Managing Type 1 and High Risk Type 2 Diabetes in the Hospital Setting: Glucose as a Vital Sign

Progress Report June 2019, IIS-2014-043

I. Enrollment

Total patient enrolled in study - 215 as of 6/30/19

Breakdown by site and type of diabetes as follows:

Hospital Site	Type 2	Type 1	Total Enrolled	Total Completed
Chula Vista	136	16	152	144
San Diego/Hillcrest	53	3	56	54
La Jolla	0	7	7	7
Total	**189**	**26**	**215**	**205**

II. **Study Completion -** Estimated Study Completion is December 2020

Enrollment has been challenging this year d/t staff turnover, but we expect to increase rate of enrollment now that we have new staff on board.

Our end point is the Type 2 enrollment for the Randomized Controlled Trial arm, versus the Type 1 which is not the RCT.

Scripps Digital Diabetes: Glucose as a Vital Sign

Update report for DRC-2018

Main goal of the research study:

To recruit patients with T1D identified during a hospital stay that qualify and are interested in using a DexCom continuous glucose monitoring (CGM) device during their hospitalization to share data with a specialized Advanced Practice Nurse (APN) for better insulin management and prevention of hypoglycemia.

Recruitment experience to date:

Total subjects recruited to date: 14

Recruitment efforts have expanded from our initial pilot site at La Jolla. Patients have been recruited from 3 different Scripps hospitals – Scripps Mercy San Diego, Scripps Mercy Chula Vista, and Scripps Memorial La Jolla, with the La Jolla and Chula Vista sites having the most success. Our efforts at Chula Vista have paralleled the study for patients with Type 2, and we have recently had success in identifying more patients with Type 1 diabetes who meet criteria at this site. This is likely in part due to our new partnership with on-site endocrinology services at that hospital over the past year which has allowed study staff to have more accurate and timely information regarding the patients' hospital course.

During the past year, a prolonged pause in recruitment at our La Jolla site was required due to the implementation of our new electronic medical record (EPIC) at that site in April 2018. Following EPIC implementation, additional time was needed to translate our research ordersets into the EPIC version from our paper ordersets. As a result, beginning in April 2018 recruitment was only focused at our two Mercy Hospitals. Despite the delays, recruitment is expected to reinitiate at all sites via our new EPIC system beginning in late October 2018 with greater opportunities to identify patients and systematically intervene.

Study updates: Protocol revision for Dexcom G6 device

In June of 2018, the study team was trained on the new DexCom G6 CGM device, and through our partnership with Dexcom we were able to switch our study devices from the original G4 CGM to the newest technology with G6. Both participants as well as staff welcomed the opportunity to trial this new technology in the hospital setting. Our research team in particular realized the benefit of the G6 not requiring twice daily calibrations.

The research protocol was updated to reflect the new G6 study device and this was then sent to IRB for approval of the protocol change. Approval was received and our first study participants to wear the G6 was enrolled in late September 2018.

Study updates: Resolution of barriers-EMRs and IV insulin

Electronic medical record (EMR) are unable to identify patients with T1D rapidly. This results in a late window of opportunity to place the CGM. As predicted, with the implementation of the new EPIC electronic medical record, this barrier has been resolved. EPIC allows an accurate diagnosis from ambulatory charts to be pulled at any hospital admission and generates a daily list with all patients with T1D. This list can be viewed remotely by any member of our research team.

Patients that are in the ICU on IV insulin drip and are already receiving hourly POC for drip adjustment have not qualified since CGM cannot be used for IV dosing at this time. Previously we would wait to enroll these patients until they were placed on a medical floor, however, sometimes there can be delays in placement due to bed availability. We amended our process to allow for enrollment of patients still in the ICU, as long as they were no longer receiving IV insulin.

Update report for DRC-2018

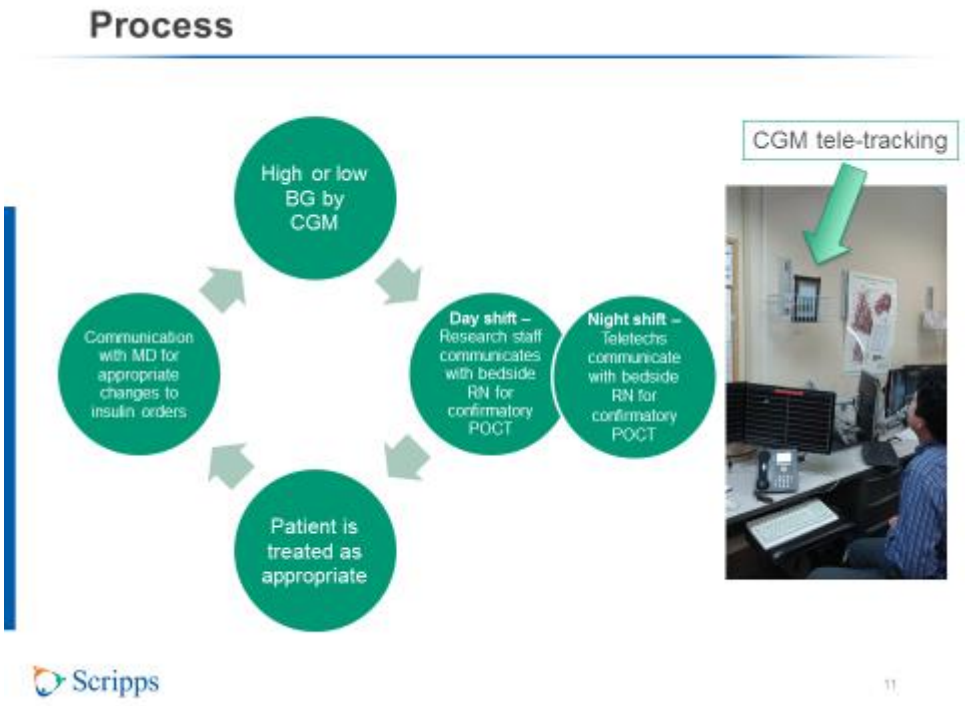
Main goal of the research study:

