Protocol Title:

Diabetes To Go Inpatient

Funding Mechanism:

NIH PAR-15-158 Planning Grants for Pragmatic Research in Healthcare Settings to Improve Diabetes and Obesity Prevention and Care (R34)

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SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

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Signed: _____ Date: _____

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** The protocol should be signed by the clinical site investigator who is responsible for the day to day study implementation at his/her specific clinical site.*

LIST OF ABBREVIATIONS

A1C	Hemoglobin A1C
ADA	American Diabetes Association
BG	Blood glucose
CDE	Certified Diabetes Educator
D/C	Discharge
DM	Diabetes mellitus
DM2go	Diabetes 2 Go
DRNC	Diabetes Resource Nurse Champion
DSME	Diabetes self-management education
ED	Emergency Department
EMR	Electronic Medical Record
FSBG	FingerStick Blood Glucose
GLP-1	Glucagon-like peptide
GOCADAN	A Genetic and Epidemiological Study of Cardiovascular Disease in Alaska Natives
HF	Human Factors
IE	Implementation Effectiveness
IT	Information Technology
LOS	Length of Stay
MDI	MedStar Diabetes Institute
MHRI	MedStar Health Research Institute
MI2	MedStar Institute for Innovation
MMAS-8	Modified Morisky Rx Adherence Score 8-item
MWHC	MedStar Washington Hospital Center
NIH	National Institute of Health
PCT	Patient Care Technicians
PCP	Primary Care Provider
PRISM	Practical, Robust Implementation and Sustainability Model
REAIM	Reach, Efficacy, Adoption, Implementation, and Maintenance Framework.
Red CAP	Research Electronic Data Capture
Rx	Medication
SANDS	Stop Atherosclerosis in Native Diabetics Study

1 BACKGROUND/SCIENTIFIC RATIONALE

The Research Problem – Hospitalizations and emergency department (ED) visits among patients with diabetes mellitus (DM) are key contributors to rising U.S. DM-related health care costs.[1] DM self-management education (DSME) has been shown to reduce utilization of acute care services. Traditionally considered a suboptimal environment in which to provide education, **the hospital may actually provide a unique opportunity to educate patients with DM.** Recent studies suggest that inpatient DSME, improving communication of discharge instructions and involving patients in medication (Rx) reconciliation may reduce risk for early readmissions[2], and improves outcomes.[3,4,5] The American Diabetes Association (ADA)[6] and The Joint Commission[7] delineate educational content to communicate to all DM patients before hospital discharge.

Inpatient delivery of DSME per national guidelines presents a challenge to hospitals.[6,8,9] Hospital-based DM specialists -endocrinologists and DM educators- cannot reach all patients who need DSME. **Methodology for delivery of learner-centered DSME to inpatients with DM at the bedside within existing workflow on nursing units is needed.** This study will deploy pre-implementation assessment methods and designs coupled with established implementation effectiveness (IE) evaluation frameworks to integrate delivery of DSME ***sustainably into ongoing hospital nursing unit processes for patient education and discharge planning***. Evidence generated by this study will be used to support a future application for NIH R18 funding.

Importance of the Problem – Studies of patients hospitalized with poorly controlled DM report that readmissions occurred in ≤30 days in 14%, ≤180 in 32%,[4] and that 17% were readmitted to the ED in ≤30 days.[10] Readmissions can be partially attributed to deficits in DM knowledge and self-management skills, including poor adherence to DM medications (Rxs). Hospitals face challenges in delivering education to all DM patients as recommended in national guidelines.[6,8.9] Hospital-based DM specialists –endocrinologists and DM educators- cannot reach all patients who need DSME. Survival skills education, teaching topics essential for safe patient discharge, is recommended for inpatient DSME[4]. Despite some success, patient factors including Rxs non-adherence remain a critical barrier to improved outcomes even when education is provided. This suggests that a more holistic approach is required including personalized feedback to effectively integrate the patient into the chronic care continuum.[11] Innovative providers are responding by implementing efforts to deliver DSME and discharge transition support to patients. **Evidence-based sustainable tactics for offering learner-centered, knowledge-based DM education in hospitals to all patients with DM are needed.**

Literature important to the study – *The data summarized in the following section directly support the need for interventions such as Diabetes To Go.*

The need for DM education. DSME, part of the chronic care and health promotion models, improves knowledge, self-care behaviors including Rx adherence,[12] clinical indicators and health status and reduces healthcare utilization.[4,7,13] Patients who receive inpatient DSME have a lower frequency of 30-day readmits than those who do not (11 vs 16%; p=0.0001).[7] DSME is usually delivered outpatient 1:1 or via classes, allowing the patient to make informed decisions regarding daily self-care, yet many patients do not return to complete the full curriculum, and readmitted patients have been shown to have dramatically low knowledge.[2]

The need for strategies to support improvement in Rx adherence. Patients are primarily responsible for safely and appropriately self-administering Rx regimens. [6] In a study of patients surveyed at discharge, only 28% were able to list all their Rxs, with only 37% being able to recount their purposes, and just 14% able to state their common side effects.[14] To gain the benefits of drug therapy while minimizing adverse drug events, patients must: have a functional knowledge of Rxs and their proper dosaging; consolidate the regimen to an efficient daily schedule; problem-solve around regimen use as changes occur (e.g., sick days); and continue the behaviors over time. Studies have shown that patients have problems performing these tasks. This need is particularly important for those with DM, a complex chronic condition requiring long-term understanding of the timing, purpose, and side effects of multiple Rxs.[15-19] **Initiatives targeting improved knowledge of and adherence to Rxs prescribed at hospital discharge are needed.**

The need for discharge care transition support. Illuri, Wallia, et al conducted a DM-specific Failure Modes Effects and Analysis, a risk assessment method used in high reliability industries. The analysis revealed that patient variability in both DM Rxs and education comprehension is a high risk barrier to improved care in the transition from inpatient to outpatient care. Of the 3 highest risks identified in this analysis, two are directly relevant to the present proposal: 1) variability in patient comprehension of DSME and DM Rxs (including use, effects and reconciliation); and 2) Rx discharge recommendation variability between providers[9].

The need for methodology for hospital DSME delivery. Few, if any, clinical trials in the DM field have utilized robust pre-implementation assessment methods and designs coupled with established implementation effectiveness (IE) evaluation frameworks to help inform and assess implementation practices. This project will help overcome these deficiencies by 1) applying the principles of implementation science (IS) and human factors (HF) engineering[9,20-25] and 2) utilizing mixed methods to design the intervention, workflow processes and plan the intervention to be sustainable within existing care delivery models. Information technology (IT) tools are increasingly being leveraged as a method to deliver content at the bedside and provide support for care transitions from hospital to home.[26] An IT platform for delivery of messaging content is used in the hospital in this study.

Prior experience and/or history relevant to the research -

This proposal seeks to build on our transdisciplinary investigators' prior work and examine ways to optimize DSME, skills training and discharge transition support integration within nursing unit workflow. This planning grant, will address concerns of the NIDDK Special Emphasis Panel on Pragmatic Research and Natural Experiments Reviewers provided in response to a PAR 13-366 R18 proposal submitted by our group (eRA Commons IR18DK108109-01; Grant11851018; reviewed 05-06-2015). Here, we will examine the feasibility of integrating a diabetes survival skills self-management education program (**Diabetes To Go)** within nursing unit workflow, assess potential 'burden' on staff, align nursing and patient time for intervention delivery, and assess nursing unit staff, hospital leadership and patient acceptance of the intervention.

The study team, led by Dr. Michelle Magee, PI, reported pilot study results for **Diabetes To Go** in which a learner-centered survival skills DSME program was offered to 125 hospitalized patients with uncontrolled type 2 DM (mean age 58±13 yrs; 66% female; 89% Black). While 70% had had prior DM education, only about half reported education within 2-5 years. Deficits identified on a pre-test (KNOW Diabetes) auto-directed the patient to video education content (view content examples at- *http://vimeopro.com/sitelvideo/diabetes* - *password* diabetes). Study team research assistants spent 30-60 min in 5-10 min time blocks per patient for intervention delivery. DM knowledge improved, with

61% answering ≥5 questions correctly at baseline and 89% at post-test (*P*<0.0001). Odds of being recognized as *highly adherent* (Modified Morisky Rx Adherence 4-item Score©) were 1.28 times higher at 2 wks (p<0.0001) and 1.36 times higher at 3 month post-discharge (p=0.0002) compared to baseline. Hospital and ED readmissions, although not powered sufficiently for statistical testing, showed encouraging results, with a decrease from 14% to 5% (*P*=0.0588).[4] The Diabetes To Go pilot showed the feasibility and preliminary efficacy of delivering DSME at the bedside. This content and delivery model will be optimized and further developed for provision of education in this proposed pilot intervention.

