Addie Fortmann, Ph.D. Updates

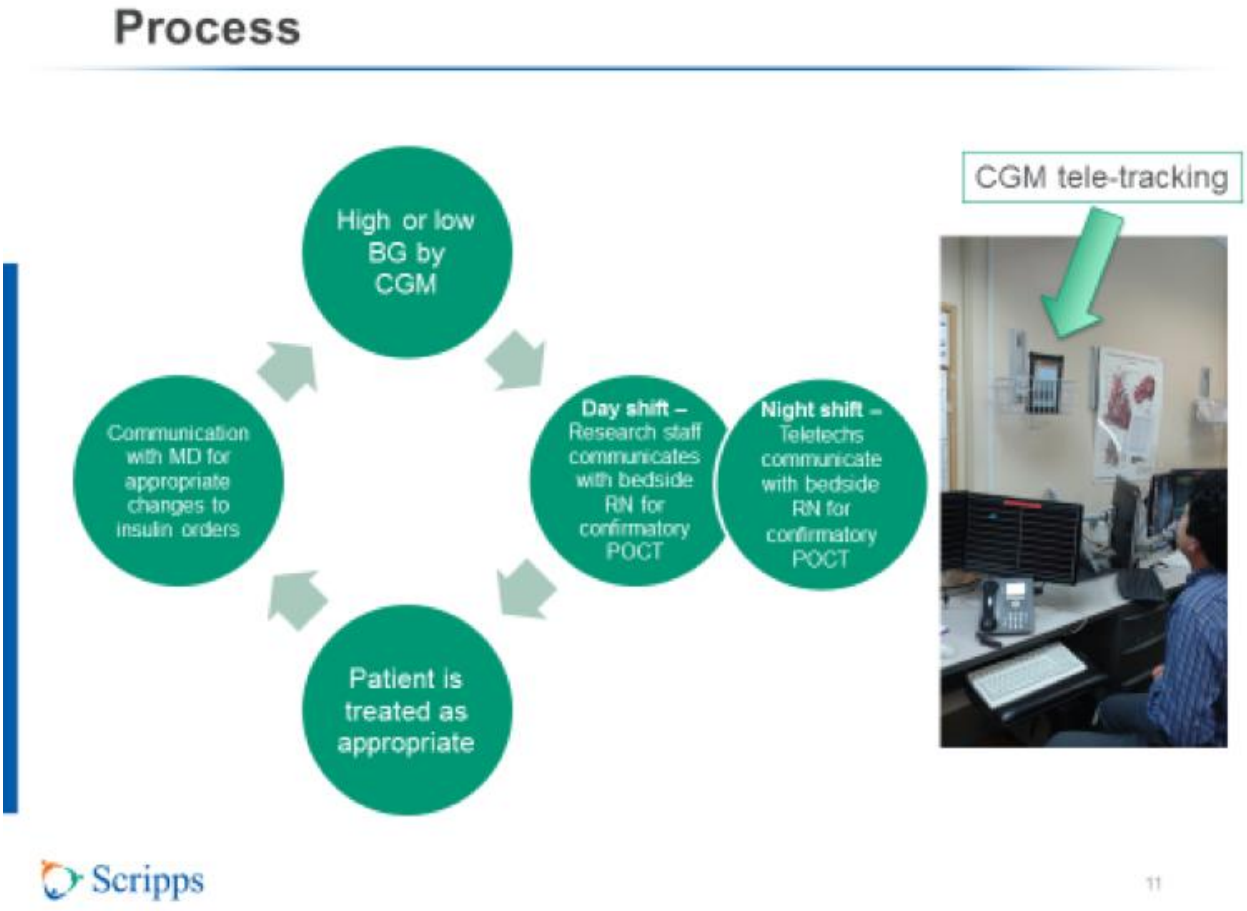
Main goal of the research study:

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 feedback 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.

