Use of Continuous Glucose Monitors in Publicly-Insured Youth with Type 2 Diabetes – A Pilot and Feasibility Study.

PI: Sejal Shah MD
Division of Pediatric Endocrinology
Stanford University
Stanford, CA 94304
E-mail: sshah2@stanford.edu

Co-Investigators:
Korey Hood, PhD
Professor of Pediatrics
Professor of Psychiatry and Behavioral Sciences
Lucile Packard Children's Hospital, Stanford Children's Health
Palo Alto, CA 94305
E-mail: Kkhood@stanford.edu

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Summary

The prevalence of type 2 diabetes in youth is rising in all age, sex, and race/ethnicity groups that disproportionately effects minority youth and those of lower socioeconomic status. Type 2 diabetes in youth is a more aggressive disease compared to adult-onset type 2 diabetes. Youth with type 2 diabetes have higher rates of diabetes complications, specifically cardiovascular and kidney disease compared to youth with type 1 diabetes and similar duration of disease. Diabetes care is a difficult, life-long undertaking by patients, their caregivers and their healthcare team. Treatment of type 2 diabetes includes lifestyle and diet management along with medications including multiple daily injections of insulin, often occurring in a complex psychosocial and cultural environment that make durable adherence to medical recommendations challenging. In the last few years continuous glucose monitors (CGMs) have become available for clinical use by children with type 1 diabetes as an alternative to self-monitoring blood glucoses, improving blood sugar control and quality of life for youth with type 1 diabetes. However, our patients with type 2 diabetes and public insurance have not been able to benefit from this technology due to a lack of insurance coverage for CGM in this patient population. We propose a pilot and feasibility trial to start CGM in youth with type 2 diabetes and public insurance, using established clinic workflows within our clinic. This feasibility trial would fill a gap in the literature with respect to CGM use in youth with type 2 diabetes in a real-world setting. The findings from this trial can provide much needed data to impact CGM coverage policy for publicly insured youth with type 2 diabetes in California and pave the way for future studies using CGM technology in this population.

Specific Aims

We propose a pilot and feasibility trial to use continuous glucose monitoring (CGM) in youth with type 2 diabetes (T2D) and public insurance. This feasibility trial would fill a gap in the literature with respect to CGM use in youth with type 2 diabetes. The findings from this trial can provide much needed data to pave the way for future studies using CGM technology in this population. Our proposal is focused on youth with public insurance, seeking to provide diabetes technology for patients and their families to use in daily diabetes management. This pilot is an expansion of our existing program of CGM access to youth with type 1 diabetes which has led to an improvement HbA1C of 0.5% over 1 year and positive feedback from patients and families.[1,2]

Specific Aim 1: Evaluate the feasibility of CGM start and continuation in youth with T2D and describe glucose metrics and patient reported outcomes (PROs). We will pilot and refine a program to test the hypothesis that CGM start and continuation in youth with T2D is feasible and then evaluate glucose metrics and PROs.

Hypothesis 1a: In phase 1, CGM use exceeding >50% of participants will be feasible and sustainable in youth with T2D, measured by days of CGM use per 2-week period (>75%). **H1b:** Following an additional needs assessment after phase 1, in phase 2 sustained CGM use per 2-week period (>75%) will exceed 75% of participants. **H1c:** Based on completion of PROs surveys, it is expected that diabetes-specific distress will decline, and overall well-being/quality of life will improve. Secondary outcome PROs (see protocol synopsis) collected at baseline will be associated with HbA1c and diabetes management outcomes. Data on glucose metrics, SDOH, and needs and barriers will be described.

Specific Aim 2: To assess the clinical outcomes (HbA1C, time in range [70-180 mg/dL], time in hypoglycemia [<70 mg/dL]) of individuals participating in this trial compared to clinic historical controls.

Hypothesis 2: Use of CGM will improve HbA1C and other clinical metrics of diabetes glucose control.

