

1) Abstract of the study

Post-discharge hospital utilization, i.e., readmissions within 30 days of discharge (30d readmissions) and emergency department (ED) visits, are a high-priority quality measure and target for cost reduction. Patients with diabetes are disproportionately over-represented in 30d readmissions, especially among racial minorities and urban populations. We have developed and validated a tool, the Diabetes Early Readmission Risk Indicator (DERRI), to predict 30d readmission risk among diabetes patients, which is a critical prerequisite for targeting limited resources for reducing readmission risk to those most in need. Currently, there are no proven interventions to reduce the risk of 30d readmission specifically among patients with diabetes. This proposal will assess the feasibility and acceptability of a novel, multifactorial intervention, the Diabetes Transition of Hospital Care Program (DiaTOHC or “My Temple Extra Care Service”), designed to reduce post-discharge hospital utilization rates in a pilot randomized controlled trial. The intervention will include inpatient diabetes and discharge education, comprehensive discharge planning and coordination of care, A1c-based adjustment of diabetes therapy, and post-discharge support. Hospitalized patients with diabetes identified as high risk for readmission based on the DERRI will be randomized to the intervention or the control group, which will receive usual care. Such work is highly relevant in the current era of soaring health care costs and national health care reform.

2) Protocol Title

A Pilot Trial to Prevent Hospital Readmission of Patients with Diabetes (NCT03243383)

3) Investigator

Daniel Rubin, MD, MSc

4) Objectives

We have **retrospectively developed and validated a tool to predict the risk of all-cause 30d readmission among patients with diabetes** called the Diabetes Early Readmission Risk Indicator (DERRI).[1] Based on easily obtained clinical and sociodemographic information available prior to the time of discharge, the DERRI accurately stratifies patients by risk of 30d readmission.

The proposed study will use the DERRI to identify diabetic patients at high-risk of readmission who will be provided with a novel intervention designed to reduce hospital utilization rates within 30 days of discharge. This multifactorial intervention builds on techniques effectively used in other inpatient populations, specifically, patient-centered discharge education, peri-discharge coordination of care, and post-discharge support by nurses and community health workers (CHWs), and adapts them to patients with diabetes.[2-8] In addition, the intervention includes adjustment of diabetes therapy upon discharge based on the admission A1c, which improves post-discharge glycemic control and is associated with a lower risk of 30d readmission.[9, 10]

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We propose a pilot randomized controlled trial to address the following aims:

Aim 1: To explore the feasibility, acceptability, and efficacy of a novel multifactorial intervention designed to reduce all-cause readmission or ED visit rates within 30 days of discharge among hospitalized patients with diabetes who are identified as high risk based on the DERRI

Aim 2: To prospectively validate the readmission risk predictions generated by the DERRI

The usual care control group will provide the baseline risk of 30d post-discharge hospital utilization in the patient population predicted to be at high risk by the DERRI. Furthermore, we will prospectively follow patients who are predicted to be at lower risk to validate the DERRI in this population.

5) Background

Significance

Post-discharge hospital utilization, i.e., readmissions and ED visits, represent a costly failure of medical care, especially among diabetic patients.[11-13] Patients with diabetes represent about 9% of the US population,[14] but they account for 23% of hospitalizations (over 8 million per year).[15, 16] The number and proportion of hospitalized patients with diabetes has increased steadily over the past two decades,[15, 17, 16] mirroring the increasing incidence and prevalence of diabetes in the general population.[18, 19, 14] While the overall 30d readmission rate is 8.5-13.5%,[20, 21] the 30d readmission rate of diabetic patients is 14.4-21.0%.[22-25] In 2012, costs associated with the hospitalization of diabetic patients in the US were \$124 billion of which an estimated \$25 billion was attributable to 30d readmissions.[26, 27, 15] ED visits of patients with diabetes also impose significant costs to health systems.[28] Reducing 30d readmissions among diabetic patients has the potential to greatly reduce healthcare costs. **A modest 5% reduction in the 30d readmission rate would result in 82,754 fewer admissions per year, translating into an estimated annual cost savings of \$1.2 billion.**[26, 16] Starting October 1, 2012, the Centers for Medicare and Medicaid Services decreased payments to hospitals that have greater-than-expected 30d readmission rates, reflecting an effort to improve care while reducing costs.[29] These data and the widespread interest in healthcare reform have prompted recent calls for more research on how to prevent 30d readmissions in this important group of patients.[30-32]

Identifying and intervening in the highest risk diabetic patients to reduce readmission rates may have a large impact. Such an approach, colloquially known as “**medical hot-spotting,**” has been successfully applied in a socioeconomically disadvantaged population to reduce hospital utilization in

Camden, NJ.[33] Identifying high risk patients, i.e., the “hot spots”, is the first step. However, there had been no published, validated tools to predict the risk of 30d readmission among patients with diabetes. Most prediction models among hospitalized patients have relatively poor discriminative ability (C-statistic <0.7).[34] Furthermore, most studies of readmission risk factors in diabetic patients are limited by the use of administrative rather than clinical data, lack of clinical utility at the point of care, and/or a narrow focus on a primary discharge diagnosis of diabetes.[35-37, 22, 38, 23] **Identifying high-risk diabetic patients will enable targeting of interventions to those at greatest need, which may optimize the cost-benefit ratio for the health care system.**