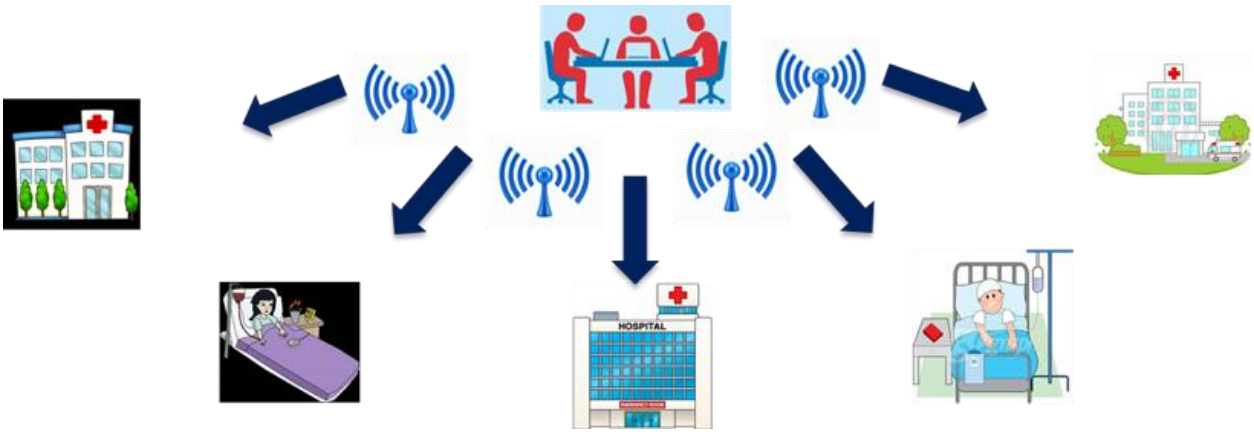


Several barriers have been encountered in the efforts to recruit patients to the study.

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 of 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 has 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 pumps and CGM order sets 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 order sets 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.

Update on 5-4-17

We have selected two cases to provide a real world "snapshot" of The Scripps Digital Diabetes study progress to-date. These cases were selected by our clinical implementation staff to demonstrate the value that is added by a Continuous Glucose Management (CGM) device in inpatient glucose management, and the patients' experiences and perceptions of CGM use while in the hospital.

Case #1

A 62 years old female with type 1 DM for over 30 years with a history of retinopathy and neuropathy was admitted for a quadruple coronary artery bypass. At home, her glucose was well-managed with a Paradigm Insulin pump and a Dexcom CGM device and recent A1c level was 7.4%. The patient was placed on the CGM Study after transitioning off the hospital intravenous infusion and placed on the standard insulin subcutaneous protocol.

The following subsequent events and interventions demonstrated the benefits of the CGM to assist with managing patient's blood glucose (hyperglycemia alert > 200 mg/dL and hypoglycemia alert < 90 mg/dL):

Post Op Day (POD) 1: RN received a call four times (8pm-5:15am) with high alert of BG > 250 mg/dL and administered Humalog (2 units) twice at 11:34pm and 3:23am.

POD 2 am: CGM alert BG > 250 mg/dL, call staff nurse early at 6:45am requested extra 10 units Humalog which staff nurse received order from consulting Hospitalist and given the 10 units Humalog at 6:53am.

Together with the patient's endocrinologist the CGM trends and total insulin doses (Lantus/Humalog) for the previous 24 hours were analyzed with recommended increases in Lantus and collaboration with the hospitalist for Humalog boluses with meals and overnight correction.

POD 3: With the assistance from CGM trends in addition to point-of-care (POCT) BGs, adjustment of the insulin therapy continued. Prior to dinner, CGM alert BG trending was noted below 100 mg/dL with POCT BG at 84 mg/dL. Nurses intervened with juice but patient precluded adequate treatment. Rapid intervention orders were obtained from the

hospitalist to give D50W 25 mL x1 intravenously. With timely administration of reversal agent, a hypoglycemia event was averted. Overnight, no high or low alerts noted with BG 151 mg/dL (9pm) and 146 mg/dL (11pm).