Measured Outcomes:

1. Sustained use of CGM by patients over one year measured by days of CGM use per every 2-week period with >80% as goal.
2. Change in HbA1C over first year of CGM use
3. Glucose profile metrics: percentage time in range, time in hypoglycemia, and time in hyperglycemia obtained from CGM.
4. Change in weight and BMI over first year of CGM use using clinic visit weight and BMI measurements.
5. PROs

Unmeasured, but documented metrics:

Reported challenges with CGM use as documented by clinical team (MD/NP, CDE)

Tracking of patients who are able to obtain insurance coverage for CGM at completion of study

Background and Significance

T2D is **increasingly affecting children of minority and lower SES backgrounds, with higher rates of diabetes complications, specifically cardiovascular and renal co-morbidities in youth with T2D compared to youth with T1D** and similar duration of disease [3–6]. Two national multi-center studies, the RISE Consortium and the Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) Study reported more rapid beta-cell damage, disease progression, and diabetes-related complications in youth compared to adults, highlighting the need for improved clinical management and treatment for these patients[6–8]. By one year after diagnosis, a majority of youth with T2D are not meeting HbA1c targets recommended by the ADA and the International Society of Pediatric and Adolescent Diabetes (ISPAD)[9–11]

Treatment of T2D includes lifestyle and diet management along with medications often including multiple daily injections of insulin, frequently in a complex psychosocial and cultural environment that challenge durable adherence to medical care. CGM is available for youth with T1D as an alternate to self-monitoring blood glucoses (SMBG) and data in adults with T2D demonstrates efficacy and cost effectiveness[12–14]. Youth with T2D have similar SMBG and insulin requirements, but have little to no access to CGM due to a lack of insurance coverage, usually public insurance, for CGM in this patient population.

Data from the SEARCH for Diabetes in Youth study found that over 50% of youth with T2D had <3 SMBG per day and almost 25% had <1 daily[15]. Diabetes distress is well recognized as a factor that impacts both glycemic outcomes and diabetes self-care behaviors, such as SMBG[16]. The use of digital health tools and technology in T2D care has the potential to increase access but also to widen disparities in care, highlighting the need for further study of CGM use in youth with T2D. Use of CGM and digital health tools in Latinx adults with T2D has been shown to be effective in short-term pilot studies[17]. The benefit of CGM has expanded to adults with T2D using basal insulin only. In a recent randomized controlled trial of CGM use compared with SMBG in adults with T2D (53% minority race/ethnicity) showed a significant reduction in HbA1c of 0.4%, demonstrating benefit of CGM use in a broader population of adults with T2D[18]. The evaluation of CGM use in youth with T2D, with specific attention to factors that influence uptake and sustained use of diabetes technology in this population is necessary due to rising incidence of T2D in youth and higher rates of diabetes complications manifesting at earlier ages thereby depriving Latinx youth with T2D of a healthy future.

In the last few years continuous glucose monitors (CGMs) have become available for clinical use by children with type 1 diabetes as an alternative to self-monitoring blood glucoses. The use of CGM has consistently demonstrated an improvement in glycemic control and quality of life in youth with type 1 diabetes.[19,20] CGMs are revolutionizing pediatric diabetes care with significant gains for youth with type 1 diabetes and are now the recommended standard of care for youth with diabetes.[20] CGM initiation in youth with type 1 diabetes is feasible and well accepted and our clinic is a leader in doing so.[21] While there has been an exponential rise in CGM use in youth with type 1 diabetes, youth with type 2 diabetes who have similar SMBG and insulin requirements, have had little to no access to CGM. CGM use in adults with T2D has proven to be both efficacious and cost effective.[12–14] However, our patients with T2D and public insurance (California Children's Services and/or Medi-Cal) have not been able to benefit from this technology due to a lack of insurance coverage for CGM in this patient population.

Preliminary Studies

Significant improvements in HbA1C have been shown in youth with type 1 diabetes with public insurance with uninterrupted CGM use.[22] This real-world data in youth with type 1 diabetes has complimented research study data and paved the way for earlier and easier CGM approval for youth, particularly publicly insured youth.

Our team has shown that youth with T1D with public insurance who have uninterrupted CGM use compared to those who lose CGM coverage due to insurance issues have significant improvements in HbA1c[22,23]. This real-world data in youth with T1D has complimented research study data and paved the way for earlier and easier CGM approval for youth, particularly publicly insured youth. We aim to translate these learnings to our T2D population. In our clinic, youth with T2D have a mean HbA1c of 8.6% with only 35% at goal HbA1c of <7% (n=311 HbA1c values), indicating that the majority of youth with T2D are not meeting this significant diabetes therapy goal. Reflective of the national data demonstrating youth with T2D are overwhelmingly minorities and from families of lower SES, a significant portion of our T2D patient population (n=131) is publicly insured (77%), minority status (73% and Latinx 66%), and has Spanish-speaking parents or guardians (56%), all groups which have lower rates of diabetes technology use[11,24].

