

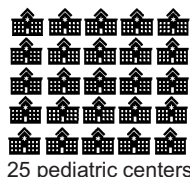
Early Continuous Glucose Monitor Use in Children and Adolescents With Type 1 Diabetes: Rates of Initiation and Impact on Glycemic Outcomes

Elizabeth A. Mann, Saketh Rompicherla, Brian Miyazaki, Nicole Riales, Holly Hardison, Lauren Golden, Jennifer Sarhis, Halis K. Akturk, Joyce Lee, Daniel J. DeSalvo, Patricia Gomez, Osagie Ebekozen, and Priya Prahalad

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Early initiation of CGM within the first 6 months of diagnosis is associated with improved HbA_{1c} outcomes at 3 years post-diagnosis for pediatric patients with type 1 diabetes (T1D)

Multi-disciplinary study from the T1D Exchange Quality Improvement Collaborative (T1DX-QI)



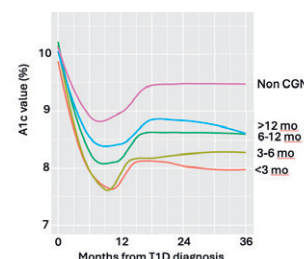
n = 4,164 children and adolescents age 18 and under



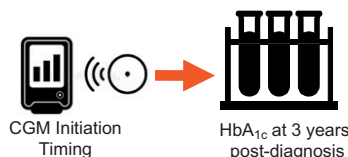
93% (n = 3,877) initiated CGM

Demographics	
Mean Age	12.6 yrs
Public Insurance	37%

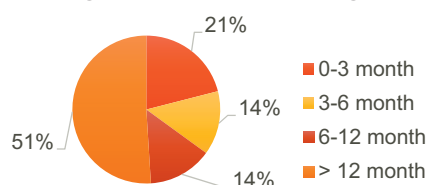
Early CGM initiation associated with lower HbA_{1c} at 3 yrs



2019-2020



Timing of CGM initiation diagnosis



Time of Initiation	Median HbA _{1c} after 3 years
0-3 Months	7.9%
3-6 months	7.9%
6-12 months	8.4%
Non CGM user	9.5%

ARTICLE HIGHLIGHTS

• Why did we undertake this study?

Diabetes technology, like continuous glucose monitors (CGM), helps with diabetes self-management and can improve glycemic levels in type 1 diabetes. Access to CGM early after diagnosis is variable. Single-center studies suggest that starting a CGM early after diagnosis improves glycemic outcomes.

• What is the specific question(s) we wanted to answer?

We explored whether starting a CGM early after diagnosis improved glycemic outcomes over time.

• What did we find?

We found that children and adolescents who started on a CGM within 6 months of type 1 diabetes diagnosis had lower HbA_{1c} levels at 3 years postdiagnosis.

• What are the implications of our findings?

These findings underscore the importance of removing barriers to accessing CGM early after type 1 diabetes diagnosis.



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Elizabeth A. Mann,¹ Saketh Rompicherla,²
Brian Miyazaki,³ Nicole Riales,²
Holly Hardison,² Lauren Golden,⁴
Jennifer Sarhis,⁵ Halis K. Akturk,⁶
Joyce Lee,⁷ Daniel J. DeSalvo,⁸
Patricia Gomez,⁹ Osagie Ebekoziem,^{2,10}
and Priya Prahalad¹¹

OBJECTIVE

Early initiation of continuous glucose monitor (CGM) after type 1 diabetes (T1D) diagnosis has been associated with lower hemoglobin A1C (HbA_{1c}) in single-institution studies. This multicenter study evaluated the association between the timing of CGM initiation and HbA_{1c} at 3 years postdiagnosis.

RESEARCH DESIGN AND METHODS

Data were obtained from the T1D Exchange Quality Improvement Collaborative (T1DX-QI) electronic health record database from 25 pediatric centers and included children and adolescents ≤18 years old diagnosed with T1D in 2019 and 2020. CGM initiation and glycemic outcomes were followed for 3 years after diagnosis. Locally estimated scatterplot smoothing plots evaluated the relationship between timing of CGM initiation and HbA_{1c} over time, and logistic regression models were used to adjust for potential confounders.

