Protocol and Statistical Analysis Plan

Study Title
"Using Behavioral Economics to Enhance Appointment Reminders and Reduce Missed Visits"

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TITLE

"Using Behavioral Economics to Enhance Appointment Reminders and Reduce Missed Visits"

INVESTIGATORS

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SPECIFIC AIMS/PURPOSE

"No-shows," which are appointments neither attended nor canceled, are a persistent problem in all health care systems. They compromise patient access, lengthen wait times, increase health care inefficiencies, and worsen clinical care[2,4–7]. Despite efforts by VHA, overall no-show rates nationally have remained at 13% for years, are especially high in mental health settings (~19%),and result in a staggering nine million missed visits in VHA outpatient clinics. Appointment reminders are vital to reducing no-shows *because forgetting is the top reason* for missing appointments[8]. Research has established the effectiveness of reminder features such as timing and modality of delivery[9–14]. However, little is known about the effect of modifying what messages are contained in appointment reminders[9,15].

Behavioral economics (BE) suggests that behavioral "nudges" can be used to make it easier for people to do the "right" thing while retaining individual autonomy. We draw from BE, psychology and related fields to identify concepts that can be applied to innovating the field of appointment reminders[16–19]. One concept is social norms, which suggests that Veterans are likely to attend appointments if they sense that it is the norm for Veterans to do so[2022]. Another concept is based on the idea that providing clear instructions and an implementation plan increases the target behavior[1,23,24]. A third approach is to highlight potential harms or losses to the Veteran from missing an appointment, while a fourth approach instead highlights potential negative consequences of no-showing to other Veterans[25–29]. Each of these approaches can be transformed into messages that can be incorporated into appointment reminders, which in turn may trigger improvements in patients' appointment adherence. For instance, stating that "More than 80 out of 100 Veterans attend their VA appointments" uses social norms to reduce likelihood of a no-show. Several large quasi-experiments and randomized trials in the federal government, U.K.'s National Health Service, and elsewhere have demonstrated that seemingly small changes incorporating these types of approaches can produce large benefits when taken to scale[19,30–36].

We believe now is the idea l moment to apply *these types of nudges* to the development of enhanced appointment reminders in VHA. The overarching objective of this proposal is to conduct a cluster randomized controlled trial of simple and scalable enhancements to appointment reminders in mental health and primary care, and prepare for larger-scale implementation. We will design and evaluate four intervention groups varying in type of nudge included in appointment reminder letters or postcards. Appointments will be randomly allocated to one of the four interventions or a usual care control group at the provider-level. Our preliminary work shows that Veterans are dissatisfied with current appointment reminders and find an intervention with enhanced reminder messages acceptable. We have established key partnerships with national VA leaders, constructed and analyzed data sets for our primary quantitative outcomes, and conducted a pilot intervention of over 8,000 appointment letters that shows promise for reducing no-shows and boosting appointment attendance.

Aim 1: Develop and iteratively refine BE-informed messages based on Veterans' perceptions, and incorporate them into enhanced appointment reminders.

Hypothesis: Perceptions of messages will be consistent with our conceptual framework and not associated with emotional harms.

Aim 2: Determine the effect of four versions of enhanced appointment reminders on measures relevant to treatment access, compared with usual reminders.

Hypotheses: 1. Each intervention group will have a lower no-show rate, as compared with usual care. 2. Each intervention group will have a higher advanced cancellation rate, as compared with usual care. Exploratory Hypothesis: Wait time will be shorter in intervention groups than with usual care.

Aim 3: Evaluate differences in treatment effect associated with four versions of enhanced appointment reminders.

Hypothesis: Effect size of nudges will vary by intervention arm such that some types of nudges will have a larger proportional effect than others.

Aim 4: Characterize potential barriers and facilitators to widespread implementation of enhanced appointment reminder messages. We will conduct semi-structured interviews with key informants (10 Veterans locally and 30 VHA staff nationally). Interview guides will be informed by selected domains and constructs from the Consolidated Framework for Implementation Research.

SCIENTIFIC RATIONALE AND SIGNIFICANCE

BACKGROUND

Why are no-shows a critical health services issue now?

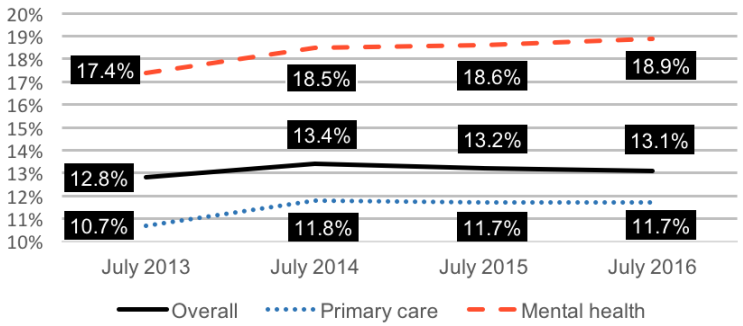
Providing and maintaining patient access to care has been declared by leadership as the Veterans Health Administration's (VHA) highest priority. Deficits in access have been shown to contribute to decreased patient satisfaction[37], higher mortality rates[38] and diminished quality of care[39]. Amidst an environment of limited access and long wait times, VHA is simultaneously struggling with "no-shows."

No-shows are defined as scheduled appointments that are neither attended nor canceled, and represent a "missed opportunity" on several levels. First, for patients, no-shows may contribute to reduced access and increased wait time. A VA Office of Inspector General audit noted that "reducing unused outpatient appointments could improve timeliness of Veterans' patient care"[7]. Another report found that inefficiencies caused by no-shows in VHA make it "difficult to meet the performance measure of seeing new patients within 30 days"[40]. Second, no-shows contribute to inefficient use of healthcare resources. No-shows result in appointment slots that unexpectedly go unused; further, after a no-show, clinics frequently spend time re-scheduling. The same Office of Inspector General audit estimated that suggested that reducing no-shows in could allow VHA facilities to more efficiently use millions of dollars each year[7]. Third, no-shows represent a missed clinical opportunity. The appointment was scheduled for a clinical reason, which does not get addressed when there is a no-show. Many vulnerable, at-risk groups, including psychiatric patients, ethnic minorities, and low-income patients are disproportionately impacted by no-shows[4,41,42], which can contribute to further disparities in clinical outcomes and quality of care[4,41].

Why are current approaches to address no-shows in VHA inadequate?

VHA struggles with elevated no show-rates, which have not improved in recent years. VHA's overall no-show rate continues to be approximately 13-14%, far above Secretary Shulkin's stated goal of five percent. In FY2015 this rate led to a total of over nine million no-shows. Despite VHA efforts aimed at reducing no-shows, such as recall scheduling and new patient orientation clinics, no-show rates have been static for years, according to VHA Support Service Center (VSSC) data (see **Figure 1**)[15].

Figure 1. National VA No-Show Rates Between 2013 and 2016



What Veterans are likely to no-show and why?