Design: This will be a two-phase pilot program focused on youth with T2D to evaluate initiation and sustained use of CGM. The focus of phase 1 will be a feasibility trial to use CGM in 30 youth with T2D and public insurance over a 12-month period. CGM will be provided to all participants. Education for youth and their families about CGM integration in diabetes care will be provided throughout the study. Barriers to CGM adoptions and sustained CGM use will be tracked throughout this phase to inform the further refinement of the program in phase 2 in 50 youth with T2D. As part of closing the disparities in diabetes technology use in youth with T2D, QoL and PROs will be evaluated. The goals of phase 2 are to utilize human factors design data, QoL and PRO metrics collected in phase 1 to address identified needs and barriers to increase initiation and continued use of CGM in this population.

Inclusion criteria

1. Diagnosis of T2D (diabetes autoantibody negative) followed in the Pediatric Endocrinology clinic at Stanford Children's Health
2. HbA1C greater than 6.5% at enrollment. This is to enroll patients who are working on improving glucose control but are still not meeting HbA1c targets.[9,25]
3. Interested in starting on a continuous glucose monitor
4. Access to a mobile device that is compatible with CGM applications or willing to use CGM receiver which will be provided. Both the receiver and mobile device allows patients to view glucose data and alerts from the CGM and upload glucose data during or in between in-person or virtual clinic visits, not necessitating that the participant have access to a mobile device.
5. Public insurance
6. Age 4-20 years inclusive

Exclusion criteria

1. Non-T2D diagnosis
2. HgA1C < 6.5%
3. Participant not willing to wear CGM
4. Private insurance

Procedures and Methods

Recruitment: The study team will review clinic schedules to identify youth with T2D from the patients in our clinic who would qualify. The informed consent process with be conducted prior to initiating the study. Following CGM initiation by a CDE, youth will have a routine 1-week clinic follow up with our diabetes team and then will be seen per clinic standard of care, every 3 months thereafter for the 12 months of the study duration. At each visit we will collect descriptive data on CGM use, CGM glucose metrics, and provide CGM supplies. PROs will be evaluated at three time points during the study. In phase 2, we will identify a new cohort of eligible patients who will be evaluated at a similar cadence as phase 1.

Visit	1	2	2a	3	3a	4	4a	5	5a	6
Weeks from start	x	2 weeks	4-6 weeks	12 weeks	4-6 weeks	12 weeks	4-6 weeks	12 weeks	4-6 weeks	12 weeks
Informed consent and assent	x (can be done In person or via TH)									
Visit Type ** this will be modified if LibreView App is available during study duration, can move visits to TH with lab A1C	In person	IP/TH	phone/IP	IP	phone/IP	IP	phone/IP	IP	phone/IP	IP
Demographics	x									
Diabetes History	x									
HbA1C	x			x		x		x		x
CGM start	x									
PROs	x			x						x
CGM metrics	x	x		x		x		x		x
CGM education	x	x		x		x		x		x
CRC check on supplies (confirm use and shipment)	x	x	x	x	x	x	x	x	x	x
Final study visit										x

Visit 1:

- Participants will be offered the opportunity to start on CGM at their scheduled clinic visit
- Participants will receive CGM education from a certified diabetes educator (CDE)
- The care team member initiating the CGM will ask patients and their caregivers if they are interested in hearing about this study to understand the use of CGM in youth with type 2 diabetes
- If a patient and/or caregiver is interested in this study, one of the study team members will discuss the study with the participant and obtain informed consent and assent (if needed).
- Participants who consent to be part of this study will have the appropriate CGM applications and readers active (Libre 2 CGM, LibreView, LibreLink) as per standard clinical care.