RESULTS

There were 4,164 people included in this analysis, mean age was 12.6 (SD 3.5) years, and 37% had public health insurance. Of the 93% (*n* = 3,877) who initiated CGM within 3 years of T1D diagnosis, 21% did so at 0–3 months, 14% at 3–6 months, 14% at 6–12 months, and 51% after 12 months. Median HbA_{1c} at 3 years postdiagnosis was lower for the 0–3 and 3–6 months groups compared with the 6–12 months and non-CGM user groups (7.9%, 7.9%, 8.4%, and 9.5%, respectively). Adjusted odds of HbA_{1c} >9% were lowest for the 0–3 months group followed by the 3–6 months group.

CONCLUSIONS

In summary, early initiation of CGM within the first 6 months of diagnosis is associated with improved HbA_{1c} outcomes at 3 years postdiagnosis.

Children and adolescents with type 1 diabetes often do not achieve target glycemic levels (1). Hemoglobin A1C (HbA_{1c}) trajectories in children and adolescents over time follow a consistent pattern with an initial drop following diagnosis until a nadir around 4 months postdiagnosis, at which time HbA_{1c} typically rises again (2,3). Long-term HbA_{1c} levels correlate with early HbA_{1c} trends and tend to plateau by

¹School of Medicine and Public Health, University of Wisconsin, Madison, WI

²T1D Exchange, Boston, MA

³Children's Hospital, Los Angeles, CA

⁴NYU Langone Health, New York, NY

⁵Cohen Children's Medical Center, Queens, NY

⁶Barbara Davis Center, Aurora, CO

⁷Susan B. Meister Child Health Evaluation and Research Center, C.S. Mott Children's Hospital, Ann Arbor, MI

⁸Texas Children's Hospital, Baylor College of Medicine, Houston, TX

⁹Miller School of Medicine, University of Miami, Miami, FL

¹⁰University of Mississippi School of Population Health, Jackson, MS

¹¹Stanford University, Stanford, CA

Corresponding author: Elizabeth A. Mann, eprange@wisc.edu

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about 12–18 months postdiagnosis (4). Therefore, interventions that improve glycemic levels in the first few months of diagnosis may have a lasting impact on glycemic outcomes and preventing future diabetes complications.

There are many known benefits of continuous glucose monitors (CGM) in children and adolescents with type 1 diabetes, and new CGMs do not require calibration and are approved generally by the U.S. Food and Drug Administration for insulin dosing decisions. Randomized control trials and real-world studies have demonstrated the association between CGM use and improved glycemic outcomes (5,6). CGMs are also key components of automated insulin delivery (AID) systems, which are now recommended as the standard of care for people with type 1 diabetes (7). Additionally, switching from self-monitoring of blood glucose (SMBG) to CGM has been associated with reduction in HbA_{1c} (8). The T1D Exchange clinic registry found that in a cohort of over 20,000 pediatric patients with type 1 diabetes, CGM use was associated with fewer episodes of diabetes-related ketoacidosis (DKA) in both insulin pump and MDI users and lower HbA_{1c} (9). However, this same analysis also identified important racial and ethnic disparities in technology use for individuals with type 1 diabetes. A qualitative analysis of 55 parents of children with type 1 diabetes identified perceived CGM benefits to the parents of decreased worry, improved sleep, increased sense of safety, and greater comfort with other caregivers (10). For people living with type 1 diabetes, using CGM is associated with reduced fear of hypoglycemia and improved quality of life (11).

Data from single-center studies suggests that early initiation of CGM positively impacts glycemic outcomes at a year or more from diagnosis. Early initiation in the new-onset period has been shown to be feasible and well accepted (12). A single-center study found that early initiation of CGM within 6 months of diagnosis improves HbA_{1c} about 2% at 6 months and 1.5% at 12 months postdiagnosis (13). Another single-center study found that initiating CGM within 12 months of diagnosis resulted in sustained HbA_{1c} improvement of about 2% up to 7 years following diagnosis; however, the number of patients included at

the end of follow-up period was only about 25% because of high study attrition (14). A multicenter study including young children ages 5–9 years also suggested that early initiation of CGM improved HbA_{1c} at 1 year following diagnosis (15).

The T1D Exchange Quality Improvement Collaborative (T1DX-QI) is a multicenter diabetes learning health network in the United States that aims to improve outcomes for people with type 1 diabetes by promoting electronic health record data sharing for real-world studies, quality improvement, and benchmarking (16–20). There are over 60 data-sharing participating centers, including 25 pediatric centers in the T1DX-QI network (1,18).

This multi-institution study leveraged data from across the 25 pediatric centers in the T1DX-QI to evaluate the association between the timing of CGM initiation and HbA_{1c} at 3 years postdiagnosis for children and adolescents with type 1 diabetes.