The MedStar team has extensive experience in focused DSME delivery in additional settings, including the ED and the community which have also generated support for such an approach and which was used to inform Diabetes To Go education content. **The Synergy To Enable Control Program for Adults with type 2 DM** study generated evidence that ED visits made by adults with DM and hyperglycemia can be used to initiate a 4-wk intervention with titration of DM Rxs and survival skills DSME. Among 101 participants (96% Black; 54% female; and 62.3% Medicaid/Medicare insurance) learner-centered survival skills DSME initiated in the ED significantly increased knowledge and few patients required meter and insulin shot instruction at follow-up, indicating skills retention. Modified Morisky Rx adherence score© improved from low to medium (p<0.001), a clinically meaningful improvement.[27,28] The **ABCs of Diabetes** placed a DSME program in a public library. Two small-group interactive DSME classes improved DM knowledge. Significant clinical outcomes included reduction in self-reported ED visits and in mean A1C.[5] These data support the contention that concise, focused DSME, as will be provided in this study, can improve DM outcomes among high-risk adults with type 2 DM.

MWHC has an established **DM resource nurse champion (DRNC) program**. Nurses interested in developing DM expertise are provided 1 hour a month to attend continuing education meetings at which a DM topic is presented and DM-related issues arising on units discussed. This group participated as a Diabetes To Go Advisory Board for the purpose of this grant submission. The proposed program was overviewed and the DRNCs were given the opportunity to ask questions and to provide input and preliminary suggestions on program design, perceived strengths and weaknesses and identification of processes to enable program success. Two areas for consideration in program development were identified. The first was in-/exclusion- criteria: Will Spanish speaking, low literacy patients, Psychiatry inpatients and/or ED patients be included? The second area was program design: It was suggested that the technology platform generate a report of survey results for each patient so the staff nurse can see in which areas education should be focused; Concern was expressed that iPads would be taken if not tethered and that attaching the iPad to a rolling pole would prevent theft; It was noted that it will be important to determine which patients are *also* seen by the hospital diabetes educators as a confounding variable of study outcomes. These observations/findings were considered in the present study design. This DRNC group will participate in the Advisory group for the R34 study.

In addition to the DM related research, the study team has significant experience in conducting pragmatic health services research in telehealth, patient safety, [29-31] and quality health improvement for patients with cardiovascular disease[32-38]. Dr Kelly Smith has experience in mixed methods and ethnographic approaches to examining how to integrate programs and processes into existing hospital workflow. Specific experiences include integrating and optimizing cardiovascular surgical approaches to off-pump surgery[34], examining effectiveness of oxygenators[39], and optimizing surgical care for elderly patients .[33,40] In her current AHRQ funded study called **We Want to Know**, Dr. Smith is partnering with hospital leadership and nursing staff to actively engage hospitalized patients to

report potential patient safety events. Detailed interviews, field observations, and focus groups with patients, providers, and leaders in 9 units have been conducted to establish a sustainable process for program integration into standard hospital processes prior to launching the program system-wide. ***We Want to Know*** is included in the MedStar Health system FY16 annual operating plan. Another example of pragmatic work is Dr. Smith's AHRQ funded contract to implement, evaluate, and spread a medical liability and communication resolution toolkit called **CANDOR**. This work is ongoing and has also been approved as part of the FY16 operating plan. Program education and training of system leadership and local hospital leaders has been completed. Processes have been established and are currently in field testing. System-wide launch began in July 2015 and will be implemented throughout all hospitals within MedStar Health by January 2016. These experiences will support successful completion of the Diabetes To Go R34 planning study.

Our transdisciplinary team of investigators has a full range of complementary expertise which will enable successful conduct of this study. **Michelle Magee, MD, PI**, is an endocrinologist and dedicated DM health services researcher. NIH funding for this study would represent the next step in moving her work forward as an independent investigator. She has experience in the conduct of major NIH clinical and Pharma trials with MHRI and her own research has focused on strategies to improve delivery of DSME and evidence-based diabetes care, including Diabetes To Go.

Kelly Smith, PhD, Co-I, is a cardiovascular physiologist and health services researcher. As Scientific Director for Healthcare Quality and Patient Safety Research at MHRI, she is committed to advancing care through applying mixed methods and IS frameworks to engage stakeholders in the development of innovations to improve health. She has experience in ethnography, field testing and leading practice improvements for quality and safety. Dr. Smith currently leads three AHRQ-funded studies that employ similar methodologies as proposed in this study to advance patient engagement in patient safety efforts (We Want to Know) and transform practice response to patient harm events (CANDOR). She is also leading a contract for AHRQ to develop, evaluation and disseminate a guide to improving patient safety in primary care settings through patient and family engagement. In addition to her roles as a PI, Dr. Smith is a Co-Investigator within the biostatistics, epidemiology, research and development (BERD) core of the CTSA. In her role with the CTSA, she serves as the lead health services researcher guiding new and existing investigators in development activities for implementation and systems delivery sciences.

Pat McCartney, RN, MSN, PhD is Director of Nursing Research with the MWHC Department of Nursing, Quality, Safety and Education. She will bring her academic and practice background to the study to enable bridging of research and practice perspectives and collaboration between the study team, nursing leadership and unit staff.

Joan Bardsley, MBA, BSN, RN, CDE RN, FAADE is a distinguished diabetes educator whose experience includes direct DSME, professional education for multidisciplinary teams, advocacy for access to and reimbursement for DSME, clinical trial management and executive administration with MHRI. She is a member of the Chief Nurse Officer Council of MedStar Health and is also a past-President of the American Association of Diabetes Educators.

Mihriye Mete, PhD is a senior statistician and Biostatistics Manager for MHRI. She has extensive experience with research design and data analysis. She is an experienced researcher who has contributed to 3 major NIH funded longitudinal studies (Strong Heart, SANDS and GOCADAN). Drs Mete and Magee have previously collaborated on the ADA Core Research Award STEP-DM study[27].

Dr Mete worked with Drs Magee and Smith in the design of the present proposal and developed the statistical analysis plan which she will conduct when the study is completed.

David Brennan, MBE is MI2 Director of Telehealth. With an extensive background in technology development, project management, applied health services research, and clinical program development, he will lead user-centered design tasks related to updating and refining the Diabetes To Go content and managing usability testing.

2. OBJECTIVES

We seek to determine the feasibility of integrating the Diabetes To Go program sustainably into ongoing hospital nursing unit processes for patient education and discharge planning. If successful, preliminary data generated will be used to develop a randomized controlled trial which will further assess program outcomes, including clinical and economic measures and potential for widespread dissemination.

The objectives of the present R34 Diabetes To Go Inpatient proposal are to refine the Diabetes To Go program content based on user feedback and experience, as well as to design and develop processes to enhance the feasibility of integrated implementation within usual nursing unit workflow within a large health system. A mixed-methods approach is used to leverage implementation science frameworks and human factors principles to make DM survival skills education and discharge support more accessible, interactive and engaging for patients. The long-term goal of this research is to optimize scalable and sustainable solutions for DSME and for DM-related discharge support. This personalized approach leverages e-health technologies to pursue the following **Specific Aims**:

Aim 1: To refine and optimize the Diabetes To Go program content and implementation processes.

This will be achieved by applying user-centered interface design principles, content development in partnership with patients and providers, detailed process mapping for program integration into existing processes and workflow, and integrating mobile and e-health technology to support care transitions. The Practical, Robust, Implementation and Sustainability Model will guide implementation planning and evaluation.

Hypothesis 1. Diabetes To Go: will be optimized for patient and provider usability and integration into nursing unit workflow; will enhance patient self-care knowledge and skills; and will support the discharge transition process.

Aim 2: To conduct iterative rapid-cycle usability testing of the enhanced Diabetes To Go program content and processes and establish a Diabetes To Go program toolkit for widespread implementation.

This will be achieved by a series of intervention-evaluation cycles of field testing, refinement, retesting of the Diabetes To Go program and evaluation through: direct observation; patient, provider and system leadership stakeholder interviews and focus groups; and evaluation of changes in early patient outcomes.

Hypothesis 2. The Diabetes To Go program will be perceived favorably by stakeholders yielding a high-quality toolkit for implementation and delivery of the program for further evaluation and testing.

Preliminary data gathered during this study will be used to design an R18 pragmatic trial in response to PAR 15-157 which will examine outcomes of implementation of the Diabetes To Go program when delivered on hospital nursing units to adult patients with diabetes across hospitals and health systems. The model has the potential to cause a paradigm shift in sustainable and generalizable approaches for delivery of patient-centered education and medication adherence and discharge transition support in the hospital

3 EXPECTED RISKS/BENEFITS

If successful, Diabetes to Go has the potential to benefit patients and the health care delivery systems within which they receive care by causing a paradigm shift in sustainable and generalizable approaches for delivery of patient-centered education and discharge transition support. We expect that enhanced delivery of education, targeted to the patient's individual learning needs, will lead to enhanced understanding of the need for and adherence to medications to control their diabetes and other comorbid conditions. Preliminary data gathered during this study will be used to design an R18 pragmatic trial in response to PAR 15-157 which will examine outcomes of implementation of the Diabetes To Go program when delivered on hospital nursing units to adult patients with diabetes across hospitals and health systems. In the future the learnings from this study may benefit nursing staff, hospitals and patients. Nursing unit staff and hospitals may benefit from the system developed if it is effectively integrated into workflow processes and discharge care to support delivery of DSME at the bedside with minimal disruption of unit workflow. Benefits to patients in terms of knowledge conveyed and potential clinical impact of the Diabetes To Go Inpatient intervention will be determined in future studies.

