Improving Diabetes Care through Effective Personalized Patient Portal Interactions (HSR&D IIR 15-307)

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1. Protocol Summary/Abstract

Objectives:	Conduct a small-scale experiment of a training intervention using a randomized encouragement design.
Research Design:	Use a randomized encouragement design to test the feasibility of engaging Veterans in a supported adoption intervention to promote effective My HealtheVet use, in a sample of 200-300 Veterans with diabetes.
Methodology	This is a supported adoption intervention designed with input from key stakeholders (e.g., primary care providers, staff, Veterans with diabetes). Patients at the Bedford/Boston VAMCs with uncontrolled diabetes who do not use My HealtheVet will be invited to participate in the intervention. Patients will be randomized to four arms: ▪ Comparison arm: My HealtheVet brochure only ▪ 2) Encouragement arm 1: My HealtheVet brochure and training guide ▪ 3) Encouragement arm 2: My HealtheVet brochure and training guide plus offering a group training ▪ 4) Encouragement arm 3: My HealtheVet brochure and training guide plus offering a group training and a one-on-one session Data will be collected via (1) patient health record data, (2) post-training evaluations, (3) semi-structured interviews, and (4) chart review and coding of secure messages.

2. Background Information

The Veterans managed by the VA Healthcare System are complex, often with chronic conditions and multiple physical and mental health comorbidities. In particular, diabetes results in many complications and negative outcomes, leads to high medical costs[1], requires intense self-management, and is complicated by changing recommendations for care. Over 20% of VA patients struggle with Type 2 diabetes[2], and effective management is even more complicated for those with co-morbid mental health conditions or living in rural areas. Rural Veterans with diabetes are more likely to have a higher number of comorbidities and to have both medical and mental health comorbidities[3].

Virtual care technologies have the potential to improve diabetes outcomes[4-9] and research shows that diabetes self-management plans are more likely to work when they are designed to fit patients' priorities, resources, and lifestyles, and are supported by virtual care technology.[10] Patient portals have been described as secure online websites that offer patients convenient access to personal health information and are connected to a healthcare organization with features that support tasks like communicating with providers, requesting prescription refills, reviewing test results and managing appointments. Although there is insufficient evidence that patient portal use improves overall health outcomes,[11] web- and portal-based interventions have shown quite promising results for diabetes management[5,12-16].

My Health*e*Vet (MHV) is the VA's personal health record portal. Registration with MHV enables Veterans to create a password-protected account to record and track personal goals and manage medications by refilling VA prescriptions (Rx Refill). Veterans who also complete an in-person authentication process receive Premium accounts linked with their CPRS records which enables access to the full array of portal features, including the ability to Secure Message (SM) with VA clinical team members, view VA chemistry/hematology results, view upcoming VA appointments, receive tailored wellness reminders (7 of the 12 are directly relevant to diabetes care), and access extracts from their CPRS records, including VA progress notes and VA medication history through the Blue Button (BB) "Download My Data" feature.

Although research to date suggests that patient portals have positive effects on patient-provider communication, satisfaction, self-management and outcomes *in diabetes*, it is often difficult to tease out whether particular features or combinations of features account for these outcomes. Portals, and diabetes interventions delivered via portals, both within and outside VA, have been multi-faceted[12,15], including a panoply of features such as synchronous and asynchronous communication with members of the clinical team, online support groups, prescription refill and/or medication reconciliation, tracking of blood sugars, diet, and exercise, and in-person or online educational or motivational components. Some include web modules specifically designed for patients with diabetes[15]. More research is needed both within and outside VA to determine which particular features are the most meaningful and effective[5]. Evidence is needed both to support the effectiveness of the "treatment"– that is, the patient portal and the array of features available through the portal – both for diabetic patients overall and for those who may be more vulnerable (e.g., rural residence, comorbid mental health diagnosis), and to better define effective use of portal features. We need to know which specific features or

combination of features show the strongest association with diabetes outcomes, and whether the strength of their association is likely to be consistent across patients.

