

Benefits and Barriers of Continuous Glucose Monitoring in Young Children with Type 1 Diabetes

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Abstract

Background: Continuous glucose monitoring (CGM) has potential to address challenges of type 1 diabetes (T1D) management for young children. CGM use is increasing, yet remains underutilized. Characterizing parents' experiences with CGM can inform clinical strategies to help parents make decisions about diabetes management, overcome obstacles to initiating and sustaining CGM use, and maximize benefits of CGM use in their children's diabetes care.

Methods: Transcripts from semistructured qualitative interviews with 55 parents of children aged 1 to <8 years, with T1D duration ≥ 6 months, and whose child currently or previously used CGM were coded and analyzed to derive themes about their experiences with CGM.

Results: Participants were 88% mothers and the mean child age was 5.0 ± 1.5 years. Parents described benefits of CGM use: decreased worry about glucose excursions, improved sleep, increased sense of safety with children who cannot recognize or express symptoms of hypo- or hyperglycemia, and greater comfort with other caregivers, especially using remote monitoring functionality when away from children. Challenges included painful insertions, wearing multiple devices on small bodies, disruptive alerts, data gaps due to lost signals, skin/adhesive problems, and difficulty interpreting the amount of information generated by CGM. For some, the challenges outweighed potential benefits and they stopped CGM use.

Conclusions: CGM may address unique challenges of T1D in young children and increase parental comfort with diabetes management, yet there are multiple barriers to initiating or maintaining CGM use. Education and behavioral support to address these benefits and barriers may equip caregivers with skills to address challenges of CGM use.

Keywords: Type 1 diabetes, Child, Parents, Health behavior.

Introduction

TYPE 1 DIABETES (T1D) management in young children (1 to <8 years) is uniquely challenging. Normal developmental factors such as unpredictable behavior and eating patterns, rapid growth spurts, and frequent intercurrent illness

make it difficult to determine precise insulin needs.¹ Many characteristics of early childhood can further interfere with parents' ability to manage their children's diabetes: young children have highly variable glucose fluctuations, require small insulin doses for diabetes management, and may resist fingerstick blood glucose monitoring.¹ In addition, young

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children and their parents are often unable to recognize signs of hypoglycemia,² and children at this age have a limited ability to communicate internal sensations or symptoms of glucose excursions. Parents may be especially concerned about their children's safety when at daycare or with babysitters.^{1,3} These difficulties have been associated with significant T1D-related distress in parents of young children.⁴⁻⁶

Continuous glucose monitoring (CGM) holds promise to address several of the challenges of T1D management in young children, such as reducing the need for multiple fingersticks for blood glucose monitoring, audible and vibration alerts indicating the need for intervention when glucose values are outside of preset ranges, and remote monitoring when the child is not in the parent's presence.⁷ Although CGM has been demonstrated to lower A1c levels in older children, adolescents, and adults with T1D when used consistently,⁸ the effectiveness of CGM in improving glycemic outcomes in very young children has not yet been established.⁹ Nevertheless, the T1D Exchange has recently reported that CGM use in children <6 years of age increased from 4.4% in 2011 to 44.5% in 2016,¹⁰ representing the largest increase in CGM use in any age group in the T1D Exchange.¹¹ Similar increases have been reported in other countries.¹⁰ Consequently, this study was undertaken to obtain a better understanding of the current experiences using CGM by parents of young children with T1D, and to inform the development of a behavioral intervention for families of young children with T1D initiating CGM in a clinical trial.

Methods

Parents of children between the ages of 1 and <8 years were recruited for this IRB-approved study from four pediatric diabetes care centers in geographically and demographically diverse locations (Northeast, South, and Midwest) in the United States. Parents were eligible to participate if they could read and speak English and they were the primary caregiver of a child diagnosed with T1D. In addition, their child had to have a duration of diabetes ≥ 6 months, age between 1 and <8 years old, and recent (within 90 days before enrollment) A1c <10.5%. Parents were not eligible if their child had profound developmental delays. Research staff mailed invitations to parents and followed up in person or by

telephone or approached parents at clinic visits to obtain consent and conduct study activities.

