Title: A Pharmacist-driven Continuous Glucose Monitoring Program for Advanced Diabetes Management in an Uninsured Population

NCT #: NCT03477838

Document approval date: March 11, 2018

Document Type: Protocol

Background, Rationale and Goals

1. * **Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

   Glucose monitoring is a necessary component of diabetes care to evaluate the safety and efficacy of treatment. In patients with type 1 diabetes, it is often preferred for patients to check their blood glucose four times daily. In patients with type 2 diabetes, the frequency of glucose monitoring depends on the types of medications patients are prescribed. Glucose monitoring is often achieved through self-monitoring of blood glucose (SMBG) by patients at home using a glucometer. Patients may not check their blood sugar as frequently as recommended due to a variety of barriers such as cost of testing supplies, inconvenience of testing, or fear of needles and pain. The cost of testing supplies is a major barrier in the uninsured population at the Center for Healthy Hearts, as well as in the patients at Hayes E. Willis Health Center. Infrequency of checking blood glucose leads to difficulty in titrating medications. A1c testing is the gold standard for assessing glycemic control which tells the average blood sugar over three (3) months, but it has its limitations and cannot detect glycemic variability.

   Continuous glucose monitors are FDA approved devices in patients with diabetes. These devices measure glucose levels as frequently as every 5 minutes which makes the use of CGM an attractable option in order to safely and effectively titrate medications. Through clinical studies, we know that CGM helps to better identify glycemic patterns in patients with diabetes compared to patients self- monitoring blood glucose. The current studies are limited in that they have not actively pursued medication changes, thus minimizing the impact on A1c levels and glycemic control.

   In addition, studies have evaluated the utility of endocrinologists in reviewing CGM data, but no studies have reported on the use of these devices in patients managed by clinical pharmacists--even though many clinical pharmacists are trained in advanced diabetes management and have the scope of practice to make such changes. Therefore, this description will provide novel insight to the larger medical community. This research aims to improve diabetes control in the patients at the Center for Healthy Hearts and Hayes E. Willis and be a model for other clinics and institutions to follow.

   Pharmacist glucose monitoring and accompanying initiation, discontinuation, or adjustment of diabetes medications is already standard of care in this patient population. Prior to being seen in this clinic, all patients are informed of the collaborative practice agreement between pharmacists and physicians at this clinic and must consent to care under this arrangement. The pharmacists working under the collaborative practice agreement follow clinical practice guidelines by the American Diabetes Association and American Association of Clinical Endocrinologist as well as using clinical judgement to make treatment-related decisions. By using a CGM, much more detailed information about glucose trends will be provided. For example, if a patient's blood sugar drops low every night, the patient's insulin can be adjusted in order to prevent hypoglycemia. Similarly, if a patient's blood sugar is running high every night after dinner, the insulin dose may be increased. These standard insulin dose titrations typically include increasing or decreasing doses by 10-20%. Based on the glucose trends, other oral diabetes medications may be increased or decreased in order to improve glucose control within the recommended range. Using the CGM will allow for much more individualized care in order to prevent adverse effects from either too high or too low blood glucose levels.

   Citations:
   (1) American Diabetes Association. Standards of Medical Care in Diabetes - 2017. Diabetes Care 2017; 40(Suppl. 1): S1–S135.
   (2) American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. Endocr Pract 2016;22(2): 231-261.
   (3) Ong WM, Chua SS, Ng CJ. Barriers and facilitators to self-monitoring of blood glucose in people with type 2 diabetes using insulin: a qualitative study. Patient Prefer Adherence 2014;8: 237–46.
   (4) Hortensius J, Kars MC, Wierenga WS, et. al. Perspectives of patients with type 1 or insulin treated type 2 diabetes on self-monitoring of blood glucose: a qualitative study. BMC Public Health 2012;12: 167–77.
   (5) Rodbard D. Continuous Glucose Monitoring: A Review of Recent Studies Demonstrating Improved Glycemic Outcomes. Diabetes Technol Ther 2017;19(3): S26-37.
   (6) Miele A, Weiland K, Dungan KM. Clinical Outcomes Associated with Referral-Based Continuous Glucose Monitoring Using a Central Standardized Interpretation Strategy. Diabetes Technol Ther 2012; 14(9):765-771.
   (7) Beck RW, Riddlesworth TD, Ruedy K et. al. Continuous Glucose Monitoring Versus Usual Care in Patients with Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. Ann Intern Med 2017[Epub ahead of print]. doi:10.7326/M16-2855

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   There are currently no studies which evaluate a clinical pharmacist using a professional continuous glucose monitoring (CGM) device on patients with type 1 or 2 diabetes to help make medication-related changes. The purpose of this study is to evaluate CGM data in a real-world clinic setting. The study hypothesis is that the use of a continuous glucose monitor (CGM) will improve glycemic control in patients with diabetes.

