DIABETES TECHNOLOGY & THERAPEUTICS
Volume 20, Number 9, 2018

DOI: 10.1089/dia.2018.0204

DTT

LETTER TO THE EDITOR

Sustained Continuous Glucose Monitor Use in Low-Income Youth with Type 1 Diabetes Following Insurance Coverage Supports Expansion of Continuous Glucose Monitor Coverage for All

Priya Prahalad, MD, PhD, Ananta Addala, DO, MPH, Bruce A. Buckingham, MD, Darrell M. Wilson, MD, and David M. Maahs, MD, PhD

Dear Editor,

Continuous glucose monitor (CGM) technology has been revolutionary for individuals with type 1 diabetes (T1D). Modern CGM technology allows individuals with diabetes to know not only their glucose values at all points in time, but also the direction of glucose change. The most recent generation CGM devices do not require calibrations. Use of CGM improves outcomes such as time in range, hemoglobin A_{1c} (HbA_{1c}), and hypoglycemia.[1,2] This can ultimately lead to lower healthcare costs.

Despite advances in CGM technology, safety profile, and clinical efficacy, use among the pediatric population in the United States was low at 7% based on 2015 data from the Type 1 Diabetes Exchange (T1DX).[3] Recent data from the T1DX and the Prospective Diabetes Follow-up (DPV) registries in 2016 reported 22% and 19% CGM use, respectively, in youth with T1D.[4] Unfortunately, children of lower socioeconomic status consistently demonstrate even lower rates of CGM usage than children of higher socioeconomic status.[5] Lack of insurance coverage, perceived lack of interest, and historic data on low rates of CGM continuation[6] are commonly cited reasons for this low adoption rate in children of lower socioeconomic status.[7]

We have been fortunate to have California Children's Services (CCS), a supplemental public state medical insurance for low-income children with chronic medical conditions, approve the Dexcom CGM for pediatric patients starting in 2016. For approval of CGM, at the time of this submission, children with CCS must (1) perform self-monitoring of blood glucose (SMBG) four times per day before starting CGM use and (2) have problems that interfere with T1D management (such as fear of hypoglycemia). Ongoing approval requires performing SMBG at least three times per day, using CGM at least 5 of 7 days per week, and improvement in clinical outcomes.

We performed a chart review of our patients who were approved for CGM use by CCS between June 2016 and June 2017 to describe our real-world experience.[8] Charts were reviewed to collect demographic information, HbA_{1c}, number of SMBG per day, date of CGM start, and last date of CGM use, if applicable. Scanned reports containing 2 weeks of CGM data were reviewed to assess percentage of time in range and hypoglycemia and hyperglycemia. Days of CGM use were assessed by reviewing the scanned report.

In the 1-year period, 40 children were approved for CGM use by CCS (Table 1). Twenty-nine children used the Dexcom receiver and 11 had the data displayed directly on a smartphone. Thirty-one out of 40 patients (78%) continued to wear CGM 6 months after initiation. Only patients using a smartphone were able to activate the Share function. One patient was lost to follow-up. Of the eight patients who stopped using CGM, two were due to lapses in insurance coverage of CGM use. The other six patients stopped due to personal preference (five stopped within the first 3 months of use). All patients who stopped CGM use were English speakers. Among those who continued using CGM at 6 months with complete data ($n = 29$, 73%), the mean number of days worn for 2 weeks was 13 ± 2.3 days (range 2–14 days) based on review of the CGM download. HbA_{1c} remained stable for 6 months of CGM use ($8.2 \pm 1.2\%$ at initiation and $8.2 \pm 1.3\%$ for those remaining on CGM use at 6 months). Time in hypoglycemia (blood glucose <70 mg/dL) was low at 6 months ($4.3 \pm 4.8\%$). We do not have blinded CGM data from prior to CGM initiation; therefore, we cannot determine whether CGM use resulted in a decrease in time with hypoglycemia. The number of SMBG remained stable with 6.3 ± 2.9 per day at initiation and 6.5 ± 3.8 per day for those who remained on CGM use at 6 months.