The earlier aims of this study focus on portal features associated with improved diabetes outcomes and will result in the development of a training guide to be developed in conjunction with Veterans living with diabetes. The goal of this small-scale trial will be to test the feasibility of engaging Veterans in a supported adoption intervention to promote effective patient portal use in a sample of Veterans with uncontrolled Type II diabetes.

3. Objectives

Primary Aims:

Conduct a small-scale experiment, using a randomized encouragement design, to test the feasibility of engaging Veterans in a supported adoption intervention to promote effective MHV use, in a sample of 200-300 Veterans with diabetes (with or without comorbid mental health problems).

Hypothesis:

We hypothesize that those randomized to the encouragement arm will increase the number and variety of features used in My Health*e*Vet.

4. Study Design

Participants will be recruited from two VA medical centers, Bedford and Boston VA. Analyses will be conducted at Bedford ENRM VA Hospital.

Study Related Procedures

We will conduct a small-scale experiment using the sites of the CHOIR center (Bedford/Boston). Participants will be identified who:

- Are current VA Bedford or VA Boston patients (including CBOC patients)
- Have uncontrolled diabetes (HbA1C≥8.5)
- Are inactive users (registered but with at least 1 year of non-use) or non-users of My HealtheVet
- Have an upcoming health visit scheduled at Bedford VA or Boston VA.
- Are age 18-85 years old at approximate time of first mailing

CPRS/VistA chart review and administrative data extraction (VSSC files and CDW tables) will be used to identify potential participants and to identify mailing addresses for the patients to be invited to participate Aim 3. As of March 2019, there were 170 eligible patients in Bedford and 539 eligible patients in Boston. (We expect these numbers to shift slightly as new appointments are made or diabetes control changes among the populations.).

All Veterans selected to participate based on these criteria will be sent a mailing including a brochure with information on My HealtheVet, a welcome letter introducing the study, an information sheet (modified consent form), and an opt-out card.

All eligible Bedford patients will be invited to participate in a first round of mailings. Based on the opt-out rate of Bedford patients, subsequent round(s) of mailings will be sent to Boston patients in order to have at least 50 patients enrolled in each encouragement arm and at least 50 patients enrolled in the comparison arm (see information about arms in following paragraphs; 200-300 maximum overall across sites).

If the potential participant does not wish to participate, they can contact study staff by telephone at the number listed on the letter introducing the study. They can also mail the opt-out postcard in order to be removed from contact lists. Potential participants who do NOT indicate that they wish to opt out of future communication from the team within approximately 10 business days of the mailing will be assumed to be enrolled in the study, unless we hear from them to opt-out at a later time. If participants opt out after randomization, we will no longer contact them for other portions of the study. However, we will look at data that we already have for these participants from Aim 1. Those receiving the information sheet (modified consent form) will be informed of the general nature of the study, what their involvement entails, the risk/benefits, and a description of confidentiality. Participants will be told that participation is voluntary, that they can withdraw at any time, and that this will not impact their treatment.

Consistent with the adaptability of a randomized encouragement design, those that do not opt-out will be divided randomly into 4 arms, with at least 50 Veterans in the encouragement arms and at least 50 participants in the comparison arm. Bedford and Boston participants will have separate randomization blocks.

- 1) Comparison arm: My Health*e*Vet brochure only
- 2) Encouragement arm 1: My Health*e*Vet brochure and training guide
- 3) Encouragement arm 2: My Health*e*Vet brochure and training guide plus offering a group training
- 4) Encouragement arm 3: My Health*e*Vet brochure and training guide plus offering a group training and a one-on-one session

All participants in encouragement arms 1-3 will be mailed a paper copy of a training guide. This guide was developed as part of this study based on findings from Aims 1 and 2 and Veteran co-investigator input and does not exist anywhere else. It cannot be posted on a publicly accessible website as this would threaten randomization.