RESEARCH DESIGN AND METHODS

Data Source

Data were obtained from the data-sharing pediatric diabetes centers in the T1DX-QI network. The Western-Copernicus Group Institutional Review Board centrally approved this as an exempt population-based study with Health Insurance Portability and Accountability Act consent waived, as no identifiable information was used. The centers also obtained necessary ethical approvals to share deidentified data with T1DX-QI. Previous publications have described this database from the T1DX-QI (5,6). The T1DX-QI data specification and data collection methods are well-documented (21,22). There have been other real-world studies published using this data set (8,21,23–26).

Using this data set, this study included children and adolescents 18 years of age or younger diagnosed with type 1 diabetes between 2019 and 2020 who had at least one HbA_{1c} documented beyond 30 months from diagnosis (Fig. 1). All HbA_{1c} values from diagnosis to last follow up were included in the analysis. CGM use was obtained from the data set and includes start date and ongoing use. For those who initiated CGM, only those who had demonstration of ongoing CGM use were included in this analysis; otherwise, they were excluded. Demographics

and diabetes management variables included age at diagnosis, gender (female/male/nonbinary or other), health insurance type (public/private/other), preferred language, diabetic ketoacidosis at diagnosis (yes/no), and insulin pump use or AID system (yes/no). Race and ethnicity were obtained from the data set but are collected variably at each center. Most T1DX-QI centers report this as a self-identified metric, and in this way, the metric is included in the analysis as a social construct rather than a biological variable. Glycemic outcomes over time were captured with clinically obtained HbA_{1c} levels.

Study population was classified into four groups based on timing of CGM initiation compared with type 1 diabetes diagnosis: 0–3 months, 3–6 months, 6–12 months, after 12 months, or not initiated within study follow-up period. Categorical variables were analyzed across subgroups using the χ^2 test, while continuous variables were compared using one-way ANOVA. To evaluate HbA_{1c} trajectories over time, locally estimated scatterplot smoothing plots were used to evaluate the relationship between timing of CGM initiation and HbA_{1c}. Logistic regression models, both adjusted and unadjusted, were used to evaluate the impact of potential confounders on the relationships between CGM initiation timing and HbA_{1c} trends. Models were adjusted for age, gender, race and ethnicity, health insurance type, preferred language, baseline HbA_{1c}, and insulin pump and AID system use.

Data and Resource Availability

The data sets analyzed in the current study are available from the corresponding author upon reasonable request.

RESULTS

Study Population Characteristics

There were 4,164 children and adolescents with type 1 diabetes included in this analysis over the 3-year study period, of whom 93% started a CGM within a 36-month follow-up period ($n = 3,877$) including 49% starting within 12 months ($n = 1,905$) (Table 1). The mean age of the cohort was 12.6 (SD 3.5) years, and 37% had public health insurance ($n = 1,548$). Of the cohort who initiated CGM ($n = 3,877$), 21% initiated between 0 and 3 months of diagnosis, 14% between

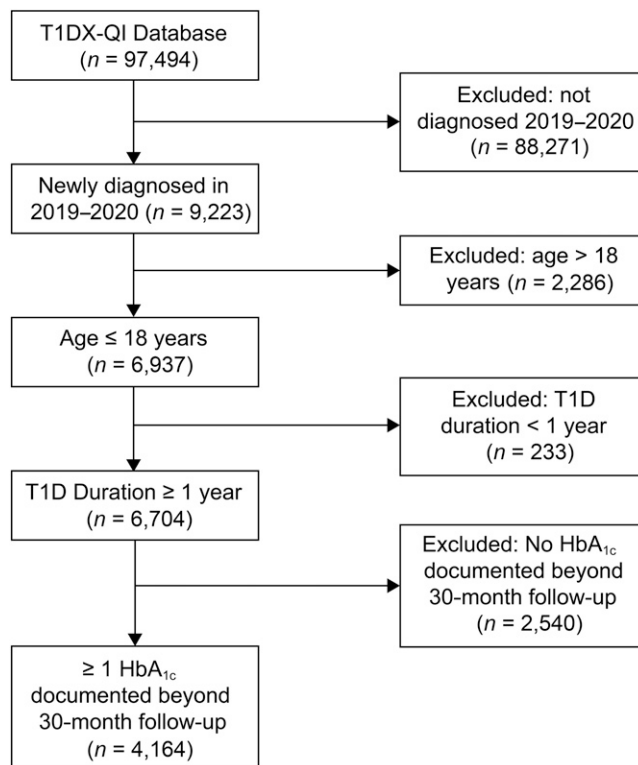


Figure 1—Study inclusion and exclusion criteria.