Our data from the first 40 CCS patients approved for CGM demonstrate sustained CGM use for 6 months, even among

Division of Pediatric Endocrinology, Stanford University, Stanford, California.

Table 1. Demographic Characteristics

Age	12.4 ± 4.8 years
Gender	
Male	57%
Female	43%
T1D duration	6.1 ± 3.7 years
Mode of insulin delivery	
Injections	35%
Insulin pump	65%
SMBG per day	
Before CGM initiation	6.3 ± 2.9
6 Months post-CGM initiation for those continuing CGM use ($n = 30$)	6.5 ± 3.8
Mean HbA_{1c}	
Before CGM initiation	8.2 ± 1.2%
6 Months post-CGM initiation for those continuing CGM use ($n = 27$)	8.2 ± 1.3%
Ethnicity	
Caucasian	37%
Minority	63%
Primary language	
English	85%
Other	15%
Method for viewing CGM data	
iOS device	17%
Dexcom receiver	73%

CGM, continuous glucose monitoring; HbA_{1c}, hemoglobin A_{1c}; SMBG, self-monitoring of blood glucose; T1D, type 1 diabetes.

non-English speakers. Our data are in contrast with historic studies using older generations of CGM systems, which showed a decrease in sensor use over 6 months in children.[6] Prior CGM studies, such as the Juvenile Diabetes Research Foundation studies, used less accurate, less user-friendly CGM systems that did not allow for sharing of data. Individuals included in this report had newer generation Dexcom G4 and G5 systems, which have higher accuracy and a lower burden of use than previous generations of CGM systems. In our cohort, users did not decrease SMBG; however, 25 of the 40 patients were started on CGM before the Food and Drug Administration (FDA) indication of nonadjunctive use of a Dexcom G5. In addition, patients continued to perform frequent SMBG since it was required by CCS for reapproval. Insurance requirement for continued SMBG is not consistent with current FDA policy, allowing insulin dosing based on CGM use, and represents an opportunity to reduce costs and barriers to use. We advocate that the requirement for three SMBG a day be removed when FDA-approved factory-calibrated sensors are used.

Our report has limitations including a small sample size and data from one clinic. Also, patients did not decrease HbA_{1c} after initiation of CGM use, although in this pediatric cohort it did not increase after 6 months as is often seen in pediatric patients with increasing diabetes duration and age.[9,10] Blinded CGM use was not available before initiation of personal CGM use, so we cannot assess whether hypoglycemia decreased. However, many of these children with CCS started CGM use due to hypoglycemia and/or fear of hypoglycemia. The incidence of hypoglycemia among the population using CGM at 6 months was very low. Also, we did not perform quality of life or patient-reported outcomes surveys, although the sustained use argues that patients and families found the CGM to be of benefit.[11,12] We also did not track use of the Share function in these families.

CGM approval varies across different insurances. In the pediatric population, most private insurance companies do provide some coverage for CGM use. However, Medicaid coverage has lagged. One reason cited for lack of insurance approval for use of CGM in pediatric patients is historic data in older generation CGM systems in which usage and continuation were low in adolescents.[5,13,14] In our real-world clinical experience, our data on sustained usability of CGM support public insurance coverage of CGMs. There is no reason to believe that people with lower socioeconomic status behave any differently than people of more substantial means in use of CGMs. Given FDA approval of CGM use for insulin dosing decisions based on established safety and efficacy, we advocate for increased approval of CGMs by public insurance to increase access to CGMs, which are associated with improved glucose control and decreased burden of care. Moreover, cost-effectiveness of CGMs regarding hypoglycemia, severe hypoglycemia, visits to emergency department, hospitalization, and major complications of hypoglycemia is established.[2] In addition, as newer generations of CGMs do not require calibration, it is important that both approval and renewal are not contingent on continued SMBG. As diabetes technology becomes more effective, it is important that all people with T1D are able to benefit.

