A Patient Portal Intervention to Address Diabetes Care Gaps: A Usability Study

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Protocol and Statistical Analysis Plan

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1.0 Background

Evidence-based diabetes monitoring and preventative services can prevent or delay many costly and highly morbid disease related complications, yet many patients do not receive all clinically-meaningful, evidence-based services. For example, while detecting and treating early diabetic eye disease can reduce the development of severe vision loss by an estimated 60%, approximately 40% of Americans with diabetes do not receive an annual diabetes eye exam. Prior research has demonstrated numerous barriers to the completion of evidence-based diabetes monitoring and preventative services including patient factors (e.g., lack of awareness and limited health literacy) and clinician/system factors (e.g., limited physician time and patient support between visits). Attempts to increase diabetes monitoring and preventative services have had only modest results. To achieve optimal rates of these services, an intervention is urgently needed that improves clinical efficiency by decreasing clinician workload, is appropriate for patients with varying levels of health literacy, and is highly scalable and sustainable. By providing an engaging and convenient means to track and visualize health data, obtain education and guidance, receive notifications, and connect patients and doctors, patient portals offer a promising platform to enhance access to health services while overcoming the limitations of costly and difficult to scale face-to-face interventions.

2.0 Rationale and Specific Aims

Thus, in this study, we will assess the usability and acceptability of a novel patient portal intervention designed in a prior study to: (a) notify patients when selected, clinically meaningful, evidence-based diabetes monitoring & preventative services (e.g., annual diabetes eye exam) become due and provide reminders for timely completion, (b) promote understanding of the importance of these services through literacy sensitive content, and (c) allow patients, when due by evidence-based guidelines, to initiate orders for the care (e.g., pneumococcal vaccination). In addition, we will assess pre-post change on secondary psychosocial outcomes including patient activation.

3.0 Inclusion/Exclusion Criteria

Participants will be eligible if they receive care at a participating VUMC clinic site and they have type 1 or 2 diabetes mellitus (DM), are able to speak and read in English, are ages 18 to 75, have a current MHAV account and reliable access to a mobile device with iOS or android operating system with internet access, and are due for any of the five guideline-based, diabetes monitoring and preventative services (i.e., hemoglobin A1C, urine microalbumin, diabetes eye exam, and/or pneumococcal vaccination).

We will exclude patients with medical conditions that affects their memory or ability to think which may preventing the use of a mobile device, severe difficulty seeing, severe difficulty hearing, a medical condition that make it hard for people to understand what they are saying, as well as pregnant women or women who plan to become pregnant during the study period.

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 performed at Vanderbilt Primary Care One Hundred Oaks – North and South Clinics located within a large ambulatory care facility in Nashville, TN. 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, My Health at Vanderbilt (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. In addition, VUMC population health and quality improvement initiatives have created a report that identifies established patients with diabetes who receive care at the primary care clinics participating in the study and have current diabetes care gaps (e.g., no diabetes eye exam in the last year). 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. As with Subject Locator, with the permission of the clinic director, these patients would be mailed a recruitment letter describing the study and providing contact information for IRB approved study personnel. With approval of the clinic

director, we will send potentially eligible patients a recruitment letter describing the study and providing them with the contact information for IRB-approved study personnel. If after receiving the letter, a patient is interested in the study, they 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 a REDCap site where interested patients can check their eligibility for study, review the consent form, and enroll.

Participants will complete an electronic consent form and enroll online via Research Electronic Data Capture (REDCap™) version 5.0.8. Our target enrollment is 60 participants. In accordance with best practices and to reflect groups with distinct usability needs, we will purposively sample to achieve representation of each of the following characteristics: (a) limited health literacy and (b) age over 65. Some participants may have one or more of these characteristics.

Intervention. The intervention involves the addition of a new feature to the Vanderbilt patient portal that will allow patients to use the My Health at Vanderbilt (MHAV) app on their mobile device (smartphone or tablet) to: (1) receive notifications when they are due for certain types of diabetes monitoring and preventative care and (2) initiate an order for the care. Automated notifications will be sent to patients if, according to the Health Maintenance section of their electronic health record and medical guidelines, they are due for a hemoglobin A1C blood test, microalbumin (kidney) urine test, diabetes eye exam, and/or pneumonia vaccine. If a patient receives a notification, the patient can initiate an order for the care using the MHAV app. After the patient initiates the order, the study team will process the order. Daily, the study team will use Epic's reporting workbench to identify patients that initiated orders and use the EHR's batch order functionality to generate the actual order for the patient's care (e.g., HgbA1c lab test). The patient will receive confirmation when the order has been processed and instructions to proceed to a Vanderbilt clinic or lab to receive the care. The patient's primary care physician will be the authorizing provider and once the patient receives the care, their primary care doctor will receive any results. If the patient has already received the care outside of Vanderbilt, the patient will be able to indicate this. For example, if according to the patient's Vanderbilt medical record they are due for a diabetes eye exam, they will receive a notification; however if they recently had a diabetes eye exam with an eye doctor outside of Vanderbilt, they will be able to report this using the same new MHAV feature.