3 and 6 months, 14% between 6 and 12 months, and 51% after 12 months.

Comparison of CGM and Non-CGM Groups

Compared with CGM initiation groups, those who did not initiate CGM were slightly older, male, more commonly using public health insurance, from racial and ethnic minority groups, and preferring Spanish language. Of those with public health insurance, 11% did not initiate a CGM at all, compared with 4% of those with private health insurance (166 of 1,548 vs. 86 of 2,103). The timing of CGM initiation was also varied by health insurance type, as 24% of those with public insurance started CGM within 6 months, compared with 40% of those with private insurance (378 of 1,548 vs. 841 of 2,103).

Additionally, the non-CGM user group was less likely to use an insulin pump or be started on an AID system, consistent with the requirement of CGM for AID use. AID system use was more likely in early CGM initiation groups, with 25% of those in the 0–3 months initiation group, 21% in the 3–6 months group, and 16% and 15% in the 6–12 months and after 12 months groups, respectively.

Median (interquartile range) HbA_{1c} was different across groups, and the group who initiated within 3 months had the lowest at 7.6% (6.8–8.6) compared with the non-CGM group at 9.0% (7.4–11.1). Rates of DKA were also significantly higher in the non-CGM user group during the follow-up period, with the largest difference between non-CGM users and 0–3 months initiation groups (13.1 vs. 6.1 per 100 person-years).

We evaluated the distribution of CGM initiation by self-reported race and ethnicity to identify influences of disparities on CGM access and use. Non-Hispanic Black and Hispanic or Latino individuals were less likely to initiate CGM early, with 13% of Non-Hispanic Black and 16% of Hispanic or Latino populations initiating CGM between 0 and 3 months of diagnosis, compared with 29% of the non-Hispanic White population (Fig. 2).

CGM Timing and HbA_{1c} Outcomes

Impact of CGM Initiation Timing on HbA_{1c} over Time

To evaluate trajectory of HbA_{1c} over time by CGM initiation group, a locally estimated scatterplot smoothing plot is shown in Fig. 3. The HbA_{1c} trajectory across all subgroups generally follows

the expected postdiagnosis drop. Nadir in this population is closer to 9 months, a bit later than previously described, before rising to a steady state (2,3). Those who initiated CGM in the earlier two groups (0–3 and 3–6 months) had the lowest HbA_{1c} throughout, including at 36-month follow-up. The CGM user groups who initiated between 6 and 12 months and after 12 months had the largest differences between HbA_{1c} during that 6- to 12-month period before converging out to 3 years. Contrasted with this, the HbA_{1c} of non-CGM users is highest throughout the 36 months.

Given the differences between CGM user groups at baseline, further analyses were completed to evaluate impact of potential confounders on HbA_{1c} findings. Unadjusted models showed the 0–3 months group had a significantly higher odds of ever having HbA_{1c} < 7% than all other groups (Supplementary Table 1). Specifically, the 0–3 months group had 28–39% higher odds than the other CGM user groups, and 44% higher odds than the non-CGM user group. Additionally, those who initiated CGM between 0 and 3 months were significantly less likely to have HbA_{1c} > 9%. Models were then adjusted for age, gender, race and ethnicity, health insurance, preferred language, baseline HbA_{1c}, and insulin pump and AID system use. The 0–3 months group maintained significantly higher odds of having HbA_{1c} < 7% than the after 12 months group (odds ratio [OR] 0.80 [0.65, 0.98]). Adjusted models showed the 0–3 months group maintained significantly lower odds of HbA_{1c} > 9% than the 6–12 months, after 12 months, and non-CGM user groups. Specifically, non-CGM users had 76% higher odds of having an HbA_{1c} > 9% than the 0–3 months group (OR 1.76 [1.25–2.47]).