We believe that this study will expose nursing unit staff and patients to "Minimal risk". The probability and magnitude of harm or discomfort anticipated in this research are not greater in and of themselves than those ordinarily encountered in daily nursing unit life or during the performance of routine physical or psychological examinations or tests. No blood is being drawn. All staff and patient level data, including focus group, 1:1 interview and satisfaction data, as well as technology usage and usability data will be de-identified. For staff and patient interviews, we will be seeking a waiver of documentation of informed consent as the only document linking the individual to the study outcomes would be the consent document itself. All data will be coded and de-identified. Data will also be presented only in aggregate form, further limiting the risks of loss of confidentiality and breach of privacy.

4. ELIGIBILITY

Study population & sources -
The participants will vary based upon the phase of the study.

Phase 1. Workflow Assessment and Processes Intervention Design

- A purposive sample of 10-14 nurses and patient care technicians (PCTs) on 4 non-critical care adult medicine nursing units, including 1 psychiatry unit

- A group of 4 patient end-users will be engaged in usability testing. In addition to the inclusion and exclusion criteria outlined below under Phase 2 that represent the target audience for the Diabetes To Go platform, the following additional criteria for inclusion will also be used:
    - Speak, read, write English
    - Inpatient admission to a MedStar hospital within the prior 12-18 months
    - Experience with the Diabetes To Go program and/or DSME

Phase 2. Pilot intervention.

- All unit staff will participate in the education delivery program which will be introduced as a unit Quality Improvement initiative.
- Staff may opt-out of participation in the interview activities without consequences.
- ALL patients on the 4 units who have a diagnosis of DM will be offered the program to minimize workflow disruption and enhance operational sustainability.

Inclusion and exclusion criteria – These criteria have intentionally been kept broad to minimize disruption to unit workflow and to increase generalizability of findings. Where appropriate, the justification for each criteria is also presented, eg exclusion of minors.

Inclusion Criteria--Age > 18 yrs (lower limit of age for admission to MWHC adult units; all of the Diabetes To Go content is designed for adult learners); English speaking (Diabetes To Go content is currently only available in English); a diagnosis of diabetes mellitus (ICD9 250.xx/ICD-10-CM E08-E11) documented in the EMR; admitted to one of the inpatient units (non-critical care adult medicine nursing units, including 1 psychiatry unit) where the study is being conducted; willing and able to participate in the program.

Exclusion criteria: Age < 18 years (MWHC does not admit minors to its Medicine units and Diabetes To Go content has been prepared for adult learners); Pregnancy or anticipated conception within 3 mos (Diabetes To Go content does not address gestational diabetes or diabetes in pregnancy where management and glycemic targets differ considerably from those for non-pregnant adults); admission to an intensive-care unit, diabetic ketoacidosis, hyperglycemic hyperosmolar state – conditions in which the acuity level would likely preclude participation in DSME; patient declines participation in the education program for any reason; and any medical condition or cognitive dysfunction that, in the opinion of unit staff, would preclude participation in the education program.

5 SUBJECT ENROLLMENT

Phase 1. Workflow Assessment and Processes Intervention Design.

Drs. Magee, McCartney and Smith will present the Diabetes To Go research project at a nursing leadership meeting. Dr. McCartney and Dr. Smith will work with unit nursing leaders to identify individuals who may serve as key informants. They will request permission to present the Phase 1 study objectives to the frontline nurses during standing team meetings and/or during team huddles on the unit. A recruitment flyer with information about the study and about how to participate in the platform usability testing will be made available to each nurse and nurse manager. Individuals who agree to participate as key informants will go through the informed consent process at the time of the usability testing and be given an information sheet for their records. A waiver of documentation of informed consent will be applied for as it will be the only document linking the staff member to the project outcomes.

Dr. McCartney and Dr. Smith will work with the nursing leaders to identify optimal dates/times to observe current rounding practices for diabetes education in order to map processes for the pilot intervention. Individuals (nurses, patient care technicians, and diabetes educators) will be shadowed by one of the project coordinators/human factors specialists. Identification of the individual shadowed will be withheld from documentation and the output of the process mapping and field observations will be presented in aggregate as flow diagrams and thematic representations of current and optimal workflow.

Phase 2. Pilot Intervention

A Diabetes To Go Inpatient Program informed consent will be provided to each patient admitted to the participating units who has a DM diagnosis.

The study team will inform the DRNC (or alternate designated staff member) via an ongoing electronic screening list of unit patients who have DM. All DM patients admitted to the unit will be considered for program participation by unit staff. Staff will assess ability to participate in the program (see Patient Screening Checklist) and if appropriate will offer each patient the program. At the time the program is offered to each patient, nursing unit staff will answer any questions that the patient may have about Diabetes To Go. Patients who agree to participate will then be asked to provide informed consent and when they have done so, will be enrolled in the program.

Reasons for exclusion from the offering (screen failures) will be recorded in the study database by the study team from the screening checklists. Patients who decline participation in the program will be also be considered as screen failures. The reason(s) for declining participation will be captured.

6 STUDY DESIGN AND PROCEDURES

An overview of the **research design** is shown (Figure 1). The work will be conducted over 2 years in 3 phases. The **study timeline and major activities by phase** are shown in Table 1. Phase 1 will be dedicated to Workflow Assessment and Intervention Design (1 yr) and geared to accomplish activities to support Specific Aim 1. Phase 2 of the study will focus on achieving Specific Aim 2 by conducting a series of iterative pilots and revisions of the Diabetes To Go program and processes (9mos) designed in Phase 1. Phase 3 will be dedicated to analysis and reporting of results and setting up a large pragmatic trial (3mos). Work plans for each phase are detailed below in Table 1.

Figure 1.

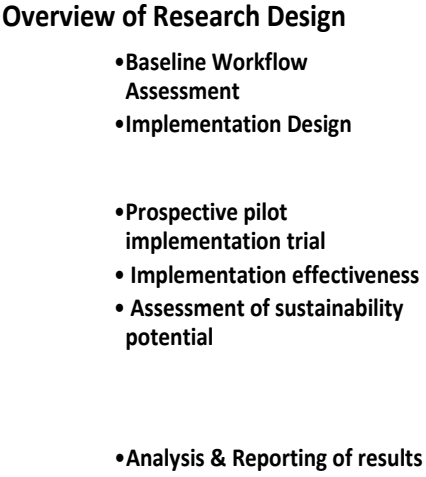


Table 1. Timeline & Major Activities	Year 1				Year 2			
Quarter								
Phase 1: Workflow Assessment and Diabetes To Go Program and Processes Intervention Design								
a. IRB approvals								
b. Workflow and initial PRISM elements assessment								

c. IT platform usability assessment & refinement								
d. Implementation design								
e. Groundwork for pilot								
Phase 2: Prospective Pilot Implementation Trial								
a. Pilot intervention								
b. Implementation Effectiveness Evaluation								
Phase 3: Analysis and Reporting of Findings								
a. Finalize data set								
b. Analysis								
c. Reporting of findings[1]								
[1] Findings will be reported following completion of phase 1 and following conclusion of the study.								

The Diabetes To Go conceptual model is shown in Figure 2. Individualized learner-centered education addresses patient's DM self-care management knowledge and skills deficits and discharge transition support. Knowledge of DM medications (Rxs) prescribed at hospital discharge, access to those medications and communication with the Primary Care Provider (PCP) to assure continuity of care will be emphasized. If successful, preliminary evidence generated by this R34 will serve to inform the design, methods and measures to support a full scale pragmatic trial (PAR- 15-157). **This prospective pilot study will examine strategies to optimize an inpatient DSME, skill building and technology-assisted discharge care transition program delivered at the bedside by existing staff on nursing units. Intervention design will be informed by mixed methods using human factors principles and implementation science approaches to optimize unit integration**.

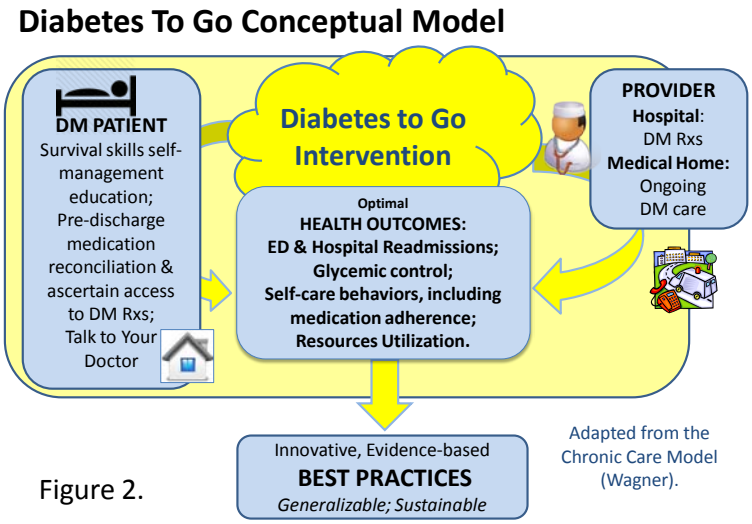


Figure 2.

