A Transition of Care Model from Hospital to Community for Hispanic/Latino Adult Patients with Diabetes

Document Date: November 9, 2021

NCT04864639

Purpose of the Study

The prevalence of diabetes in adults over the age of 20 is significantly higher in the Hispanic/Latino population compared to non-Hispanic whites. Admitted patients with diabetes are at higher risk for readmission and Emergency Department (ED) visits than those without diabetes especially those in lower socioeconomic status and racial/ethnic minority groups. The goals of this proposed study are to explore patients and providers perceptions (n=15, 6 providers and 4 patients) of the current discharge process which will inform the development of a patient-centered transition of care model for Hispanic /Latino adults (≥18 years of age) with diabetes from hospital to the community. It is hypothesized that a culturally tailored transition of care model tailored for Hispanic/Latinos adults with diabetes will result in fewer ED visits, hospital admissions, and re-admissions.

The objective remains the same for Aim2. Our hypothesis is that participants enrolled in the newly developed transition of care model will have less Emergency Room visits post discharge, lower rates of unplanned readmission at 30 days post discharge and will report more follow up visits with a health care provider within 30 days of discharge than those individuals discharged on the usual transition of care plan. In addition, patient experience will be better in those in the new transition of care model.

Background & Significance

The prevalence of diabetes in adults over the age of 20 is significantly higher in the Hispanic/Latino population compared to non- Hispanic whites. Diabetes imposes a large economic burden partially due to the significantly higher rates of hospital admission compared to those individuals without diabetes. In 2014, a total of 7.2 million hospital discharges were reported with diabetes as any listed diagnosis among U.S. adults aged 18 years or older. Admitted patients with diabetes are at higher risk for readmission and Emergency Department (ED) visits than those without diabetes especially those in lower socioeconomic status, racial/ethnic minority groups, history of prior admission, diabetes associated comorbidities, public insurance, and emergent or urgent admission.

Diabetes is one of the most common conditions managed in the hospital, yet how to transition a patient with diabetes to the outpatient setting is understudied and outcomes of patients with diabetes after discharge is unknown. The importance of the transition of care from hospital to the community for patients with diabetes has been identified as a major area of improvement in diabetes care. Despite the economic burden and growing interest in factors leading to readmission, a paucity of research exists focusing on the transition of care among patients with diabetes. The American Diabetes Association (ADA) recommends a well-structured, patient-centered, transitions of the care, which includes a discharge plan and follow up within 30 days from discharge to help reduce the rates of readmission as well as a hospital stay. Unfortunately, this transition is significantly challenging for patients with fewer resources, language barriers, cultural differences, and low health literacy which collectively can lead to an increase risk of readmissions and emergency department visits. Further, the limited available data looking at outcomes post-discharge in patients with diabetes shows that being Hispanic/Latino is associated with a higher risk for multiple hospitalizations and re-hospitalization. Despite the increasing

advances in diabetes care, Hispanic/Latino patients remain a leading subgroup of patients not reaching diabetes goals. Therefore, developing a transition of care model that is patient/culturally centered for Hispanic/Latino adults with diabetes from the hospital to the community/home will reduce the existent gap in diabetes care.

Design & Procedures

Aim 1: To develop the transition of care model for Hispanic/Latino adults, patients and providers will be selected from Duke Regional Hospital (DRH) and Duke University Health System (DUHS), the local Hispanic/Latino community, and local clinics in Durham delivering care to Hispanic/Latino patients with diabetes. Drs. Corsino and Padilla will collect the data. It is anticipated that a total of 15 participants (4 patients) and (6 providers - physicians [MD, DO], nurse practitioners (NPs), and physician assistants (PAs)) will be obtained. We seek to explore patients' and providers' perspectives on the transition of care from hospital to community. All participants will complete a brief questionnaire. The information collected will be instrumental in developing a transition of care model that is culturally/patient centered.

Aim 2: Overall common themes have been collected from the 4 patient participants and 6 provider participants interviews and questionnaires thus far. Providers and patients uniformly expressed a need for a simple discharge summary that is more visual and in Spanish, language barriers and financial constraints.

Duke CTSI will conduct a Community Consultation Studio with community Engaged Research Initiative Core as a part of Pro00103450. They will interview 6-8 participants from Hispanic/Latino communities with diabetes. The common themes from this interview along with the common themes from the first 10 participants in this protocol will be combined to develop a transition of care model.

The first set of 16 participants will be discharged on the newly developed model based on interviews and data collected already and CTSI CCS protocol Pro00103450. The participants will be asked to complete a set of questionnaires and a 30-day post discharge telephone interview.

This interactive approach will use the Plan-Do-Study-Act (PDSA) framework. Changes can be reassessed and modified swiftly as a part of the continuous improvement cycle to allow for adjustments that facilitate the desired outcomes.

