (blue) or trait (red) anxiety scores above cut point (>45) indicating clinical anxiety, grouped by primary reason for starting CGM.

up period. When assessing reasons for not starting CGM, we found that nine (64%) did not start it because they were too busy with other life challenges and did not get the chance to start the process, four (28%) had difficulty getting insurance to approve it, and one (7%) reported that, despite insurance coverage, the out-of-pocket expense was too much.

There were no differences in demographic characteristics observed between the children who did and did not start CGM (Table 2). Families with caregivers who wanted to add CGM to improve QOL ($n = 6$) ended up successfully starting CGM during the follow-up period, compared with 50% of the families with caregivers who wanted to add CGM to reduce BGM, 33% of families with caregivers who

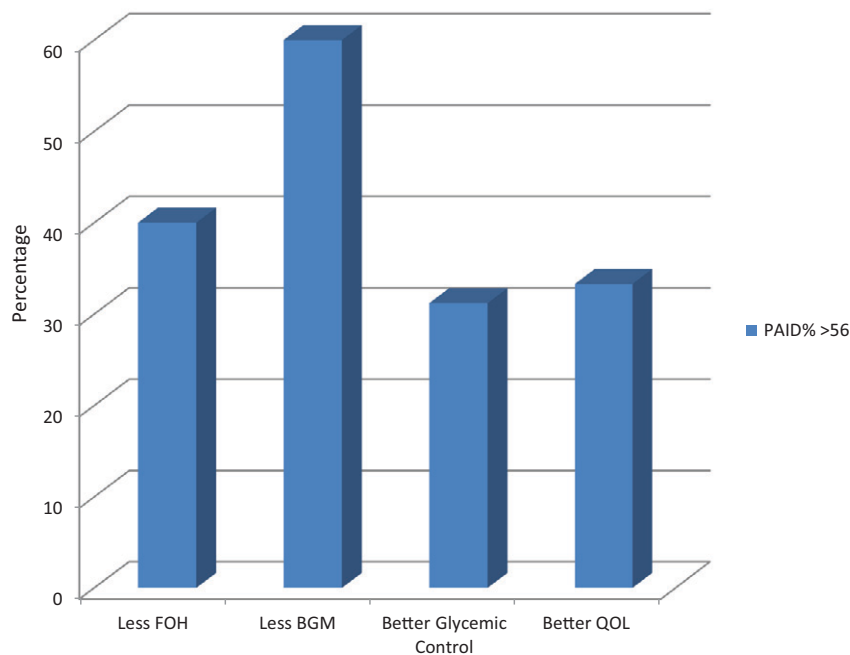


FIGURE 2 PAID-PR results. Percentage of caregivers with PAID-PR scores above the cut point (>56) indicating the need of medical or psychological support, grouped by primary reason for starting CGM.

TABLE 2 Baseline Characteristics of Participants Who Started CGM Versus Those Who Did Not

	CGM (n = 14)	No CGM (n = 14)	P
Age, years	9.3 (2.9–14.4)	11.2 (4.5–15.8)	0.30
Male sex	8 (57)	9 (64)	0.70
Diabetes duration, years	3.0 (0.5–9.5)	4.4 (0.5–12.5)	0.60
A1C, %	8.2 (6.5–12.7)	9.5 (6.9–13.7)	0.13
Number of BG checks/day	4.8 (2.6–7.6)	4.0 (1.7–6.0)	0.20

Continuous variables are described with medians and ranges, and nominal variables with frequencies and percentages. Wilcoxon rank sum test or χ^2 test was used as appropriate. BG, blood glucose.

wanted to decrease FOH, and 38% of families with caregivers who wanted to achieve improved glycemic control.

Discussion

In this small, prospective pilot study, we were able to demonstrate that the most common reason for caregivers to add CGM to their child's diabetes management was to achieve more optimal glycemic control. The results of this study showed that, while the majority of caregivers did not have scores above the clinical cut point on the PAID-PR (62.5%) or the STAI (68.8% for state anxiety and 71.9% for trait anxiety), 72% expressed worry about helplessness during a hypoglycemic episode. In addition, close to 30% of caregivers scored above the cut point for state anxiety (31%), trait anxiety (28%), and the PAID-PR (37.5%) survey.