1. Informed consent and assent - this can be done in person or virtually
2. CGM start – done by CDE in clinic
    a. 4 weeks of supplies given – CRC to confirm with family preferred way to get supplies every 6 weeks and best way to contact them.
    b. Standard clinic CGM education
3. Routine clinic visit

4. PRO completion - participants who speak and write English and Spanish will be asked to complete PROs surveys

Visits 2a,3a,4a,5a:

1. CRC check in with family/patient
    a. Confirm CGM use
    b. Address CGM issues – CRC to address or forward to CDE if clinical question
    c. Ship or arrange for supply pick up (6 weeks of supplies)
    d. Confirm next clinic visit

Visits 2,3,4,5,6:

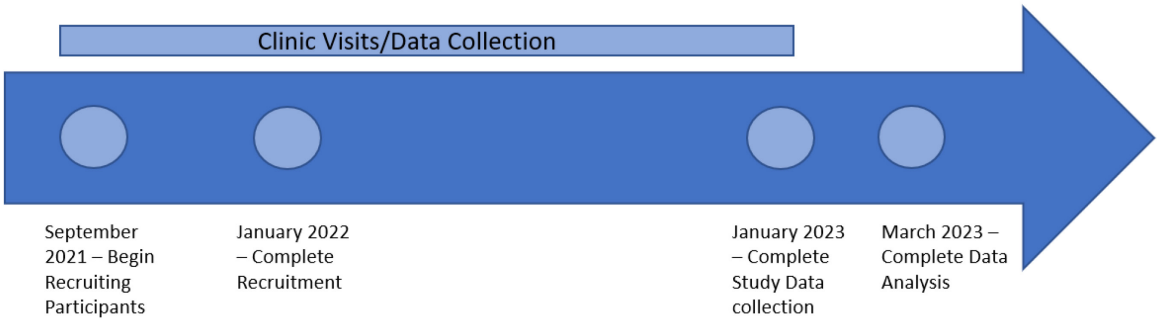
1. Routine Clinic visit including CDE visit. The purpose of these visits is to reinforce prior teaching, answer questions, and review CGM data, making changes as necessary to the patient's care regimen to better control their diabetes.
2. CRC check in, supplies provided (for all visits except visit 6)
3. PRO questionnaires administered for visits 3 and 6

Biostatistical plan

Statistical methods: We will generate descriptive statistics for all participants included in the study and will create a STROBE diagram[26] to describe participants screened, recruited, and followed in both study phases. To address the feasibility of CGM use in T2D, we will estimate the proportion of participants who have sustained CGM use in both phase 1 and 2. Our feasibility analysis will include all participants. To address H1c, we will fit linear regression models using GEE to estimate the association of PROs with longitudinal HbA1c. Logistic regression models fit with GEE will be used to estimate the association of PROs with dichotomous diabetes management outcomes (e.g., presence of diabetes distress).

At each visit we will collect descriptive data on CGM use, clinical glucose outcome metrics, and provide CGM supplies. Mixed affects modeling will be used to characterize the trajectory of measured variables and to account for patient-level correlation of this data. To account for gaps in CGM use we will use intention to treat analysis and consider a censoring method for a patient who leaves the practice or are lost to follow up. We will also perform an exploratory analysis of the relationship at a patient-level between days of CGM wear and time in range.

Study Timeline



Data Collection and Entry

1. Study participant data entry will be collected and entered in Stanford RedCap by the study team.
2. PRO will be collected in RedCap

The initial survey is filled out in person during the CGM visit during which, parents provide an email that will be the platform for contact for the future surveys. At the follow up points, the RedCap data base will automatically trigger survey link to the email on file. If the survey is not completed, a second email is sent as a reminder followed by provider team reminders. Participant data will be included for analysis for the time frames that are available when.

These measures will assess issues of adherence or illness distress and provide valuable information for providers to better understand the impact of early CGM initiation. The patient/guardian will have the option of filling out the questionnaires in English or Spanish. Based on the evidence in the PROs literature and our clinical experiences, we have developed an algorithm for responding to PROs screen scores that are outside of the normative range triggers a response from social worker and/or diabetes psychologist[27]. Study personnel will complete a chart review to collect relevant health information including diagnosis, duration of disease, indicators of health status, and regimen information (e.g. medication, doses). These medical record data are required to assess the validity and usefulness of the clinical PROs screening measures. Additionally, reliability analysis will be conducted to examine the psychometric properties of the PROs measures, and the satisfaction questionnaire data will be aggregated to assess the acceptability of the PROs procedure from the patient's perspective.

- PROMIS global health (youth): BELOW 22 for the PROMIS global health scale. Anyone who scores 21 or lower would trigger an alert to place a diabetes psychology referral.

When psychosocial issues are identified through screening, referrals will be made to the psychology service staffed by 4 licensed psychologists. Treatment will follow guidelines provided in the ADA Position Statement on Psychosocial Care of People with Diabetes[28].