Phase 1 Project – Design Diabetes To Go Program & Processes

Aim 1: To refine and optimize the Diabetes To Go program content and implementation processes. This will be achieved by applying user-centered interface design principles, content development in partnership with patients and providers, detailed process mapping for program integration into existing processes and workflow, and integrating mobile and e-health technology to support care transitions. The PRISM will guide stakeholder engagement, implementation planning and evaluation. **Hypothesis 1-** The Diabetes To Go program: will be optimized for patient and provider usability and integration into nursing unit workflow; will enhance patient self-care knowledge and skills; and will support the discharge transition process.

E1a. Baseline Workflow and Initial PRISM Elements Assessment. The MHRI Implementation Science team will collaborate with the MedStar Diabetes Institute (MDI) clinical research team and MWHC Nursing to perform **an ethnographic study** examining workflow of identified staff engaged in DSME and discharge planning to develop a process map for integrating Diabetes To Go into day-to-day practice. A purposive sample of **nurses and patient care technicians (PCTs) (n=10-14) will be observed** for 6- or 10-hr blocks on 4 non-critical care adult medicine nursing units, including 1

psychiatry unit, resulting in a total of 280 hrs of observational data. The sample size is consistent with other observational studies of nursing care.[41, 42] The time blocks were chosen to avoid shift turnovers, when no education will be taking place and will be varied so that all days of the week and shifts will be covered. **Semi-structured interviews** with nurses and PCTs will be conducted to solicit perceptions of how intervention integration could be optimized. Participatory action methods will be employed to iteratively identify common themes and validate the themes and process maps that are developed with relevant nursing staff and leaders and hospital leadership.[43-49]

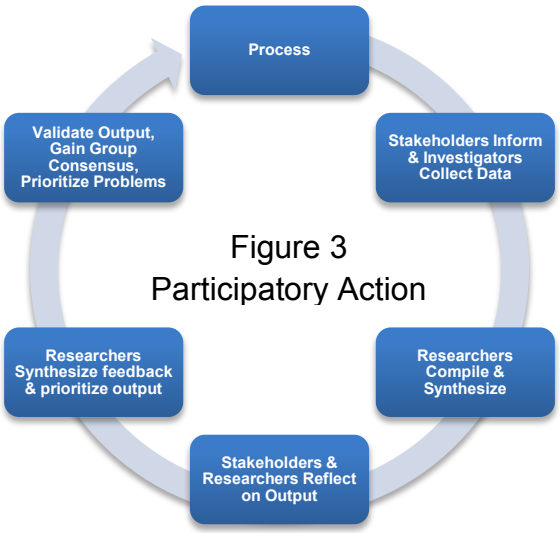


Figure 3
Participatory Action

Participatory action research is an iterative process that seeks to understand and improve the problem and reduce deficiencies through involving the recipients (stakeholders) of the intervention in the process of development who, in turn, take actions to improve the system. Figure 3 depicts the iterative cycle of data collection, information synthesis and analysis, feedback and refining of assumptions, synthesis and prioritization, and output validation, prioritization and group consensus. The process continues until researchers and stakeholders comes to ***consensus***. This is a rapid process, quickly moving from base knowledge to group consensus. It can also be used iteratively. Field observations will be recorded and time-stamped to document and code each staff task performed and time spent on the task in the patient room. Data on key characteristics of each task will be collected, such as whether the task is an interaction with the patient that is cognitive or physical or both, is required or optional, and whether the task is interrupted. Descriptive statistics will be calculated to determine the total staff time spent in the room, and the nature and duration of the tasks performed there. Initial **key informant interviews** will be conducted 1:1 with patients, with physician providers (inpatient and primary care providers) and with nursing and hospital leadership. **Initial PRISM elements** will be assessed.Dr. Smith and her team have experience in applying these methods in support of hospital practice transformation.

User-Centered Development and Usability Testing of the Tablet-Based Learning Platform. The MedStar Institute for Innovation (MI2) team, under the direction of Dave Brennan, MBE, will plan and carry out the user-centered design of two additional Diabetes To Go modules. **How to Talk to Your Doctor** (adapted from the AHRQ, NIH Office of Research in Minority Health endorsed Baylor College of Medicine "How to Talk to Your Doctor" (and get your doctor to talk to you!) program content [50.]) will focus on strategies for enhancing patient-provider-communication and generate take-home printed handouts patients can use during post-discharge PCP visits to generate discussions around DM targets and the importance of appropriate medication choices. The **DM-related skills management module** will guide patients through insulin (vial and syringe or pen) and GLP-1 analog shot self-administration instructions and through the technique of performing fingerstick self-blood glucose monitoring. Each module will consist of a mix of content format and type (images, videos, animation –eg for role modeling for patient-provider communication- and text) developed in-house or from external industry partners. **MedStar's e-Visit platform** will also be integrated into the post-discharge support process for patient and provider use and its' uptake/adoption assessed.

A user-centered design approach will be employed during development of both the new modules as well as revisions to the entire tablet-based learning platform, which will be built using MedStar Health's existing patient engagement and data collection engine, Tonic Health (https://tonicforhealth.com/). MI2 Human Factors and Medical Usability specialists

(*http://medicalhumanfactors.net/*) will provide heuristic review of initial designs and conduct 3 sequences of rapid-cycle usability testing, each with 4 patient end-users (a sample size which has been cited as being adequate to identify 80% of usability problems with a system[51]). Results from each cycle will be used to drive iterative improvements in design and to study the program processes. During usability testing, participants will be asked to complete an entire education session from registration through follow-up survey. To support the *Research Data Collection* needs of the study, the MI2 Team will **code the required data collection instruments in the REDCap** (Research Electronic Data Capture) **web-based research data system**.[51] MedStar is a partner in the REDCap Consortium and this study will leverage an existing operational best practices for secure data access/storage and system-wide training.

Implementation Design/Planning

Implementation design and the **pilot protocol** will be informed by the workflow assessment and initial PRISM elements evaluation; **Analysis of observational and key informant interview data, and resource nurse focus group data** will provide insight into implementation barriers and strategies to overcome them **to assure integration of the intervention with minimal workflow impact.** PRISM will enhance the translation of research into practice[52] by guiding Phase 1 implementation planning and Phase 2 evaluation in support of **Specific Aim 1** – **Optimization of intervention design**. The PRISM elements addressed during planning and throughout the trial are shown on Table 2.

Phase I activities aim to identify barriers and facilitators of intervention success across organizational, patient, and environmental (internal and external) stakeholders. Representatives from each group will be interviewed (semi-structured interviews/focus group). Data on barriers and facilitators will be validated with the
stakeholders using a participatory action methods approach. Phase 2 approaches are detailed in the Implementation Effectiveness Evaluation section below.

Early identification and evaluation of barriers and facilitators of implementation will allow for creative solutions to be embedded into the study protocol prior to clinical implementation, ***thus, creating an innovative, sustainable program for patients and clinical stakeholders***.

Table 2. PRISM Framework for planning and evaluation

PRISM element	Characteristics	Operationalization
Intervention/Program		
Organizational Perspective	Organizational readiness; evidence strength; frontline staff barriers; coordination across depts; burden (complexity & costs); Usability & adaptability; trialability & reversibility; ability to observe results	Engagement of clinical leadership (Nursing; Nursing Research; MD leadership & providers) and unit staff (nurses, PCTs) in all processes of protocol and intervention development and refinement; satisfaction
Patient Perspective	Patient-centeredness; addresses patient barriers; seamlessness of transitions between program elements; service and access; burden (complexity and costs); feedback of results	Patient (from prior hospitalizations) and family advisory group engaged in all processes of protocol & intervention development & refinement; identify barriers & facilitators; study patient interviews with IE team.
External Environment	Payer satisfaction; competition; regulatory environment; reimbursement; community resources	Engagement of regulatory compliance, payer, & other key environmental stakeholders to support IE.
Implementation & Sustainability Infrastructure	Performance data; dedicated team; adopter training & support; relationship & communication with adopters; adaptable	Enhance adaptability via early & ongoing stakeholder engagement, design & development, including human factors/systems

	protocol & procedures; facilitate sharing best practices; plan for sustainability	engineering integration implementation assessment; iterative evaluation of barriers/facilitators
Recipients		
Organizational Characteristics	Organizational health and culture; management support and communication; shared goals and cooperation; clinical leadership; systems and training; data and decision support; staffing and incentives; expectation of sustainability	Patient & nursing staff advisory groups and clinical leadership engaged throughout processes of pilot protocol & intervention development & refinement; clear expectation setting; leverage existing resources to foster sustainability within nursing units
Patient Characteristics	Demographics; disease burden; competing demands; knowledge and beliefs	Early patient engagement in process; sensitive to local & individual cultures; readiness to change; satisfaction; pilot focus groups to identify barriers/facilitators of IE.