To recruit patients with T1D identified during a hospital stay that qualify and are interested in using a DexCom continuous glucose monitoring (CGM) device during their hospitalization to share data with a specialized Advanced Practice Nurse (APN) for better insulin management and prevention of hypoglycemia.

Current experience to date:

Total subjects screened: 62; Total subjects recruited: 4.

Patients that have participated to date have been extremely satisfied with their experience which offers a CGM and enables immediate readings as well as having an APN tracking their results in real-time. The intervention offers rapid feed-back to floor nursing staff for insulin management and prevention of hypoglycemia during the day and middle of the night. Telemetry techs have been trained at all hospitals to provide tracking and alerts to floor nurses for middle 10 pm to 7 am monitoring for abnormal CGM readings.



Several barriers have been encountered in the efforts to recruit patients to the study.

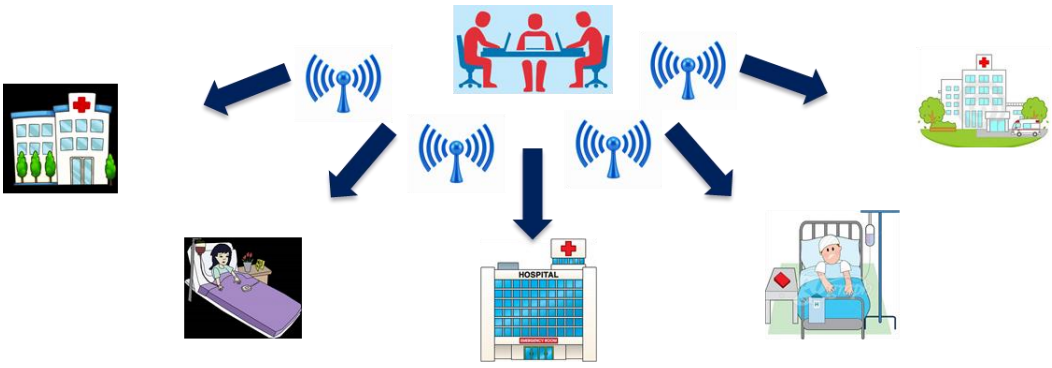
1. Electronic medical record (EMR) are unable to identify patients with T1D rapidly. This results in a late window of opportunity to place the CGM. The CGM requires a 2-hour timeframe for start-

up calibration and 12 hours for warm-up before accurate readings can be used for intervention. Most patients are here for only 3-4 days visits and are near discharge when identified. We will be able to address this better in 2018 with the roll-out of EPIC EMR at all sites. EPIC allows an accurate diagnosis from ambulatory charts to be pulled at any hospital admission and can also generate a daily list with all patients with T1D. A plan is in place for the system wide APN group to generate a daily list of all patients admitted with T1D to offer the placement of a DexCom CGM and to offer glucose management advice to all partnering hospitalists.

2. Patients that are in the ICU on IV insulin drip and are already receiving hourly POC for drip adjustment have not qualified since CGM cannot be used for IV dosing at this time. Many of these patients are discharged home within 24 hours of their ICU stay which doesn't allow for the start-up time needed for the CGM.
3. Cognitive impairment during the stay such as dementia, developmental delay or complex psychological issues related to multiple stressors including substance abuse have made the consenting process for placement and maintenance difficult.

Future state:

Ideally, we would like to create a centralized review process with daily lists from all 5 Scripps hospitals to identify all patients with T1D entering the hospital and deploy our glucose management staff to the bedside. Once there, they can place CGM devices on patients that consent and then conduct centralized monitoring and management based on the tracked glucose results. Point of care glucose monitoring will continue for any patients that decline the CGM or that are having procedures that preclude them from wearing a CGM.



Over the last year, new insulin pump and CGM ordersets have been created and approved by the Diabetes Careline Steering Committee. Training provided to all nursing staff (over 2000 nurses) has been conducted and the ordersets are now live at all 5 hospitals. These will be transitioned to the EPIC EMR at all 5 hospitals by the end of 2018 to offer patients with T1D the opportunity to maintain their pump during their hospitalization if criteria are met to allow this.