   This pilot study is designed as a prospective cohort study at two different sites, Center for Healthy Hearts, a free health clinic, and Hayes E. Willis Health Center, a VCUHS entity. All study activities and procedures are already occurring as standard of care at this clinic. The clinical pharmacists at this clinic already monitor glucose levels in patients as part of routine care. Patients presenting to the clinic with CGM already implanted would undergo the exact same procedures, monitoring, and follow-up (by the exact same clinical pharmacists) as those who enroll in this study. As such, the monitoring of the glucose by CGM by the clinical pharmacists is not research per se. The only research interventions in this study are to (1) provide access to CGM to patients (purchased through a grant to the Center for Healthy Hearts) and (2) systematically record and analyze the results of the glucose monitoring.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   This proposed study will be a pilot project to assess the following specific aims:

   Aim 1: Evaluate the impact on glycemic control after evaluation of CGM in patients with diabetes. Our goal is to help patients meet their diabetes-related treatment goals.The primary outcome is the change in A1c from baseline to week 14. Secondary outcomes will evaluate the percentage of patients achieving A1c less than 7% and/or a 10% relative reduction in A1c.

   Aim 2: Describe the medication changes implemented after analyzing the CGM data. The investigators of the study work under a Collaborative Practice Agreement allowing for the prescribing and de-prescribing of diabetes related medications. The change in total daily insulin dose, number of dose adjustments and number of new additions of diabetes-related medications will be collected as secondary endpoints.

   Aim 3: Describe the feasibility of a CGM program managed by clinical pharmacists. This study will serve as a pilot project prior to implementing as a larger service available to community physicians. This project will help us determine

the appropriate number of follow-up visits and uncover any weaknesses in the process from sensor placement to data download and interventions.

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

   Using a clinical pharmacist to evaluate CGM data is a way to improve diabetes care in the general population. This study may show the benefit of such a program for patients who are either uninsured or do not test their blood glucose at home as recommended. This study will serve as a model for other pharmacists and thus expand pharmacy services while improving patient care.

5. * **Describe any potential for direct benefits to participants in this study:**
   Using a CGM sensor will allow for a very detailed picture of a patient's level of glycemic control. By having a better understanding of the patient's glucose variability, treatment can be individualized. This may be especially beneficial in the uninsured population who often have financial difficulties in affording home glucose testing supplies. As a result of this study, patients may experience improved glucose levels, which may improve overall well-being and outcomes.

6. **Upload a supporting citation list if applicable:**

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ID: HM20012049

View: SF2 - Study Population

HM20012049 - Evan Sisson
A pharmacist-driven continuous glucose monitoring program for advanced diabetes management

Study Population

1. * **Provide the maximum number of individuals that**

   1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
   AND/OR
   2. You obtain any data/specimens about (regardless of identifiability)

   at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
   35

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**
   35

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   The grant to the Center for Healthy Hearts has sufficient funds to support 15 CGMs. The grant to Hayes E Willis has sufficient funds to support 20 CGMs. This pilot study is designed to capture the data recorded by all 35 of these CGMs. Therefore, we are only enrolling 35 subjects.

