2021 LEAD Capstone Poster Session

Real- time Remote Continuous Glucose Monitoring in high- risk adolescents with Type 1 Diabetes

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Abstract

- Hemoglobin A1C (HbA1C) targets are achieved by only 17% of the pediatric patients with Type 1 diabetes (T1D) in the United States
- Medication non- adherence and access to care contribute to sub-optimal HbA1C
- DKA risk score (EPIC)
  - Multivariate prediction model to identify a subset of patients with an increased risk of hospitalization
  - Variables include admission in the previous 12 months, HbA1C and non- commercial insurance

Objectives

- Improve HbA1C in patients who are at a higher risk of hospitalization by placing continuous glucose monitor (CGM) and remotely monitoring in real- time using a two-way texting messaging platform for communication with patients and their parents 12 hours/ day for a duration of 90 days
- Improve education and problem- solving skills with texting messages
- Improve access to technology by providing them CGM

Background Information

- Achieving optimal glycemic control in patients with T1D is a challenge, especially in the adolescent population
- The demands for self-care in this group is not trivial- expected to check blood glucoses 4 times/ day and administer 4-6 insulin injections/ day
- Poor glycemic control increases risk for acute diabetes complications including diabetic ketoacidosis (DKA) and increases risk for long-term complications including nephropathy, neuropathy, retinopathy, and macrovascular disease
- Neglectful parental supervision can lead to poor diabetes control which raises the question of potential role for a clinician in supervising and guiding diabetes management in real time

Specific Aims

- Improve HbA1C in the high-risk group based on the risk score
- Improve education- which includes the technical aspect of diabetes care and management skills in both patient and parents
- Improve access to care and technology

Project Plan- IRB Approved!!

Remote Realtime CGM Monitoring

This study involves:

- Placement and use of Dexcom G6 for study duration
- Real time monitoring of participants' blood sugars
- Use of protected messaging system to stay in close contact with participants
- 7 months study duration
- 4 visits

Highlights of Inclusion Criteria

- Age between 13-18
- Diagnosis of type 1 diabetes for at least six months.
- Subject and at least one parent able to communicate in English.
- Poorly controlled T1D as evidenced by a ≥40% annual risk of developing DKA in the following year
- Willing to wear CGM

Most Pertinent Exclusion Criteria

- Type 2 diabetes, secondary diabetes or CF related diabetes.
- Regular CGM for the month preceding study period.
- Other severe chronic disease (e.g., cancer)
- Developmental delay or behavioral disorder

If you have any potential candidates, please contact Pooja Choudhari (803-387-9144 or Teams/TigerText) or Dr. Abha Choudhary.

- Open-label, single-center, single-arm and two-period study
- Sample size: 20 adolescents aged 13-18 years
- Written informed consent from guardians, assent from study participants
- Main inclusion: T1D, **40% risk of DKA admission in the upcoming year based on our predictive model**

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Project Plan

Inclusion Criteria

Ages between 13-18 years

Diagnosis of type 1 diabetes for at least six months

Both sexes and all ethnicities included

Subject and one parent able to communicate in English

Poorly controlled T1D as evidenced by a > 40% annual risk of developing DKA in the following year

Treated with subcutaneous insulin, either with a basal/bolus insulin regimen or a continuous subcutaneous insulin infusion (CSII)

Willing to wear CGM and utilize the share function to clinician and guardian, with measuring blood glucose checks as required by the CGM.

Owning a smartphone compatible with Dexcom G6 software to allow the use of share/follow features with internet access capabilities

Willing to participate in secure text messaging

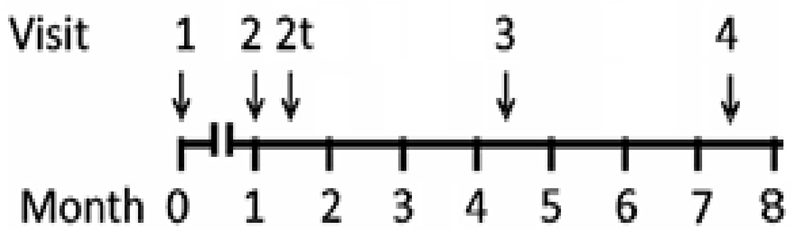
Female participants must have a negative pregnancy test