To date, preventive interventions targeting 30d readmissions have included multiple components but have not focused on diabetic patients. Several trials have shown significant relative risk reductions in 30d readmissions ranging from 30% to 75%.[2-8] Of the successful studies, all except one tested multi-component discharge bundles, suggesting that bundled interventions may realize an additive effect beyond that seen with a single intervention. Common components of these interventions were patient-centered discharge education, peri-discharge coordination of care, and post-discharge support. The majority of trials that targeted higher risk patients showed a benefit in reducing readmissions.[3, 5, 6, 4] In contrast, trials that failed to reduce readmission risk did not focus on higher risk patients.[2, 39] This suggests that targeting higher risk patients is an important component of an effective intervention, and efforts to reduce readmissions may be more effective in a high risk population. A major limitation of these studies, however, is that they did not report data stratified by diabetes status or address diabetes management. **Our proposal will address important knowledge gaps concerning readmission risk prediction and prevention strategies in patients with diabetes.**

Innovation

This research proposal consists of important innovations. There are no proven strategies specifically developed for patients with diabetes to reduce the risk of 30d readmission. This proposal combines elements of successful readmission risk reduction interventions designed for other populations to create a novel multi-component intervention for a high-risk diabetic population. Furthermore, the DERRI will be used to select patients at the highest risk of 30d readmission to receive the intervention, which has a higher likelihood of success than testing the intervention without regard for predicted readmission risk. Readmission interventions in other populations that focused on higher risk patients have been successful;[3, 5, 6, 4] however, **none** of these used a validated model specifically developed to predict 30d readmission risk. **This approach could serve as a model to test and target interventions in other populations at high risk of readmission.** Lastly, although the DERRI has been internally validated in a retrospective sample, the proposed study will test the model prospectively in a new population. External prospective validation is important for demonstrating generalizability.[40, 41] **Achieving these aims**

would represent a major advance in the peri-discharge care of hospitalized diabetes patients, reducing 30d readmissions, socioeconomic disparities, and healthcare costs.

Preliminary studies

Qualitative assessment of readmission risk factors and causes

We conducted semi-structured interviews of 20 adult inpatients with diabetes readmitted to TUH within 30 days of discharge and performed thematic analysis.[42] In 76% of cases, reasons for the index admission and the readmission were similar. While 65% of patients felt they needed help after discharge, only 47% reported getting the help they needed. Only 29% of patients were aware of the A1c test. Despite 65% of discharge instructions listing a scheduled follow-up visit, only 41% of patients recalled having a scheduled follow-up visit. Most patients said they followed the discharge instructions but did not accurately answer questions about them. Few could list their medications or the reasons for taking them. Discharge instructions rarely addressed diabetes care other than medications, even for patients with a diabetes-related primary discharge diagnosis.

We concluded that recurring reasons for admission of patients with diabetes are not being sufficiently addressed to prevent 30d readmission, and many patients do not get adequate discharge support. Furthermore, readmitted patients lack important knowledge about their diabetes and medications. The discharge process does not successfully communicate instructions to patients, and instructions often fail to address diabetes. These findings inform the planned intervention, and a similar qualitative method will be used to assess the intervention.

6) Setting of the Human Research

Potential subjects will be recruited at Temple University Hospital. All research procedures will be performed on the Temple Health Science Center Campus.

7) Resources Available to Conduct the Human Research

We estimate that in order to meet the desired final sample size, up to 300 subjects will need to be enrolled. Approximately 27,500 patients with diabetes are hospitalized at TUH annually. Assuming 25% of them will not meet eligibility criteria, there will be 20,600 potential subjects remaining over 1 year. We will therefore need to recruit 1.14% of potential subjects.

This work is being funded by an NIH K23, which covers 75% of the PI's total effort through February of 2019. A majority of the PI's research effort will be devoted to this project. One full-time Research Specialist (Shaneisha Allen) will support the study, including screening, consenting, and enrolling patients, entering data, and managing regulatory requirements. Our base of operation is at the General Clinical Research Center (GCRC), located at Rock Pavilion, room 422. Shaneisha Allen will

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supervise the following research assistants for screening, consenting, and enrolling patients, and entering data (Samantha Watts, Felicia Dillard, Madeline Amberge, Dominic Recco, and Samuel Tanner). Dr. Cherie Vaz, one of the PI's colleagues in the Section of Endocrinology, will serve as a co-investigator to help with the clinical management of patients in the study.

In addition to the research specialist, a Nurse Navigator in the TUH Care Transitions Program (Jeff Slocum) will deliver parts of the intervention, including diabetes education, coordination of care, and post-discharge follow-up.

All persons on the team administering the trial will be fully trained on the protocol and their study-related duties and functions. The Nurse Navigators have participated in protocol development.

8) Study Design

a) Recruitment Methods

We will recruit study subjects as follows:

1. We will review a daily computer-generated admission log of patients admitted to medical-surgical units at TUH who have been ordered for routine glucose testing. This captures most patients with recognized diabetes.
2. We will review the medical chart of patients on the admission log to determine potential eligibility. We request a waiver of consent and HIPAA to identify candidates. We will access only the minimum data needed to obtain this information.
3. We will request permission to approach the potential subject about the study from a physician on the primary team providing hospital care.
4. Study participants will be provided \$50 after 30 days of follow-up has been completed and outcomes have been assessed. Subjects who also provide an in-depth interview after the follow-up period will be given another \$50.

b) Inclusion and Exclusion Criteria

Screening for eligibility will be performed by chart review and brief history of the potential subject.