CONCLUSIONS

This was a multicenter analysis of more than 4,000 children and adolescents with type 1 diabetes from 25 pediatric diabetes centers across the United States that showed lower HbA_{1c} after 3 years of follow-up for individuals able to initiate CGM within 3 and 6 months of type 1 diabetes diagnosis. Median HbA_{1c} throughout the follow-up period was also lowest for those able to initiate CGM within 3 and 6 months of diagnosis. This trend

Table 1—Summary of study population

	CGM initiation in 0–3 months	CGM initiation in 3–6 months	CGM initiation in 6–12 months	CGM initiation after 12 months	Non-CGM user	P value
No.	825	541	539	1,972	287	
Age at diagnosis (years), median (IQR)	12.9 (9.7, 15.4)	13.2 (10.3, 15.4)	13.3 (10.3, 15.4)	13 (9.9, 15.5)	14.8 (12.1, 16.4)	<0.001
Gender (female)	397 (48)	272 (50)	260 (48)	957 (49)	129 (45)	0.01
Health insurance type						<0.001
Public	209 (25)	169 (31)	218 (40)	786 (40)	166 (58)	
Private	525 (64)	316 (58)	248 (46)	928 (47)	86 (30)	
Other	91 (11)	56 (10)	73 (14)	258 (13)	35 (12)	
Race and ethnicity						<0.001
Non-Hispanic Black	83 (10)	80 (15)	90 (17)	317 (16)	78 (27)	
Hispanic or Latino	90 (11)	64 (12)	105 (19)	235 (12)	61 (21)	
Non-Hispanic White	566 (69)	325 (60)	272 (50)	738 (37)	77 (27)	
Other/not reported	86 (10)	72 (13)	72 (13)	682 (35)	71 (25)	
Preferred language						<0.001
English	792 (96)	520 (96)	484 (90)	1,759 (89)	222 (77)	
Spanish	22 (3)	16 (3)	34 (6)	157 (8)	49 (17)	
Other	11 (1)	5 (1)	21 (4)	56 (3)	16 (6)	
Pump use (yes)	681 (83)	417 (77)	383 (71)	1,072 (54)	32 (11)	<0.001
AID system (yes)	208 (25)	115 (21)	86 (16)	305 (15)	0 (0)	<0.001
Median A1C (IQR)	7.6 (6.8, 8.6)	7.7 (7, 8.8)	8.1 (7, 9.4)	8.1 (7.1, 9.4)	9.0 (7.4, 11.1)	<0.001
Median time in range (IQR)	59 (47, 71)	58 (42, 69.8)	54 (37, 68)	53 (37, 68)	n/a	<0.001
DKA at diagnosis (yes)	55 (7)	79 (15)	46 (9)	72 (4)	11 (4)	<0.001
DKA per 100 person-years	6.1	9.8	11.4	8.8	13.1	<0.001
SH per 100 person-years	3.2	2.7	2.3	2.1	2.2	0.08

Distribution of $n = 4,164$ children and adolescents by timing of CGM initiation after type 1 diabetes diagnosis. All data are presented as mean (SD) unless otherwise defined. IQR, interquartile range.

persisted when controlling for age, gender, race and ethnicity, health insurance, preferred language, baseline HbA_{1c}, and insulin pump and AID system use, suggesting early initiation of CGM is associated with lower HbA_{1c} at 3-year follow-up. This is the largest-scale longitudinal analysis that demonstrates improved glycemic outcomes out to 3 years after diagnosis with early CGM initiation (13–15). Building on prior findings, these data support early introduction of this important technology to children and adolescents with a new diagnosis of type 1 diabetes.

The association between early CGM initiation and lower HbA_{1c} over 3 years is likely multifactorial. With continuous access to glycemic levels and customizable alerts to rising or falling glucose levels, CGMs provide awareness to the wearer and anyone sharing data (27). Access to these data early after diagnosis likely accelerates learning about glycemic trends, leading to self-management

practices that improve glycemic levels. Specifically, when making decisions about insulin dosing or self-management behaviors, parents whose children use CGM are less likely to engage in hypoglycemia avoidance behaviors (28). Similarly, in adults with type 1 diabetes, CGMs may reduce the fear of hypoglycemia (11), which may affect insulin dosing or other diabetes self-management behaviors. Finally, early CGM uptake might accelerate the uptake of other diabetes technologies. Insulin pumps, particularly AID systems, are independently associated with increased time in range and lower HbA_{1c} (29). In this analysis, those who adopted CGM were also more likely to adopt insulin pumps and AID systems, particularly if CGM was started within the first 12 months. When controlling for insulin pump and AID use, however, HbA_{1c} outcomes at 36 months were improved for those with early access to CGM.