The MWHC Chief Nursing and Medical Officers and the MedStar Health Executive Medical Officer have expressed support for the study (See Letters of Support). These leadership stakeholders will be engaged for the provision of Administration input throughout the study as Key Informants.

Phase 2 Project – Iterative Pilot Testing

Aim 2: To conduct iterative rapid-cycle usability testing of the enhanced Diabetes To Go program content and processes and establish a Diabetes To Go program toolkit for widespread implementation.

This will be achieved by a series of intervention-evaluation cycles of field testing, refinement, retesting of the Diabetes To Go program and evaluation through direct observation, stakeholder (patient, provider, system leadership) interviews and focus groups, and evaluation of changes in early patient outcomes. This will enable demonstration of uptake and adoption of the program by unit staff and by patients. **Hypothesis 2-** Diabetes To Go will be perceived favorably by patients, providers, and health system leaders yielding a high-quality toolkit for implementation and delivery of the program for further evaluation and testing.

Pilot Implementation (9 months). Phase 2 activities will enable accomplishment of Specific Aim 2. **Diabetes To Go will be piloted in 4 units** as a Quality Improvement initiative. *All methods described in this section are subject to revision per baseline workflow and PRISM assessments and the optimized study design developed by the team based on those findings.* The program will be offered by staff to ALL patients on the unit with DM to minimize workflow disruption and enhance operational sustainability. A series of iterative implement-observe-refine cycles will be conducted during the Phase 2 to assess process, workflow and patient receptivity to the program. This will provide opportunities to make rapid-cycle improvements. Details of the pilot study work plan are provided below.

Study Participants. Table 3 outlines characteristics of the proposed study participants.

Table 3. Study Participant Characteristics.

Participant	Description/Characteristics
Unit Staff	All unit staff will participate in the program. Staff will be invited to participate in focus groups and 1:1 interviews. Staff may opt-out of participation in the interview activities without consequences.
Patients	All adults admitted to the target units with a diagnosis of DM will be identified daily via the hospital's electronic data repositories. All DM patients will be offered the program by unit staff. Inclusion and exclusion criteria have been intentionally kept broad to minimize disruption to unit workflow and to increase generalizability. **Inclusion Criteria--**Age ≥ 18 yrs (lower limit of age for admission to MWHC adult units); English speaking; and diabetes mellitus (ICD9 250.xx/ICD-10-CM E08-E11); **Exclusion**

	criteria: Pregnancy or anticipated conception within 3 mos, admission to an intensive-care unit, diabetic ketoacidosis, hyperglycemic hyperosmolar state, patient declines participation, and any medical condition or cognitive dysfunction that, in the opinion of unit staff, would preclude participation.

Pilot Study Timeline & Events. The proposed schedule of visits and events are shown on Table 4.

Table 4. Study Schedule	Intervention Visits			Follow-up visits	
	Baseline	**Interim**	**Pre-d/c**	**2-5 d[10]**	**30 d**
Baseline Data-- by study team					
Demographics	x				
Clinical history & baseline data[1] with admit DM Rxs[2];	x				
Admit & last pre-d/c glucose	x		x		
Discharge DM Rxs[2]			x		
Diabetes To go Intervention - by existing nursing unit staff					
Surveys – KNOW Diabetes; Modified Morisky 8-item	KDM; MMAS-8		KDM		MMAS-8 item
DM2Go content completed(%)	x				
FSBG/shot competency[3]	x	Prn[3]	Prn[3]		
D/C DM Rxs[1] & access[4]	x		x	x	
Report to PCP[5]			x		
Talk to your Doctor questions[6]			x	x	x
Post-program – by study staff					
Patient satisfaction					x
Nurse/PCT satisfaction				x	
Implementation costs[7]	x				
Post-discharge patient telephone follow-up					
DM meds access & barriers[8]				x[10]	x
Survey – Morisky 8-item					x
ED/hospital readmissions[9]					x
Missed days work/usual activities					x

Legend: [1] Clinical information to include DM type, co-morbid medical conditions; height, weight, BMI, education history, including prior DSME and skills instruction (timing and extent), access to Rxs, including co-pays; current laboratory results (Cr_s, AST, ALT, A1C if available in EMR. [3] FSBG/shot competency = fingerstick blood glucose monitoring technique/self-injection technique if applicable, repeated prn until competent; [4]access=confirm DM Rxs on formulary &/or if pre-authorization required/obtained, can afford co-pay; [5]Report to PCP=d/c DM Rxs, follow-up (f/u) DSME recommendation; [6] Talk to Your Doctor questions provided at time of d/c; [7]implementation costs (staff time, supplies, hardware, software licenses); [8] f/u phone call=confirm Rxs filled, other barriers to taking meds;[9]emergency department (ED) or hospital readmisions=*self-reported* ED/hospital readmissions since index admit –plus- augmented by local EMR/hospital data repository data as needed to minimize missing data to provide preliminary data for pragmatic study. [10]TBD – who will do the 2-5 d rapid post-discharge f/u call (unit staff, hospital post-d/c call team or the study team).

Outcomes – Proposed Outcomes for the pilot trial are provided on Table 5.

Table 5-PIlot Outcomes	Outcomes	Measures	Data Source(s)
PATIENT			
Knowledge & Skills Acquisition	DM knowledge and skills	DM knowledge test score	KNOW Diabetes Survey
Behavioral	Rx adherence	Morisky score; DM Rxs names, doses, timing, side effects, access, barriers	MMAS-8© Survey; self-report

Healthcare resources utilization	LOS**; Hospital based acute care visits	LOS; ED/hospital readmissions	Self-report augmented by EMR
DM2go platform adoption	Platform user uptake	#, % modules viewed; time used; content skipped and/or replayed	Tonic platform
Satisfaction with Diabetes To Go program	Expressed satisfaction	Satisfaction with program & IT platform	Survey; interviews; Tonic IT platform
STAFF			
Satisfaction with DM2go program	Expressed satisfaction	Satisfaction with program & IT platform	Survey; interviews
Program adoption	DM2go program uptake	#, % DM patients offered program; #, % patients completing program	Patients; Tonic IT platform
COST ANALYSIS			
	Implementation costs	Staff time/effort; capital costs; IT effort	Observation; interviews; costs for IT and education tools
Legend: DM2Go = Diabetes to Go intervention ** LOS will be collected to allow preliminary determination of the LOS correlation with time required for meaningful content delivery.			

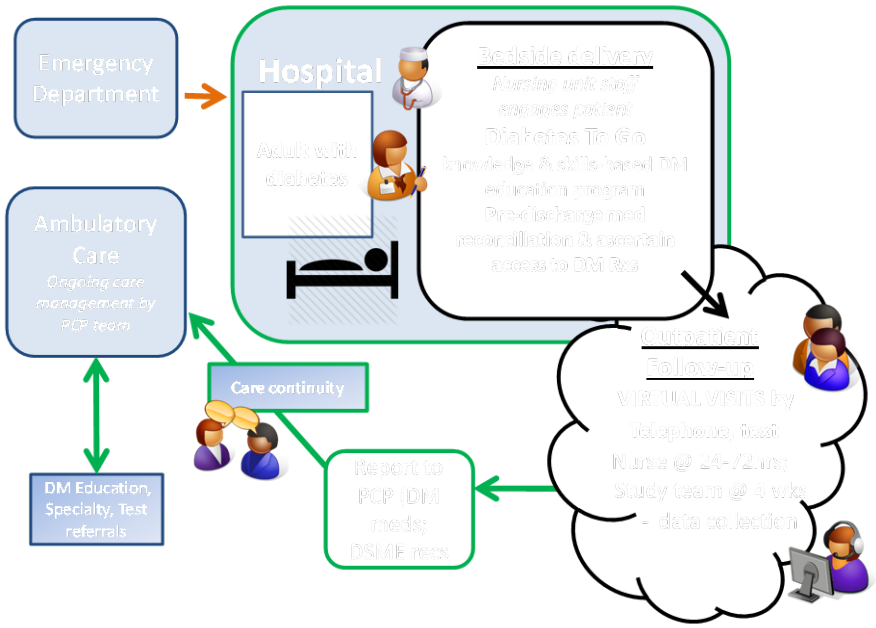
General Methods.

Baseline Assessment: All participants on intervention units will undergo baseline assessment as shown in Table 4. After unit staff have provided the patient with program information about the program, the study team will obtain baseline data as shown on Table 4. Because this pilot study, by design, is not assessing lab clinical outcomes the study will not be conducting any study-provided laboratory tests.

Patient outcomes surveys. The KNOW Diabetes knowledge survey and the Modified Morisky[53] Rx Adherence Survey 8-item (MMAS-8© with permission from D. Morisky) are delivered via the Tonic platform. Delivery oversight will be provided by the unit staff. The KNOW Diabetes survey was developed by MedStar for use with the STEP-DM and Diabetes To Go programs. Each knowledge question is linked to video content so that education addresses knowledge deficits directly via the platform when an incorrect response is entered.