Semistructured qualitative interviews were conducted between December 2015 and April 2016 with 79 parents across the four sites. The interview scripts included questions about parents' experiences with blood glucose meters, insulin pumps, and CGMs, including questions about the benefits and challenges of each device they had used. For devices that they used previously, interviewers inquired about reasons for pausing or stopping the device. For devices they had never used, interviewers queried participants about what they had heard about the devices and their reasons for not using them. Rigorous qualitative data collection and analysis methods were used.¹² First, two central investigators trained interviewers at each site to follow the semistructured interview script and to use probes and prompts to elicit additional information from participants. Table 1 presents example questions and prompts/probes related to CGM use. At each of the four sites, one to two interviewers who received this training conducted the interviews with participants in person or by telephone (87% took place through telephone). The interviews lasted ~30 min. Interviews were audio-recorded and transcribed by professional medical transcriptionists, with all personal identifiers removed. Using NVivo Software, study investigators created a codebook through a hybrid thematic analysis of the interview transcripts: the study team created broad thematic categories from the interview scripts, used inductive coding to identify and define specific themes based on participant responses to the interviews, and expanded and refined the codes through an interactive process of applying the codebook to the 79 transcripts. Study staff double-coded all interviews to ensure coding reliability. For this analysis, transcripts of interviews with the 55 participants whose child either previously or currently used CGM were reanalyzed specifically to identify themes about participants' experiences with CGM.

Results

Participants were $n=55$ parents whose child currently ($n=47$, 85%) or previously ($n=8$, 15%) used CGM. The majority (88%) were mothers and 87% self-identified as non-Hispanic Caucasian. The mean child age was 5.0 ± 1.5 years,

TABLE 1. EXAMPLE QUALITATIVE INTERVIEW QUESTIONS

<i>Example questions</i>	<i>Example prompts/probes</i>	<i>Current users</i>	<i>Previous users</i>
What factors led you to start using CGM?		X	X
What do you feel are the best aspects, if any, of using CGM for you and your child?	What benefits have you found, if any, using CGM in your family?	X	X
What are the more challenging aspects, if any, of using CGM for you and your child?	Are there certain times or situations where you find it more challenging for your child to wear a CGM? What concerns do you have about how the CGM works? How much effort does it feel like CGM requires of you?	X	X
Has your child stopped using CGM for a significant period of time?	What reasons led you to decide to stop using CGM? How long did your child use CGM before s/he stopped?		X

CGM, continuous glucose monitoring.

mean diabetes duration 2.4 ± 1.3 years, and mean HbA1c was $7.9\% \pm 0.9\%$.

Qualitative analyses indicated two major themes of responses: benefits and barriers of CGM use, each with multiple subthemes indicating specific positive aspects of CGM use and CGM challenges the parents encountered. Table 2 summarizes the subthemes in each category. Excerpts from interviews are included to illustrate the themes.

Perceived benefits of CGM use

Parents described benefits of CGM use, including decreased worry and increased confidence about their child's health and safety due to immediate access to their child's current glucose level. One father of a 4-year-old boy explained, "It allows us to let him try to be a tad bit more normal, I guess. He can run around, and I don't have to test him constantly...It was a constant thing. The [CGM] allows us to live a little bit more and sleep and let him be more normal and let us not...worry as much when we see the numbers look ok." They noted this was particularly helpful in identifying glucose excursions (hypo- and hyperglycemia) for children who were not able to recognize or communicate their symptoms, especially for very young children. A mother of a 5-year-old boy described, "The CGM has taken a lot of stress off because you can see what is happening...before we were just hoping everything was ok."

Parents also reported that the remote monitoring capabilities of CGM devices gave them continual access to children's glucose levels, which made them more comfortable leaving their children in the care of others (e.g., teachers, sitters). A father of a 4-year-old boy noted, "It allows me to have much more knowledge of the situation and also to feel

more comfortable leaving him with other people." In addition, CGM made it easier for other caregivers to be involved in diabetes management.

Alerts for glucose excursions decreased parents' worry about missing dangerous hypoglycemia while the child was asleep and reduced their need for overnight fingerstick glucose checks, which improved parental sleep quality and duration. A mother of a 3-year-old girl described her experience, "I feel like I can sleep at night...I don't have to disturb her when I check...I really don't feel like I slept until I got that, since diagnosis."

In terms of diabetes management, parents reported that data provided by CGM assisted them in making immediate management decisions by providing information regarding the direction and rate of change of sensor glucose levels. Retrospective analyses also informed parents regarding patterns of glucoses at certain times of day or around certain activities/foods when fingerstick blood glucose values may not have been taken. For example, one mother of a 6-year-old girl explained, "It adds that extra sense of security...It definitely helps me...see how her body responds to certain times of day, or certain foods, or activity." The real-time data allowed them to make in-the-moment care decisions with fewer fingerstick blood glucose checks, and they perceived that CGM allowed for more in-range glucose values. As the mother of a 3-year-old girl explained, "she is in much better control because I can stop a bad high before it gets that bad or I can catch a trend on a day much better by looking at the graph...She has, in my opinion, better numbers and overall better A1c because she has it."