Exclusion Criteria

Type 2 diabetes, secondary diabetes, CF related diabetes
Other severe chronic disease (e.g., cancer) which can affect glycemic control
Patients on systemic corticosteroids at enrollment because of adverse effects on glycemic control, but we will not disqualify subjects who require such therapy during the study. Inhaled or topical corticosteroids are permissible.
Patients with hypothyroidism or hyperthyroidism must be clinically euthyroid and have free T4 and TSH within age-appropriate reference ranges at last test
Developmental delay or behavioral disorder in the patient of sufficient severity, in the judgment of the investigator, to interfere with study activities.
Medical or psychiatric disorder in a parent of sufficient severity, in the judgment of the investigator, to interfere with study activities.
Severe uncontrolled depression defined as PHQ-9A >9 at time of enrollment
Pregnancy, planned pregnancy or breast feeding
CGM adhesive allergy or skin condition that makes CGM placement contraindicated
Sickle cell disease or hemoglobinopathy
Red blood cell transfusion within 3 months prior to study

Project Plan

	Screening Visit (1)	Baseline Visit (2)	Telephone Follow-up (2t)	First Follow-up visit (3)	Second Follow-up visit (4)
Consent Inclusion/Exclusion	X				
Demographic Information	X				
Full physical exam		X		X	X
Vital signs		X		X	X
Height and Weight		X		X	X
Hemoglobin A1c		X		X	X
Blinded continuous glucose monitor placement		X		X	X
Un-blinded continuous glucose monitor placement			X		
Education about continuous glucose monitor use and placement		X		x	X
Review of CGM data			X	X	X
Establishing messaging platform with patient and parent		X			
Patient Health Questionnaire (PHQ-9A)		X		x	X
Pediatric Quality Life Inventory for teens 13-18, PedsQL4.0		X		x	X



Primary outcomes

- Primary outcome:

  Change in HbA1c between baseline visit (Visit 2) and three-month follow-up visit (Visit 3) after active remote monitoring and secure text messaging (paired t-test for statistical analysis)

- Safety outcomes

  DKA admission rates

  Severe hypoglycemia or hyperglycemia requiring ED visit or admission

  Moderate – large ketones

- Feasibility outcomes

  Log of time used by clinical personnel to monitor CGM use.

  Number of texts utilized

  Average time to read a text (read receipt time) and reply back

Secondary outcomes

- The difference in HbA1c between clinical remote monitoring HbA1c (Visit 3) and self-monitoring utilizing CGM (Visit 4)
- The difference in HbA1c from baseline (Visit 2) and after the two phases of the study intervention (Visit 4).
- Change in depression score (PHQ-9A)
- Change in quality-of life score (PEDS-QOL4)
- Change in Collaborative Parent Involvement Scale
- Change in SCI - Self-Report Measure of Self-Management of Type 1 Diabetes for Adolescents
- Change in Self-Efficacy for Diabetes Self-Management measure (SEDM)

The following outcomes will be compared between baseline, three months and six months using repeated measure ANOVA as follows:

Time spent in the target glucose range from 70–180 mg/dL

Time spent below target glucose 70 mg/dL

Time spent above target glucose 180 mg/dL

Average of time the participants wore the CGM

Application of What You Learned at LEAD

- Executive Coaching- helped me prioritize my academic goals and improve my time management skills
- Communication and Influence- helped me to advocate for resources to support my professional goals at UTSW
- Negotiation and communication skills to bring together the stakeholders
  - Dexcom investigator- initiated research program- CGM devices for the study
  - Division chief- funding, time and support
  - Diabetes educators – time for patient monitoring
  - Administrator – funding and educator time approval
  - Fellow- time for patient monitoring
- Delegation and teamwork – utilizing the team in this pilot project

Proposed Budget

- CDE time- 40 hours /week × 20 weeks × $40/hour = $32,000
- IPad devices for monitoring– 2 devices × $350/IPad= $700
- Incentive gift cards – $10 × 3 visits × 20 participants)= $600
- Dexcom CGM for 6 months – $2,270 × 20 participants= $45,400

Funding provided by Foundation funds
CGM is provided by Dexcom as a part of an investigator- initiated study
* CDE: certified diabetes educator

Innovation and Significance

- No published studies describing direct monitoring and oversight of CGM by medical professionals in an outpatient setting
- Pilot project is powered to detect a HbA1C change and if successful, it can be expanded to include more subjects to show a change in hospitalizations
- Formal reimbursable remote patient monitoring can be set up for a larger group of patients
- Can leverage technology for other disease states which are amenable to remote monitoring

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