4. * **List the study inclusion criteria:**
   Center for Healthy Hearts:
   1) adult 18 years of age or older, 2) diagnosis of Type 1 or Type 2 diabetes, 3) A1c greater than 7%, 4) prescribed basal insulin plus either prandial insulin or a glucagon-like peptide-1 (GLP-1) receptor agonist, and 5) patient provides written informed consent to participate

   Hayes E. Willis:
   1) adult 18 years of age or older, 2) diagnosis of Type 2 diabetes, 3) A1c greater than 7%, 4) prescribed basal insulin plus either prandial insulin or a glucagon-like peptide-1 (GLP-1) receptor agonist, and 5) patient provides written informed consent to participate

5. * **List the study exclusion criteria:**
   Center for Healthy Hearts:
   1) pregnant or breast-feeding, 2) on dialysis, or 3) not appropriate for CGM use based on clinical judgment by the investigators 4) patients with limited English proficiency

   Hayes E. Willis:
   1) pregnant or breast-feeding, 2) on dialysis, or 3) not appropriate for CGM use based on clinical judgment by the investigators

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**
   - ○ Included
   - ● **Excluded - safety concerns if participants are unable to communicate with the study team**
   - ○ Excluded - instruments/measures only validated in English
   - ○ Excluded - no prospect of direct benefit to individual participants
   - ○ Excluded - minimal risk study
   - ○ Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]
   - ○ Excluded - other reason [provide an explanation in next question]

7. **Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.**
   Patients with LEP will be excluded because the Center for Healthy Hearts does not have access to medical interpreters. This may compromise the patient's ability to understand the research study.

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View: SF2 - Study Procedures

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A pharmacist-driven continuous glucose monitoring program for advanced diabetes management

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
There are currently no studies which evaluate a clinical pharmacist using a professional continuous glucose monitoring (CGM) device on patients with type 1 or 2 diabetes to help make medication-related changes. The purpose of this study is to evaluate CGM data in a real-world clinic setting. The study hypothesis is that the use of a continuous glucose monitor (CGM) will improve glycemic control in patients with diabetes.

   This pilot study is designed as a prospective cohort study at two different sites, Center for Healthy Hearts, a free health clinic, and Hayes E. Willis Health Center, a VCUHS entity. All study activities and procedures are already occurring as standard of care at this clinic. The clinical pharmacists at this clinic already monitor glucose levels in patients as part of routine care. Patients presenting to the clinic with CGM already implanted would undergo the exact same procedures, monitoring, and follow-up (by the exact same clinical pharmacists) as those who enroll in this study. As such, the monitoring of the glucose by CGM by the clinical pharmacists is not research per se. The only research interventions in this study are to (1) provide access to CGM to patients (purchased through a grant to the Center for Healthy Hearts) and (2) systematically record and analyze the results of the glucose monitoring.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
This proposed study will be a pilot project to assess the following specific aims:

   Aim 1: Evaluate the impact on glycemic control after evaluation of CGM in patients with diabetes. Our goal is to help patients meet their diabetes-related treatment goals.The primary outcome is the change in A1c from baseline to week 14. Secondary outcomes will evaluate the percentage of patients achieving A1c less than 7% and/or a 10% relative reduction in A1c.

   Aim 2: Describe the medication changes implemented after analyzing the CGM data. The investigators of the study work under a Collaborative Practice Agreement allowing for the prescribing and de-prescribing of diabetes related medications. The change in total daily insulin dose, number of dose adjustments and number of new additions of diabetes-related medications will be collected as secondary endpoints.

   Aim 3: Describe the feasibility of a CGM program managed by clinical pharmacists. This study will serve as a pilot project prior to implementing as a larger service available to community physicians. This project will help us determine the appropriate number of follow-up visits and uncover any weaknesses in the process from sensor placement to data download and interventions.

3. * **Choose all types of recruitment materials that may be used and upload them below:**
   - [ ] E-mail invitations
   - [x] **Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)**
   - [ ] Flyers, Mailed Letters or Newspaper/TV/Radio Ads
   - [ ] TelegRAM announcements
   - [ ] Website text
   - [ ] Study-specific web sites (provide the design and text)
   - [ ] Social Media
   - [ ] Psychology Research Participant Pool (SONA) study descriptions
   - [ ] Scripts for announcements made to groups
   - [ ] Other recruitment material
   - [ ] No recruitment materials

4. * **Describe the study procedures/methods for identifying and recruiting participants. Address the following three aspects of recruitment in your response.**

   1. Identification of potentially eligible participants or secondary data/specimens of interest.
   - What database(s) will be queried to identify secondary data/specimens
   - How potential participants' contact information will be obtained