Evaluation of Implementation Costs. Preliminary costs for program implementation will be collected by the study team and will include unit clinical staff effort/time accrued in program delivery and costs for technology, for licenses and for printed nurse and patient education tools.

Staff training. The DRNC will train staff via change of shift in-services. Each staff member will also take the knowledge pre-test, view the program education content and take the post-test. A web-based training module will be available so that staff may also complete the training online. A pocket version (print & tablet/smartphone app) of the education content will be provided. A CDE member of the study team will serve as the unit program liaison/champion. Unit in-services will address 1) Evidence- including research, clinical & patient experience, local data/information; 2) Context-setting in which proposed change will be implemented; culture-how things are done at the site, values, beliefs, assumptions; leadership; evaluation, effectiveness 3) Facilitation- including purpose, role and description of skills and attributes.



Pilot Intervention. An overview of intervention flow and key activities is provided in Figure 4.

Education implementation. A CDE member of the study team will serve as the unit program liaison/champion. Unit in-services will address 1) Evidence-including research, clinical & patient experience, local data 2) Context-setting in which proposed change will be implemented; culture-how things are done at the site, values, beliefs, assumptions; leadership; evaluation, effectiveness 3) Facilitation-including purpose, role and description of skills and attributes.

The study team will inform the DRNC (or alternate designated staff member) via an ongoing electronic list of unit patients who have DM. Staff will assess ability to participate and if appropriate will offer them the program. Training in use of the technology until the patient feels comfortable with it will be provided. It is likely that most patients will use the tablet to complete surveys and access education content. The option to take the surveys on paper and to read the education content in the Diabetes To Go book will be available should a patient prefer the print modality. Using the methods agreed upon during the design phase, staff will encourage patients to progress through the program and provide an opportunity to ask questions when in the room.

Individualized education assignments are driven by the pre-test knowledge assessments. The patient takes the knowledge and MMAS-8 pre-tests via the Tonic platform. After the patient responds to each question, the program lets him/her know if the response was correct or not and gives the correct response as a first teaching point. At pre-test completion, the platform auto-directs the patient to each module corresponding to the areas in which a knowledge deficit existed. The unit staff member will be provided with a report card detailing the survey questions where deficits were identified so they can focus on these areas for subsequent education with the patient. Mandatory modules include those on each DM Rx which will be prescribed at discharge (including insulin or GLP-1 analog injection technique), when to call the doctor or go to the ED, and Talk To Your Doctor. DSME includes 7 core areas; 5 of these will be tailored for each patient based on knowledge deficits identified by the KNOW Diabetes survey: 1) know your DM numbers (sugar and A1C), 2) know when your blood sugar is low, 3) know when your blood sugar is high, 4) basic diet education, 5) self-monitoring of BG. Rx adherence issues identified on the MMAS-8 will also be addressed. DSME will be delivered via brief video clips (3-5 minutes in length) via the tablet. When assigned content has been completed, the patient will take the post-test surveys. Each patient will be given a Diabetes To Go book with the same content delivered on the videos to use as a reference following discharge.

Discharge DM Rxs management and Arrangement for follow-up 'virtual' visits. Prior to discharge, unit staff will review the DM Rxs prescribed with the patient and flag the matching content in the Diabetes To Go book. Access to the Rxs will be assessed via the tablet/internet (*http://drg-fingertipformulary.com/*) and/or the hospital EMR formulary database. If Rx access is an issue, staff will consult the provider writing the discharge Rxs to reconcile. When possible, a 30d supply of any

Rxs newly prescribed or in need of resupply will be delivered to the bedside prior to discharge by the MWHC Pharmacy **"Meds to Beds"** program to facilitate access. Staff will let patients know that they will be called 2-5 days post-discharge and will ask for preferred contact information and the best time to call/text/videochat. We anticipate aligning these processes with current unit discharge medication management processes in order to minimize disruption to workflow.

Rapid cycle redesign and redeployment. During the pilot, 2-3 implement-observation-revision cycles for the program and process will be conducted (Figure 5). The approach to observations and refinement are detailed in section 1a-c. Each iteration will take approximately 2-3 mos to complete. The final **Diabetes To Go Toolkit deliverable** will be refined and revised based on user feedback at the end of the 3rd pilot. Stakeholders will be interviewed for user experience feedback. Process will be directly observed for ≥ 3 days on each unit/iteration to collect implementation process information and feedback. **Recruitment and retention approaches** are detailed in table 5 below.

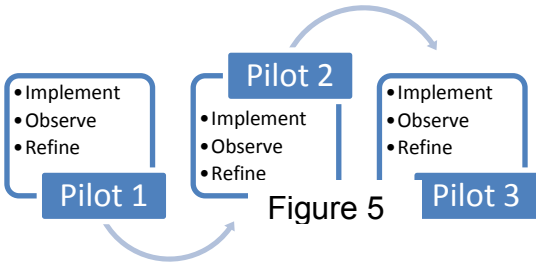


Figure 5

Table 5. Recruitment and Retention Strategies	
Subject	**Description**
Unit Staff	The main key to unit staff retention will be design optimization so it does not negatively affect workflow. Engaging unit staff and Nursing Leadership in study design will enhance program engagement. Staff will be invited to provide feedback to the study team during the intervention phase so that issues may be addressed. DRNCs will be enabled to have a specialized expertise in DM that will support nursing ladder advancement. Light food and beverages will be offered during staff advisory group meetings, during in-services and during training to help minimize time spent off the units/ non-productive time.
Patients	A stipend in the form of gift cards will be offered to each patient completing the program after the the 30 day follow-up visit to promote retention as described in the budget justification section. Follow-up virtual visits will be arranged at the patient's convenience, including early AM, late PM and weekends to minimize disruption to usual daily activities, including work schedules.

Strategies for sustainability outside the study setting. Unit nurses previously provided input into the existing program education content and delivery format. The intervention will be further developed by a multi-disciplinary team with strong representation from nursing unit staff and leadership, research and education stakeholders. It will be delivered by existing staff. Our intent is to show that the program model could be implemented on non-critical care hospital units by existing staff. The MedStar Institute for Quality and Safety has strong experience in quality, efficiency, reliability, and safety improvement, including workflow process implementation (see Investigators and Facilities sections), and will conduct this study's workflow process analysis to assure efficient, effective program implementation. MedStar implementation scientists will employ the PRISM framework to optimize likelihood of implementation success and enhance generalizability. The resulting program could potentially be incorporated into the education delivery paradigm for all hospitals. Developing systems to understand individualized operability, and then using existing personnel and current scopes of practice for education delivery will be efficient in terms of resources utilization and broad applicability. Additionally, offering DRNCs the opportunity to develop expertise in diabetes is aligned with professional development and supervisor and peer recognition of the expertise gained.

Potential for generalizability. Our study's inpatient medical and surgical environment reflects the general U.S. hospital population, in that up to 30% of inpatients have DM and standardized strategies and tools to educate patients are lacking. If successful in a subsequent RCT, the Diabetes To Go learner-centered, technology assisted model could potentially be applied in other clinical settings (e.g., the Medical Home and/or

on other inpatient services) to bring DM subspecialty education directly to high volumes of patients who often do not access formal outpatient DM education programs. This model could also be applied to other chronic complex medical conditions in in- and outpatient settings to deliver education and thus improve outcomes.

Implementation Cost Analysis. Professional labor and other personnel time will be determined using time-motion analysis supplemented by provider/staff interview. Unit labor costs will be determined from hourly wage or annual salary data as determined by the U.S. Department of Labor. Capital costs for technology (hardware, software) and education tools (printed books and pocket guides) will also be determined.

F. Environment. The MWHC hospital environment and the spectrum of support for conduct of clinical research offered by MHRI will aid in the success of this study. The transdisciplinary clinical and scientific environment detailed in the Investigators and Facilities sections will contribute to successful conduct of the study. Institutional support from Hospital Leadership, MHRI, and MedStar Health's Chief Medical Officer (see letters of support) will assure successful implementation and sustainability of the proposed delivery model.

G. Limitations/Pitfalls

Our study has potential limitations. Most notably, as described by the NIH Reviewers of our R18 proposal is that it may not be possible to fit the proposed intervention into unit workflow. Every effort is being made in our study design to avoid this pitfall; however, the following situations may arise which could impact outcomes:

Nursing unit staff have many competing demands on their time. The intervention will not work if the staff do not support it. Incorporating HF/IE principles and early nursing leadership and staff engagement in the process design will provide an opportunity to avoid this challenge via thorough baseline assessment and ongoing IE. In the event that the intervention does not succeed, a fallback plan will be examination of the potential for deployment of staff dedicated to patient education program delivery that is deployed across units.