Inclusion criteria

1. Diabetes, defined by pre-admission use of a diabetes-specific medication and/or documentation of the diagnosis in the medical record.
2. Age 18 years or older at the time of admission
3. Admission to a non-critical care unit

Exclusion Criteria:

1. Female subjects who are pregnant and/or admitted to an obstetric service

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2. Binge drinking (5 or more alcoholic drinks for males or 4 or more alcoholic drinks for females on the same day) or drug abuse within 3 months before admission
3. Receiving palliative care during the hospitalization
4. Participation in another readmission risk reduction program
5. Inpatient death
6. Planned or actual transfer to another hospital or subacute facility
7. Discharge to hospice or a long-term care facility
8. Discharge by signing out against medical advice
9. Discharge expected within 12 hours or admission to a short-stay unit
10. Lack of access to a phone
11. Living more than 30 miles away from TUH
12. Mental condition rendering the subject unable to understand the nature, scope, and possible consequences of the study
13. A1c <5.7%
14. Inability to speak English

c) Local Number of Subjects

Up to 300 subjects will be enrolled locally across the following study groups: 60 subjects in the intervention group, 60 in the high-risk control group, and 180 in the low-risk control group.

We estimate that 25% of screened patients will not meet eligibility criteria, which means that at least 300 patients will be screened.

d) Study Timelines

Subjects will be enrolled during their hospital stay and will participate in the study for 3 months following hospital discharge. The intervention will be delivered during the 4 weeks following discharge. Final assessment for outcomes will be performed at 3 months after discharge. We anticipate enrollment will occur between July and December of 2019. We estimate that primary analyses will be completed by June of 2020.

e) Study Endpoints

The primary outcome will be the number of initial hospital readmissions within 30 days of discharge. Secondary outcomes will also be assessed at 30 days of discharge unless otherwise specified. Secondary outcomes will include:

1. time to first readmission
2. number of emergency department (ED) visits
3. a composite of 30d readmissions and ED visits

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4. number of primary care and specialist provider follow-up visits scheduled and attended
5. incidence of medication review or reconciliation post-discharge
6. cost of post-discharge care as a sum of ED visits, readmission, home health services, and outpatient provider visits
7. cost of the intervention
8. subject experience assessed by a brief questionnaire
9. self-monitored blood glucose levels and frequency of testing
10. change in well-being from baseline to 5 weeks after discharge as measured by the World Health Organization Well-Being Index (WHO-5).[43]
11. change in diabetes-related distress at 5 weeks after discharge as measured by the Problem Areas in Diabetes (PAID) scale.[44]
12. change in perceived social support at 5 weeks after discharge as measured by the Multidimensional Scale of Perceived Social Support (MSPSS).[45]
13. change in perceived stress at 5 weeks after discharge as measured by the perceived stress scale (PSS).[46]
14. change in diabetes knowledge at 5 weeks after discharge as measured by the Diabetes Knowledge Test (DKT2).[47]
15. change in A1c level from baseline to 3 months after the index discharge

f) Procedures Involved in the Human Research

After enrollment, subjects will be sorted into 2 groups based on the predicted risk of readmission by the DERRI: high risk and low risk (Figure 1).

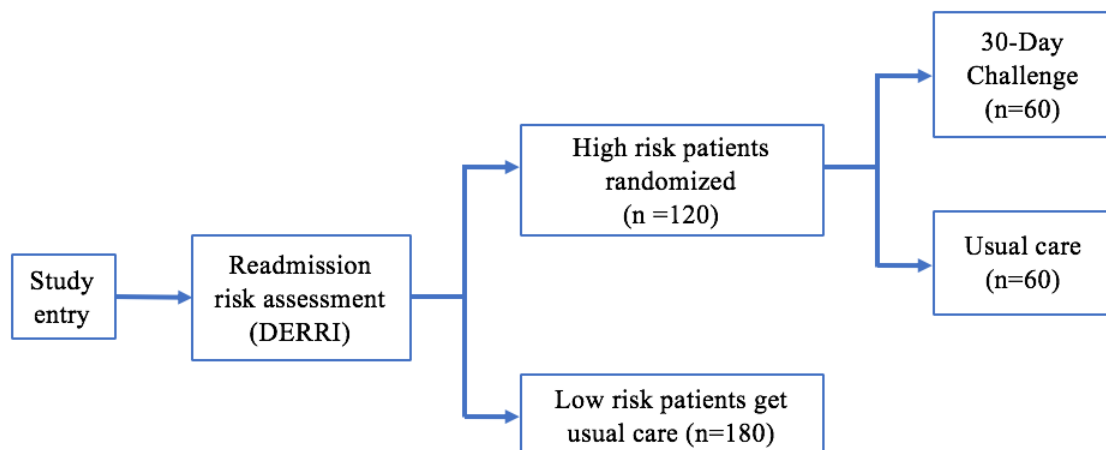


Figure 1. Allocation of study participants

Low-risk group:

The **low-risk group** will be followed in a prospective, observational arm of the study. About 5 weeks after hospital discharge, the Temple medical record will be reviewed for the presence of any hospital or ED visits within 30 days after discharge. If no post-discharge acute visits are found, then the subject will be contacted to determine if any hospital or ED visits occurred at another institution.