Research led by our operational partner Dr. Davies has described some common characteristics of Veterans who miss visits: mental health and rehabilitation are the service lines with the highest no-show rates; no-show rate increases with age of the appointment (i.e., how long ago it was scheduled); new patients have higher no-show rates; male Veterans have somewhat higher no-show rates than females until age 65, after which it equalizes[2].

The National Initiative to Reduce Missed Opportunities was a large VHA project that established many of the reasons for and risk factors related to no-shows, and their results reinforce the importance of appointment reminders. One of their national surveys (n=4,749) determined that forgetting was the most frequent reason (19%) cited by Veterans for a no-show[8]. In contrast, issues that would not be addressed by reminders (e.g., poor weather, sickness, and transportation issues) were much less common reason for no-shows (all cited by <8% of Veterans). Furthermore, Veterans who received a reminder letter, postcard, or call were significantly more likely to remember their appointment (85%) than those who did not receive a reminder (75%).

Why use appointment reminder systems and mailed letters or postcards to address access issues?

Appointment reminders are a key ingredient to promoting appointment attendance and cancellation of appointments that are no longer needed. (In this proposal, we use the term "**appointment reminder**" to refer to either reminders sent before an appointment or messages sent after a no-show.) Decades of research has definitively established the efficacy of appointment reminders in reducing no-show rates[11,14,43] and recent trials have suggested that appointment reminders can trigger more patients to cancel, rather than no-show, presumably because they no longer feel the appointment is necessary[31,44].

No-shows are not simply limited to a small group of outlier patients. Our preliminary data compiled from VSSC show that 40% of unique patients in mental health clinics, and 15% in primary care, had at least one no-show in VA Portland Health Care System (VAPORHCS) in 2016.

Appointment reminders letters and cards will continue to play an essential role in VHA. Rachel Goffman, MHA, former National Project Manager of the National Initiative to Reduce Missed Opportunities (NIRMO) at the VA Pittsburgh Healthcare System's Veterans Engineering Resource Center (VERC) noted that appointment reminders are "not going away" despite an evolving access landscape. In addition, VA Directive 1230, released recently on July 15, 2016, reinforces the use of multiple appointment reminders as standard practice in mental health.

Although other modalities may be used, in this proposal, we focus on enhancing letter and/or postcard reminders for several reasons: 1) a VA systematic review concluded that "evidence does not demonstrate that any particular reminder type (i.e., phone, postal, or text) has a clear net benefit over any other"[15]; 2) other approaches such as phone and text message reminders frequently do not reach their targeted audience[31,44,45]; 3) letters and postcards are reliably received by Veterans (see "Intervention Feasibility" in section "C" below); and 4) letters and postcards are VHA's most common reminder strategy, used in 87% of VHA service lines nationally[46], providing major advantages for large-scale implementation of a reminder intervention.

Why change current appointment reminders?

Appointment reminders typically only provide a "bare bones" reminder of time, date, and place, which—while certainly helpful—is more or less as was done 30 years ago[11,14,43,47]. The graphic above (see **Figure 2**) shows the body of a current reminder letter at VAPORHCS, and our review of appointment reminders from several VHAs across the nation (provided to us by the Office of Mental Health Operations) revealed similarly basic reminders. While some reminder features have been frequently examined, the content of the reminder message has rarely been studied[10,12–15,44,47–51].

Figure 2. VAPORHCS Current Reminder Letter

Dear Mr. First Middle Last,

A mental health appointment has been scheduled for you on:

Date/Time: MONDAY OCT 01, 2016 1:00 PM
Clinic: MH1I NAME 104-P2
Location: P2
Telephone: 503-555-5555 Telephone Ext.: 5-5555
Provider: LAST,FIRST

If you are unable to keep your appointment, please telephone us Monday through Friday, from 8 a.m. until 4 p.m. at:

From Portland: 503-220-8262 ext. 5-7360
From Vancouver: 360-696-4061, extension 5-7360
From outside Portland/Vancouver: 1-800-949-1004, extension 5-7360

This appointment is located on the **P2 Level of Building 104, across from the main hospital at the address above.**

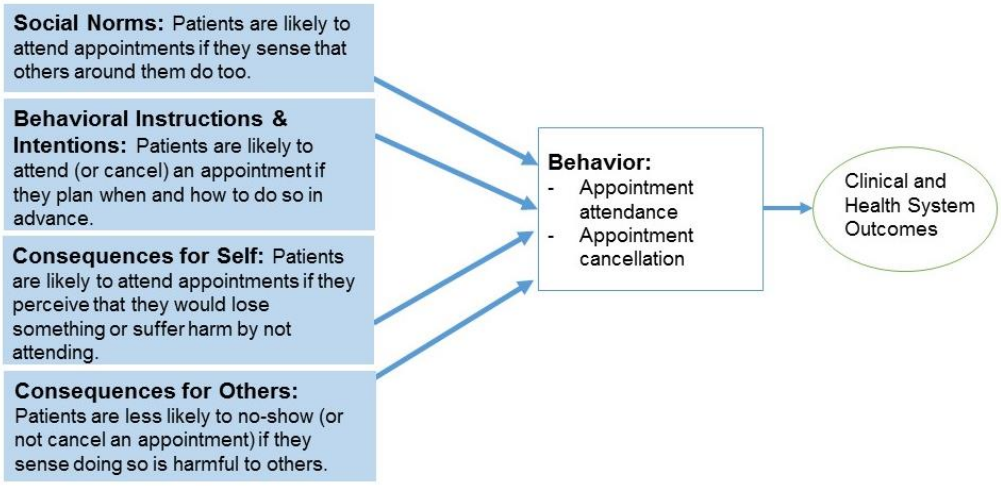
If you carry **private health insurance, please bring your insurance cards with you.** Your insurance may help cover the cost of your VA co-pays.

Thank you for letting us serve you.

What theoretical concepts can be applied to improve appointment reminders?

We use concepts from behavioral economics (BE)[52] and the Theory of Planned Behavior[53] to inform our intervention content. **Figure 3** presents our conceptual framework for this study. One of the overarching principles within BE is that people, while often well-intentioned, are often imperfect. To help overcome these predictable limitations, "nudges" can be designed that makes it easier for people to do the "right" thing while still retaining choice. In addition, the Theory of Planned Behavior suggests other drivers of a patient's likelihood of performing a target behavior (here, attendance of a healthcare appointment), including their level of intention, which is in turn influenced by attitudes, norms, and perceived behavioral control. We believe effective nudges to reduce no-shows can be designed using both BE and TPB concepts and inserted into appointment reminders.

Figure 3. Key Concepts Proposed to Influence Appointment Behavior



1. Social Norms: The field of social psychology has established how the social environment influences our perceptions and behaviors. In particular, the tendency for people to model their own behavior on what people around them are doing is called a descriptive social norm. Conforming to social norms is often an individual's chosen behavior because it provides a convenient decision-making heuristic that obviates the need to think critically about the consequences of each decision before acting on it, a process called fixed-action patterns[54].The effect of social norms may be especially strong among Veterans who tend to view themselves as part of a tight knit peer group[55].