These real-world data also highlight disparities in technology access, both in

overall CGM use and also in timing of initiation. The lower rates of CGM use and later timing of initiation for children and adolescents with public health insurance is consistent with prior findings and likely represents a combination of variable coverage but also differences in socioeconomic status (30). Adolescent-reported barriers to CGM use highlight cost and insurance coverage as a top concern, followed by wear-related issues, and these barriers could be modifying these findings (31). In addition to structural barriers of cost and insurance coverage, additional barriers could include education access and quality, social norms around use, and structural inequities around access. Given that social drivers of health may underscore barriers at each of these levels (patient, provider, health care system), screening for and addressing social drivers of health is imperative for addressing this disparity (32,33). Advocacy work should continue to push state public insurance

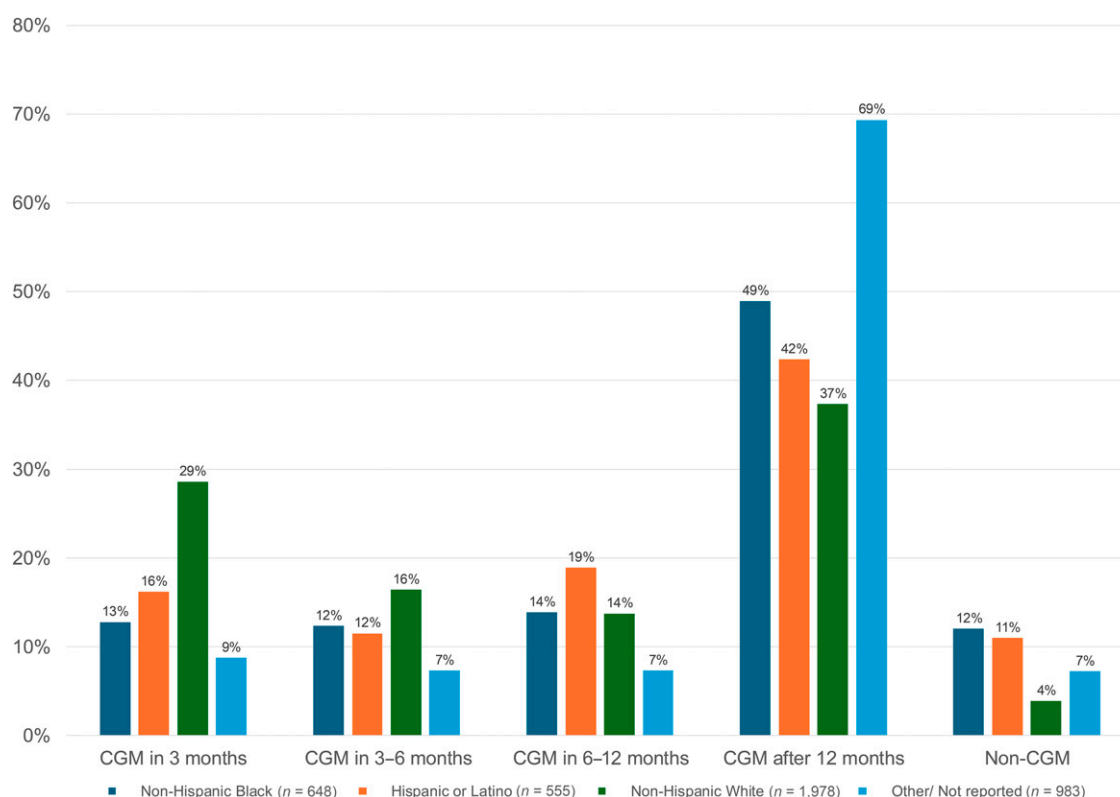


Figure 2—Timing of CGM initiation by self-reported race and ethnicity in children and adolescents with type 1 diabetes. Included in Other: Asian, American Indian/Alaska Native, Pacific Islander.

plans to universally cover CGM as a pharmacy benefit (34,35) rather than as a durable medical equipment benefit and encourage private insurance plans to lower out-of-pocket costs for their members. These efforts will improve access, lead to more timely initiation, and reduce prescribing burden for providers.

Racial and ethnic disparities were also identified in this cohort, with children and adolescents who self-identified as non-Hispanic Black or Hispanic more likely to have delays in CGM initiation or not use it at all compared with those who identified as non-Hispanic White. This disparity represents the impact of structural racism on diabetes management in marginalized children and adolescents. Given the impact of structural racism on type 1 diabetes management and outcomes, and the rising availability of diabetes technology, these disparities need to be addressed to prevent further widening of the gap (9). A recent analysis of over 100 pediatric and adult endocrinologists demonstrated provider implicit bias to recommend diabetes technology based on insurance and race and ethnicity (36).