- The following data will be collected at baseline: sociodemographics, medical history, including HIV, substance abuse, and mental health status, which are likely risk factors for admission, relevant laboratory results, admission diagnoses, well-being (WHO-5), diabetes-related distress (PAID scale), perceived social support (MSPSS), perceived stress (PSS), diabetes knowledge (DKT2), depression screening by the 2-item Patient Health Questionnaire (PHQ-2), [48] and health literacy by the Brief Health Literacy Scale (BHLS). [49, 50] Subjects who score 3 or more on the PHQ-2 will complete the PHQ-9. [51] Subjects with a PHQ-9 score of 5 or more will be referred to their primary care physician (PCP) for evaluation and management of possible depression. [52] For subjects without a PCP, a study physician will begin medical therapy for depression as needed. For subjects newly discovered to be suicidal, psychiatry will be consulted in the hospital.
- The following data will be collected during follow-up: A1c, discharge diagnoses, hospital readmission (date, primary diagnosis), ED visits (date, primary diagnosis) and patient experience according to a brief questionnaire (Appendix Item 3a).

High-risk group:

For the **high-risk group**, there are two phases in the protocol. Phase A is the pilot RCT to explore the feasibility, acceptability, and efficacy of the intervention. Phase B consists of in-depth interviews with intervention participants and research staff to further explore acceptability and effects of the intervention and to refine the protocol for future study. Subjects in the high-risk group will be randomly assigned with a computer-generated randomization scheme 1:1 in randomly permuted blocks of 2, 4, or 6 to receive either the intervention, the Diabetes Transition of Hospital Care (DiaTOHC) Program (“My Temple Extra Care Service”) or usual care (control).

Phase A: RCT of readmission risk reduction intervention

Intervention protocol: The multifactorial intervention is based on strategies that reduced 30d readmissions in other populations, Temple’s successful readmission reduction program for heart failure patients (Temple Advantage), and the PI’s own preliminary studies. There are four components of the intervention: 1) patient-centered discharge education, 2) peri-discharge coordination of care, 3) A1c-based adjustment of diabetes therapy upon discharge, and 4) post-discharge support.

1) Patient-centered discharge education:

1a) *Standardized diabetes discharge instructions and education:* A Navigator will review instructions containing basic diet, activity, and diabetes-specific self-care guidance, as well as education on how to recognize and treat hypoglycemia and hyperglycemia (**Appendix Item 1**). These instructions are based on the model published by one of the PI’s mentors, Dr. Mary Korytkowski, and others.[53] They also include a table that allows a provider to specify how and when insulin should be taken and discussion of the subject’s A1c level, of which many patients are not aware according to Preliminary studies. Lastly, patients who have not completed a formal diabetes education program in the past year will be referred to a Certified Diabetes Educator at the Temple Diabetes Center, an American Diabetes Association-certified outpatient diabetes education center.

1b) *Comprehensive discharge plan review:* Prior to discharge or soon after discharge, a Navigator will review the discharge plan with participants, including medications, reasons for and importance of follow-up appointments and testing, and how to reach post-hospital providers.

2) Peri-discharge coordination of care: Soon after discharge, a Navigator will assess and address barriers to following the discharge plan, including obtaining medications. A Navigator will confirm the scheduling of follow-up appointments and testing (including a visit with the primary care provider), help organize post-discharge services, assess barriers to keeping appointments, and confirm plans to attend follow-up appointments including transportation. In addition, a Navigator will assist subject with obtaining medications if needed. See **Appendix Item 2** for script.

3) A1c-based adjustment of diabetes therapy: Upon hospital discharge, diabetes therapy will be determined by the PI or co-Investigator (Endocrinologists) based on an algorithm tested in patients with type 2 diabetes,[9] and the American Diabetes Association Standards of Medical Care guidelines as follows [54]:

a) For A1c <7%, resume the pre-admission treatment regimen.

b) For A1c 7-7.9%

- Patients who did not take insulin before admission, discharge on optimized pre-admission treatment regimen (see definition below) or add a non-insulin agent if the prior regimen was already optimal.
- Patients who took basal insulin but not prandial insulin before admission, increase the home daily dose of basal insulin by 10-15% in addition to any non-insulin pre-admission treatments. Non-insulin pre-admission treatments should be optimized.
- Patients who took multiple daily insulin injections (MDI) before admission, increase the home total daily dose of insulin by 10-15% in addition to any non-insulin pre-admission treatments. Non-insulin pre-admission treatments should be optimized.

b) For A1c 8-9%

- Patients who did not take insulin before admission, discharge on 50% of the last inpatient insulin glargine daily dose or 0.2 units/kg in addition to the pre-admission treatment regimen, which should be optimized.
- Patients who took basal insulin but not prandial insulin before admission, discharge on 50-80% of the last inpatient insulin glargine daily dose or increase the home daily dose of basal insulin by 10-15% and/or add rapid-acting insulin before the largest meal at 50-80% of the last inpatient dose or 0.1 units/kg in addition to any non-insulin pre-admission treatments. Non-insulin pre-admission treatments should be optimized.
- Patients who took multiple daily insulin injections (MDI) before admission, discharge on 50-80% of the last inpatient total daily insulin dose or increase the home total daily dose of insulin by 10-15% in addition to any non-insulin pre-admission treatments. Non-insulin pre-admission treatments should be optimized.

c) For A1c >9%

- Patients who did not take insulin before admission, discharge on 80-100% of the last inpatient insulin glargine daily dose or 0.3 units/kg in

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addition to the pre-admission treatment regimen, which should be optimized.