The training guide will include information for new My Health*e*Vet users on the mechanics of logging in, resetting password, and other basic tips. Additionally, it will include sections dedicated to the 3 most useful My Health*e*Vet features for diabetes patients identified in Aims 1 and 2. The sections each provide a step-by-step direction on how to navigate through the feature on My Health*e*Vet. The training guide contains links to online user guidance and resources such as videos to guide My HealtheVet use. If we are able to post an electronic (PDF) copy of the training guide in a location where Veterans in the encouragement arms could download an electronic copy without it being accessible to those in the comparison arm, we will do so. It cannot be posted on a publicly accessible website (such as directly on the My HealtheVet website) as this would threaten randomization.

For the group training, Veterans and their family caregivers will be invited by mail to attend a 60- to 90-minute hands-on training session for My Health*e*Vet in a computer lab at a VA facility. Project staff will call the Veteran and provide them with a few options of dates and times to come to VA Bedford or Brockton to attend the training. The training will provide a review of the content included in the training guide including the basics of My Health*e*Vet and how to access and use core features such as Blue Button, secure messaging and prescription refills.

The one-on-one session will be directed by project team staff. Project staff will call the Veteran and schedule a date and time to come to VA Jamaica Plain/West Roxbury/Brockton to meet with a VA staff member to receive the training. During the session, a discussion will be facilitated of how My HealtheVet can be helpful in achieving goals related to diabetes self-management. The training guide will be referenced to practice cases relevant to patients living with diabetes. The training will provide a review of some of the content included in the training guide including the basics of My HealtheVet and how to access and use core features such as Blue Button, secure messaging and prescription refills.

Protocol Modifications for 2020 Coronavirus Interval [added March 2020]
During the COVID-19-related suspension of in-person interactions with research participants, in-person group trainings and one-on-one trainings cannot take place. Those patients who have already been invited to attend an in-person training and expressed interest in attending will be invited to attend a virtual training instead through VA Video Connect (VVC) or a similar virtual modality such as Zoom. They will also be informed that an in-person training *may* be offered in the future. The virtual group and one-on-one trainings will follow the same format as the in-

person trainings. The VA trainer will share screens showing YouTube videos, Powerpoint slides, guidance documents and the My HealtheVet test account. The trainer will provide virtual guidance as the participants practice logging into and exploring their own My HealtheVet accounts.

Unless the administrative hold on in-person interactions with human research subjects lifted at the time when invitation letters are mailed to participants randomized to Encouragement Arm 3 for the one-on-one trainings, we will mail the amended letter inviting participants to an online training instead.

In this protocol, whenever "group trainings" or "in-person trainings" are mentioned, during the COVID-19-related suspension of in-person interactions with research participants starting 3/18/2020, these trainings refer to virtual trainings.

If the COVID-19-related suspension of in-person interactions with research participants is lifted before the study is completed, then in-person group trainings and one-on-one trainings may be offered again to the invited patients. If it no longer fits into the timeline of the study to offer the trainings, they will not be offered.

All Veterans will be invited to participate in the phone interview, regardless of which arm they are in, or whether they participated in in-person trainings that might have been offered to them. At the end of the Aim 3 intervention, all Comparison arm study participants who did not opt out or did not have an undeliverable mail address will be mailed a training guide.

5. Study Subject Selection

Sample Description

All participants will be Veterans aged 18 and older.

This aim builds on prior study aims and involves the refinement and pilot testing of an intervention. Using a randomized encouragement design, we will randomize 200-300 Veterans ages 18-85 years old from the Bedford/Boston VAMCs with uncontrolled diabetes (HbA1c>8.5) and no or minimal prior history of using the key MHV features to receive an invitation to one of the following groups, after they have been mailed a brochure and have had the opportunity to opt out of the study. We will aim for each encouragement arm to have at least 50 Veterans, and for the comparison arm to have 50+ enrolled Veterans.