   2. Recruitment procedures to invite participation in the study (when applicable):
   - How each of the written or verbal recruitment materials and reminders (selected above) will be used
   - Who will contact or respond to potential participants
   - Locations where recruitment procedures will take place
   - The timing and frequency of recruitment attempts

   3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

   See the help text for additional guidance.
   Patients will be identified through pre-existing relationships and during routine appointments for diabetes management. Potential patients may also be contacted by the investigators to inform them of the study and invite them to come in for a screening visit. Only the clinical pharmacists (with whom potential subjects already have an existing patient-provider relationship) will contact potential subjects to inform them about the study. The investigators will only consider patients with whom they have an existing relationship and will not be systematically searching through the database for potential participants. At Hayes E Willis, primary care physicians may identify and refer patients during routine appointments to the clinical pharmacist for diabetes management whereas all patients at the Center for Healthy Hearts see a clinical pharmacist. A phone script has been uploaded.

   The actual informed consent process (and all other study activities) will take place in a private room at the study site.

5. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**

○ Yes

● **No**

6. * **Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

1. A statement explaining the study design
2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
3. A description of all research measures/tests/interventions that will be used (if applicable)

See the help text for additional guidance
This is a pilot study being conducted at two different sites based on two different grants that were awarded to the investigators. Based on a requirement from the grant, the study cohorts must be from 2 different locations. The overarching goal is the same between the two sites which minor differences in study population and procedures.

This study is designed as a prospective cohort study at the Center for Healthy Hearts, a free health clinic in Richmond, as well as Hayes E. Willis (HEW) Health Center, an entity of VCUHealth. All study activities and procedures are already occurring as standard of care at these clinics. Both sites have clinical pharmacists who already monitor glucose levels in patients as part of routine care. Patients presenting to the clinic with continuous glucose monitors already implanted would undergo the exact same procedures, monitoring, and follow-up (by the exact same clinical pharmacists) as those who enroll in this study. As such, the monitoring of the glucose by continuous glucose monitors by the clinical pharmacists is not research per se. The only research interventions in this study are to (1) provide access to continuous glucose monitors to patients (purchased through a grant to the Center for Healthy Hearts and a separate grant from the American Society of Health-System Pharmacists to use at HEW) and (2) systematically record and analyze the results of the glucose monitoring.

Patients will have up to 6 visits in a 14 week time period. Each visit consists of the following:
Visit 1 (week 0): Upon enrollment, a baseline A1c will be obtained through a small blood sample. The CGM sensor will be placed on the back of the patient's arm with a tiny filament inserted under the skin to collect glucose levels. The sensor is about the size of a quarter and has a filament <0.4 mm thick that is inserted 5 mm beneath the skin surface. The patient will wear the sensor for two (2) weeks and will be asked to record insulin doses administered and food intake through a log book which will be provided. Prior to enrollment, we will review potential for pregnancy with all women of child-bearing potential. We will screen for pregnancy based on last menstrual cycle. Women of child-bearing potential will be required to be using a reliable source of contraception since the timing of their last menstrual cycle.

Visit 2 (week 2): After two (2) weeks of continuous CGM wear, the patient will return to the clinic for removal of the sensor and downloading of data.

Visit 3 (week 3-4): 1-2 weeks after returning the sensor, the patient will have a follow-up visit to discuss the results. The patient may return for a face-to-face visit or this may occur over the phone. Medication dose adjustments or medication changes may occur based on interpretation of the glucose results. After the changes are communicated, the patient will continue with usual care, monitoring blood glucose at home.

Visit 4 (week 6-8): This visit is a routine monthly appointment for diabetes management. Medication changes will continue to be made based on review of the patient's home blood glucose log.

Visit 5 (week 10-12): This visit is another routine monthly appointment. At this appointment, the CGM sensor will be placed for a second time and worn for two (2) weeks for additional data collection.

Visit 6 (week 12-14): The patient will return to clinic for sensor removal. An updated A1c will be obtained and the intervention period will conclude.

