Study Title: Does the use of continuous glucose monitoring (CGM) in the immediate postpartum period in women with pregestational diabetes admitted to the hospital decrease hypoglycemic episodes?

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Research hypothesis:

The use of continuous glucose monitoring (CGM) to monitor glucoses in patients hospitalized in the immediate postpartum period is more effective at identifying patients with hypoglycemia than the traditional point of care (POC) blood glucose testing.

Population: pregnant women with type 1 or type 2 diabetes

Inclusion criteria: Pregnant women with type 1 or type 2 diabetes managed with insulin, who own a smart device (which will serve as a receiver for the CGM device).

Exclusion: patients less than 18 years of age, non-English speaking patients, gestational diabetes, extensive skin changes/diseases that inhibit wearing a sensor on normal skin, known allergy to adhesives

Number of subjects proposed to complete this study:

This is a pilot study to evaluate the role of a CGM device to decrease hypoglycemic events in hospitalized patients in the postpartum period, a power analysis has not been pre-specified.

30 patients were chosen as this appears to be attainable number based on the number of DM1/DM2 pregnant patients which are seen in the high-risk OB clinic.

Patient recruitment:

Pregnant patients with type 1 or type 2 diabetes managed with insulin will be approached during their OB clinic visit during the third trimester prior to 28 weeks, to describe the study and assess if they would be interested in participating. If they meet inclusion criteria and opt to enroll in the study, they will be consented during that visit. If patients would like time to discuss study with family/friends, they will be given up until the time of delivery (~10-12 weeks) to determine if they would like to participate in the study. During the consenting process, patients will be aware that participation in this study will not have any effect on routine standard of care.

If patients opt to enroll in the study, a CGM device will be placed by research personnel during their clinic visit if seen within 3 days of their planned induction of labor or planned cesarean section. If a patient is not seen for a prenatal visit 3 days prior to their delivery (i.e. missed clinic appointment), the device will be placed upon arrival to L&D for delivery. Patient will be assisted in getting the Dexcom G6 app on their cell phone to be the receiver of glucose data.

Patients who are currently using the Dexcom CGM for routine monitoring of their glucoses, will be allowed to continue using their own sensor and transmitter. Upon presentation to Labor and Delivery, patients will be assisted in activating the Share App on their cell phone.

Labor and Delivery Nursing Staff will be given a Samsung phone with the Follow app in order to receive glucose data. The Samsung phone will be transferred to the Mother/Baby Unit with the patient after delivery.

CGM sensors and transmitters will be kept locked in the MFM offices in a secure file cabinet. Study personnel will have a key to the file cabinet and access to the devices. Upon arrival of a study

patient to labor and delivery, study personnel will remove a sensor and transmitter from the secure file cabinet in order to place the CGM on the patient.

Glucose values from the CGM device will then be available to nursing through the Samsung phone. Nursing will be able to see current glucose data on their patient and would receive alarms to indicate hypoglycemia or impending hypoglycemia. Nursing will be provided with instructions for how to access the CGM follow app and how to appropriately respond to the alarms. Nursing will continue to perform standard POC blood glucose monitoring per routine protocol but will also obtain a finger stick to validate a blood glucose level whenever a low CGM alarm sounds. Low blood glucose values <70 mg/dl will be treated per hospital nursing policy. Monitoring of glucose levels through the CGM device will continue throughout the postpartum hospital stay. Patients who do not use CGM as part of their routine care, will have their CGM sensor and transmitter removed prior to discharge from the hospital.

Following discharge from the hospital, there will be no additional long-term follow-up.

Participants will be provided compensation of $25 e-voucher upon completion of the study and discharge from the hospital. The e-voucher is provided through University Accounting Services.

Data collection and analysis:

Data variables to be collected include the type of diabetes (DM1/DM2), POC glucose values, number of hypoglycemic events, number of times treated for hypoglycemia.

Subjects will be de-identified with the use of a separate document correlating subjects medical record number with the study ID number. The study data will be entered into a REDCap database. At the conclusion of the research project, the key will be destroyed.

With DEXCOM CGM services, glucose values will be uploaded to a DEXCOM password protected website to see glucose values in real time.

Continuous variables will be analyzed using a fishers exact t-test (i.e. blood sugar measurements). Categorical variables will be compared using a chi square analysis (i.e. hypoglycemic events). $P < .05$ will be considered statistically significant.