Evaluation of a Patient Portal Intervention for Diabetes: A Pilot Randomized Controlled Trial

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Protocol and Statistical Analysis Plan

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Table of Contents:

1.0 Background

Diabetes is a leading cause of kidney failure, heart disease, stroke, visual impairment, and non-traumatic lower limb amputations. Diabetes self-management can prevent or delay many diabetes-related complications, yet patients struggle to consistently engage in recommended self-care behaviors. Patient activation (i.e., knowledge, skills and confidence to manage their own health and care) is essential to achieving optimal diabetes self-management and is associated with lower costs.

By providing an engaging and convenient means to track and visualize health data, obtain education and guidance, and connect patients and doctors, patient portals offer a promising platform to increase patient activation, enhance care and promote self-management while overcoming the limitations of costly and difficult to scale face-to-face interventions. We recently applied user-centered design sprint methodology and key strategies for patient engagement to develop a patient web portal intervention for patients with diabetes called the My Diabetes Care (MDC; formerly Diabetes Dashboard).

MDC is embedded within an established patient portal, My Health at Vanderbilt (MHAV). MDC is a multi-faceted intervention designed to help patients better understand their diabetes health data as well as support self-management. The MDC uses infographics to visualize and summarize patients' diabetes health data, incorporates motivational strategies (e.g., social comparisons), and provides literacy-level appropriate educational 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 levering 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 create more informed and activated patients leading to improved outcomes.

2.0 Rationale and Specific Aims

This study aims to evaluate the effects of MDC on patient activation in adult patients with type 2 diabetes mellitus (T2DM). In addition, we plan to explore secondary outcomes, including system use and usability, and the effects of MDC on diabetes self-efficacy, knowledge, self-care, medication adherence, distress, and clinical endpoints. The study will serve as a pilot for a larger definitive trial evaluating the effect of MDC on clinical endpoints. We will recruit patients into two study arms which will receive: (1) usual care arm and (2) the intervention arm. Participants in Arm 1 (usual care) will have access to the standard version of My Health at Vanderbilt (MHAV), the Vanderbilt patient portal. Participants in Arm 2 will be provided access to a version of MHAV embedded with the intervention, MDC. Participants in both arms will be told the purpose of the study is *to determine satisfaction with two versions of MHAV among patients with diabetes*. The study will utilize questionnaires to quantify participants' responses to MDC in comparison to usual care. Each participant will be enrolled in the study for six months.

3.0 Inclusion/Exclusion Criteria

Participants will be eligible for the study if they are a patient at one of the 14 participating VUMC-affiliated adult primary care clinics and have T2DM, are currently being treated with at least one diabetes medication, are able to speak and read in English, are age 21 or over, have an existing MHAV account, and have reliable access to a desktop or laptop computer with internet access.

We will exclude patients living in long term care facilities, patients with known cognitive deficits, patients with severe visual impairment, and patients currently participating in another diabetes related research study.

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. The study coordinator will verify all eligibility criteria prior to randomization. The procedure and risks will be explained to the participants and the consent form signed as per standard practice. All participants are randomly assigned to one of two groups: (1) intervention group which will have access to a version of MHAV embedded with the MDC or (2) usual care group which will have access to the currently available version of MHAV. Participants randomized to the intervention are advised to view MDC on a desktop or laptop device because the present version of MDC is not mobile friendly. The randomization sequence will be generated by the research team biostatistician using a permuted block randomization scheme stratified by clinic site and participants' age group (age 65 and over vs under 65). The randomized assignment for eligible participants will be accessible to the study coordinator and biostatistician using the Research Electronic Data Capture (REDCap™) Randomization Module. Once a randomization assignment is provided, the participant will be entered into the study and will be included in an intention to treat analysis in accordance with the CONSORT guidelines. Our target enrollment is 300 participants (150 per arm).

5.0 Study Procedures

Setting. Participants will be recruited from 14 VUMC-affiliate adult primary care clinics located throughout Middle Tennessee (4 urban, 10 suburban). An EHR (Epic Systems Corp.) stores all clinical data and patients receive access to their clinical data via an integrated and highly-adopted patient web portal, MHAV.

Participants and Recruitment. On a rolling basis, potentially eligible patients will be selected from a randomly ordered list of established adult patients with diabetes from participating clinic sites and sent a recruitment letter describing the study. In addition, we will use My Research at Vanderbilt to send the recruitment letter to current patient portal users who elected to allow investigators to contact them about research opportunities via email. Interested patients can contact a research assistant to learn more about the study. To enroll, participants will complete a web-based study eligibility screener and electronic consent form on the web via REDCap (Research Electronic Data Capture) version 5.0.8.

Intervention and Control. Participants randomized to the intervention arm will be provided access to a version of MHAV embedded with the MDC viewable on a desktop or laptop device (MDC is not currently available on mobile devices). MDC includes infographics to visualize and summarize patients' health data, incorporates motivational strategies (e.g., social comparisons and gamification), provides literacy-level appropriate educational resources, and contains secure-messaging capability. Participants randomized to the usual care arm will have access to the currently available version of MHAV that includes the ability for patients to review pertinent health data, review medical information about their conditions, and communicate with their health care team.

Data Collection and Outcome Measures. Study participants will complete questionnaires electronically via email using REDCap™ at three time points: enrollment (T_0), three-month follow-up (T_1), and six-month follow-up (T_2). Enrolled participants will be asked to provide information on the following covariates: socioeconomic status, marital status, race/ethnicity, education level, and health literacy.

The primary outcome measure will be change in patient activation as assessed by the Patient Activation Measure (PAM-13). Secondary intermediate outcomes include diabetes self-efficacy, diabetes knowledge, diabetes distress, diabetes self-care, system usability/satisfaction, and system usage. Additional secondary outcome such as blood glucose control, blood pressure control, cholesterol control, and flu vaccination status will also be assessed by EHR abstraction. To ensure the fidelity of the intervention, monthly quality assurance checks will be used to ensure the MDC is functioning correctly (e.g., displaying data correctly).

Based on pilot testing, we estimate time to completion for questionnaires to be about 25 minutes at T_0 and about 20 minutes at T_1 and T_2. Participants will be compensated $40 for completing the enrollment questionnaire (T_0) and $35 each for completing the three-month (T_1) and six-month (T_2) follow-up questionnaires.

6.0 Statistical Analysis Plan

The study is designed to evaluate the effects of MDC on patient activation (primary analysis) and explore the effects on other secondary cognitive and behavioral outcomes relative to the control group. We will use a t-test to compare the change in PAM score between the MDC and control groups. If the normality assumption is violated, the non-parametric Wilcoxon rank sum test will be used. We will use mixed-effects regression models to estimate the intervention effects across time while adjusting for the baseline measure of the outcome. Nonlinear associations will be modeled with regression splines. The mixed-effects model will use fixed effects for patient-level characteristics and random effects for health care provider variables. We will provide point estimates with CIs and graphically depict our results. If necessary, multiple imputation will be used to impute the missing values. The analysis with multiple imputation assumes missing at random (i.e., the model properly handles missing data by including covariates associated with reasons for dropout). The characteristics of participants who do not complete the study or do not comply with the treatment will be compared for both

conditions. Independent t-tests or if appropriate, Wilcoxon rank sum tests will be used to compare change in secondary outcomes between the MCD and control groups. Mixed-effect models will also be used to evaluate the effects of MDC on secondary outcomes across time.