POD 4: Discharge day – POCT BG 139 mg/dL (5:20am) and 148 mg/dL (7:10am). The patient resumed her own insulin pump at 9:30am in anticipation of discharge.

Overall, patient's satisfaction with the use of CGM for her glucose management was rated as positive (9 out of 10) with Fair in the rating of her blood glucose control, especially since she just received a complex surgery that cause tremendous stress on her body. Patient found the CGM to be another way for her to participate in her care and to address her concerns in a timely manner. Her husband was also appreciative of the attention to her glucose management.

Case #2

We had the opportunity to place a DexCom CGM on a post-partum patient during a 4-day post-partum hospitalization. Although the post-partum unit was not initially included in the scope of study, an IRB exception was obtained in order to include this patient as the research staff recognized the clinical benefit that could be obtained by having continuous blood sugar data available. During the 4-days that the patient was wearing the CGM, there were 8 notifications to the telemetry staff between the hours of 7:30PM and 6:30AM, when staff otherwise would not have been obtaining a point of Care blood sugar check. These were all instances when the patient was experiencing low blood sugar (though not necessarily hypoglycemia of BG < 70mg/dL) which would not have otherwise been detected. The patient refused our pro-active treatment of glucose gel, but instead preferred to treat with her own remedy of food (crackers, juice, etc.). However, she most likely would not have been aware of the need to eat, if it weren't for our notification because of the CGM data.

When queried about her satisfaction related to wearing the CGM while in the hospital, the patient gave us an overall positive score of 9.5 out of 10, with 10 being "completely satisfied". The one complaint was occasionally being woken up for additional BG testing due to concerning trends, in her case low BG. However, she said she preferred management with sub-cutaneous insulin and the CGM data, as compared to being on the IV insulin drip which may provide tighter control but requires every 1-2 hour testing even when in good control. Overall, she stated that she would definitely recommend the CGM to other hospitalized patients.

Update on 4-27-16

Currently, all start-up activities have been completed – i.e., the protocol is IRB-approved, research staff is trained, technology is integrated within the hospital, and provider/hospital staff education is complete. So, we are now ready to enroll – expect

the first patient to be enrolled any day now. This is a closed trial as it identifies patients who are currently in the Scripps Hospital system.

Update on 9-1-16

Study procedures have been piloted with 40 patients to-date at a separate hospital site, and our protocol has been refined to ensure feasibility and acceptability from all perspectives. Based on feedback, we have revised our consent form (and obtained IRB approval) to permit patient participation in other trials that do not have the potential to interfere with the proposed research. Additionally, a comprehensive, HIPAA-compliant data tracking system has been built in *Research Electronic Data Capture* (REDCap), and the research team has been trained to code and enter data for analysis. All patient- and staff-reported data from pilot participants have been entered and database modifications have been made to ensure accuracy of data management and eventual analysis.

At the target hospital, n=9 T1D patients' charts have been reviewed for possible enrollment; however, 8 were not approached for screening due to short length of stay (i.e., < 48 hrs) and/or other factors that deemed them ineligible for participation (e.g., on IV insulin drip). The remaining patient was successfully screened and enrolled as the first official study participant on 8/25/16. Based on the short lengths of stay observed to-date with the other patients, we have worked with the Scripps Health Project Management Office to produce daily, automated ("real time") lists of potentially eligible patients. These lists will allow our research team to identify patients earlier in their hospitalization. Our research team will also consider adding a neighboring hospital site (of similar patient demographic) to the sampling pool should this be needed to meet enrollment targets and satisfy study objectives. However, based on the new automated lists, the average number of potentially eligible hospital patients to approach is 4/day, so we anticipate meeting recruitment goals without issue.