Perceived barriers to CGM use

Parents also described challenges related to CGM use in their young children. Physical issues were commonly described, including painful insertions of the sensor, skin reactions, and irritation from the adhesive. For example, one mother of a 5-year-old boy described the difficulty with sensor insertions, "The insertion system I think is horrific. It's a big needle. It's gonna hurt...It's all based on the person that's delivering that needle and if you push too light it doesn't go in. If you push too hard, it hurts even more." A mother of 7-year-old boy talked about problems related to the adhesive, "Getting it to stick to his body for the week. That's probably the most difficult...We've literally tried everything...He's a very active child...There have been times when the tape has caused marks on him. That's definitely difficult when you're trying to make sure you're not hurting his skin either with all this tape." Several parents also described difficulty with the child wearing multiple devices, such as the mother of a 6-year-old boy, "He doesn't have a lot of places to put things anyway...he's little...it's a challenge."

Emotional reactions to CGM were also commonly reported as challenges with this technology. Parents described the continuous data as creating a constant need for diabetes-related attention, which prevented them from being able to focus on other issues or take a cognitive break from diabetes. Some described the CGM as giving "too much information" and noted that they felt overwhelmed by the frequency and detail of the data and found it difficult to interpret. One mother of a 7-year-old girl who had stopped using the CGM described her experience, "It fed into the fact that I was so

TABLE 2. CORE THEMES REPRESENTING PARENT-DESCRIBED BENEFITS AND BARRIERS OF CONTINUOUS GLUCOSE MONITORING USE IN YOUNG CHILDREN

<i>Theme</i>	<i>Subtheme</i>
Benefits of CGM use	Decreased parental worry overall
	Increased parental confidence about child's safety
	Improved parental sleep
	Helpful for identifying low or high glucoses in children who cannot recognize or express symptoms
	Facilitates involvement of other caregivers
	More data help inform diabetes management decisions
	Decreased need for fingerstick blood glucose checks
Challenges to CGM use	Allows for more in-range glucoses
	Painful insertions
	Difficulty wearing multiple devices on small bodies
	Disruptive alerts
	Gaps in data due to lost signals
	Skin irritations/adhesive problems
	Constant flow of diabetes-related information/attention
	Too much information—overwhelming, difficult to interpret

anxious about it. It kinda wasn't worth it to me. I needed to sort of back away from diabetes a little bit. I'd be so intense about it."

There were also technical challenges described, including feeling disturbed or disrupted by the alerts for low and high glucose values, concerns about device inaccuracy or failure, and frustrations related to gaps in data due to lost signals between the transmitter and display device. One mother of a 5-year-old girl explained, "I did use the CGM, but I took it off because it wasn't giving accurate readings and it was alerting the whole house a thousand times. Then I would go to rush to do the sugar and I would check it and their sugar was nowhere near where it said it was." The father of a 4-year-old boy described experiences with signal loss that counteracted the benefits of continual monitoring, "Another big problem with it is that sometimes in the middle of the night the signal is lost, for some reason—I don't know why it happens. Sometimes the signal will go out for an hour. When that happens..the CGM won't beep."

Discussion

The qualitative comments from parents of young children in this study indicate that for some parents CGM offers peace of mind, whereas for other parents CGM seems to magnify the challenges of T1D management. One significant benefit that parents perceived was that CGM can give parents information about glucose levels in their child who otherwise cannot sense or communicate their symptoms of hyper- or hypoglycemia. The frequent sensor glucose data reduced the number of required fingerstick blood glucose measurements, especially given to the increased accuracy of current devices^{13,14} and recent FDA approval of some CGM devices as a replacement for blood glucose monitoring. Management decisions could be made in the moment based on the sensor glucose level and the direction and rate of change in glucose values. Parents also noted that retrospective analyses of CGM profiles also enhanced their understanding of factors that influence glucose levels at different times of the day and with different types of food, information that parents could use to modify their diabetes management routines.