- 1) Comparison arm: My HealtheVet brochure only
- 2) Encouragement arm 1: My HealtheVet brochure and training guide
- 3) Encouragement arm 2: My HealtheVet brochure and training guide plus offering a group training

- 4) Encouragement arm 3: My HealtheVet brochure and training guide plus offering a group training and a one-on-one session

We estimate that 15 to 25 (30-50 percent) of those randomized to each of the 3 encouragement arms will choose to participate by using the training guide or attending a group training or one-on-one session. Feedback on the intervention and patients' intent to use MHV will be gathered from the patient at the one-on-one meeting, the group session, and during their phone interview.

a. Subject Inclusion Criteria

Our primary inclusion criteria are that Veterans:

- Are current VA Bedford or VA Boston patients (including CBOC patients)
- Have uncontrolled diabetes (HbA1C≥8.5 at last test)
- Are inactive users (registered but with at least 1 year of non-use) or non-users of My HealtheVet
- Have an upcoming health visit scheduled at Bedford VA or Boston VA.
- Are age 18-85 years old at approximate time of first mailing

b. Subject Exclusion Criteria

Veterans are excluded if they do not meet the above criteria (e.g., they are already active MHV users, their most recent HbA1c at the time of recruitment was <8.5%, or they are age 86 and over at the time of the initial mailing).

c. Recruitment

Subject Identification and Pre-Enrollment Screening:

Local Veterans from the Bedford/Boston VA healthcare systems ages 18-85 years old with uncontrolled glucose (A1c>8.5) who have not used the patient portal or have only minimally used it in the past (and have had no use in at least the past 12 months), will be recruited for the study. Based on data from March 2019, we estimate this sample to be 170 eligible Veterans in Bedford and 539 eligible Veterans in Boston. We will mail the My HealtheVet brochure, welcome letter, information sheet, and an opt-out card with prepaid postage to all Bedford Veterans who meet eligibility criteria. All those that do not opt-out within 10 business days by telephoning or returning the opt-out card will be considered enrolled, and will be randomized to one of four arms:

- 1) Comparison arm: My HealtheVet brochure only
- 2) Encouragement arm 1: My HealtheVet brochure and training guide
- 3) Encouragement arm 2: My HealtheVet brochure and training guide plus offering a group training for how to use key My HealtheVet features

- 4) Encouragement arm 3: My HealtheVet brochure and training guide plus offering a group training and a one-on-one session

Based on the opt-out rate of Bedford patients, subsequent round(s) of mailings will be sent to Boston patients in order to have at least 50 patients enrolled in each encouragement arm and at least 50 patients enrolled in the comparison arm and a total of 200-300 total enrolled across both sites.

HIPAA Authorization for Recruitment and/or Screening:

A HIPAA waiver of authorization is required. It is necessary to obtain HIPAA identifiers (e.g., contact information and study eligibility) to contact participants for recruitment purposes.

Consent for Recruitment and/or Screening:

We have requested a waiver of consent for recruitment and/or screening. To help identify potential eligible participants (e.g., study eligibility, contact information), it will be necessary for us to obtain a waiver of consent for recruitment purposes.

Enrollment:

Patients will be considered enrolled in this portion of the study if they do not opt out of the study. If participants opt out after randomization (by returning the opt-out postcard or leaving a voicemail message for the project staff), we will no longer contact them for other portions of the study. Not participating in an in-person training or a telephone interview will not be considered opting out. However, even if patients opt out, we will still look at data that we already have for these participants from previous study aims. Those receiving the information sheet (modified consent form) will be informed of the general nature of the study, what their involvement entails, the risk/benefits, and a description of confidentiality. Participants will be told that participation is voluntary, that they can withdraw at any time, and that this will not impact their treatment.

HIPAA Authorization:

This is a minimal risk study and we are requesting a waiver for the study.

We will protect identifiers, as outlined in this protocol (see **Data Security)** and destroy the identifiers in accordance with the VA records control schedule. PHI will not be used and or disclosed to any other person or entity, except as required by law, for authorized oversight of the

research study, or for other research for which the use of disclosure of the requested information would be permitted by the Privacy Rule.