Future efforts to support equitable CGM use, therefore, need to focus on addressing provider implicit bias and building systems to support early CGM initiation. Efforts should be made at the state and national levels to improve access universally, but this may not be enough to close the gaps in access (37). There also need to be interventions targeted at increasing CGM uptake by individuals from disadvantaged or marginalized populations to reduce disparity (38,39).

It is well known that the use of insulin pumps, particularly AID systems, is associated with improved glycemic levels (29). In this cohort, those who initiated CGM at any point were more likely to use both continuous subcutaneous insulin infusion and AID. While this may represent individual preference and lack of barriers to accessing technology, it may also suggest that starting CGM early lowers barriers to starting other technology. Because AID systems have been demonstrated to improve outcomes, they are now recommended as standard of care for all people with type 1 diabetes (7). Because AID systems depend on CGM, increasing use of CGM

can increase uptake of AID systems and potentially further improve outcomes.

There are several important limitations to this study. First, because the data represent associations for children and adolescents in the real world, there are likely many confounders contributing to the association between CGM initiating timing and glycemic outcomes beyond what can be controlled in adjusted analyses. Given that the HbA_{1c} outcomes persisted when adjusting for many demographic and social determinants of health, however, they are suggestive that a true association exists. The longitudinal and observational nature of data collection, while increasing strength of association with HbA_{1c}, limited the ability to measure patient-reported outcomes outside of routine clinical care, like quality of life measures. Early CGM initiation has previously been shown to improve patient and caregiver quality of life (5,6,10,11), and clinicians should consider all these benefits when prescribing CGM. Access to CGM is highly variable by state policies and local practices, which also influences timing of CGM initiation. Children and adolescents in this study represented