2. Behavioral Instructions and Intentions: Providing easy-to-understand instructions is a simple but effective technique to increase the likelihood of a person following through on the target behavior[23]. In addition, nudging people to develop a plan in the form of "If situation A occurs, I will implement B response" (called implementation intentions) increases attainment of goal. Both lab-based and real-world experiments demonstrate effectiveness of this nudge[1,24].

3. Consequences for Self: The Theory of Planned Behavior suggests the perceived consequences of a behavior can be a potent motivator. Further, BE research on taking risks suggests that we feel losses to be about twice as painful as the pleasure from an objectively equivalent gain, and has led to use of the term loss aversion[25,26]. More broadly, a large literature on framing effects suggests that stating a behavior in terms of a potential loss (e.g., to one's health or to their scheduled appointment) can also be an important motivator for health behaviors[27].

4. Consequences for Others: Another major behavioral insight is that, in contrast to traditional economic theory, humans do not act purely out of self-interest; fairness and consideration to others can also be a significant influence on our behavior,[28,29] particularly with people belonging to the same group. The "band of brothers" belief in

caring for and respecting other Veterans acts as an especially strong social and moral bond, and qualitative interviews suggest Veterans' perceptions of "other Veterans" play a major role in decisions to attend appointments and engage in treatment[56,57]. Therefore, pointing out harm of missing an appointment to other Veterans may promote the pro-social sharing use of public goods such as VA appointments[58].

What knowledge gaps need to be addressed to effectively apply these insights to reduce no-shows and enhance access?

How to adapt BE and Theory of Planned Behavior principles into messages in enhanced appointment reminder letters or postcards: While the theoretical and empirical basis for nudges is fairly well-established, the operationalization and translation of these concepts into the setting of appointment reminders is not. Moreover, it is not known whether psychological harms might be associated with these messages.

Relative impact of different nudge strategies: There is evidence to suggest the utility of each individual BE principle in enhancing appointment reminders[16,18,19,21,31,59]. However, studies evaluating multiple nudges and appointment reminders are lacking. It is also unclear whether effect sizes vary depending on the particular concept or principle used in a nudge. A recent large systematic review concluded that studies including multiple appointment reminder strategies are lacking[10].

Effectiveness of enhanced appointment reminders in varying clinical and patient populations: Although not all studies have been consistent, empirical data often suggest that the largest impacts on reducing no-show rates with appointment reminders have been in mental health[11,44,47,60]. This may result in part from higher baseline no-show rates in mental health compared to other specialties. Having more room for improvement may be important for success of BE interventions trying to improve patient adherence[61]. Primary care is also a vital setting to conduct this research. First, treatment access in primary care is a VHA high priority. Second, the risk for missed appointments may be rising in primary care[62]. Because many VHA primary care clinics are shifting to patient-centered scheduling (from recall scheduling), more appointments are being scheduled months in advance (i.e., at the time of the last appointment), a well-known risk factor for no-shows[2]. Reminders may be especially vital for new patients: they are known to have higher no-show rates than established patients[2], may be unfamiliar with clinic procedures, and especially responsive to appointment-related messages[63].

SIGNIFICANCE AND INNOVATIONS

This proposal directly tackles the priority areas of access and mental and behavioral health. In personal discussion with Dr. Teo, Senior Medical Advisor to the

Office of Veterans' Access to Care, Dr. Mike Davies, has described reducing no-shows as "critical to efforts to improve access," a belief supported by empirical data linking no-shows to access and wait time[7,40]. We use mental health clinics as one of the treatment settings in this proposal because of their elevated no-show rates[6,10,43] and because mental health appointments are typically allocated more time, with therefore fewer available slots.

Applying insights from BE to enhance appointment attendance is innovative. With the exception of a few studies in the U.K.'s National Health Service[21,31], BE has not been incorporated and evaluated in the design and content of appointment reminders. Nonetheless, BE has a robust scientific grounding, with a broad array of successful applications in contexts ranging from financial planning to consumer energy use to healthcare[19,27,64,65].

This proposal is closely aligned with VHA operational partners and their priorities. Our partnerships include the:

- Office of Veterans Access to Care (OVAC): We have had discussions with Senior Medical Advisor to OVAC, Dr. Mike Davies, who is strongly supportive of strategies to reduce no-shows, views this proposal as addressing key needs in improving Veteran access, and has offered to advise on future implementation opportunities.
- Office of Mental Health Operations (OMHO): We have discussed our research plan with leaders including Executive Director Dr. David Carroll and Senior Consultant Dr. Lisa Kearney who are enthusiastic about the proposal, its potential to enhance Veterans' mental health care, and dissemination in VHA mental health.
- National Initiative to Reduce Missed Opportunities (NIRMO): We have had discussions with leadership at the Pittsburgh Veterans Engineering Resource Center (VERC), where NIRMO is managed. They strongly support a research focus on appointment reminders, and will also be proactive in advising on dissemination of improvements to appointment reminders.
- VAPORHCS Executive Leadership: Multiple members of our local leadership team, including the Acting Chief of Staff, vigorously support this proposal, deem it a high priority and high-impact area, and fully back its implementation.

VHA is uniquely and strategically positioned to magnify small intervention effects at a population-level. VHA is an ideal target for applying BE insights to healthcare because of the opportunity to scale up across VHA settings. If large numbers of Veterans in VHA receive small but effective behavioral "nudges" through improved appointment reminder letters and/or postcards, the benefits quickly accrue. Even a one percent reduction in no-show rates nationally would translate, annually, into 90,000 additional completed patient visits.

This proposal has potential to directly and rapidly improve routine clinical practice, and perhaps the Triple Aim of healthcare[66]. This proposal was intentionally

designed to focus on making modifications to existing appointment reminder systems in order to be integrated at minimal cost with routine practice in VHA**.** Intervention design includes multiple elements that enhance real-world effectiveness (e.g., lack of exclusion criteria, no demands on clinicians, and a simple format)[67].

Preliminary Studies

In this proposal, the project team will leverage its considerable experience with randomized trials in VHA settings, health services research on mental health and access, and Veteran and other stakeholder engagement. The preliminary work in preparation for this proposal includes:

1. VHA administrative data preparation: The team has extensive experience using and generating local, VISN-level, and national data reports from the Corporate Data Warehouse (CDW) and VSSC databases, which contain accurate and up-to-date information on no-shows, cancellations, and other appointment information[68–72]. In addition, through an ongoing quality improvement project, Drs. Teo and Kaboli have working relationships with VSSC data scientists, constructed data definitions on appointment status and no-shows, and prepared and tested code to extract CDW data of sufficient granularity for our proposed analyses.
2. Large project management experience: Our team has the skills and experience to manage a RCT examining BE and access-related outcomes. Dr. Dobscha has served as PI of two HSR&D-funded cluster RCTs in VHA[75,76]. Dr. Zikmund-Fisher has current and recent experience as PI of numerous federally-funded grants testing interventions using communication strategies related to BE[77–79].
3. Intervention acceptability: Two local VHA patient educators have provided input on draft interventions to ensure appropriateness for Veterans of lower literacy and numeracy backgrounds. In addition, Dr. Teo conducted, recorded, and transcribed four focus groups with a total of 14 Veteran stakeholders at VAPORHCS. Qualitative comments revealed the following key results. Veterans do receive, review, and rely on appointment letters and/or postcards from VHA (some even bring them to appointments, especially for visits in a new clinic). Veterans are frequently dissatisfied and confused by current appointment letters and postcards. The kinds of changes proposed in our interventions are acceptable to Veterans. They described sample intervention reminders as “interesting,” “caring,” and “engaging.”
4. Intervention feasibility: We have conducted several tests to ensure smooth implementation of our proposed intervention. First, we have verified that patients have a very high probability of actually receiving pre-appointment letters or postcards. To evaluate this, Dr. Teo used administrative data to construct a sample of 1,110 VAPORHCS patients who had had an in-person primary care visit and positive depression screen in the last year. Of these patients, postal

addresses were correct for 95.6% based on phone and postal verification efforts. Second, we have confirmed that the vast majority of appointments are scheduled at least two weeks in advance, which is a timeframe used to determine whether to mail a reminder letter or postcard. To determine this, we extracted data comparing scheduled appointment "create date" and appointment date. Results from the VSSC pending appointment report showed that in July 2016, 92.8% of all VHA scheduled appointments nationally in mental health were created at least two weeks in advance (94.7% in primary care), with similarly high rates at VAPORHCS.

5. Pilot effectiveness study: We conducted a pilot effectiveness study of a version of the most basic proposed intervention. Reminder templates were changed on July 1, 2016 in randomly selected mental health clinics across VAPORHCS, and no-show rates were compared between intervention and control clinics in the pre- (April-June 2016) and post-intervention (July-Sept. 2016) periods. Difference-in-difference results showed an absolute decrease of 0.6% in no-shows, and 3.8% increase in appointment attendance in association with the intervention. This suggests that in three months in just a handful of clinics, over 100 no-shows were averted by making a one-time change to pre-appointment reminder templates. Assuming this same effect size and application to all mental health and primary care clinics in VAPORHCS, we estimate this basic intervention alone could avoid over 1,500 no-shows [.006*(102,060 mental health + 157,587 primary care appointments/year)].

Research Design and Methods

A. Design Overview:

The primary objective of this study is to systematically develop and test the effectiveness of a series of changes to appointment letters or postcards in a cluster RCT with the goal of reducing no-shows and increasing access. First, we will iteratively obtain feedback and refine messages in our draft interventions (**Aim 1**). Then, we will evaluate the effects of four enhanced appointment reminder interventions informed by BE and the Theory of Planned Behavior, and compare them to usual care and each other (**Aims 2 and 3**). Appointments will be randomly allocated to one of the four interventions or usual care at the provider-level, with providers blinded to allocation. The trial will be conducted at eight locations across VAPORHCS in both mental health and primary care. In addition, we will conduct a qualitative assessment with key informants (**Aim 4**) to provide data that will be useful for future implementation (if the intervention is effective) or suggest modifications to the intervention (if it is ineffective).

Sites: The effectiveness trial will be conducted in mental health and primary care clinics at eight locations, both metropolitan and rural, across VAPORHCS: one Medical Center (Portland), one Division (Vancouver), and six Community-Based Outpatient Clinics (Hillsboro, Fairview, West Linn, Salem, Bend, and North Coast). Conducting this study

in a single VA Health Care System containing numerous locations allows us to harness sufficient power for our analyses and a shared geography for logistical ease, while still maintaining representation of the broader VHA population. Primary care is included as a second treatment setting to evaluate generalizability of treatment effects, given distinctive characteristics of patients in mental health. Analyses will be conducted separately for each specialty.

B. Data Source: Aims 1, 2, 3: All research material will be derived from existing records. VHA Corporate Data Warehouse (CDW) and VHA Support Service Center (VSSC) databases will be used to identify the main study sample and provide descriptive characteristics of the scheduled appointments and patients in our sample. VHA Survey of Healthcare Experiences of Patients (SHEP) data will be used to assess appointment wait time. Permissions will be obtained and data use agreements completed as appropriate to access data from CDW, VSSC, and SHEP. CDW data will be accessed via VA Informatics and Computing Infrastructure (VINCI) and will be saved locally. The research team has extensive experience obtaining permissions for, and working with, these data sources.

We will obtain data from these databases for up to two years preceding the study start date and two years following the study completion date. Variables extracted from these databases will include patient demographics (age, sex, race/ethnicity, service connection status, and rurality), patient diagnoses (proportion with common chronic conditions such as depression, PTSD, diabetes, and hypertension), appointment features (provider, location, specialty, clinic type, new vs. follow-up, date, outcome [i.e., completed, canceled, or no-show].

Aim 4: Research materials will include audio files, transcripts, and cards/notes from qualitative interviews with patients. These materials will be obtained specifically for this research project.

C. Study Population:

Sample and Recruitment: This project has two primary study populations involved in the 4 Specific Aims:

1. Patients treated at VAPORHCS with at least 1 scheduled individual outpatient appointment in a primary care or mental health clinic during the 12-month intervention period (Aims 1, 2, and 3).
2. VHA staff located throughout VHA nationally (Aim 4).

We expect our study sites to yield patients with characteristics (except for race) very similar to elsewhere in VHA. Specifically, CDW data from the 12 months ending June 2016 indicate that our no-show rates vary from national figures by just 0.1% in mental

health and 1.5% in primary care (<0.5 standard deviation of variation). Similarly, there is <1% difference in proportion of Veterans with service disability, PTSD diagnosis, or male gender between local and national figures; mean age differs by just 1.6 years. Proportion of racial minorities (including unknown/declined) is 21% locally vs. 28% nationally.

A sample for Aim 1 interviews in this project cannot be pre-specified as the study design involves iterative refinement to the intervention based on ongoing input from the participants. However, we will conduct at minimum three waves of six interviews (n=18). Interviews will be audio-recorded and last approximately one hour.

The number of subjects for Aims 2 and 3 in this project is estimated based on the number of patients and providers associated with the approximately 102,060 and 157,587 scheduled appointments in mental health and primary care clinics, respectively, over a 12-month period. This includes up to 64,000 unique patients, 275 unique mental health providers, and 150 unique primary care providers. The number of subjects for Aim 4 in this project is estimated as 40, consisting of 10 patients at VAPORHCS and 30 VHA staff nationally.

Based on our recruitment procedure and data available regarding the number of eligible appointments, unique patients, and providers in mental health and primary care at VAPORHCS, we do not anticipate any difficulties achieving our recruitment goals for Aim 2 and Aim 3. For Aim 1, our sample size (n=18+) is small and the pool of potentially eligible subjects large. Similarly, for Aim 4, our sample size (n=40) is small and the pool of potentially eligible subjects large. If subject recruitment and enrollment lags, we will try to identify and address causes in meetings with research team members and Co-Investigators.