Because study materials will be distributed via mail, we are requesting a HIPAA authorization waiver. Additionally, a HIPAA authorization waiver is necessary because requiring participants to complete and return a HIPAA waiver may bias our study results (i.e., those who return the waiver may have different clinical profiles or experiences on My Health*e*Vet (i.e., be more active) than those who might not return the form).

We will protect identifiers, as outlined in this protocol (see modified consent form or information sheet) and destroy the identifiers in accordance with the VA records control schedule. PHI will not be used and or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of the requested information would be permitted by the Privacy Rule.

Informed Consent:

Data analysis requires the use of information regarding enrolled patients' usage of My HealtheVet for both recruitment and analysis, which would be biased if consent were required. We already have access to data describing their use of My HealtheVet via a previous study Aim, therefore we are requesting a waiver of documentation of consent. We will provide all participants with an information sheet (modified consent form) containing information about their rights and any risks of participation, as well as study team contact information, with the initial mailing so that they will have time to review it prior to deciding whether or not to opt-out of the study.

6. Data Collection/ Study Measures

Data Collection:

For each in-person component of the intervention (group trainings and one-on-one sessions), Veterans will be asked to complete an immediate post-intervention feedback evaluation measuring their intent to use features of My Health*e*Vet covered in the trainings. We will follow all Veterans randomized to the encouragement arms and comparison for 4-6 months and measure the number of My Health*e*Vet features used, and the frequency with which they use them. We will look at My Health*e*Vet use data of everyone invited to participate in the study.

Beyond this quantitative data, we will also conduct a semi-structured phone interview and demographic questions with Veterans in all arms at 4-6 months, seeking feedback on the intervention components and on their continued intent to use MHV for communication and

information sharing with VA and non-VA providers. The interview will be expected to last 15-20 minutes. We will not audiotape interviews. The interviewer will take notes on paper and/or enter responses into a secure VA REDCap database.

Feasibility data on the resources and time expended for intervention delivery will also be gathered to inform future implementation. All project staff will document hours spent planning training sessions, running training sessions, and interacting with participants over the phone. We will also document costs expended on printed materials and any other incurred project expenses.

7. Planned Statistical Analyses

Analysis Plan. For this small-scale experiment, we will focus our primary analyses on measuring the effect of the randomized encouragement design on the key proximal process measure of using MHV. We will measure MHV use, including the variety of features (SM, Rx Refills, EHR-extracts (Blue Button, lab views), and frequency of feature use. Because we are interested in the effect of the intervention in the sample targeted, we will conduct an intent-to-treat analysis based on randomization arm regardless of participation in intervention components. As many in the encouragement arm will not participate, this ITT does not directly assess the intervention-attributable effect. Thus, in addition to ITT, we will utilize a complier average causal effect (CACE) analysis to estimate intervention effects for those who engaged with the intervention. CACE estimation makes it possible to estimate the intervention effect for only those who engage. The CACE estimation considers both random assignment and receipt of treatment to estimate intervention efficacy. CACE estimations have been published using instrumental variables, expectation-maximization algorithm, maximum-likelihood, and integrated methods. CACE seeks to compare outcomes for individuals in the intervention condition with those who would have complied with treatment given the opportunity to do so and can often be used to improve power over ITT methods. Like all instrumental-variable methods, CACE estimation requires that certain assumptions be met: that randomization has a causal effect on the exposure (relevance assumption), that the randomization affects the outcome only through the exposure (exclusion restriction), and that randomization and the outcome (MHV use) don't share a common cause (exchangeability assumption). If these assumptions are violated or the instrument is weak, we will fall back on an ITT analysis, using the chi-square test as the statistical test to determine the effect of receiving encouragement on MHV use.

Power: Below, we provide power for ITT analyses, and anticipate additional power when implementing the CACE. We will have power to detect reasonable differences in use of MHV. We have used pilot data, looking at Veterans who did not use the patient portal in 2013 and

their use patterns in 2014 to estimate behavior in the control. Among diabetics who did not use MHV in 2013, 98% were still not using in 2014, 1% were using at least one feature, and 1% were using more than one feature. A priori estimates are that 30% of Veterans will comply with the encouragement they are randomized to, and among those, 50% will use MHV at least once. With these assumptions, we have 80% power (alpha 0.05) to detect a difference in Intent-to-Treat analysis with a sample of 70 per arm. Although we do not know the exact number who will comply or will go on to use the system, we feel that it is reasonable that half of those who receive the encouragement will begin to use.