Many factors contribute to poorly controlled DM and to readmissions. We will examine a few key variables—DSME and skills education, their delivery at the bedside and strategies to enhance medication management during the discharge process. Our intention is to address these **high risk** factors in our study in a focused concise way in order to assure delivery of key DSME and skills content and to support Rxs management and to engage the patient in healthy self-care behaviors which will promote outcomes improvement. We will identify additional variables affecting outcomes and address them as appropriate in this or future interventions.

Our post-discharge assessment period is 30 days, due to the short (2 yr) duration of this study. This time period will allow us to generate sufficient preliminary data for assessment we propose for this intervention. It will not however, permit determination of intermediate or long-term outcomes. These would be the focus of a future RCT if our preliminary data shows promise. Evaluation to determine long-term impact is beyond the scope of the present study and could be addressed in a future study.

Additional Information.

The Behavioral Intervention

"Diabetes To Go" is a learner-centered behavioral self-mangement education and medication adherence intervention that has been developed by a multidisciplinary team led by the present

proposal's PI (Magee). It has also been pilot tested. The Diabetes To Go intervention and findings of the pilot study which assessed its preliminary impact on diabetes knowledge and medication adherence are described in the Section above on "**Prior experience and/or history relevant to the research".**

During Phase 1 of this study, we will **refine and optimize/adapt the Diabetes To Go program content and implementation processes** to enhance the likelihood of optimal uptake and impact of the behavioral intervention. This will be achieved by applying user-centered interface design principles with our human factors partners, development of additional content in partnership with patients, providers and MDI and MI2 content development experts, detailed process mapping for program integration into existing processes and workflow, and integrating mobile and e-health technology to support care transitions. The Practical, Robust, Implementation and Sustainability Model, deployed by our implementation science experts will guide implementation planning and evaluation. **Audio** recordings obtained during focus groups will be immediately transcribed following the interview. Transcripts will be reviewed and validated for accuracy. Once accuracy of the transcripts has been validated, the original audio recordings will be destroyed.

The Diabetes To Go program (surveys and video content) will then be deployed in Phase 2 of the present study as an integrated teaching tool at the bedside to enable assessment of the effectiveness and short-term sustainability of the workflow processes developed in Phase 1 of the study. We will be gathering pilot behavioral intervention patient outcomes related to knowledge and skills acquisition, Rx adherence, healthcare resources utilization, platform adoption, and satisfaction with the program.

***Fidelity and competence of the behavioral intervention will be maintained and demonstrated throughout** the study as described below.*

Fidelity of the intervention process will be assured by reviewing to ensure that each education content area is consistently offered to each patient. Nursing Unit staff will encourage each patient to complete the program content during the time that they are on the unit prior to discharge. Reasons for failure to complete the full program will be captured from the patient and the unit staff's perspective in the program platform prior to or at the time of discharge from the unit. The study coordinator will conduct audits to assess the degree of compliance with the program. Data for survey completion, survey results and video content usage will be auto-extracted from the Tonic for Health platform for provision to the data management team and will also be used in the assessment of fidelity.

Competence or compliance with fidelity will be demonstrated via analysis of the number of content areas accessed by each patient*, time spent viewing video content which corresponds to knowledge deficits on the surveys and time spent viewing mandatory video content.*

Focus Group Specifications.

Dr. Smith and her team have extensive experience in conducting interviews and focus groups for the purpose of developing and designing sustainable solutions for implementation within hospital in-patient settings. These experiences include focus groups for patients with chronic disease (diabetes, cardiovascular disease, obesity), frontline staff (nurses, patient care technicians, transporters, administration), physicians, and senior hospital and healthcare leaders (board members, chief executives, middle management). In her current work on the We Want to Know project, Dr. Smith employs multiple interview methods include participatory action, cognitive interviewing, motivational

interviewing and focus groups to interview patients and family members about perceived breakdowns in care as well as healthcare staff and leaders about their experience with the We Want to Know program implementation and sustainability of the program after grant funding.

A comprehensive interview guide will be created during the development phase of the Diabetes To Go project and submitted to the IRB prior to initiating any interviews or focus groups. Focus groups will be conducted using a semi-structured interview approach, with questions on usability of the technological platform, content of the Diabetes To Go program, and identification of any perceived challenges or barriers to implementation.

Focus groups will be limited to English speaking patients and participants. For patient focus groups, we will work to ensure that all patient focus group guides are written in plain language at no higher than a 6th grade level.

Information will be captured during the interviews/focus groups in two ways. First, the members of the focus groups will be asked to provide verbal consent to be audio recorded for the purpose of the project. Second, in addition to the Focus Group Facilitator, a note take for the project will be in attendance to take notes and assist the facilitator with ensuring attention to all the key components of the interview. Information from the focus groups will be reviewed, synthesized, and aggregated using standard approaches for thematic review using grounded theory. Transcripts of the focus groups will be reviewed independently by two investigators for common themes. Adjudication of differences will be presented to a third investigator for validation and resolution. Once the common themes have been identified, this information will be presented back to the participants for validation and revision. Once validated, a final report on the outcomes of the focus groups will be generated and the information gained from the participants will be used to revise the Diabetes To Go platform, educational content, and expected processes as appropriate. Digital audio recordings of the focus groups will be destroyed upon completion of validation of the written transcripts.

Permission to audio record participants will be included in the informed consent process and assented to verbally. Recording of the verbal assent will be conducted after initial agreement to be recorded. Information of the need to audio record the focus groups will also be a part of all recruitment materials so that any volunteer is aware of the need to record responses prior to their attendance at the focus group.

Methodology Specific to Study Surveys

Phase 1.

All information for Phase 1 will be collected using semi-structured interviews and/or focus groups. Approaches to these activities are presented above.

Phase 2. Pilot Intervention

Survey methodology – all surveys (baseline data, knowledge survey and medication adherence, satisfaction) will be self-administered via the Tonic for Health platform. Patients will be provided instruction in use of the platform until they feel comfortable using it and in an ongoing fashion if needed during the participation period. Patients who prefer not to use the technology platform will be provided with print copies of the surveys and if needed, eg the patient cannot read, then the surveys will be administered by the study team (baseline data and satisfaction) and the nursing unit staff (knowledge and medication adherence). Staff will be trained in methods for administration of surveys so that bias in patient responses will not be introduced as a variable.

As described in the approach sections above, two surveys are embedded in the Diabetes To Go program. The first is the **KNOW Diabetes survey**. This tool was developed by the MedStar Diabetes Institute in recognition of the fact that there is no existing validated diabetes knowledge survey which specifically addresses diabetes "survival skills" self-management education content areas. This survey is used as the pre- post-knowledge survey in this study. Importantly, responses to the survey determine which video content area patients will be directed to for viewing. When a patient answers a question incorrectly, the platform provides a link to the video content which provides information on the topic for which a knowledge deficit was identified; thus, the content is tailored to the patient's learning needs. In an ongoing study, the MDI is currently in the process of validating the KNOW Diabetes survey.

The second survey is the **Modified Morisky Medication Adherence Survey, 8-item**. This is a validated survey which is used with permission from David Morisky.

In addition to these surveys, a baseline survey will be administered to each patient participating in the program to gather data which will be used to augment data extracted from the hospital EMR (See Baseline patient data survey). A patient satisfaction survey will also be administered at the time the patient completes the education program. This survey will address patient perceptions of the inpatient education experience and with the technology platform. These surveys will be developed during Phase 1 and submitted to the IRB for approval prior to use in Phase 2.

Other Consideration Relative to Study Specifications:

- **Specimen Collection –** No biological specimens will be collected in this study.
- **Studies involving use of product (licensed, labeled of small size, simple) –** No product will be used in this study.

7 DATA COLLECTION AND MANAGEMENT PROCEDURES

The source document will contain the original signed informed consent document, completed baseline data collection forms, and copies of all survey responses and will be kept in a locked cabinet on the MDI study team unit.

Consented, participants will undergo baseline assessment as shown in Table 4. The study team will obtain all study-specified baseline data from the patient and/or from the EMR, with the exception of the knowledge and medication adherence survey responses.

The education program-specific KNOW Diabetes knowledge survey and the Modified Morisky[53] Rx Adherence Survey 8-item (MMAS-8© with permission from D. Morisky) are delivered by the nursing unit team via the Tonic platform. As part of the education program, nursing unit staff delivering the program to an individual patient will have access to his/her survey responses in order to enable tailoring education at the bedside to identified knowledge deficits and medication adherence issues.

Data entered into the platform by the patient will be transferred to REDCap in a file format and de-identified prior to presentation to the data management and statistics team for analysis.

The Tonic for Health platform is cloud based. The platform is currently in use MedStar system-wide clinical settings, including in MedStar Medical Group practices and for the MedStar patient portal. The platform interfaces with MedStar systems have been structured by MedStar to meet all system-required security and privacy requirements.

Because this pilot study, by design, is not assessing lab clinical outcomes the study will not be conducting any study-provided laboratory tests.

8 STATISTICAL CONSIDERATIONS & DATA ANALYSIS

Analysis Plan. A convenience sample of 4 nursing units and approximately 60 patients/unit, for a total of 240 patients for whom data will be collected and analyzed, will be utilized in this pilot study designed to generate preliminary data to inform a future pragmatic trial.