For Aim 1 subjects who agree to join and do not withdraw from the study before all procedures are complete, participation in this study will last for up to one year. For Aim 2 and Aim 3 subjects, participation will last for four years. For Aim 4 subjects, participation will last for up to one year.

D. Subject Identification/Recruitment:

Inclusion/Exclusion Criteria: All subjects will be a minimum of 18 years old. The health status of the patients will be variable, although all will be patients in ambulatory care settings. Race and ethnicity will not be used in determining inclusion or exclusion of subjects.

Aim 1

- Eligibility Criteria for Subjects: 1) patient with at least 1 ambulatory appointment scheduled at least two weeks before the appointment date during the study period; 2) appointment is in either primary care (limited to stop code 323) or mental health (limited to individual stop codes used by VSSC and tracked nationally: 502, 534, 513, and 540); and 3) 1 of the above eight VAPORHCS locations.
    - Exclusion Criteria for Veteran Subjects: 1) patients with hearing problems; 2) lack of regular access to a telephone
- Recruitment of Subjects: First, we will use CDW to identify all patients meeting the above eligibility criteria. Patients will be stratified along several criteria to promote purposive sampling based on: number of scheduled appointments in the prior 12 months (both primary care and mental health), number of scheduled appointments attended vs. no-showed in the prior 12 months, new vs. established patient, service era, and gender. Second, we will mail opt-out study invitations in batches of 50 letters. Third, we will conduct a phone call to determine Veteran interest in an in-person interview, as well as capacity to give informed consent. Fourth, during an in-person study visit, we will consent and enroll participants who indicated interest and have apparent capacity to give consent. We will enroll between 18-36 participants for the Aim 1 interviews and design sessions.

Aim 2 and Aim 3

- Eligibility Criteria for Subjects: 1) patient with at least 1 ambulatory appointment scheduled at least two weeks before the appointment date during the study period; 2) appointment is in either primary care (limited to stop codes 179, 322,323, 324, 338, 690, 692, or 693) or mental health (limited to individual stop codes used by VSSC and tracked nationally: 502, 513, 527, 528, 542, 545, 534, and 540); and 3) 1 of the above eight VAPORHCS locations.
    - Exclusion Criteria for Veteran Subjects: 1) patients with hearing problems; 2) lack of regular access to a telephone
- Recruitment of Subjects: These subjects will not be individually enrolled. Instead, we will modify pre-appointment reminder letters or postcards sent routinely to Veterans with scheduled individual outpatient mental health and primary care appointments. We will obtain a waiver of authorization and informed consent for screening/recruitment, and waiver of informed consent documentation for subjects. Based on FY 2015 data, we estimate our locations to provide 102,060 and 157,587 scheduled appointments in mental health and primary care clinics, respectively, over a 12-month period. These appointments are associated with a total of about 64,000 unique Veterans, 275 unique mental health providers, and 150 unique primary care providers.

Aim 4

- Eligibility Criteria for Subjects: **Aim 4** subjects will consist of two groups of key informants: Veterans and VHA staff. Eligibility for Veteran subjects will be the same as described above for Aim 1.
    - Exclusion Criteria for Veteran Subjects: 1) patients with hearing problems; 2) lack of regular access to a telephone
- Eligibility for VHA staff will require being a full-time VHA employee. Administrators recruited for interviews will have administrative oversight of access, scheduling, or appointment operations and procedures. This would include group practice managers. At a national level, this would include leadership at VHA offices such as OVAC and NIRMO, as well as the Office of Connected Care, which is leading development and implementation of text messaging-based appointment reminders via the "Annie" app. Other VHA staff that will be recruited for interviews will be those directly involved in patient scheduling, who have responsibilities involving the building, allocation, and/or printing of appointment reminder letters.
- Recruitment of Veterans: Although Aim 4 Veteran subjects will be distinct from the Aim 1 Veteran subjects, recruitment processes will be similar: 1) use of CDW data to identify and sample potential participants; 2) opt-out study invitation letters mailed in batches of 50 letters; 3) phone calls to determine Veteran interest, capacity to give informed consent, and interview modality preference (in-person, telephone, or video conference – if this modality is preferred we will obtain the potential participant's email address to send invite for consent discussion meeting); and 4)consent and enrollment of the participant (in-person, telephone, or video conference), followed by an interview (either in-person, over the phone, or over a video conferencing application). Veterans (n=10) will be purposively sampled to provide representation of new and established patients in both primary care and mental health settings at VAPORHCS. Among established patients, those with both lower (<10%) and higher (>20%) no-show rates will be included. Ten interviews are typically sufficient for obtaining key themes when using the rapid assessment process proposed in our data analysis for this aim[81].
- Recruitment of VHA staff (n=30;): will be recruited via email, with support from our operational partners (OVAC and NIRMO). After recruitment via email, before the interview is conducted, we will ask the employee if they would prefer to be interviewed on VA time or non-VA time. If they would prefer to be interviewed on VA time, we will obtain permission from their supervisor to conduct the interview on their VA time. VHA staff will only participate in one phone/virtual interview – no other study activities or procedures will be conducted; however, we can contact the VHA staff after the interview for follow-up questions and/or clarification.

Required and Maximum Enrollment

A maximum of 84 participants will be consented and enrolled. Patients will be enrolled at the VA Portland health Care System for a maximum of 51 patients. The maximum number of VHA staff to be consented and enrolled is 33. These maximums are based on a 10% screening failure/decline rate such that:

Human Subjects	Required	Maximum (Required + 10%)
Aim 1 patients	18-36	40
Aim 4 patients	10	11
Aim 4 VHA staff	30	33
Totals	**76**	**84**

A maximum of 70,400 records will be accessed. This maximum is based on a 10% failure rate such that:

Records	Required	Maximum (Required + 10%)
Aims 2 and 3	64,000 unique veteran records	70,400
Totals	**64,000**	**70,400**

E. Intervention Development:

Intervention Development (Aim 1): We will conduct qualitative interviews informed by design thinking to iteratively develop and refine our draft interventions[82]. The goals of this intervention development process are to compare whether message perceptions align with our predicted BE theoretical constructs, understand how patients perceive each intervention and its component messages, and minimize risks of emotional harm induced by the messages.

During interviews, we will conduct two activities. The first will involve a pile sorting exercise. Pile sorts, also called card sorts, have methodological roots in anthropology and can be a simple but powerful way to explore and map relationships between concepts[83]. Participants will be introduced to our conceptual framework and the meanings of key concepts (e.g., social norms, behavioral intentions). Then, they will receive cards with various brief messages written on them, including our draft messages. They will sort messages into piles, with each pile representing a different

concept. Blank label cards will be included to allow introduction of new piles (concepts) in which to categorize the draft messages. In the context of our interviews, pile sorting will facilitate a conversation in which participants organize and map out the relationship between messages and their underlying meanings. It would be difficult for a Veteran to directly answer the question "What concept is represented by X message?" The pile sort approach helps determine what a participant includes in their universe, or their thinking, and grounds generalizations in particulars. In addition, by doing pile sorting first, we will be able to sufficiently orient the participant to our conceptual framework to facilitate elicitation of feedback on appointment reminder messages in the second phase of the interview. Once the participant has sorted the cards, the interviewer will take a photograph of how the cards are laid out on the table, to be referred to later during data analysis. The participant, along with any PHI/PII, will not be included in the photograph.