8. Ethical Issues

a. Risks

The risks of the study are minimal in that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Participants will be asked about their diabetes management and how they use My HealtheVet.

There is a minor risk of accidental disclosure of information (loss of confidentiality); however, several steps will be taken to minimize the risk of breaches of confidentiality. VA CDW data will be stored within the VA Informatics and Computing Infrastructure (VINCI), a secure analytical workspace that provides analytical workspace with regulated data access for research, and access to data analysis software features and high performance servers for data analysis. All VHA data files from CDW will be assembled within our project folder on VINCI, using approved secure methods. Once in VINCI, we will employ standard security protocols. A subset of data needed for contacting survey respondents will be transferred electronically from the VINCI environment onto the VA network and stored on a secure server located at the Bedford VA behind the VA firewall, or on VA REDCap. Data will be accessed only by project staff IRB-approved to work on this study. Survey data will be entered by staff onto a secure VA server via VA REDCap or other VA-approved survey program and then merged in with the CDW data within our VINCI folder. A random study identification number (ID) will be generated to identify participants who participate in survey or interview data collection. The crosswalk between the VHA identifier number and the study ID will be kept on VINCI or on a secure VA server so that the CDW data can be merged with data from other sources.

b. Potential Benefits

There are no immediate direct benefits to participants in this study. Others may ultimately benefit from the knowledge obtained in this research project, as our findings will provide new information about effective use of patient portal features that can be translated to improved

management of diabetes or other complex chronic conditions. With the precautions addressed above, it is likely that the benefits of this study far outweigh the potential risks.

The primary benefit for participants will be that they may learn how to use My Health*e*Vet in order to support their own health. Patients that are randomized to the encouragement arm will receive a training guide and support to help them learn how to use My Health*e*Vet. In addition to the guide, depending on their arm, they may receive assistance with signing up for an authenticated account with My Health*e*Vet, participate in (and, if desired, have caregivers participate in) a one-on-one session, or group training on how to use the My Health*e*Vet portal. Additionally, project staff will be available to answer questions regarding the My Health*e*Vet portal. In sum, participants will receive knowledge regarding the My Health*e*Vet portal and its uses as well as information on ways to interact and communicate with their medical care providers via MHV.

Alternative Procedures:
Not applicable

c. Analysis of Risks in Relation to Benefits

All staff is trained in HIPAA compliance and will complete all human subjects training. Training of staff will include information about the importance of confidentiality and techniques to maintain confidentiality of all information reported by research participants. Individual identifier information will be removed from study data files and transcripts, as soon as possible. Unique study-specific identifiers will be assigned to support accurate linkage of data on the same individuals across multiple data files (including surveys, in-depth interview recordings and transcripts, etc.). The participant code will appear on data forms, including surveys, and abstracted audio taped forms/recordings. A file stored separately from the data will contain participant identifiers and codes. Data, recordings, and transcripts will be destroyed when feasible and in accordance with VHA Records Control Schedule. In no way will individual participant data be released to the public or cited in a publication.

Aim 2 Interviews will be audio-taped using a VA approved digital recorder and audio-recordings will be stored on a VA secure server with limited access. Transcription will be completed by an internal VA transcription service or local staff. Electronic data, including any paper forms scanned into electronic form will be stored on a VA secure server with limited access. All paper records will be stored in locked file cabinets in locked offices, with access limited to those with appropriate training and IRB approval.