- Patients who took basal insulin but not prandial insulin before admission, discharge on 80-100% of the last inpatient insulin glargine daily dose or increase the home daily dose of basal insulin by 20-30% and/or add rapid-acting insulin before the largest meal at 80-100% of the last inpatient dose or 0.1 units/kg in addition to any non-insulin pre-admission treatments. Non-insulin pre-admission treatments should be optimized.
- Patients who took multiple daily insulin injections (MDI) before admission, discharge on 80-100% of the last inpatient total daily insulin dose or increase the home total daily dose of insulin by 20-30% in addition to any non-insulin pre-admission treatments. Non-insulin pre-admission treatments should be optimized.

Optimization of non-insulin diabetes therapy is defined as using the next higher dose up to the maximum tolerated dose. The maximum dose specified below will be used unless the subject must use a lower dose to avoid side effects or there is a contraindication.

- DPP4-inhibitors (i.e., linagliptin, saxagliptin, sitagliptin): FDA-approved maximum daily dose
- GLP1-analogues (i.e., albiglutide, exenatide, dulaglutide, liraglutide): FDA-approved maximum daily dose
- Metformin: 2000 mg per day
- Pioglitazone: 30 mg per day
- Secretagogues (i.e., sulfonylureas, repaglinide, nateglinide): Half the FDA-approved daily maximum dose. Pre-admission daily dose will be reduced by 50% in patients starting prandial insulin or those at risk for hypoglycemia. Secretagogues will be discontinued in patients with inpatient hypoglycemia (BG <70 mg/dL) within 48 hours of discharge.
- SGLT2-inhibitors (i.e., canagliflozin, dapagliflozin, empagliflozin): FDA-approved maximum daily dose

Patients who cannot use insulin glargine as outpatients will have the equivalent dose substituted with another basal insulin. **Only FDA-approved diabetes therapies will be used in the study.** Pre-admission diabetes medications may be adjusted to optimize patient safety and benefit. Deviations from the above protocol will be allowed on a case-by-case basis if the PI or co-Investigator deems it necessary for patient safety.

4) Post-discharge support: At 24 to 48 hours post-discharge, a nurse Navigator will call the patient to assess the patient’s status, confirm receipt of and compliance with medications, verify the follow-up appointment schedule, assess for barriers to following the discharge plan, determine the need for a community health worker (CHW) referral, and review blood glucose control (patients who are discharged on non-insulin regimens will be expected to test their blood glucoses at least once a day, and patients who are discharged on an insulin regimen will be expected to test their blood glucoses at least twice a day). Similar phone calls will be made weekly for four weeks following discharge by a Navigator. If a patient reports significant high or low blood glucose levels, then the PI or a co-Investigator (Endocrinologists) will call the patient to adjust diabetes therapy (See Tables 1a and 1b for insulin dose adjustment protocols). Eligible patients will receive a referral for a nursing visit from a local home care agency to assess medical needs for support at home and medication reconciliation. Referral to a CHW may be made if subjects are found to have non-medical needs and/or obstacles to maintaining self-care and attending follow-up appointments. Such non-medical support might include transportation to and from medical appointments, food, housing, or legal assistance, relief from utility bills, verification of insurance, support groups and delivery of durable medical equipment.

Table 1a. **Outpatient basal insulin dose adjustment:**

Basal Insulin	
If mean FBG > 180 mg/dL for the last 2 consecutive days and no episodes of hypoglycemia	Increase daily basal dose by 4 IU
If mean FBG > 140 mg/dL for the last 2 consecutive days and no episodes of hypoglycemia	Increase daily basal dose by 2 IU
If mean FBG between 100 to 140 mg/dL for the last 2 consecutive days and no episodes of hypoglycemia	No Change
If any FBG between 70 – 99 mg/dl	Decrease by 4 IU or 10% of total daily basal dose
If any FBG < 70 mg/dl	Decrease by 8 IU or 20% of total daily basal dose
If any FBG < 40 mg/dl	Decrease total daily basal dose by 30%

FBG=Fasting blood glucose; Hypoglycemia=typical symptoms (e.g., sweating, tremor, acute hunger, anxiety) and/or blood glucose <70 mg/dL

Table 1b. **Outpatient prandial/pre-meal insulin dose adjustment based on subsequent mealtime/HS BG values:**

Pre-meal Rapid Insulin		
Pre-meal Dose, U	BG 70 – 100 mg/dl*	BG 141-180 mg/dl**
≤ 10 U	Decrease by 1 U	Increase by 1 U
>11- 19 U	Decrease by 2 U	Increase by 2 U
≥ 20 U	Decrease by 3 U	Increase by 3 U
Pre-meal Dose, U	BG 40-70 mg/dl x 1	BG 180-240 mg/dl x 1

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≤ 10 U	Decrease by 2 U	Increase by 2 U
>11- 19 U	Decrease by 3 U	Increase by 3 U
≥ 20 U	Decrease by 4 U	Increase by 4 U
Pre-meal Dose, U	BG < 40 mg/dl x 1***	BG > 240 mg/dl x 1
≤ 10 U	Decrease by 4 U	Increase by 3 U
>11- 19 U	Decrease by 6 U	Increase by 4 U
≥ 20 U	Decrease by 8 U	Increase by 5 U

Pre-meal insulin dose adjustment is based on the subsequent BG value, e.g., pre-breakfast insulin dose is based on the pre-lunch BG.

