Effects of a Patient Portal Intervention to Address Diabetes Care Gaps: A Pragmatic Randomized Controlled Trial

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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

In a prior study (IRB # 200241), we designed a patient portal intervention to:

a) notify patients when selected, clinically meaningful, evidence-based diabetes monitoring & preventative services (eg, annual 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 an order for the care (e.g., pneumococcal vaccination).

Then, in a subsequent study (IRB# 202281), we tested the usability of the patient portal intervention.

In this study, we aim to evaluate the effect of the above patient portal intervention on completion of selected evidence-based, clinically-meaningful, diabetes monitoring & preventative services and secondary intermediate outcomes (e.g., diabetes self-efficacy). We hypothesize that a pragmatic, cluster randomized controlled trial will demonstrate the patient portal intervention described above will increases completion of selected evidence-based, diabetes monitoring & preventative services and secondary intermediate outcomes such as diabetes self-efficacy.

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 read in English, are ages 18 to 75, and have a current MHAV account and reliable access to a mobile device with iOS or android operating system with internet access.

We will exclude patients with a medical condition that prevents them from using a mobile device, severe difficulty seeing, pregnant women or women who plan to become pregnant during the study period, and patients on dialysis.

4.0 Enrollment/Randomization

The study will be a pragmatic, parallel-design, randomized controlled trial (RCT). We will recruit patients into two study arms which will receive: (1) usual care (n=250) and (2) the patient portal intervention (n=250). Participants in Arm 1 (usual care) will have access to the standard version of MHAV. Participants in Arm 2 will be provided access to a version of MHAV embedded with the intervention. Participants in both arms will be told the purpose of the study is "to determine patients' satisfaction with MHAV among patients with diabetes."

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 study procedures and risks will be explained to the participants and the consent form signed as per standard practice. The randomization sequence is generated by the research team biostatistician using a permuted block randomization scheme uploaded to REDCap. The randomized assignment for eligible participants is accessible to the study coordinator via REDCap.

5.0 Study Procedures

Setting. Participants will be recruited from Vanderbilt Primary Care Clinics throughout middle Tennessee. 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. 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 (study phone number and e-mail address) 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 also include a QR code and URL link to a REDCap site where interested patients can review eligibility criteria, review the consent form, and enroll. Within each step of this REDCap process, we have emphasized (i.e., underlined) statements encouraging potential participants to call or email study staff with any questions or concerns at any time and provide the study's phone number and e-mail address. For self-initiated consent, the study contact information is provided (email and phone) for prospective participants to contact trained study personnel with questions, prior to consent. Trained key study personnel will also contact patients after receiving the completed REDCap informed consent document to provide another opportunity to ask questions, confirm eligibility, and onboard the patient to the study. 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, study flyers may be posted at participating clinics. As with the recruitment letter described above, the study flyer includes a QR code to a REDCap site 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.

eStar Reporting Workbench

Reporting Workbench Reports are available/viewable in eStar, our local EHR. These reports are developed using real-time data and can be customized to meet study-specific inclusion/exclusion criteria that are computable in the EHR. The reports often include additional variables to help the study team determine which type of outreach may be appropriate, such as Research OK to Contact status, MHAV account status, and patient portal message status. While the report displays certain variables/data, it provides easy access to a patient's record for additional screening and confirmation of eligibility. Research team members with appropriate eStar access can view/run the reports as frequently as needed. The report results will then be used to send recruitment requests through MHAV (managed centrally by the Vanderbilt Institute for Clinical and Translational Research (VICTR)) to only those with the status of Research OK to Contact. We will not be utilizing "EMR Recruitment - Existing provider relationship".

eStar My Health at Vanderbilt Recruitment Requests

My Health at Vanderbilt (MHAV) is VUMC's patient portal where the patient may sign up and participate in managing his/her health care. MHAV can also be used for sending recruitment requests (managed centrally by VICTR) to a predefined cohort of patients who meet certain study-specific inclusion/exclusion criteria, have explicitly said OK to Contact for research, and have an active MHAV account. The messages are sent by a central team that is managed by the VICTR/Health Information Technology (IT) teams, meaning they send the messages on behalf of the study team.

Potential participants who have an explicit OK to Contact documented in eStar will receive a research invitation. The notification preferences for the research invitations can be managed by the patients in MHAV. If the patient has chosen not to receive notifications, the study will just be listed on their research studies page in MHAV.

Once the patient gets to the Research Studies page, the new study will be listed under the heading - Studies you may be able to join.

If a patient clicks I'm Interested, an automated In Basket message is sent to the study team notifying them that the patient expressed interest in the study.

If a patient clicks No, Thank You, the study will fall off their research studies page in MHAV and their eStar record will be marked as not interested.

The study personnel will be able to run a report to generate a list of all patients who clicked I'm Interested and then send a bulk direct-to-patient follow-up message through MHAV's patient clinical communication. The follow-up message will also include a URL link to a REDCap site where interested patients can review the eligibility for study, review the consent form, and enroll similar to the above recruitment methods. If a patient is interested in the study, they may contact study personnel via phone or e-mail at any time to learn more and consider participating in the study. The study contact information is included in the MHAV follow-up message.