The second set of 16 participants will be discharged on a model based on the first 16 participants experience and feedback. Five participants enrolled in the first set will be re-interviewed to assess their feedback regarding the process. Based on this information the TOC model will be revised.

The second set of participants will complete a set of questionnaires and a 30-day post discharge phone interview similar to the first set of participants.

Key personnel will administer informed consent, eConsent or verbal consent depending on the participants access to resources at the time of enrollment. Covid-19 face to face interactions has limited the ability of face to face contact strictly for research purposes. We would like to keep the face to face option available for consent and questionnaires because some participants may be recruited by the key personnel rounding on the patient.

The Hispanic/Latino population has limited access to e-mail and smart phones. In the event that participants do not have access to email and cellphone we will obtain verbal consent. The informed consent, questionnaires and 30 day follow up phone call may all be done verbally in these cases. The 30 day follow telephone call will be recorded with an encrypted recorder. The recording will be used for review purposes only.

The 30-day follow up telephone survey will also collect data from participants receiving care outside of the Duke University Health System and systems not sharing the same electronic medical record.

3 additional providers will be reconsented and repeat the original interview.

Selection of Subjects

Aim 1 inclusion criteria:
Patients:
1. 18 years or older
2. Self-Identified as Hispanic/Latino
3. Previous diagnosis with Diabetes Mellitus
4. Ability to provide informed consent without a proxy
5. An admitted patient at a Duke University Hospital or Duke Regional Hospital facility.
6. English or Spanish speaking

Providers:
1. See patients at Duke Regional Hospital or Duke University Hospital
2. Working in the local clinics proving care for the local Hispanic/Latino patients.

For Aim 2 the patient inclusion criteria will only include patients that are currently hospitalized.
There is not exclusion criteria based on comorbidities.

Subject Recruitment and Compensation

Subjects will be introduced to the study by Dr. Corsino, Dr. Padilla or other key personnel. They are both bilingual. Approximately 4 patients will be recruited from Durham, NC. Inclusion criteria include age ≥18 years, self-identified as Hispanic/Latino, previous diagnosis of diabetes, Spanish and/or English speaker, ability to provide informed consent without a proxy, with a recent (within 3 months) hospitalization at Duke Regional Hospital (DRH) or Duke University Hospital. Maestro care/Epic slicer dicer will be used to

identify participants with a recent hospitalization. Patient word of mouth may also be used from local Hispanic organizations. Both methods have been previously implemented by Co-PI (Corsino) while enrolling Hispanic/Latino participants in research studies. Approximately 6 health care providers will be recruited from the DRH and Duke University Hospital. We aim to enroll a diverse group of providers including MDs, DOs, NPs and PAs. Providers will be approached for recruitment by the Co-PIs or designated trained research staff. Both inpatient and outpatient providers will be targeted. Compensation will be $10 per person. If the participant is not interested in sharing their social security number with the research team they will receive a gift of similar monetary value.

Aim 2: Participants will be recruited using Slicer Dicer or the inpatient diabetes admission list. Trained key personnel on the study will introduce the potential subjects to the study. A total of 32 subjects will be recruited and enrolled. The subjects will be compensated $25 dollars from petty cash for their participation. For the re-interviews (providers) will receive $10 dollars.

Risk/Benefit Assessment

This is a minimal risk study. We will not include vulnerable populations.

This study should result in better understanding of factors that impact the transition of care of Hispanics/Latinos patients with diabetes. Identifying and understanding internal and external barriers to the transition of care should be determined when considering designing a culturally sensitive transition of care model. A better method to transition from inpatient setting to home for Hispanic/Latinos with regard to factors such as lower socioeconomic status, language, and health literacy along with a fragmented delivery system may result in better outcomes during the transition phase from acute to the outpatient setting.

The benefits to the subject are that the participant may require fewer visits to the ED and less admissions to the hospital in the 30 days following their hospitalization.

The importance of this study is to optimize the transition of care of Hispanic/Latino patients with diabetes because it is poorly understood. This study will inform a more aligned discharge and follow-up process for Hispanic/Latino patients discharge in future and will also inform future larger randomized trials.

Data Analysis & Statistical Considerations

General Data Analytics. The recording will be reviewed by the Co-PI, each independently, they will identify themes and will color code them. Subsequently themes will be combined into common themes.

Analysis. For all outcomes and demographic information collected, descriptive analysis (means and standard deviations for continuous variables and frequencies and percentages for categorical variables) overall and by randomization arms. The non-feasibility outcomes will be compared

between the usual care and intervention group. Chi-squared or Fisher's Exact tests will be conducted to assess the differences of each outcome between groups. Logistic regression models will be conducted to access the adjusted differences of each outcome between usual care and intervention groups. The models will be adjusted for a limited number of variables that are theoretically thought to explain some variation in the value of the outcomes.

For Aim 2 we would like to ensure that we are able to at minimum detect a difference in the primary outcomes in the number of Emergency Department visits and hospital re-admissions.