At this clinic, patients routinely follow with the clinical pharmacist for chronic disease state management. Routine care consists of monthly appointments and involves reviewing a patient's blood glucose log, ordering labs, and prescribing medications. The study procedures above will be incorporated into the patient's routine appointments. Vital signs (blood pressure, heart rate, and weight) will be taken at every visit which is standard of care. At visit 1 and 6, 4 milliliters of whole blood is needed as the sample for the hemoglobin A1c test for the patients at the Center for Healthy Hearts. Patients at HEW will have an A1c collected through the use of a point-of-care device which requires a single drop of blood by a finger stick. This testing is standard of care to monitor diabetes control. All appointments will be face-to-face encounters with the exception of visit 3 which will occur by telephone. Medications will be prescribed in the standard manner, following the laws of the Collaborative Practice Agreement.

Practice guidelines recommend that patients check their blood glucose at home before every insulin injection. For example, if patients are prescribed one basal injection daily, they check fasting blood glucose every morning. For patients, on basal and mealtime insulin three times daily, they should be checking blood glucose four times daily. Because the patients at the Center are low-income, uninsured patients, most patients are not checking blood glucose as frequently as recommended. As mentioned before, insured patients also face many barriers to testing blood glucose at home and may have difficulty affording testing supplies and other factors. All patients have an A1c monitored every 3 to 6 months. When patients come to appointments, they also have a point-of-care blood glucose collected. If patients are checking blood glucose at home, their log is reviewed by the pharmacist.

The CGM being used in this study, FreeStyle Librepro, is FDA approved for use by healthcare providers in patients with diabetes. It will be used in the same manner as approved by the FDA. A1c testing every 3 months is standard lab for diabetes monitoring.

Scheduling and follow-up will occur by usual procedures at both centers.

For the Center for Healthy Hearts:
Upon conclusion of the appointment, patients will be provided with a "check-out sheet" indicating when follow-up is needed. The patient will present the form to the front office staff to have their next appointment scheduled. A member of the investigative team will call patients the day prior to remind them of their scheduled appointment.

At Hayes E. Willis:
At the end of the appointment, the patient will be scheduled for their next appointment by the pharmacist. A member of the investigative team will call patients the day prior to remind them of their scheduled appointment. Patients also receive an automated call by Hayes E. Willis.

If a patient misses their scheduled appointment, a member of the investigative team or a member of the front office staff will assist in re-scheduling the patient by phone. Two contact attempts will be made. Patients will be re-scheduled based on the next available appointment, +/- 1-2 weeks of their next scheduled protocol visit. If significant time has elapsed (>2 weeks from expected appointment), the subsequent appointment will be classified as the next closest appointment and the patient will have missing data points for the missed appointment. Patients who are unable to have an appointment rescheduled will have data recorded in an intent-to-treat manner.

Secondary outcomes will assess what types of medication changes are made with the use of CGM. For example, if insulin doses increase or decrease. Other secondary outcomes are based on the data provided by the CGM. (e.g. time in therapeutic range, duration of hypoglycemia, etc.) See attached data collection form for more information.

For patients at Hayes E Willis, we will be collecting the type of insurance patients have (Medicaid, Medicare, commercial, none) for characterization of this population, but no identifying health plan numbers will be collected. This is the only data point that is different from the Center for Healthy Hearts.

All patients who are included in this study will also have a retrospective chart review completed for the 12 week period prior to the study start date. Information to be collected includes the following: age, gender, race, weight, A1c at week 0 and 12, number and type of diabetes medications prescribed, total daily insulin dose. Patients will be evaluated on change in A1c and different medication changes.

7. * **The IRB only reviews research activities, so indicate which of the study activities are:**

   - Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study) VERSUS.
   - Alterations of routine activities/procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.) VERSUS.
   - Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
   Standard of care (SOC) procedures will take place in the same manner regardless of the research. SOC procedures include standard medical tests (vitals, point of care testing, laboratory work), referrals for behavioral health counseling, medication adjustments based on standard medical tests, and any additional patient education necessary.

   Procedures that are performed exclusively for research purposes include (1) application of continuous glucose monitors and (2) analysis and interpretation of the results of the continuous glucose monitor.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
   If a patient does not want to use the CGM, he/she will continue with routine appointments with the clinical pharmacist for diabetes management which involves monitoring A1c levels and home blood glucose readings.

9. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

   Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

   Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

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View: SF2 - Sample Collection Details

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Sample Collection Details

1. * **Select all of the types of samples that will be collected as part of this study.**
   - [ ] Amniotic Fluid
   - [x] **Blood**
   - [ ] Buccal Smears
   - [ ] Saliva
   - [ ] Tissue
   - [ ] Urine
   - [ ] Other
   - [ ] None of the Above

2. * **Select all of the methods of blood collection that will be utilized in this study:**
   - [x] **Individual Needle Stick(s)**
   - [ ] Indwelling Catheter Placed Solely for This Study
   - [ ] Indwelling Catheter Placed for Other Reason(s)
   - [ ] Blood Collected at the Same Time as Non-Research Blood Collection(s)
   - [ ] Other

3. * **Describe how the sample will be collected and the collection schedule. For each type of sample, include information about**

   - The procedures that will be followed to collect the sample
   - The role(s) of the individuals who will collect the sample
   - The volume/size range of the sample
   - The timing and frequency of sample collection
   At the Center for Healthy Hearts: A 4 milliliter whole blood sample will be collected at visit 1 and 6 for a hemoglobin A1c test. The sample will collected by a phlebotomist at the Center for Healthy Hearts. The sample is then sent to Lab Corp for processing.

   At Hayes E Willis: A 1 microliter drop of blood (finger stick) will be collected by the pharmacist at visit 1 and 6 for a hemoglobin A1c test. The sample will be processed in clinic by the use of a point-of-care system.

   The frequency of blood tests will not change for study participants. All blood testing in this study is considered standard of care.

4. * **Will genetic testing or analyses be conducted on any of the samples:**
   - ( ) Yes
   - (•) **No**

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View: SF2 - Secondary Data/Specimen Details

Secondary Data/Specimen Details

1. * **Describe the source(s) and nature of the information/specimens being obtained. This response should:**

   a. Identify where the data/specimens will come from (e.g., another researcher's registry, pathology lab, commercial source, medical records, etc.); and
   b. List what types of specimens will be obtained (when applicable); and/or
   c. List all data elements that will be obtained (when applicable). A data collection form or other documentation may be uploaded and referenced here.
   The data will be from the patient's electronic medical record in Practice Fusion or Cerner depending on which site the patient is enrolled from.

2. * **Describe whether any agreement exists between you and data/specimen provider that states you will never have access to the ability to identify the participants (i.e. access to identifiers or the code key) and that you will not attempt to re-identify individuals.**
   The patients name will be provided on the initial consent form. Once the patient consents they will be assigned a de-identified code which will be used on the data collection sheet.

   There will be different data collection sheets for each site.

3. * **When the information/specimens were originally collected, did individuals provide consent for secondary research use of their data/specimens (i.e. consent to another research study or to a research registry)?**
   - ○ Yes
   - ● **No**

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View: SF2 - Costs to Participants

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Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**
   - [ ] Participants will have no costs associated with this study
   - [x] **Study related procedures that would be done under standard of care**
   - [ ] Study related procedures not associated with standard of care
   - [ ] Administration of drugs / devices
   - [ ] Study drugs or devices
   - [ ] Other

2. * **Provide details of all financial costs to the participant, other than time and transportation. Additional details regarding standard of care costs will be requested on another screen, if applicable.**
   Patients will be responsible for medication co-payments. The prescribing of diabetes-related medications for this study will be standard of care.

3. * **Describe any procedures, therapy, lab work, x-rays, drugs, or devices, etc that are considered standard of care and will be charged to the participant or their insurance.**
   At the Center for Healthy Hearts: The study participants are uninsured. The patients will be responsible for diabetes-related medication(s) and home blood glucose testing supplies. Lab work is free-of-charge for all patients.

   At Hayes E Willis: The patients will be responsible for diabetes-related medication(s) and home blood glucose testing supplies. This may be charged to the patient and/or insurance company.

4. * **Describe the process to determine whether participants' insurance will cover the expenses.**
   At the Center for Healthy Hearts: The study is being conducted in an uninsured population so insurance companies will not be billed.

   At Hayes E Willis: Medications are prescribed by standard of care following insurance companies formularies which are available online.

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Compensation

1. * **Describe any compensation that will be provided including:**
   1. **total monetary amount**
   2. **type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)**
   3. **how it will be disbursed**

   At the Center for Healthy Hearts, patients are asked to provide a $10 donation per clinic visit. For the study visits in this project, these visit co-payments will be waived for participants. Participants will not be paid or receive direct compensation.

