My Diabetes Care: A Scalability and Usability Study

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Protocol and Statistical Analysis Plan

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1.0 Background

Diabetes is a leading cause of cardiovascular disease, renal failure, vision loss and non-traumatic lower limb amputations. Diabetes self-management can prevent or delay diabetes-related complications, yet patients struggle to consistently engage in recommended self-care behaviors. Patients with diabetes may lack the understanding and motivation necessary to successfully manage their disease. Among patients with diabetes, studies have found that higher patient activation (i.e., knowledge, skills and confidence to manage their own health and care) is associated with healthy eating, blood sugars monitoring, eye exams and immunizations. Many of these findings were reported in diverse and disadvantaged populations.

Patient portals offer a vehicle for interventions aimed at increasing patient activation, improving understanding, and promoting self-management, while overcoming the limitations of costly and difficult to scale face-to-face programs. We recently applied user-centered design sprint methodology and key strategies for patient engagement to develop a multi-faceted patient portal intervention, My Diabetes Care (MDC), designed to help patients better understand their diabetes health data as well as support self-management. MDC was embedded within an established patient portal on Epic's MyChart platform and best viewed on mobile devices. MDC uses infographics to visualize and summarize patients' diabetes health data and provides literacy-level appropriate educational and self-management resources. MDC is grounded in a well-established Chronic Care Model (CCM) adapted for eHealth (i.e., healthcare practices supported by electronic processes and communication). By leveraging elements within the Model's five domains (self-management support, delivery system design, decision support, clinical information systems, and eHealth education), MDC has the potential to create more informed and activated patients leading to improved outcomes.

2.0 Rationale and Specific Aims

To demonstrate scalability and assess usage patterns, user experience, and to uncover errors in functionality at two study sites prior to a larger randomized trial (to be proposed separately), we will conduct a scalability and usability study MDC. The study will utilize questionnaires to quantify participants' perceptions and responses to the MDC and semi-structured interviews to comprehensively assess users' experience, barriers to use, and reasons for non-use or discontinued use. Combining qualitative and quantitative assessments of usability identifies more usability concerns than quantitative (e.g., questionnaires) assessments alone. Each participant will have access to the MDC for 1 month from the time of enrollment. This duration allows sufficient time for participants to become familiar with MDC and determine if and how to use MDC in the management of their diabetes.

3.0 Inclusion/Exclusion Criteria

Participants will be eligible for the study if they have T2DM, currently taking at least one medication for diabetes, are able to speak and read in English or Spanish, are age 18 to 75, have reliable access to a smartphone or tablet with internet access and have a patient portal account at a participating site (i.e., a Patient Gateway account at Brigham & Women's Hospital (BWH) or a My Health at Vanderbilt account at Vanderbilt University Medical Center (VUMC).

We will exclude patients with a medical condition that affects their memory or ability to think, severe visual or hearing impairment, or a medical condition that make it hard for people to understand what they are saying (e.g., dysarthria).

4.0 Enrollment/Randomization

Participants will be able to complete an electronic consent form and enroll online via Research Electronic Data Capture (REDCap™) version 5.0.8.

5.0 Study Procedures

Setting. The study will be conducted at two sites: (1) the VUMC Primary Care (including Shade Tree Clinic) and Diabetes clinics located throughout the greater Nashville, TN area, and (2) the BWH Primary Care clinics located throughout the greater Boston, MA area. At both sites, an electronic health record (EHR) from Epic Systems Corp. stores all clinical data and patients receive access to their clinical data via an integrated patient web portal that is accessible on desktops and via a native mobile app for iOS and Android mobile operating systems.

Participants and Recruitment. At VUMC, potential participants will be identified automatically using VUMC's Subject Locator to query the EHR for patients with upcoming clinic appointments who meet the discrete inclusion and exclusion

criteria. In addition, we will use EHR-based recruitment. We will use a Custom Reporting Workbench Report to identify established adult patients with type 2 diabetes who receive care at participating clinics. These patients are the target population for study (i.e., Vanderbilt primary care patients with diabetes) and as such these patients are potentially eligible to participate in the study.

At BWH, potential participants will be identified using a similar EHR-based recruitment strategy. The BWH EHR will be queried to identify patients that meet the eligibility criteria.

With permission of the clinic directors at both sites, potentially eligible patients, will be mailed a recruitment letter describing the study and providing contact information for IRB approved study personnel. If after receiving the letter, a patient is interested in the study, the patient may contact study personnel to learn more and consider participating in the study. The recruitment letter will include a QR code and URL link to the eligibility screener in REDCap. After reviewing the study eligibility criteria on the REDCap pre-screener, interested patients who believe they are eligible can advance to the REDCap Informed Consent Document (ICD). Participants will complete a self-administered electronic consent form and enroll online via REDCap. participants may have one or more of these characteristics. Study staff will be available to answer questions of potential participants during the consent process and will also review the ICD and study participation with all patients who enroll. Patients who do not respond to the recruitment letter may be contacted by phone to ensure they received the letter and offer them information about the study.

