Usability of Diabetes Dashboard Embedded Within a Patient Web Portal: A Prospective Longitudinal Study

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Protocol and Statistical Analysis Plan

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1.0 Background

Diabetes is a leading cause of kidney failure, heart disease, stroke, visual impairment, and non-traumatic lower limb amputations. Diabetes self-care and preventative health services can prevent or delay many diabetes-related complications, yet few patients consistently receive all recommended services or engage in recommended self-care behaviors that are challenging to implement and sustain. 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 portal intervention for patients with diabetes called the Diabetes Dashboard (also known as My Diabetes Care).

The Diabetes Dashboard is embedded within an established patient portal, My Health at Vanderbilt (MHAV). The Diabetes Dashboard is a multi-faceted intervention designed to help patients better understand their diabetes health data as well as support self-management. The Diabetes Dashboard uses graphics to visualize and summarize patients' diabetes health data, incorporates motivational strategies (e.g., social comparisons), and provides literacy-level sensitive educational resources. The Diabetes Dashboard is grounded in a well-established Chronic Care Model 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), the Diabetes Dashboard has the potential to create more informed and activated patients leading to improved outcomes.

2.0 Rationale and Specific Aims

In order to assess dashboard usability, usage patterns, and user experience over time, and to uncover errors in dashboard functionality prior to a larger interventional trial, we will conduct a longitudinal usability study. The study will utilize questionnaires to quantify participants' perceptions and responses to the dashboard and semi-structured interviews to comprehensively assess users' experience and barriers to 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 dashboard for 1 month from the time of enrollment. This duration allows sufficient time for participants to become familiar with the dashboard and determine if and how to use the dashboard in the management of their diabetes.

In the current study, we aim to assess: (1) the usability and acceptability of the Diabetes Dashboard, (2) users' attitudes about dashboard features and potential improvements, and (3) the potential impact of the dashboard on secondary cognitive and behavioral outcomes including patient activation.

3.0 Inclusion/Exclusion Criteria

Participants will be eligible for the study if they have type 2 diabetes mellitus, 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 (i.e., Vanderbilt patient portal) account, and self-report reliable access to a computer with internet access.

We will exclude patients living in long term care facilities, patients with known cognitive deficits, patients with severe visual or hearing impairment, patients with unintelligible speech (e.g., dysarthria), 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.

5.0 Study Procedures

Setting. The Vanderbilt Adult Primary Care (VAPC) clinics and Eskind Diabetes Clinics are located within a large ambulatory care facility in Nashville, TN. An electronic health record (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, that is accessible on desktops and via a native mobile app for iOS and Android mobile operating systems.

Participants and Recruitment. 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. We will send identified patients a letter describing the study. Study flyers will be placed in participating clinic sites. Interested patients will contact a research assistant to learn more about the study and confirm eligibility.

Participants will complete an electronic consent form and enroll online via REDCap. Our target enrollment is 70 participants. In accordance with best practices and to reflect a range of patient experience with diabetes and groups with distinct usability needs, we will recruit a purposive sample to achieve at least 20% representation of each of the following characteristics: (a) limited health literacy and (b) age 65 or over. Some participants may have one or more of these characteristics. Health literacy will be assessed using a validated on one-item screener that asks respondents to rate their confidence independently filling out medical forms. Consistent with prior studies, we will categorize participants noting any lack of confidence filling out medical forms as having limited health literacy.

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). The enrollment questionnaire (T_0) will include basic demographic questions, items about computer/smartphone usage, and validated measures of health literacy and eHealth literacy. Both questionnaires will contain

validated scales to assess study outcomes. Participants will be compensated $40 for completing the enrollment questionnaire, $35 for completing the study end questionnaire, and $5 for first 10 minutes of dashboard use.

The primary outcome measures will be: (a) ease of use and satisfaction as assessed by the System Usability Scale at T_1, (b) user experience as assessed by end of study questionnaire and semi-structured interviews at T_1. Secondary outcomes will include system usage (total number of dashboard visits, total duration of dashboard use, and use of embedded educational links, secure messaging, and a link to the American Diabetes Association Online Community) and the potential impact of the dashboard on the following secondary cognitive and behavioral outcomes assessed using validated scales at T_0 and T_1: patient activation, diabetes self-efficacy, diabetes knowledge, diabetes care understanding, diabetes self-care, and diabetes distress.

At the conclusion of their one month of dashboard access, we will conduct one-on-one, semi-structured interviews with a subsample of at least 10 participants. 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 in person and will last approximately 30 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 dashboard functionality as well as barriers to use. Additional participants will be enrolled 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

Statistical Analysis. We will use descriptive statistics to characterize the study participants and survey responses. We will use a one sample t-test to compare the mean SUS score at T1 to the threshold score of 68 indicative of "above average" usability and a two-sample t-test to compare SUS scores of independent groups (e.g., participants with limited vs. adequate health literacy). If SUS score distributions suggests asymmetry or nonnormality, we will use the one sample median test to compare the median SUS scores at T1 to the threshold score of 68 and Wilcoxon-Mann-Whitney test to compare the SUS score distributions of two independent groups.

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 and Fischer's Exact test for independent proportions. All analyses will be completed using statistical software under the supervision of a biostatistician in the Vanderbilt Center for Diabetes Translational Research (CDTR).

Sample Size. In the context of the primary outcome, SUS score, and assuming a standard deviation of 12 based on prior studies, with a sample size of 50, a one sample t-test would detect an absolute difference in mean SUS scores of at least 5 points above the threshold score of 68 with 82% power. Conservatively assuming study dropout of 20%, we aim to enroll 70 participants.

7.0 Qualitative Analysis Plan

We will transcribe participants' semi-structured interviews for coding and analysis of user experience. We will use selective coding to identify participants' statements addressing six established elements of user experience (i.e., the core category): (1) useful - fulfilling a need, (2) useable - ease of use, (3) accessible - easy to access and comprehend, (4) desirable - design elements that evoke emotion or appreciation, (5) findable - easy to navigate, and (6) credible - trustworthy and believable. Two research assistants will independently code all interviews then resolved any differences by consensus. We will review participant statements in each category for inform potential revisions that could improve user experience with the dashboard.