All aspects of data collection and data storage will be carefully monitored to ensure rapid detection of errors, inconsistencies or other problems. Data are reviewed systematically on a monthly basis throughout the data collection period so that data cleaning will happen close to "real time". The data collectors will follow a strict written protocol that describes study measures and details for conducting measures accurately and in a manner that protects data privacy. They will explain to each participant that s/he has the right to refuse to participate or to refuse to answer any individual question that s/he finds objectionable, and emphasize the importance of telling the truth. All institutions associated with this application are experienced in training data collection fieldwork personnel how to handle, store, and process sensitive and confidential data.

Certain routine administrative, personnel, physical security, information management, and computer system or network security practices are always in place. These practices include security, nondisclosure pledges, and account/keyword security on computer networks. In addition, we take multiple project specific steps to protect subjects from the risk of a breach in confidentiality. All data will be collected using study identification numbers. Thus, no questionnaire will contain identifying information, and the list that links identification numbers to names will be kept in a password-protected file that is accessible only to authorized staff at the respective clinical sites. Only aggregate data that cannot be used to identify individuals will be included in any reports released to other agencies or for publication.

PRO Surveys will be completed via RedCap and according to the following table:

Measure	***Respondent***	***Construct Measured / Relevant Points***
Paediatric **Quality of Life** Inventory (PedsQL) Diabetes	All youth and All parents	**YOUTH** - All youth ages 6-18 will complete age-appropriate PedsQL Diabetes module. Versions are included for 6-7 year-olds, 8-12 year-olds, and 13-18 year-olds. **PARENTS** – All parents complete a proxy version reporting on their child's quality of life. Versions of the parent proxy correspond to age of child.
Problem Areas in Diabetes – Pediatric (**Diabetes Burden**)	Youth 8-17 and all parents	**YOUTH** – Youth will complete this survey on psychological distress and burden associated with taking care of diabetes. Child survey for 8-11 years, Teen survey for 12-17 years. PARENTS – complete a proxy version as well as a report of their own distress.
Use of and Comfort with Technology	Youth ≥11, All parents	**YOUTH** – Youth ages 11-18 will complete this survey on use of and comfort with general technology and diabetes devices. **PARENT** – All parents complete the same questions on technology and devices.
PROMIS Global Health scale (PGH-7)	Youth ≥ 11	**YOUTH** – Youth will complete this survey on their overall health, integrating patient experiences across physical, mental and social health

Community Partnership and Engagement

Once complete, results from this study will be shared with medical leadership of California Children's Services (public insurance which provides coverage of diabetes-related care for our youth with type 2 diabetes) at the state and county level to advocate for coverage and access to CGM technology for all youth with type 2 diabetes. We will also engage with the Pediatric Endocrinology Family Advisory Counsel at Stanford Children's Health to combine results from this study with patient/parent advocacy efforts to gain insurance coverage for CGM in all youth with T2D.

Potential Pitfalls and Contingency Plans

Study participants are asked to attend clinic appointments as recommended by their care provider. Our clinic standard is to have patients attend at least 4 visit per year, on average 1 clinic visit every 3 months. There may be missed appointments. Efforts will be made to remind families of appointments the day before the visit by phone or MyChart messaging. If a patient misses an appointment, the team will make efforts to re-schedule the appointment and address barriers to attending clinic appointments. Participants may have challenges with CGM supplies, upload of glucose data, or questions about CGM use. Our team will be available to patients and their families to address these issues including attempts to avoid gaps in CGM supplies to support continuous use of CGM. If a patient misses more than 3 appointments or decides to stop using CGM they will be withdrawn from the study and asked to resume usual care. We are in the process of obtaining CGM supplies for all participants for the duration of the study to ensure continued access to CGM supplies. If we are not able to secure funding for CGM supplies we will use budgeted funds from this grant to cover the cost of CGM supplies for 50 participants over 6 months in place of salary support for a research assistant and home HbA1C kits, with the PI salary support going towards PI FTE towards completing study related tasks and working with participants to facility an in-person clinic visit. Even with a shorter duration, the study can provide meaningful pilot data about the feasibility of CGM use and key clinical outcomes in youth with T2D.

Future Steps

Data from this feasibility trial would fill a gap in the literature with respect to CGM use in youth with type 2 diabetes. The findings from this trial can provide much needed data to impact CGM coverage policy for publicly insured youth with type 2 diabetes in California and pave the way for future studies using CGM technology in this population.

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