d. Stopping Rules

Because there is a small risk that participants may experience some distress or psychological discomfort when answering survey or interview questions, participants will be made aware of their right to refuse to answer any questions that make them uncomfortable or that they do not wish to answer, and they will be informed of their right to withdraw from the study at any time without penalty. Participants may also be informed that they can take breaks. Additionally, study staff will be trained to respond to emotional distress and to discuss concerns and issues should they arise. If a participant becomes very distressed during the phone conversation, we may directly transfer the Veteran to the Veteran Crisis Hotline. This will be conducted via a "warm handoff." Prior to study staff contacting the "Veteran Crisis Hotline (VCH)," study staff will request the participant's contact number and/or take note of the telephone number via the caller ID (if available). Study staff will try to maintain contact with the participant until he/she is connected to the VCH. Participation in this research project is voluntary. Refusal to participate in the research project will involve no penalty or loss of rights to which veterans are entitled. If they choose to participate, they may withdraw from this study at any time without penalty or loss of VA or other benefits to which they are entitled. If they withdraw from the study, the data provided may be used in our analysis, unless otherwise requested.

If they decide they do not wish to participate in any part of the study, they can simply return the enclosed Opt-Out Card immediately or call us, and they will not be contacted again.

9. Safety Monitoring Plan

a. Data Security

CDW data security: CDW data will be stored within the VA Informatics and Computing Infrastructure (VINCI), a secure analytical workspace with regulated data access for research, and access to data analysis software and high-performance servers for data analysis. All VHA data files from CDW will be assembled within our project folder on VINCI, using approved secure methods. Once in VINCI, we will employ standard security protocols and data will not be moved outside the system. Data will be accessed only by project staff IRB-approved to work on this study. A subset of data needed for contacting survey respondents will be transferred electronically from the VINCI environment onto the VA network and stored on a secure server located at the Bedford VA behind the VA firewall, or on VA REDCap. Survey data will be entered onto a secure VA server and then merged in with the CDW data within our VINCI folder. A random study identification number (ID) will be generated to identify participants who participate in survey, interview, or pilot data collection. The Bedford data analyst will keep the crosswalk between the VHA identifier number and the study ID on a secure VA server so that the CDW data can be merged with data from other sources.

Electronic data that is not stored on VINCI will be stored on a secure server located at the Bedford VA behind the VA firewall. All computers are password protected. Hardcopy files will be stored in locked file cabinets located in study staff locked offices (i.e., PI, project manager). Any records that contain direct subject identifiers (e.g., name, social security number) will be stored in a separate locked filing cabinet. A file stored separately from the data will contain participant identifiers and codes. Data will be coded with a patient code (for example, patient001). Only individuals listed on the staff form for this study will have access to the database. When any study personnel are no longer a part of the research team, the PI/study staff will remove that person's access to all study data. In no way will individual participant data be released to the public or cited in a publication. Any hardcopy files will be stored in locked file cabinets at each respective site.

De-identified data reports (i.e., data analysis in aggregate) may be transferred between investigators via a shared VA network drive or via VA email with encryption according to VA specifications.

b. Costs and Payments

Participants will receive $25 for completion of semi-structured phone interview.

c. Providing for Reuse of Data

Data from this study will not be stored for future use in other studies.

10. Adverse Event/Unanticipated Problems Reporting Plans

The Principal Investigator Dr. Shimada and Boston Site Principal Investigator Dr. Miller will be responsible for monitoring the safety of the study. They will report unanticipated problems and adverse events to their respective IRBs in accordance with VHA Handbook 1058.01 and IRB SOP. Risks to study participants relate mostly to loss of confidentiality, which will be minimized by using participant numbers on data, when applicable. Any breach, or other instances of adverse events will be reported to the IRB within the required reporting time frames and/or in accordance with local site IRB guidelines. Breaches and AEs may be discovered via meetings or review of study documentation and/or consent forms by study staff, including the project manager and principal investigator. Study data will be kept in accordance with the Department of Veterans Affairs record control schedule 10-1 (RCS 10-1). Access to data by study personnel will be removed from when they are no longer part of the research team. Dr. Miller (Boston VA site PI) will provide input on the clinical and diabetes self-management needs of patients with mental health diagnoses and oversee Aim 3 recruitment efforts for Boston.

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