Participants will complete an electronic consent form and enroll online via Research Electronic Data Capture (REDCap™) version 5.0.8. Our target enrollment is 500 participants. Given the high prevalence of type 2 diabetes mellitus (T2DM) among racial and ethnic minority groups, it is important to ensure that these groups can benefit from digital health interventions. Therefore, we will ensure fair representation of minorities in the proposed research. Racial and ethnic minorities account for approximately 40% of patients with diabetes in the United States. We will use purposive sampling and over sampling as needed to help ensure our study sample is representative of the population as whole.

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. Each weekday, 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, the patient 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 four time points: enrollment/baseline (T_0), 3-month follow-up (T_1), 6-month follow-up (T_2), and 12-month

follow-up (T_3). Participants will complete an enrollment/baseline questionnaire (T_0) including basic demographic questions, items about computer and internet use, health literacy, numeracy, and eHealth literacy. Based on prior experience, we estimate time to completion for each questionnaire to be about 20 minutes. Participants will be compensated $40 each for completing questionnaires ($160 total if they complete all four).

The primary outcome measure will be the number of diabetes care gaps out of the four selected DM monitoring & preventative services through 12-months follow-up.

Table 2: Outcomes and Measures

Primary Outcome	Measures	Variable Type	How Collected	Time Point
Number of Diabetes Care Gaps through 12 Months	Number of diabetes care gaps per patient out of four possible: 1. no diabetes eye exam in the last 12 months, 2. no hemoglobin A1C blood test in the last 6 months, 3. no urine microalbumin in the last 12 months, and 4. no pneumococcal vaccination of any kind (i.e., never received PPSV-23, PCV-13, PCV-15, or PCV-20)	Ordinal	EHR abstraction	T_0 - T_3
Secondary Outcomes				
Number of Diabetes Care Gaps at 6 Months	Number of diabetes care gaps per patient out of four possible: 1. no diabetes eye exam in the last 12 months, 2. no hemoglobin A1C blood test in the last 6 months, 3. no urine microalbumin in the last 12 months, and 4. no pneumococcal vaccination of any kind (i.e., never received PPSV-23, PCV-13, PCV-15, or PCV-20)	Ordinal	EHR abstraction	T_0 - T_3
Attitudes toward Managing Diabetes in General	Items adapted from the Manage Disease in General Scale of the Chronic Disease Self-Efficacy Scales.	Continuous	Questionnaire	T_0 - T_3
Diabetes self-efficacy	Perceived Diabetes Self-Management Scale (PDSMS)	Continuous	Questionnaire	T_0 - T_3
Understanding of Diabetes Monitoring and Preventative Care	Unique study specific items to assess participants' understanding of recommended diabetes monitoring and preventative care	Categorical	Questionnaire	T_0 – T_2
Diabetes distress	Problem Areas in Diabetes Scale (PAID-5)	Continuous	Questionnaire	T_0 - T_3
Satisfaction with MHAV	System Usability Scale and user experience questions	Continuous	Questionnaire	T_0 - T_3
Patient-initiated orders	# of patient-initiated orders for evidence-based diabetes monitoring & preventative services (e.g., A1c)	Continuous	EHR Abstraction, Tableau & Clarity Servers	T_0 - T_3

Reported completion outside VUMC system	# of reports diabetes eye exams outside the VUMC system in response to the To-Do item received via the intervention # of reports of outside diabetes eye exam that meet criteria for screening for diabetic eye disease.	Continuous	EHR Abstraction, Tableau & Clarity Servers	T_0 - T_3
Blood glucose control	Hemoglobin A1C	Continuous	EHR abstraction	T_0 - T_3
Treatment intensification	Addition of: a. antihyperglycemic medications b. antihypertensive medications	Categorical	EHR abstraction	T_0 - T_3

T_0 = baseline, T_1 = 3-month follow-up, T_2 = 6-month follow-up, and T_3 = 12-month follow-up

Secondary intermediate outcomes include attitudes toward managing diabetes in general, diabetes self-efficacy, understanding of diabetes monitoring and preventative care, diabetes distress, satisfaction with MHAV, patient-initiated orders, and reported completion outside VUMC system. Additional secondary outcomes, blood glucose control and treatment intensification, will also be assessed by EHR abstraction.

6.0 Statistical Analysis Plan

We will use descriptive statistics to characterize the study participants and the primary and secondary outcomes. For the primary analysis, an ordinal mixed effects regression model will be used. For dichotomous outcomes, a logistic mixed effects regression model will be used. For continuous outcomes, a multivariate mixed effects regression model will be used. If there is imbalance, we will control for baseline patient level covariates, including socioeconomic status, marital status, race/ethnicity, education level, age, sex, health literacy, technology use, and diabetes distress. We will allow for nonlinear associations by modeling continuous covariate with restricted cubic splines when needed. Similar models will be used for all the secondary outcomes except for HbA1c. Due to the frequency of HbA1c measurements, we will use a linear regression model as opposed to a mixed effects model with the HbA1c value at the 12-month timepoint as the dependent variable. Appropriate statistical methods, such as multiple imputation, will be used where missing data are present.