Another important benefit of CGM in young children related to the remote monitoring functionality of current CGM devices. In the past, parents often reported stresses related to being the sole adult capable of taking care of their child, feeling that daycare providers, schools, and babysitters were ill-equipped to manage a child's diabetes.¹⁵⁻¹⁷ In contrast, participants in this study perceived the remote monitoring capability of current CGM devices as facilitating constructive interactions between parents and other caregivers. Parents reported being more comfortable with other caregivers, given their awareness of the child's well-being from afar, which may in turn improve parental quality of life. It is also noteworthy that parents of young children using CGM have lower target glucose levels than those who are not using CGM.¹⁸

A strength of this research was the careful assessment of parent perceptions of CGM that allowed them to share both positive and negative experiences. Parents perceptions regarding barriers to initiating or maintaining CGM use in their children focused on physical, emotional, and technical challenges with the devices. Pain on insertion of sensors, adverse

skin reactions to adhesives, and limited space for insertion of sensors and pump infusion sites were noted. Technical difficulties, including alarm fatigue, signal loss, and inaccuracies, negated the potential benefits of CGM for some families. Although we did not ask parents which models of CGMs they used, it is possible that those reporting technical problems may have given up using CGM based on negative experiences with early generation devices. Given marked improvements in performance, insertion ease, and duration of sensor wear,^{14,19-21} it may be important to ensure families of young children receive up-to-date education about current diabetes devices.

As CGM technology continues to advance, the experiences of wearing these devices will likely continue to evolve.^{13,19} For example, consistent use of CGM sensors is a central component of hybrid closed-loop insulin delivery systems that regulate between meal and overnight insulin infusion rates automatically.²² The parents in this study endorsed benefits, including increased sense of security and having fewer diabetes care tasks to do, and barriers focused on physical, emotional, and technical challenges with the devices, which were similar to experiences of adults using hybrid closed-loop devices.^{23,24} This research extends the field by demonstrating multiple positive and negative perspectives of parents of young children related to CGM specifically.

Unlike studies with adults, this research with parents of young children focuses on caregiver experiences and not the personal perspective of the person with diabetes who is wearing the device. This is developmentally appropriate for young children, for whom parents are the primary diabetes managers. Taken together, this body of research suggests that advances in diabetes management technologies may be beneficial and appealing for many families, but rarely work for all parents given families' individual differences with respect to problem-solving abilities, anxiety levels, and comfort with technology. Indeed, some parents reported being overwhelmed by the quantity of sensor glucose data, suggesting that they were more comfortable making immediate corrections of high or low glucose levels than in making adjustments in their child's treatment regimen based on retrospective review of CGM profiles. Qualitative data with people using automated insulin delivery systems suggest that these systems may ultimately reduce burden on wearers by minimizing the need for problem-solving based on real-time or retrospective data review.^{25,26}

As with all research, this study's limitations should be considered. Although geographically diverse, this sample was restricted to parents of children with HbA1c <10.5% and who had been diagnosed with T1D for at least 6 months to approximate the characteristics of the planned sample for the subsequent CGM trial this qualitative research was designed to inform. As CGM use becomes more widespread, understanding the experiences of families closer to diagnosis and for the management of higher HbA1c values will be important. The sample was majority non-Hispanic Caucasian mothers, which reflects T1D prevalence in the United States and the common pattern of higher maternal involvement in research. However, this may limit our understanding of how families from other backgrounds and compositions feel about CGM use in their young children. Finally, given the nature of qualitative research and the small subset of participants who had stopped using CGM ($n=8$), we were unable to compare

themes between families that stopped versus that continued using CGM. As diabetes management devices continue to advance, understanding the reasons some families choose to stop using them will help technology developers and clinicians improve the devices and/or strategies to support effective device use to meet families' needs.

In sum, there was no single reaction to CGM use in the 79 families interviewed for this study: parents' individual differences and children's temperaments shape the family's response to CGM and should be considered when making decisions about care. These findings highlight the importance of understanding the range of family experiences with respect to how individuals and families use diabetes technology. Attention to individual differences in parents and to temperamental differences in young children can inform clinical strategies to support families in making diabetes management decisions, and pave the way to future success of various diabetes management devices, including CGM and automated insulin delivery systems. Indeed, the themes identified in this qualitative research were used to inform the design of a randomized clinical trial comparing standard T1D care without CGM to CGM with basic education to CGM with basic education plus a family behavioral intervention to support CGM use in families of children under age 8 with T1D (ClinicalTrials.gov Identifier: NCT02912728).

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