Author Disclosure Statement

Dr. Maahs has research support from the NIH, JDRF, NSF, and the Helmsley Charitable Trust, and his institution has research support from Medtronic, Dexcom, Insulet, Bigfoot Biomedical, and Roche. Dr. Maahs has consulted for Abbott, the Helmsley Charitable Trust, Sanofi, and Eli Lilly, and has served on an advisory board for Insulet. Dr. Maahs is supported by grant P30DK116074. Dr. Buckingham, Dr. Wilson, and Dr. Prahalad have received donated CGM sensors from Dexcom. Dr. Buckingham has received honoraria from Dexcom.

References

1. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group: Effectiveness of continuous glucose monitoring in a clinical care environment: evidence from the Juvenile Diabetes Research Foundation continuous glucose monitoring (JDRF-CGM) trial. Diabetes Care 2010;33:17–22.
2. Danne T, Nimri R, Battelino T, et al.: International consensus on use of continuous glucose monitoring. Diabetes Care 2017;40:1631–1640.
3. Miller KM, Foster NC, Beck RW, et al.: Current state of type 1 diabetes treatment in the U.S.: updated data from the T1D Exchange clinic registry. Diabetes Care 2015;38:971–978.
4. De Salvo D, Miller KM, Hermann JM, et al.: Continuous glucose monitoring (CGM) and glycemic control among youth with type 1 diabetes (T1D): international comparison from the T1D exchange and DPV initiative. Pediatr Diabetes 2018; 1–5. DOI:10.1111/pedi.12711.

5. Wong JC, Foster NC, Maahs DM, et al.: Real-time continuous glucose monitoring among participants in the T1D exchange clinic registry. Diabetes Care 2014;37:2702–2709.
6. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Tamborlane WV, Beck RW, et al.: Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med 2008;359:1464–1476.
7. Tanenbaum ML, Adams RN, Hanes SJ, et al.: Optimal use of diabetes devices: clinician perspectives on barriers and adherence to device use. J Diabetes Sci Technol 2017;11: 484–492.
8. Jarow JP, LaVange L, Woodcock J: Multidimensional evidence generation and FDA regulatory decision making: defining and using ''real-world'' data. JAMA 2017;318: 703–704.
9. Clements MA, Foster NC, Maahs DM, et al.: Hemoglobin A1c (HbA1c) changes over time among adolescent and young adult participants in the T1D exchange clinic registry. Pediatr Diabetes 2016;17:327–336.
10. Miller KM, Beck RW, Bergenstal RM, et al.: Evidence of a strong association between frequency of self-monitoring of blood glucose and hemoglobin A1c levels in T1D exchange clinic registry participants. Diabetes Care 2013;36:2009–2014.
11. Prahalad P, Tanenbaum M, Hood K, Maahs DM: Diabetes technology: improving care, improving patient-reported outcomes and preventing complications in young people with type 1 diabetes. Diabet Med 2018;35:419–429.
12. Naranjo D, Tanenbaum ML, Iturralde E, Hood KK: Diabetes technology: uptake, outcomes, barriers, and the intersection with distress. J Diabetes Sci Technol 2016;10: 852–858.
13. Chase HP, Beck RW, Xing D, et al.: Continuous glucose monitoring in youth with type 1 diabetes: 12-month follow-up of the Juvenile Diabetes Research Foundation continuous glucose monitoring randomized trial. Diabetes Technol Ther 2010;12:507–515.
14. Giani E, Snelgrove R, Volkening LK, Laffel LM: Continuous glucose monitoring (CGM) adherence in youth with type 1 diabetes: associations with biomedical and psychosocial variables. J Diabetes Sci Technol 2017;11: 476–483.

Address correspondence to:
Priya Prahalad, MD, PhD
Division of Pediatric Endocrinology
Stanford University
300 Pasteur Dr., Room G313
Stanford, CA 94305

E-mail: prahalad@stanford.edu