Although not reaching statistical significance, caregivers who wanted to add CGM to optimize glycemic control had children with a nominally higher A1C than those in the other groups. In addition, 60% of caregivers who wanted to start CGM to reduce BGM had increased levels of diabetes burden, and 60% of caregivers who wanted to add CGM to lessen FOH had scores higher than the clinical cut points on the STAI. Worrying about helplessness during a hypoglycemic episode was a clinically meaningful baseline finding in our group of caregivers. Interestingly, existing research suggests that, while hypoglycemia fear is common among parents of children with established type 1 diabetes, initiating CGM may help to reduce parents' use of hypoglycemia avoidance behaviors but has little effect on parents' level of hypoglycemia worry (18).

Despite caregivers' interest in CGM initiation for their child with type 1 diabetes, only 50% of the families actually initiated CGM during the follow-up period. Caregivers reported barriers to starting CGM, including not having enough time to initiate the process, lengthy times to insurance approval, insurance denials, and high out-of-pocket expenses. Further

efforts are needed to eliminate these barriers. One possible solution is to improve clinic-based case management to offer more assistance with the steps necessary to order a CGM and get insurance approval. The insurance approval process should be simplified and insurance coverage expanded so that families can access CGM more universally. It would be helpful to reduce requirements for CGM approval such as BGM records and evidence of hypoglycemia and/or hypoglycemia awareness.

The results of our study highlight the importance of understanding why caregivers want to add CGM to their child's diabetes management and what their expectations are. Understanding caregivers' goals, fears, and worries will better equip the diabetes team in supporting each family in successfully integrating CGM into their child's diabetes management. It is important to explore caregivers' mental health, including stress, depression, and anxiety, as the presence of any or all of these can affect diabetes management and glycemic outcomes (19,20).

The main limitation of this pilot study is its small sample size. A larger study will be necessary to further assess whether caregivers' FOH, diabetes burden, and anxiety are related to their reasons for adding CGM to their child's diabetes management. In addition, repeating the measures of FOH, diabetes burden, and anxiety after a period of time on CGM would help to determine whether these psychosocial variables remain stable, improve, or worsen with CGM use. In turn, it may be interesting to examine other caregiver-defined goals for adding CGM, such as improving sleep or catching missed boluses, and whether they are met with the addition of CGM.

We did not collect data on race/ethnicity or insurance status. This information would have been interesting, particularly when comparing those who did and did not initiate CGM. When we were designing the study, we did not anticipate that 50% of participating families would be unable to initiate CGM. Future studies designed to explore barriers to CGM initiation should include these important social determinants of health.

We excluded non-English-speaking parents because questionnaires are not available in all languages; however, our clinic has a very small percentage of non-English-speaking parents. Larger studies should include non-English-speaking families, as they are likely to have additional barriers to initiating CGM.

Finally, given the reported concerns about insurance, it will be important for future studies to assess the role of caregivers' financial stress.

In conclusion, CGM and other forms of diabetes technology have the potential to transform care for youths with

type 1 diabetes, with the potential of optimizing TIR and improving QOL. Understanding caregivers' reasons and expectations for adding CGM to their child's diabetes management and removing any potential barriers to acquiring the technology are both important strategies to improve the care of youths with type 1 diabetes.

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DUALITY OF INTEREST

No potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

L.A. was responsible for the study design, data collection, data analysis, and manuscript preparation. M.O. was responsible for data analysis and reviewed and edited the manuscript. S.M. and R.H. contributed to the study design and reviewed and edited the manuscript. J.R.W. contributed to study design, data collection, and data analysis and reviewed and edited the manuscript. All authors approved the final version of the manuscript. L.A. is the guarantor of this work and, as such, had full access to all 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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