* If > ½ of the mealtime/HS BG values for the week were below target.

**If > ½ of the mealtime/HS BG values for the week were above target.

*** Decrease by 30-40% in the event of severe hypoglycemia (mealtime/HS BG < 40 mg/dl).

BG=blood glucose; Mealtime/HS=pre-lunch, pre-dinner, or bedtime

The above algorithm provides recommended insulin doses and may be modified based on clinical judgment of the investigator or co-investigator.

Usual care: Most aspects of the intervention go above-and-beyond usual care. Patients in the usual care group will receive the standard discharge instructions and medication reconciliation process. Those who are new to diabetes receive training by a floor nurse on using a glucometer as well as a stock set of printed educational materials. The floor nurses also train patients who are new to insulin injections as needed. Patients with diabetes are referred to outpatient diabetes education at Temple on a case-by-case basis as determined by the primary hospital provider team. Diabetes therapy upon discharge is decided on a case-by-case basis by the primary team. Discharge instructions are routinely sent to the primary care physician either by fax or EPIC. Most TUH patients receive a phone call 2 to 4 days after discharge from a CHW that includes checking on the status

Table 2. Timeline for assessments of subjects

Visit #	1	2	3	4	5	6	7	8
Time (weeks)	0	2 days	1	2	3	4	5	13
Intervention group								
Phone call/clinic visit								X
Psychometric assessments	X							X
Diabetes knowledge	X							X
30d endpoints								X
Interview							X	
A1C	X							X
Navigator call		X	X	X	X	X		
Blood glucose		X	X	X	X	X	X	
Adverse events		X	X	X	X	X	X	
Usual care group								
Phone call								X
Psychometric assessments	X							X
Diabetes knowledge	X							X
30d endpoints								X
A1C	X							X
Blood glucose								X
Adverse events								X
Low-risk group								
Chart review/phone call								X
Psychometric assessments	X							X
Diabetes knowledge	X							X
A1C	X							X
30d endpoints								X

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of follow-up appointments, confirming access to medications, and answering questions.

Data collection: The following data will be collected at baseline: A1c, sociodemographics, medical history, including HIV, substance abuse, and mental health status, which are likely risk factors for admission, relevant laboratory results, admission diagnoses, self-reported goals for health and diabetes, well-being (WHO-5), diabetes-related distress (PAID scale), perceived social support (MSPSS), perceived stress (PSS), diabetes knowledge (DKT2), depression screening by the PHQ-2/9, and health literacy by the BHLS (Table 2).

The following data will be collected during follow-up: A1c, discharge diagnoses, hospital readmission (date, primary diagnosis), ED visits (date, primary diagnosis), physician follow-up appointments scheduled and/or attended, post-discharge medication reconciliation (yes/no), cost of post-discharge care, self-monitored blood glucose levels, Nurse Navigator time to deliver the intervention (minutes), well-being (WHO-5), diabetes-related distress (PAID scale), perceived social support (MSPSS), perceived stress (PSS), diabetes knowledge (DKT2), depression (PHQ), and patient experience according to a brief questionnaire (**Appendix Item 3a [usual care] or 3b [intervention]**). These follow-up data will be collected during a phone call about 5 weeks after the index discharge. Baseline and 3-month post-discharge A1c levels will be obtained as part of standard-of-care. A letter reminding patients to do the 3-month blood draw for the A1c test will be sent by mail.

Data will be collected by phone interviews with subjects and review of the electronic medical record (EMR). The Research Specialist will be primarily responsible for screening and recruiting subjects, data collection and data entry.

Phase B: Qualitative evaluation of intervention

In Phase B, in-depth individual interviews with intervention-group participants and the Navigators from Phase A will be conducted in-person to develop a better understanding of the intervention's acceptability, feasibility and effects. The interviews will be conducted between one and two months after the index discharge. These findings will provide critical information about the intervention to guide a future proposal for a definitive RCT. In addition to this formal qualitative work, the research team's experience with implementing the study will help refine the manual of procedures for the trial.

Study sample: Approximately 20 (maximum of 25) intervention-group participants in the Phase A pilot trial will be interviewed. The final sample size will be determined by achieving saturation of themes, the point at which no new information is being collected. This will be based on continual assessment by the investigators as the interviews are analyzed.[55] In the PI's prior study with a similar design (see Preliminary studies), 20 patients were included.[42]

Data collection and analysis: The PI will use an in-depth guide for semi-structured participant interviews that addresses the following topics: 1) the participants' experience in the intervention; 2) the acceptability of written materials; 3) barriers and facilitators to working with the Navigators and CHWs; and 4) suggestions for improving the intervention (**Appendix Item 4**). In a semi-structured interview, the interviewer uses the guide to address topics of interest and is encouraged to pursue relevant lines of questioning as they arise during the interview. Interviews will be conducted by the PI or research staff. Each interview will take about 30 to 45 minutes and will be recorded with a portable digital recorder. Hand-written observations and impressions during the interviews will complement the transcribed audio data. Thematic analysis will be used to identify common themes that reflect the underlying attitudes, values, and contextual constraints of participants in the intervention.[56, 55] Each interview will be coded by the interviewer then reviewed by the PI and research staff together to assure accuracy and consistency of coding. Initial codes will be standardized then organized into themes.