Patients reporting an outside eye exam will be contacted by study staff and asked to complete an Authorization for Release of Medical Information to VUMC via REDCap. If the patient agrees and signs the release, trained study staff will request the records accordingly. Once the eye exam records are received, trained study staff will review the records to determine if the records document screening for diabetic eye disease (i.e., was the participant's self-report of a diabetes eye exam accurate). If the eye exam records do not indicate screening for diabetes related eye disease (i.e., a diabetes eye exam), KSP will contact the participant by phone with this information and encourage the participant to call their eye doctor to schedule a diabetes eye exam. If the participant prefers, the participant will be invited to schedule a diabetes eye exam at Vanderbilt Eye Institute. If the participant can't be reached by phone, they will be sent a letter with this information. Any outside eye exam records received will be scanned into the participant's VUMC medical record and their primary care physician will be notified.

Data Collection and Outcome Measures. Study participants will complete questionnaires electronically via email using REDCap™ at three time points: enrollment (T_0), after first use of the intervention (T_1), and end of study (T_2). Participants will complete an enrollment questionnaire (T_0) including basic demographic questions, items about computer and internet use, and eHealth literacy. Based on prior experience, we estimate time to completion for each questionnaire to be about 20 minutes. Participants will be compensated $30 each for completing questionnaires ($90 total if they complete all three). In addition, participants can receive $10 for using the intervention for the first time.

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 user analytics at T_2, (c) user experience as assessed by 'after first use' and final questionnaires and semi-structured interviews at T_2. In addition, we will assess pre/post change in the following secondary psychosocial 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 (SUS)	Continuous	Questionnaire	T_1
User experience	Unique study specific items to assess participants' perspectives on content, acceptance, and features and functionality	Categorical	Questionnaire & Interviews	T_1 and T_2
Secondary Outcomes	Measures	Variable Type	How Collected	Time Point
Diabetes self-efficacy	Manage Disease in General Scale of the Chronic Disease Self-Efficacy Scales	Continuous	Questionnaire	$T_0 – T_2$
Understanding of Diabetes Monitoring and Preventative Care	Unique study specific items to assess participants' understanding of recommended diabetes monitoring and preventative care	Continuous	Questionnaire	$T_0 – T_2$
Diabetes distress	Problem Areas in Diabetes Scale (PAID-5)	Continuous	Questionnaire	$T_0 – T_2$
Patient-initiated orders	# of patient-initiated orders for evidence-based diabetes monitoring & preventative services (e.g., A1c)	Continuous	EHR Abstraction, Tableau & Clarity Servers	T_2
Service completion	# of completed (i.e., care received) patient-initiated orders for evidence-based diabetes monitoring & preventative services (e.g., A1c)	Continuous	EHR Abstraction, Tableau & Clarity Servers	T_2

T_0 = baseline, T_1 = after first use of the intervention, T_2 = 3-month follow up

At the conclusion of their 3-months of access to the intervention, we will conduct one-on-one, semi-structured interviews with a subsample of at least ten participants including at least two participants from each of the purposively sampled groups **(see *Recruitment* above)**. In addition, we will conduct semi structured interviews with up to five primary care physicians (PCPs) that cosigned a patient-initiated order to under their perceptions of the intervention and impacts on workflows. This methodology is most appropriate for in-depth assessment of individuals' perceptions and reactions regarding the intervention. Interviews are preferred over focus groups for understanding usability because focus groups can amplify bias and individual opinions. Participant interviews will take place by phone or via Zoom within two weeks of participants concluding their 3 months of access to the intervention and will last approximately 30 minutes. PCP interviews will take place after all participants have completed the study. A trained interviewer will use a semi-structured interview guide to facilitate the interviews and elicit in-depth understanding of individuals' perceptions and experiences with the intervention. 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. Interviewees will be compensated $40 for their time.

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. 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 test will be performed in lieu of paired t-tests. We will use the McNemar's test for to compare paired proportions. Our primary outcome will be System Usability Scale (SUS) score at first use (T1).