In addition, we will distribute study flyers to participating clinic sites. As with the recruitment letter, the study flyer will include the QR code and URL link to the eligibility pre-screener in REDCap where interested patients can review eligibility criteria, review the consent form, and enroll. If a patient is interested in the study, they may contact study personnel to learn more and consider participating in the study. Contact information (study phone number and e-mail address) is included on the study flyer and throughout the REDCap process. In accordance with best practices and to reflect a range of patient experience with diabetes and groups with distinct usability needs, we will use oversampling and purposive sampling with the aim of achieving approximately 25% or more representation of each of the following characteristics: (a) limited health literacy and (b) age 65 or over, and 40% or more racial and ethnic minorities.

Data Collection and Outcome Measures. Study participants will complete questionnaires electronically via email using REDCap™ at two time points: enrollment (T_0) and end of study (T_1). Participants will complete an enrollment questionnaire (T_0) including basic demographic questions, items about computer usage and internet access, and validated measures of health literacy, numeracy, and eHealth literacy.

The primary outcome measures **(Table 1)** will be: (a) ease of use and satisfaction as assessed by the System Usability Scale at T_1, (b) system usage data as assessed by MDC user analytics at T_1, (c) user experience as assessed by end of study questionnaire and semi-structured interviews at T_1. In addition, we will assess pre/post change in the following secondary cognitive and behavioral outcomes (Table 1) to estimate effect size and standard deviations for power analyses necessary to plan a subsequent randomized controlled trial to be proposed in a subsequent IRB application.

Table 1. Outcome Measures

Primary Outcomes	Measures	Variable Type	How Collected	Time Point
Usability	System Usability Scale	Continuous	Questionnaire	T_1
System usage data	Number of MDC visits	Continuous and categorical	System analytics (if available), self-report	T_1
User experience	Unique study specific items to assess participants' perspectives on content, layout, acceptance, and particular features and functionality	Categorical, Qualitative	Questionnaire, Interviews	T_1
Secondary Cognitive/Behavioral Outcomes				
Diabetes knowledge	Revised Brief Diabetes Knowledge Test (DKT2)	Continuous	Questionnaire	T_0 and T_1
Diet adherence	Summary of Diabetes Self-Care Activities (SDSCA) – Diet Subscale	Continuous	Questionnaire	T_0 and T_1
Exercise adherence	SDSCA – Exercise Subscale	Continuous	Questionnaire	T_0 and T_1
Glucose self-monitoring adherence	SDSCA – Self-monitoring of Blood Glucose Subscale	Continuous	Questionnaire	T_0 and T_1
Medication adherence	Adherence to Refills and Medications Scale (ARMS)	Continuous	Questionnaire	T_0 and T_1
Diabetes self-efficacy	Perceived Diabetes Self-Management Scale (PDSMS)	Continuous	Questionnaire	T_0 and T_1
Diabetes distress	Problem Areas in Diabetes Scale (PAID)-5	Continuous	Questionnaire	T_0 and T_1

Knowledge of Diabetes Measures	Unique study specific items to assess participants' knowledge of measures of diabetes health status	Categorical	Questionnaire	T_0 and T_1
Diabetes Readiness for Change	Four items assessment resources to assess stage of change based on the Transtheoretical Model (TTM) of behavior change. It includes questions on physical activity, medication management, glucose self-monitoring, and diet.	Categorical	Questionnaire	T_0 and T_1

Based on pilot testing, we estimate time to completion for questionnaires to be 20 minutes at T_0 and T_1. Participants will be compensated $40 for completing the enrollment questionnaire, $35 for completing the study end questionnaire, and $5 for first 10 minutes of MDC use during which participants will be encouraged to familiarize themselves with the full functionality of the MDC.

At the conclusion of their one month of MDC access, we will conduct one-on-one, semi-structured interviews with a subsample of participants including participants from each of the purposively sampled groups (see *Recruitment* above). This methodology is most appropriate for in-depth assessment of patients' perceptions and reactions regarding a proposed intervention. Interviews are preferred over focus groups for understanding usability because focus groups can amplify bias and individual opinions. Interviews will take place by phone or via Zoom after concluding their one month of MDC access. Interviews will last approximately 30-40 minutes. A trained interviewer will use a semi-structured interview guide to facilitate the interview and elicit in-depth understanding of participants' perceptions and experiences with specific MDC functionality as well as barriers to use, and reasons for non-use or discontinued use. Additional participants will be interviewed until saturation is reached. Saturation will be defined as no new usability concerns raised in the preceding two interviews and typically occurs between 10 and 30 interviews. Participants will be compensated an additional $40 for the interview.

6.0 Statistical Analysis Plan

We will use descriptive statistics to characterize the study participants and survey data. We will use a one sample t-test to compare the mean SUS score at T1 to the threshold score of 71 indicative of "good" usability. If the distributions of SUS scores suggest asymmetry or nonnormality, the non-parametric sign test (highly asymmetrical) or Wilcoxon signed-rank test (non-normality) will be performed in lieu of one-sample t-tests. To assess whether there was a significant improvement in the continuous secondary cognitive/behavioral outcomes from baseline to end of study (T0 to T1), we will perform two-sided paired t-tests on the pairwise differences. If any of the distributions of pairwise differences suggest asymmetry or nonnormality, the non-parametric Wilcoxon signed-rank sum test will be performed in lieu of paired t-tests. We will use the McNemar's test for to compare paired proportions.