g) Data and Specimen Banking

All data collected by the research team will be considered part of the participant's confidential record. Data collected on paper from research participants will be placed in a locked file cabinet in the GCRC within 24 hours. The destruction date of paper files will be at least 7 years from the termination of the study and will be authorized by the PI. Access to research and confidential records will be limited to clinical investigators and research coordinators.

h) Data Management

Statistical analysis: Distributions of the data will be assessed by descriptive statistical and graphical methods. To assess the randomization procedure, baseline values of all variables will be compared between the intervention and usual care group. Between-group differences for continuous variables will be compared using the Wilcoxon test. Proportions will be compared between groups using the chi-square test or exact tests when expected cell counts are less than 5. The primary outcome of 30d readmission rate will be compared between intervention and control groups with the chi-square test. Point estimates of 30d readmission rates will be obtained and presented with 95% confidence intervals. Time to readmission will be estimated by Kaplan-Meier curve and compared between groups by log-rank test. The composite of 30d readmission and ED visits will be compared by Cox regression model. Continuous secondary outcomes will be compared using Wilcoxon test. Categorical secondary outcomes will be compared using chi-square test. The primary analyses for all outcomes will be performed in the intention-to-treat (ITT) population. Secondary analyses for all outcomes will be performed in a per-protocol population restricted to subjects who complete at least one follow-up phone call. In addition, outcomes will be assessed for differences by the number of follow-up phone calls

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completed (dose-response analysis). Lastly, all outcomes will be assessed in the ITT subgroup of subjects with a baseline A1c >7%. Statistical significance will be claimed at an alpha level of 0.05.

Power analysis: The sample size for Phase 2A was based on an expected drop-out and post-enrollment exclusion rate of 25% as well as the capacity of the research team. Because this is a pilot feasibility trial, the study is not powered to detect a difference in outcomes.

Data Entry Requirements: All data will be coded by the research assistant prior to entry. The research assistants will maintain a log of any reviewed data issues so that future occurrences of problems will be handled in the same manner. The data entry system (REDCap) will require a login identification and password to gain access to the data. When appropriate, validation and range rules will be applied to the actual entry fields. Only the research assistants will be able to view the data in its raw state. All other authorized personnel (i.e. the PI, statistician and Data Safety Officer) will view data via forms and reports created by the research assistants.

Audit/Verification of Entered Data:

Primary Outcome Data: Data designated as primary outcome date (i.e., presence or absence of 30d readmission) will be subject to a 100% cross-reference check with original hard copies. This audit must have an error rate less than 0.5%. If the verification fails the audit, all data will be re-entered, the original computer files discarded, and the newly re-entered data audited. This process will continue until the audit no longer exceeds the maximum allowable error rate. All audits will be supervised and documented by the study's research assistant.

All Other Information: All other entered information will be subject to a 20% sample that will be cross-referenced with the original paper copy. This audit must have an error rate less than 0.5%. If the sample fails the audit, all data will be verified against the paper originals. If the error rate of the complete audit is greater than 0.5%, all data will be re-entered, the original computer files discarded, and the newly re-entered data audited. This process will continue until the audit no longer exceeds the maximum allowable error rate. At the discretion of the PI, the full audit may be omitted in favor of a complete re-entry of the original paper data. All audits will be supervised and documented by the research assistant.

Storage of Data: Data collected on paper from research participants will be placed in a locked file cabinet in the locked GCRC office. The destruction date of paper files will be at least 7 years from the termination of the study and will be authorized only by the PI. Electronic data will not include personal identifiers other than the unique study ID. Audio files for the in-depth interviews will be stored on the Research Specialist's password-protected computer and erased from the digital recorder after storage. All data will remain confidential. Access to

research and confidential records will be limited to trained clinical investigators and research coordinators.

Access to Cleaned Computer Data: Once the study is complete and data have been collected, entered, and passed the audit process, the Research Specialist will make the data available to the PI and anyone he designates. Only the PI can give permission for the release of aggregated study data. No confidential information may be released without the expressed written consent of the study participants. Only copies of the finalized, aggregated data will be released so that original data can remain confidential.

i) Confidentiality

Only trained research staff will have access to individually identifiable information under supervision of the PI. Staff will be trained to collect data for the study and maintain participants' confidentiality. Printed materials with identifiable participant information will be stored in a locked filing cabinet in the GCRC. The destruction date of paper files will be at least 7 years from the termination of the study and will be authorized only by the PI. Electronic data will be entered into REDCap, which requires a login identification and password to gain access. Electronic data will not include personal identifiers other than the unique study ID. Audio files for the in-depth interviews will be stored on the Research Specialist's password-protected computer and erased from the digital recorder after storage.

Presentation of the study results at regional or scientific meetings or in publications will not identify the subjects.

j) Provisions to Monitor the Data to Ensure the Safety of subjects

All participants will be given unique study identifiers. Data with personally identifiable information will be stored securely on HIPAA-compliant TUH servers. Data exported for statistical analysis will be stripped of personal identifiers. Participants will be free to withdraw from the study at any time.

Phase A: To minimize the risk of hypoglycemia, only patients with uncontrolled diabetes according to an elevated A1c will have their diabetes therapy adjusted. Patients will be followed closely for 30 days after discharge with weekly phone calls, and glycemic control will be monitored. Patients discovered to have hypoglycemia or hyperglycemia will be referred for adjustment of their diabetes therapy by the PI, an Endocrinologist.