After pile sorting, the second activity during the interview will be a user experience design session[84], an area that Co-I Zikmund-Fisher has expertise in from his work designing health communication tools and decision aids. This process, which draws on techniques used in design thinking, prioritizes consulting with prospective users early and often, and will help the study team to better incorporate patient perspectives in the design of the final appointment reminder messages. In the design session, we will present participants with: a) a status quo appointment reminder letter; and b) draft intervention appointment reminder letters. After identifying the changes with highlighting, we will query participants about how each message is perceived, interpreted, and comprehended. Questions will also specifically probe about potential harms (e.g. feelings of guilt) and the principles we are trying to evoke (e.g., social norms).

Iterative design process: We will begin with a wave of six interviews (pile sort + design session). After each wave of design sessions, we will construct a spreadsheet compiling participants' feedback for each draft message. This spreadsheet will function similarly to a codebook—facilitating identification of themes in participants' interpretations of the messages. The research team will collectively review these responses to make consensus decisions about revisions to the interventions. Members of the Veteran Engagement Group (VEG) at our HSR&D Center to Improve Veteran Involvement in Care (CIVIC) will also participate in selected design meetings to offer additional Veteran-centered input. Depending on whether messages map onto our proposed BE and Theory of Planned Behavior concepts and how messages are perceived, the team may change wording in messages, delete messages, or develop multiple message versions to test in the next wave. We will continue these six-interview waves until we reach stable intervention content. Because the design process is iterative, a final sample size cannot be pre-specified, although based on experience we expect to

conduct at minimum of three waves (18+ interviews). Six or more waves are possible. Interviews will last approximately one hour, and be audio-recorded to facilitate accurate capture of all relevant comments.

We expect two deliverables from this work. First, we will possess refined intervention messages and an empirically-validated mapping of messages onto theoretical concepts. Second, we will prepare one or two manuscripts, tentatively titled "Operationalizing Behavioral Economic Principles in Appointment Reminders: A Qualitative Study" and "Pile Sorting and Design Sessions as Methods for Qualitative Analysis."

F. Randomization:

Randomization (Aims 2 and 3): The unit of randomization will be provider, with two independent randomization procedures for primary care and mental health providers. Providers will be blinded to study group (treatment) assignment because appointment reminder templates are managed administratively without providers seeing them. Randomization will be blocked by location to account for variation in clinic procedures, no-show rates, and to ensure balance in treatment assignments within each location. Because some providers work in multiple locations and clinics, they may be randomized more than once.

G. Study Groups and Intervention Description:

Overview: There will be a total of five study groups, four intervention conditions and usual care (control group), with equal treatment allocation. There will be a total of five study groups, four intervention conditions and usual care (control group), with equal treatment allocation. As shown in **Table 1**, each intervention arm contains two or more different types of behavioral nudges: social norms, behavioral instructions, consequences for self, consequences for others, and caring. As described in the Background and conceptual framework, we used principles from BE and Theory of Planned Behavior to inform the messages in each intervention arm. For example, Intervention 1 will test the nudges based on the concept of social norms and behavioral

Table 1: Summary of Type of Nudge in Each Study Group

Study Group	Nudge
Intervention 1	Social Norms
	Behavioral Instructions
Intervention 2	Caring
	Consequences for Others
	Behavioral Instructions
Intervention 3	Caring
	Consequences for Self
	Behavioral Instructions
Intervention 4	Caring
	Consequences for Others
	Consequences for Self
	Social Norms
	Behavioral Instructions
Control	None

instructions messages. All intervention arms will include techniques to increase salience of nudges (e.g., selective bolding of text).

By examining different types of nudges in different intervention arms, this project will help advance scientific understanding of the mechanisms behind behavior change related to appointment attendance. If successful, it would also lay the groundwork for a subsequent study where we would have the resources to conduct full factorial testing, identify optimal combinations of messages/nudges, and determine whether synergistic effects can be achieved by combining messages. **Table 2** contains a more detailed description of what kinds of messages fall into each of the four categories of nudges. For most of the four concepts, multiple draft messages are presented.

Table 2: Messages included in the appointment reminder based on the related concept

Concept	Message
Caring	**We're here for you.**
Consequences for Others	**Call now so we can help another Veteran in need.**
Consequences for Self	**Attending appointments lowers your chances of being hospitalized.**
Consequences for Self	**If you miss your appointment, you may have to wait a while to be seen.**
Social Norms	**Most Veterans make a point to attend their VA appointments. If they can't make their appointments, most Veterans also make an effort to let us know.**
Behavioral Instructions	**Need to change or cancel your appointment?** **Take these 2 simple steps today:** 1) Call the clinic at 503-555-5555. 2) Give your name, last 4, and appointment information. It's fine to leave a message.

Intervention 1 (Social Norms + Behavioral Instructions): A letter with two types of nudges. One points out the common behavior of attending appointments. And one provides clear, specific instructions for making appointment changes. The appointment reminder also includes usual care (basic appointment information on date, location, and phone number(s) for scheduling changes).

Research has shown that social norms messages have a positive impact on behavioral action, however it is not clear how effective it is in comparison to messages framed around consequences. Additionally, we did not use the caring message in this intervention arm to allow for comparison of whether the caring message on it's own has a positive impact.

Intervention 2 (Caring + Consequences for Others + Behavioral Instructions): A letter with three types of nudges. One suggests that the institution cares about the patient. One highlights a potential negative consequence for others if the patient no-shows. And one provides clear, specific instructions for making appointment changes.

The appointment reminder also includes usual care (basic appointment information on date, location, and phone number(s) for scheduling changes).

During the development of the conceptual messages the gain framed consequences for others message and the caring message both received favorable responses, and participants often put these messages together. These messages emphasize a personal connection between the recipient of the letter, the clinic, and other patients at the clinic. This positive message and personal connection calls upon a sense of social responsibility, which we anticipate will have a positive impact on no-show rates.

Intervention 3 (Caring + Consequences for Self + Behavioral Instructions): A letter with three types of nudges. One suggests that the institution cares about the patients. One highlights potential negative consequences for the patient if s/he no-shows. And one provides clear, specific instructions for making appointment changes. The appointment reminder also includes usual care (basic appointment information on date, location, and phone number(s) for scheduling changes).

On their own, each consequences-for-self message had mixed reactions. By including both messages we hope that if one concept does not appeal to a participant, that the second will. By including the caring message, we are conveying the idea that the reminder of the consequences if they no-show is coming from a place of caring for the recipient of the letter, and thus whether framed as a personal gain or loss the recipient may be more open to hearing the consequences-for-self messages and be gently nudged to action.