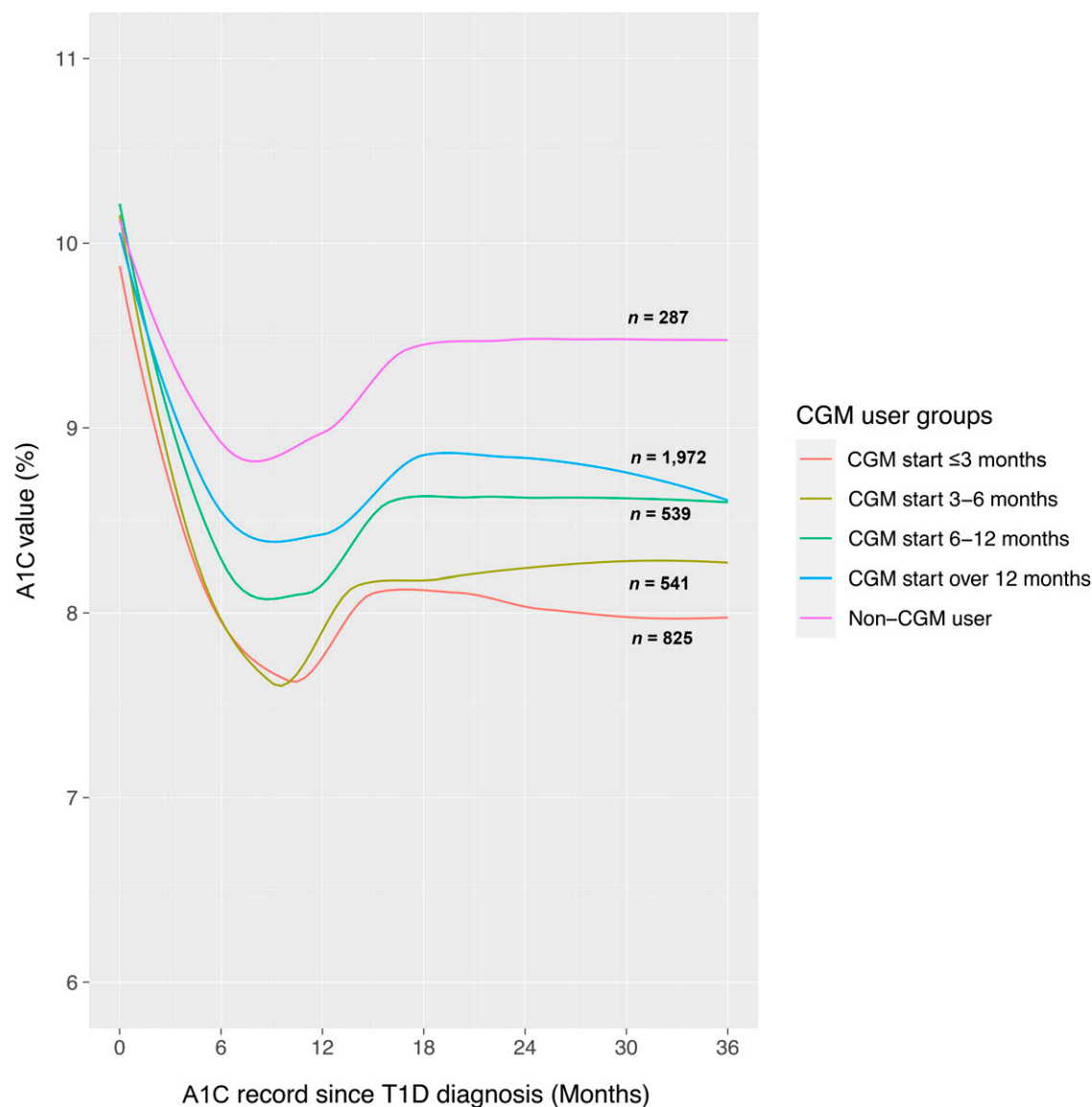


Figure 3—HbA_{1c} trajectories by CGM initiation groups from time of diagnosis of type 1 diabetes to 36 months in children and adolescents.

25 clinical diabetes centers across the T1DX-QI Collaborative and therefore are more likely to be representative across the United States. Another limitation is that, while data were collected from electronic medical record data uploaded by clinical centers, some variables are captured by self-report, and therefore there are gaps and potential inaccuracies associated with that data collection method. The data collection period also included the early years of the coronavirus disease 2019 pandemic, which caused interruptions in the health care system, potentially contributing to gaps in clinical data.

Continuous glucose monitoring metrics derived from the CGM, including time in range (70–180 mg/dL), were not

collected early in this data set, making time-in-range data availability limited for this study, so these data were not included in this analysis. The T1DX-QI data set now does include time in range in addition to percent wear in the last 14 days, so future studies can evaluate these outcomes in addition to HbA_{1c}. Finally, in this analysis, the use of intermittent scan-continuous glucose monitors (is-CGM) was included along with all CGMs. While the functionality differs between continuous and is-CGM, outcomes are demonstrated to be similar (40). Given the expansion and availability of CGMs, the prevalence of is-CGM systems in pediatric type 1 diabetes will likely continue to decline.

Building on these findings that early CGM initiation is associated with lower

HbA_{1c} at 3 years after diagnosis, future studies will explore the persistence of glycemic improvement beyond 3 years measured by HbA_{1c} and time in range. The association between timing of CGM initiation and time to AID use will also be explored. To address the impact of social determinants of health and structural racism on CGM access, efforts to address disparities in CGM use are underway via local quality improvement efforts across the T1DX-QI Collaborative.

CGM uptake within the first 6 months of type 1 diabetes diagnosis is associated with lower HbA_{1c} up to 3 years after diabetes diagnosis. Unfortunately, early uptake of CGM is significantly lower in children and adolescents from marginalized communities. Therefore, early CGM

uptake should be standard of care, with efforts focused on increasing uptake in historically marginalized children and adolescents.

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Duality of Interest. O.E. is an advisor for Medtronic Diabetes and Sanofi. O.E. is the principal investigator for several studies funded by Eli Lilly, Insulet, Dexcom, Tandem, Vertex, and Medtronic. Financial transactions for all industry-funded studies are through his organization, T1D Exchange. P.P. is a consultant for Sanofi. D.J.D. has served as independent consultant for Dexcom and Insulet separate from this work, and his institution has received research support from Medtronic and Insulet. H.K.A. received, through University of Colorado, research support from Dexcom, Tandem, Abbott, and Medtronic and received honoraria from Dexcom, Tandem, and Medtronic. No other potential conflicts of interest relevant to this article were reported.

Author Contributions. E.A.M. and P.P. contributed to the discussion, conceptualized the study, and wrote the first draft of the manuscript. S.R. contributed to the discussion, performed data analysis, and edited the manuscript. B.M., N.R., H.H., L.G., J.S., H.K.A., J.L., D.J.D., P.G., and O.E. contributed to the discussion and edited the manuscript. All authors approved the final version of the manuscript. E.A.M. 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.

Prior Presentation. These data were presented in an oral presentation at the 83rd Scientific Sessions of the American Diabetes Association, San Diego, CA, 23–26 June 2023.

Handling Editors. The journal editors responsible for overseeing the review of the manuscript were Elizabeth Selvin and Michael J. Haller.

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