   At Hayes E Willis, patients will be provided up to two $10 gift cards (at visit 2 and 6) which are occurring outside of the patient's usual monthly appointment. At this clinic, patients do not pay a co-payment to see the clinic pharmacist which is why compensation is different between study sites.

2. **If compensation will be pro-rated, explain the payment schedule.**
   Compensation is not pro-rated.

3. * **Will Social Security Numbers be collected for compensation purposes only?**
   - ○ Yes
   - ● **No**

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Risks, Discomforts, Potential Harms and Monitoring

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**
   - **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
   - **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
   - **Research data risks (e.g. loss of confidentiality and privacy)**
   - **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
   - **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
   - **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

   See the help text for additional guidance.

   1. Physical
   (a) Skin irritation - patients may experience itching, redness, or irritation from the adhesive on the CGM sensor. In the clinical study for the device's approval, the frequency was less than 9% and rated as mild. Moderate to severe reactions occurred 0.5% of the time.
   (b) hypoglycemia - patients may experience low blood sugar. The device will not alert patients of low blood sugar values. Hypoglycemia is a common effect of insulin therapy, however doses will be titrated by standard of care. Insulin doses will be adjusted by 10-20% to minimize hypoglycemia. Patients should continue to check blood sugar levels at home and treat if feeling symptomatic. Patients will be educated on the symptoms of hypoglycemia and how to appropriately treat.

   2. Research data risks
   (a) loss of confidentiality and privacy - There is minimal risk for loss of patient privacy as patient protection and confidentiality is at the forefront of the study. Data will be securely stored as described before and all patient encounters, direct and via phone, will be conducted in private, individual rooms.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   The CGM device will be used as approved by the FDA. The sensor will only be placed on the back of the arm and not on another location of the body not approved by the FDA. To minimize risk, the sensor will not be applied to areas with scars, moles, stretch marks, or lumps. An area of skin that generally stays flat during normal daily activities will be chosen for sensor placement. If a participant experiences an adverse reaction to the adhesive, they should contact an investigator.

   All medication changes will be standard of care and not for research purposes. Insulin doses will be adjusted by 10-20% to minimize hypoglycemia. Patients should continue to check blood sugar levels at home and treat if feeling symptomatic. Patients will be educated on the symptoms of hypoglycemia and how to appropriately treat. Patients will have close follow-up, approximately every 4 weeks, to assess safety and tolerability of medications.

   To minimize potential threats to privacy and confidentiality, data will be securely on password encrypted drives and all study procedures will be conducted in private, individual rooms.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
   The study is on the general population. It is not expected to produce results that are stigmatizing.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
   If a patient has a severe skin reaction from the CGM sensor they will be withdrawn from the study and resume usual care. If the patient is unable to comply with the protocol, such as not returning the CGM sensor, they will be withdrawn from the study.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
   If patients experience an unwanted reaction or are unable to comply with frequent clinic visits, the patients will be withdrawn from the study.

   Data and Safety Monitoring
   Data and safety monitoring is a system for checking the study's data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

   The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
   - Participant safety (physical, psychological, etc.)
   - Data validity
   - Early stopping (termination) based upon changes in risks and benefits.

7. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**
   - ☐ DSMB
   - ☑ **DSMP**
   - ☐ No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]

8. * **Describe your Data Safety Monitoring Plan for monitoring the study's data to ensure the safety of participants. This plan should include (but is not limited to) the following elements:**
   1. Who will monitor data
   2. What data and/or processes will be reviewed
   3. When and how frequently monitoring will occur
   4. What report/documentation will be submitted to the IRB at the time of continuing reviews

   See the help text for additional guidance.

   This is an unblinded study in which all of the patient data will be available for real-time monitoring by the investigators--which precisely mirrors standard of care practices for this CGM. Moreover, the investigators will review the data and any adverse events with the medically responsible investigator at the respective site (Dr. Dow at Center for Healthy Hearts, Dr. Ryan at Hayes) after the 7th participant has completed the study procedures, on a yearly basis (including other potential safety concerns). A copy of the findings from this meeting will be included with continuing review applications.