Intervention 4 (Caring + Consequences for Others + Consequences for Self + Social Norms + Behavioral Instructions): A letter with all four types of nudges combined. One suggests that the institution cares about the patients. One highlights a potential negative consequence for others if the patient no-shows. One highlights potential negative consequences for the patient if s/he no-shows. One points out the common behavior of attending appointments. And one provides clear, specific instructions for making appointment changes. The appointment reminder also includes usual care (basic appointment information on date, location, and phone number(s) for scheduling changes).

While we anticipate that each intervention arm will have an impact on No-Show rates, it is not clear which messaging combination will have the greatest impact. While we combine some messages, we also anticipate that combining more messages will not have an additive effect. Instead, too many messages may dilute the effectiveness of all the messages. To test this, we developed this intervention arm to include every

message, to determine if behavioral nudges are best used in shorter and smaller combinations.

H. Procedure: Because VHA appointments are managed in the Veterans Health Information Systems and Technology Architecture (VistA) and related data systems, letters and postcards will be designed and formatted within the constraints of VistA and related system requirements. The research team will work with and support clinical application coordinators in mental health and primary care to modify, audit, and maintain letter template changes. Our research team is experienced with staffing resources and procedures necessary in preparing large and customized patient mailings[85]. Because letter templates are unique to each provider and his/her associated clinic(s), the research team will take advantage of this specificity when tailoring messages. Intervention content will be applied to pre-appointment reminder letters and/or postcards, which in VAPORHCS are mailed at the time of scheduling. (Our preliminary data shows that, as of July 2016, in VAPORHCS, appointments are scheduled, on average, 22-33 days before the appointment in primary care and mental health.) In addition, intervention content will also be adapted to no-show letters and/or postcards, which are sent after a no-show, to help reduce risk of repeated no-shows.

I. Measures:

Outcomes for Aim 2 (Determine the effect of four versions of enhanced appointment reminders on measures relevant to treatment access, compared with usual reminders) **and Aim 3** (Evaluate differences in treatment effect associated with four versions of enhanced appointment reminders): **Table 3** summarizes the outcomes used in these Aims.

Table 3. Trial Outcomes (Aims 2 & 3)

Outcome	Measure	Data Source
Primary	No-show rate	CDW
Secondary	Cancellation rate	CDW
	Advance cancellation rate	CDW
	Patient-initiated cancellation rate	CDW
Exploratory	Raw wait time	CDW
	Clinically indicated wait time	CDW
	Waiting room time	SHEP
	New mental health appointment wait time	CDW

Our primary outcome will be no-show rate, or the proportion of total appointments that are classified as a no-show, relative to the total number of appointments scheduled. The numerator ("no-shows") consists of appointments marked as a no-show and appointments canceled by the patient or clinic after the appointment time. The denominator ("total appointments") consists of no-shows and completed appointments. No-show rates will be measured at the provider-level.

Our secondary outcome will be cancellation rate, defined as the proportion of scheduled appointments that are marked as canceled. In addition to overall cancellation rate**,** we will also determine the rate amongst the subset of cancellations that are advance cancellations and patient-initiated cancellations. Advance cancellations, defined here as at least five days before appointment, provide a metric with a reasonable window of time (informed by preliminary data provided by our schedulers) that allows the opportunity to fill a cancelled slot with another waiting Veteran. Patient-initiated cancellations provide a more specific indication of intervention effects on cancellation behavior. Cancellation rates will be measured at the provider-level.

Finally, as exploratory outcomes, we will calculate wait time and number of unique patients seen per day. The latter is simply the number of daily completed encounters, adjusting for patients who have multiple encounters in the same day. For wait time, we will use multiple validated metrics:

- Raw wait time is defined as the length of time in days between the date an appointment was created and the date the appointment was completed[74]. If an appointment is cancelled or a no-show, the wait time will be calculated based on the next appointment that is scheduled and completed in the same clinic stop code.
- Clinically indicated wait time accounts for the "return to clinic" date assigned by the patient's provider. In this metric for established patients, wait time is defined as the length of time in days between the provider-entered clinically indicated date and the date of the appointment. This is to account for the fact that appointment create date as the start date for measuring wait times may not reflect patient or provider preferences of when the patient should be seen. Limitations in VHA scheduling software have prevented systematic capture of these data until summer of 2017 when a technological fix was implemented. Co-I Dr. Prentice will be examining this metric in the spring of 2018 using a VHA national dataset, and we will include this measure if validated.
- Waiting room time will help determine intervention impact on wait time on the day of the appointment. To assess this, we will examine clinic- and facility-level data from the VHA Survey of Healthcare Experiences of Patients (SHEP), which includes several variables related to patient experience and satisfaction with wait time (e.g., "Wait time includes time spent in the waiting room and exam room. In the last 6 months, how often did you see this provider within 15 minutes of your appointment time?"). Our research team has been in communication with SHEP leadership and confirmed the feasibility of obtaining and analyzing these measures for our study sites. We also have experience with obtaining data use agreements for SHEP and linking data to individual Veterans. A sample size of approximately 4,000 subjects is available annually from SHEP data obtained from our study sites, many of who are likely to be included in the trial. We will conduct descriptive comparisons of Veterans in intervention and control arms.
- New mental health appointment wait time helps capture wait time for an important group: Veterans new to mental health. We will calculate this using another validated metric, defined as the length of time in days between the date the consult was created and the date the consult was completed[89].

These no-show, cancellation, and wait time metrics are consistent with ones used by our operational partners and VSSC. To construct these standardized measures, we will extract administrative data in CDW on appointment/encounter variables, including date, location, provider, stop code, and cancellation remarks. Wait time measures will be stratified based on new vs. established patients. “New patients” are those who have not completed another appointment in a given specialty and parent VA facility during the prior 24 months.

Baseline characteristics (Aims 2 and 3): To demonstrate balance among study arms, we will extract information from CDW on subject demographics (age, sex, race/ethnicity, service connection status, and rurality), diagnoses (proportion with common chronic conditions: depression, PTSD, diabetes, and hypertension), and appointment features (clinic type, new vs. follow-up, provider, and time between appointment creation and actual appointment). We will use protocols and code for data extraction previously established by Drs. Prentice and Dobscha for these variables.

Qualitative assessment (Aim 4): The primary goals of our semi-structured interviews are to identify features of our interventions that act as facilitators or barriers to widespread implementation, and to suggest potential modifications or adaptations to the interventions that would promote larger-scale implementation, long-term maintenance, and adaptability to other reminder modalities. We will develop and pre-test interview guides for VHA staff and Veterans.

The VHA staff interview guide will be informed by selected constructs from domains (i.e. intervention characteristics, outer setting, and inner setting) in Consolidated Framework for Implementation Research (CFIR). CFIR is a widely used implementation framework, and bears relevance for our goals of conducting a formative evaluation prior to extensive implementation[90]. Constructs selected will be those most relevant to the stage of pre-implementation, consistent with the scope of this proposal[91]. Interviews with VHA staff (n = 30, conducted remotely) will address issues such as the interventions’ relative advantage, adaptability, complexity, and design quality and packaging, as well as features across and within varying VA facilities and operational offices that might impact implementation. Potential barriers to implementation, such as unintended consequences of the intervention, impacts on clinical workflow, and existing clinic practices (e.g., overbooking), will bear special attention in interviews. Likewise, we will solicit suggestions on how to overcome such barriers. In order to promote potential adaptation and implementation of the intervention to text messaging-based appointment reminders, interviews will explicitly explore issues related to use of this newer modality of reminder delivery. Interviews with the Office of Connected Care, which oversees the “Annie” app that employs text messages, will be especially targeted to these

discussions. Interviews will last approximately 45-60 minutes, and be audio-recorded and transcribed.