Baseline Characteristics: Summary statistics, including means, medians, standard deviations for continuous variables and, frequencies and percentages for categorical variables on all baseline data will be obtained for the overall sample and by nursing unit. The factors that may influence patients' non-participation decision will be examined by testing associations with baseline variables such as gender, race, age or severity of patients' conditions. Two-sample t-tests, Analysis of Variance (ANOVA), chi-square analyses and other nonparametric tests will be conducted as appropriate for the proposed bivariate analyses. DM2-related measurements A1C and blood glucose will also be described using summary statistics for the baseline and before the patient gets discharged and the differences will be tested using paired t-tests (or non-parametric tests when needed). The data collected at this stage will allow us to better evaluate the effectiveness of the education by controlling for patients' DM2 measures at discharge.

Pilot Outcomes: The effect of the intervention on **Knowledge and Skills Acquisition outcomes** will be examined by computing the differences in the total score of KNOW Diabetes survey between baseline and discharge. The differences will be tested using paired t-test for the continuous scores and McNemar's or symmetry test for the categories of specific items of interest The data collected on the number of times the education module replayed until competency demonstrated, the time used, the amount of content skipped (skills acquisition) will be summarized using descriptive statistics and correlated with patients' characteristics to better understand the difficulties experienced by the patients. **Medication Adherence**, a patient-centered behavioral outcome, will be measured at baseline and 30-day follow-up**.** To test if medication adherence has increased as a result of the intervention, the changes in continuous scores at baseline and at 30 days will be computed and the percentage of patients who show "improvement in Rx adherence*"* will be obtained. **ED/Hospital readmissions and missed work/activity days** within the 30 days after discharge will also be summarized using descriptive statistics and their associations with baseline and discharge characteristics will be explored using bivariate analyses. Multivariate analyses using linear (change in continuous scores of KNOW Diabetes and MA8), logistic (increase in medication adherence) and Poisson (count outcomes such as the number of replays, readmissions, days of missed work/activity) regression models will be conducted by adjusting for potential confounders at baseline or discharge (age, race, BMI, gender, comorbidities, A1C – when available- and blood glucose) within the constraints of the final sample size of approximately 240 patients). **IT Platform Adoption Metrics- #** and % of modules viewed; time used; content skipped; content replayed.

Implementation Effectiveness Evaluation Approach

Implementation effectiveness evaluation will be guided by the RE-AIM[32,33,54,55] framework. Our approach will consider differences in hospital and nursing workflow, patient characteristics and be sensitive to differences in patient culture, knowledge and beliefs. Our mixed methods approach to operationalizing the RE-AIM framework will select qualitative and quantitative outcomes at the setting, staff, and patient levels. Table 6 provides an overview of the RE-AIM domains, definition, and proposed strategy for evaluation data.

Table 6. RE-AIM Characteristic Definitions and Project Operationalization

RE-AIM Domain Definition	Operationalization
Reach The number, proportion, and representativeness of participants.	*Setting*: Descriptive characteristics of intervention settings (geographic location, size of hospital and units, staffing levels, acuity level); *Staff*: Provider characteristics (male/female; profession (leader, management, clinician, administrative); other relevant characteristics); *Patient*: Characteristics of those exposed to intervention (age, gender, race/ethnicity, discharge site/status, co-morbidities; others)
Effectiveness Key outcomes impact, including: potential negative effects; economic outcomes.	***Primary outcome: Emergency Dept/Hospital Readmissions*** ***Additional outcomes:*** Patient satisfaction***;*** provider satisfaction, others as defined by project (See Tables 4 & 5 – Timeline & Study Outcomes).
Adoption Number, proportion, and representativeness of settings and intervention agents ("Recipients")	*Setting:* Medicine implementation environments; representativeness will be assessed using descriptive data; *Staff:* Number and proportion of staff participating in development, training, implementation, and evaluation stages/phases of prototype intervention; *Patient*: Number and proportion of patients exposed to intervention; engaged in solution design and development
Implementation Fidelity to intervention protocol, including delivery consistency as intended, time/cost of intervention.	*Setting*: Ethnographic analysis of prototype intervention implementation fidelity via direct observation, policy review, leadership informant interviews; *Staff:* Key informant interviews, focus groups to identify barriers/facilitators of prototype implementations; *Patient*: Informant interviews, nursing discharge calls, other project specific outcomes
Maintenance Extent to which program becomes institutionalized.	Clinicians' and leaderships' intent to continue the intervention beyond the initial period; perceived alignment with organizational mission; sustainability; intent to institutionalize/ spread to other units/hospitals/clinics. *Patient*: Sustainability of outcomes at 30 days.

The team, led by **Dr. Smith**, will identify and validate barriers and facilitators of reach, effectiveness, adoption, implementation, and maintenance in each study phase. The PRISM and RE-AIM will utilize a combination of interviews, surveys, direct observations, and existing data systems to inform intervention fidelity and effectiveness (Table 7).

Table 7. Methods for Patient, Organizational & Environmental Data Collection for PRISM and RE-AIM

Method	Description	Stakeholders/Audience
Semi-structured interviews & focus groups	Processes to solicit information to better understand barriers/facilitators to behavior change adoption within each stakeholder group as well as the perceived relevant factors impacting it.	Clinicians, frontline staff, organizational and clinical leadership, patients.
Ethnographic observations	Immersion in the environment; direct observations of process and workflow on units for purposes of intervention and implementation planning and evaluation. Identify environmental factors acting as barriers/facilitators to implementation success.	Clinical teams within their environment of care

Outcomes Identification and Analyses: A mix of quantitative and qualitative data is expected to be available to evaluate intervention effectiveness. Quantitative data may be sourced from case record forms, clinical databases, patient and provider surveys and other data captured during implementation (Tables 4 & 5). Qualitative data from ethnographic observations, key informant interviews and focus groups will be analyzed using standard techniques.[56,57] Content codes will be

generated using an iterative process involving transcript review, generation of preliminary codes, team review, revision, application or codes to transcripts, elaboration, and continued application and elaboration as needed. When the full team concurs that the code list captures all themes identified in the transcripts, a research assistant will be trained to code all transcripts. Another team member will also code a subset of at least 10% of the transcripts to check coding consistency. Dr. Smith (IE lead) will meet with the coders to resolve any discrepancies and to discuss any text that is not readily coded with the existing list. Review will continue until coding is reliable..

9 QUALITY CONTROL AND QUALITY ASSURANCE

As described in the data collection and management process there will be review of by the study team of the data to ensure consistency of coding. A sub set will be by another member of the team to check consistency of data entry.

10 REGULATORY REQUIREMENTS

10.1 Informed Consent

- This study is considered minimal risk and therefore is submitted for expedited IRB review. An IRB-approved informed consent document will be used to consent all potential participants into the study. Trained study coordinators will be responsible for conducting the informed consent process with oversight from the PI. The informed consent process will be documented in the participant's study chart. An inclusion/exclusion checklist will be used to ensure recruitment and enrollment of eligible participants only.
- The research will not require the participation of minors and therefore an assent document will not be required.
- The proposed informed consent document is attached as an appendix. The informed consent document is written in layman's language understandable to the potential participants. The document includes the following information:
    - A statement that the study involves research.
    - An explanation of the purposes of the research.
    - The expected duration of the subject's participation.
    - A description of the procedures to be followed.
    - Identification of any procedures which are experimental.
    - A description of any reasonably foreseeable risks or discomforts.
    - A description of any benefits to the subject or to others that may reasonably be expected from the research.
    - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
    - An explanation of whom to contact for answers to pertinent questions about the research and the research subjects' rights, and whom to contact in the event of research-related injury to the subject.
    - A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

10.2 Subject Confidentiality

- The participants' personal health information (PHI) will be kept private to the extent allowed by law. Study records identifying participants will be kept confidential and will not be made publicly available. Participants will not be identified by name in any publications resulting from this study. Participants will be asked to authorize the investigator, representatives from government agencies, including the Food and Drug Administration (FDA), institutional review boards, the sponsor and/or the sponsor's representative(s), and certain other people, agencies or entities, to look at and review the records related to this study including any personal health information and the information discovered during this study.
- For the purposes of data analysis, only the study investigators and research staff will have access to the data which identifies participants by name.
- Minimal Personal Health Information (PHI) will be used for this study. All participants will receive a study ID number that will be used to identify their surveys. Surveys will be administered through the use of special software currently used by MedStar Health for all clinical data collection activity. The data from these surveys will be maintained on a secure, password-protected server within the MedStar Health firewall.
- A Certificate of Confidentiality will not be requested for this project.

10.3 Unanticipated Problems

- The PI will report all unanticipated problems to the IRB per MHRI IRB policy. This policy requires serious, unexpected and related (or possible related) events to be reported to the IRB within 24 hours. Adverse events that do not meet the criteria for a serious adverse event will be reported to the IRB at the time of continuing review of the project.

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APPENDICES

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