A Data Safety Officer (DSO) not otherwise directly involved with the research, a senior diabetologist and clinical investigator with inpatient diabetes research experience, Dr. Boris Draznin at the University of Colorado Denver, will review de-identified data every 3 months. Adverse events will be reported to the Temple Institutional Review Board and the NIH according to standard policy.

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Phase B: Every effort will be made to ensure that all qualitative data are kept confidential. The digital audio files produced will be used only for the purpose of this study. They will be downloaded from the recording device and stored on a secure computer in the research assistant's private GCRC office. The audio files will be transcribed. In the transcript, each subject will be assigned an anonymous study identification number. The data file linking personal identifiers and study identification numbers will be stored separately from the transcript data. The files with the transcribed data will have no personal identifiers and will contain no information linking an individual participant with their study code. The DSO will not monitor Phase B because there is minimal risk involved with this phase.

The following procedures will be implemented to ensure data safety and adequate monitoring:

- The PI will monitor study progress on an on-going basis and ensure the protection of human subjects, including the safe and secure collection and storage of data. An annual review will include assessment of accrual, adverse events, and data management practices.
- All data linking subjects to de-identified information will be maintained in a password-protected, encrypted computer with access limited to only those research personnel with a reasonable need to have such information.
- Reporting Adverse Events
 - Definitions:
 - Adverse Event: Any medical problem that manifests during the course of the study, as a result of an assessment or an aspect of the study intervention.
 - Serious Adverse Event: An adverse event that is fatal or life-threatening, results in significant or persistent disability, or requires hospitalization.
 - Unexpected Serious Adverse Event: Any event that has not been described in the protocol or informed consent document.
 - Reporting Mechanisms
 - All adverse events will be discussed at weekly operations meetings and reported to the PI and IRB according to standard operating procedure.
 - Serious adverse events (expected and unexpected) will be reported to the PI immediately and to the IRB in writing within 1 business day.
 - The NIH procedure for Reporting Clinical Study Serious Adverse Events will be followed for the reporting of expected and unexpected serious adverse events to the study sponsor.
- The DSO will review the protocol and study procedures every 3 months to ensure that proper regulatory processes are followed during study execution. In this role, he will:

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- Review all adverse events or complications related to the study and make recommendations for protocol changes if indicated.
- Assure scientific integrity of the study by providing regulatory oversight.
- Assure participants' confidentiality and informed consent by reviewing study procedures.
- Provide advice, as requested, on quality assurance measures.

k) Withdrawal of Subjects

Subjects may withdraw at will at any time. Subjects may be withdrawn from the trial at the discretion of the PI due to a safety concern, if judged non-compliant with trial procedures, or pregnancy during the primary follow-up period (30 days after discharge). For subjects in the intervention group, we will obtain permission to continue to collect data from the electronic medical record.

9) Risks to Subjects

The study involves low risk from interviews and the intervention, which entails education, coordination of care, and post-discharge support. A1c-based adjustment of diabetes therapy poses the usual risk of hypoglycemia associated with diabetes therapy. However, only patients with uncontrolled diabetes according to an elevated A1c will have their diabetes therapy adjusted. Patients will be followed closely for 30 days after discharge and glycemic control will be monitored. Because the study will only be using FDA-approved medicines and checking routine A1C blood tests, it is unlikely that costs will be more than if a doctor was managing the subject outside the study.

10) Potential Benefits to Subjects

Participants in the intervention may have a lower risk of readmission and improved glycemic control with 30 days of discharge.

11) Privacy and Confidentiality

The study will use PHI and a HIPAA Authorization has been submitted. Paper data collection records with personal identifiers will be stored in locked file cabinets. Electronic data will not include personal identifiers other than the unique study ID. Audio files for the in-depth interviews will be stored on the research assistant's password-protected computer and erased from the digital recorder after storage. Access to research and confidential records will be limited to clinical investigators and research coordinators. All data linking subjects to de-identified information will be maintained in a password-protected, encrypted computer with access limited to only those research personnel with a reasonable need to have such information. Staff will be trained to collect data for the study and maintain participants' confidentiality. Interviews with subjects will be conducted in private. Presentation of the study results at regional or scientific meetings or in publications will not identify subjects.

12) Compensation for Research-Related Injury

If study volunteers sustain injury as a result of their participation in this study, they will be advised to seek immediate medical attention. However, there is no commitment by Temple University, Temple University Health System or its subsidiaries to provide monetary compensation or free medical care in the event of a study-related injury. The study volunteers have not waived any of their legal rights which they would otherwise have as a participant in an investigational study.

13) Economic Burden to Subjects

No additional cost to subjects or the institution will be incurred for research purposes.

14) Consent Process

We will follow INVESTIGATOR GUIDANCE: Informed Consent (HRP-802).

15) Process to Document Consent in Writing

We will follow INVESTIGATOR GUIDANCE: Documentation of Informed Consent (HRP-803).

16) Drugs or Devices

Most subjects will obtain their diabetes medications through insurance. For high-risk subjects in the intervention group who cannot afford their diabetes medication, the TUH research pharmacy will provide medication for the duration of the study.

17) Sharing of Results with Subjects

Data obtained beyond standard of care will not be shared.

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