The Veteran interview guide will be informed in part by the intervention characteristics domain within CFIR. Interviews with Veterans (n = 10, conducted in-person at VAPORHCS or remotely) will identify relative advantage of letter and postcard reminders, adaptability to other Veteran populations, and Veterans' support needs if the intervention were used implemented more broadly. We will also probe Veteran perspectives on barriers and facilitators to expanding the intervention to other non-postal modes of appointment reminder delivery. Specifically, we will probe adaptations to the intervention (e.g., timing, frequency, and length of reminders) that would make it more appropriate to deliver by phone (AudioCare), secure messaging (MyHealtheVet), and/or text messaging (Annie app, VEText).

J. Data Analysis:

Aims 2 and 3: We will first conduct univariate analyses to describe the "Table 1" baseline demographic, diagnostic, and appointment utilization characteristics of subjects and clinics in the usual care and intervention conditions. Then we will tabulate the total number of no-shows and total number of unique subjects with at least one no-show during the study period. For subjects with no-show(s), we will calculate the proportion with a single vs. multiple no-shows, and the mean and median number of no-shows. To analyze our primary outcome, no-show rate, we will use standard mixed effects correlated logistic regression since the outcome is binary at the individual-level. (We will use a similar approach to analyze intervention effects on our secondary outcomes, cancellation rates.) These will model the odds of no-shows as $\log[\ \text{odds}(p_{ij})\ ] = b_i + \beta_0 + \beta_1 * \text{trt}(1)_i + \beta_2 * \text{trt}(2)_i + \beta_3 * \text{trt}(3)_i + \beta_4 * \text{trt}(4)_i + \text{location}_j$, where p_{ij} is the no-show probability for provider i in location j, trt(k) are indicators for the 4 interventions, and location_j corresponds to the location for provider i. The random effect, b_i, is assumed to be normal with mean 0 and constant variance (σ^2_b) and will be used to account for repeated measures correlation for the individual subject outcomes for each provider; the model parameters, (β_1, β_2, β_3, β_4), represent log odds ratios of no-shows comparing the four intervention groups to the control group. They will be estimated using maximum likelihood estimation and will be used to test the hypotheses of Aim 1. This mixed model is a longitudinal model and can accommodate some forms of missing data, provided the missingness mechanism is non-informative. We can also estimate absolute risk differences between the interventions and usual care. No-show rates will also be presented in several ways: overall rate (i.e., for all study participants in each of the five study arms), stratified by specialty (mental health vs. primary care), stratified by patient type (new vs. follow-up), and over multiple follow-up periods (six and 12 months to determine duration and decay over time of any effect). We will also conduct exploratory subgroup analyses, which may identify particular patient populations where

effectiveness of interventions varies. For example, we will explore whether the effect of the interventions differ between men and women. To analyze our exploratory outcomes on appointment wait time, we will evaluate time-to-completed appointment using an extended multivariate Cox regression model to account for multiple appointments at the patient level and clustering at the provider level.

Aim 2 Hypotheses: To address Hypothesis 1 (Each intervention group will have a lower no-show rate, as compared with usual care) and Hypothesis 2 (Each intervention group will have a higher cancellation rate, as compared with usual care), we will conduct pairwise comparisons to test for differences between the interventions and usual care as H_0: $\beta_j=0$ for Interventions j=1,2,3,4.

Aim 3 Hypothesis (Effect size of nudges will vary by intervention arm such that some categories of nudges have a larger proportional effect than others): We will conduct pairwise comparisons of no-show and cancellation rates by testing the linear combinations between each of the four intervention arms (e.g., Intervention 1 and Intervention 2; H_0: $\beta_1=\beta_2$).

Aim 4: ATLAS.ti software will be used for data management. We will employ a "rapid assessment process," which is useful for quickly developing understanding from an insider's perspective and informing future implementation efforts[81,92]. This multi-step process will be as follows: 1) create domain names for each interview question; 2) create and test a summary template; 3) summarize interview transcripts using the summary template, and 4) transfer summaries into a matrix (respondent x domain) data display[93]. Our summary template will consist of domains and constructs from our interview guides (i.e., CFIR), and we will compose a templated summary for each interview. We will review these summaries on a regular basis (approximately every five interviews) to ensure interviews build iteratively on emergent findings.

K. Power Analyses: For our Aim 2 and Aim 3 power calculations, we used FY2016 stop code-level no-show rates at each of the eight locations and the provider-level number of scheduled appointments at each location to conduct Monte Carlo simulations. We assumed two possible differences in no-show and cancellation rates for the interventions (1.9% and 2.7%), which represent changes in appointment attendance on par with our pilot data and two prior RCTs using similar variations in BE messages in appointment reminders[31]. Because baseline no-show rates in the RCTs were lower than ours, leading to possible floor effects, these estimated effects are relatively conservative[94]. We assumed a total of 256 providers randomized to the interventions. In addition, to account for intra-class correlation among providers and the effects of over-dispersion, we allowed for correlated binary measurements to be correlated with parameter rho = $(\sigma^2_b/\sigma^2_b + \pi^2/3)$. We varied rho between two and five percent. All hypothesis tests were two-sided, with no adjustments for multiple comparisons. As the

number of providers, patients and scheduled appointments within providers and no-show rates differ between primary care and mental health, separate Monte Carlo simulations were performed to address power and sample size requirements for the two specialties. Each simulation was run a minimum of 500 times. We calculated power as the proportion of times the stated statistical hypothesis was correctly rejected.

Power calculations are conducted separately for primary care and mental health. In primary care, results of the power analyses show that there is >99% power to detect a no-show rate difference of 2.7% between the intervention and usual care, and 82% power to detect a no-show rate difference of 1.9% (2.7%-0.6%) between two interventions. In mental health, results of the power analyses demonstrate that there is 80% power to detect a no-show rate difference of 2.7% between the intervention and usual care, and 45% power to detect a no-show rate difference of 1.9% (2.7%-0.6%) between two intervention groups. In summary, the power analyses demonstrate it is possible to detect relatively modest effects in our Aim 2 outcomes (i.e., 2.7% differences in no-show or cancellation rates between interventions and usual care); it may also be possible to detect smaller effects in our Aim 3 outcomes (e.g., 1.9% differences in no-show or cancellation rates between different intervention arms).

L. Limitations and Alternatives

Single-site effectiveness study: We considered whether to design this study as a multi-site trial to address concerns about external validity. Ultimately, we favored testing our interventions across one VA Health Care System for three reasons. First, a single site allows us to examine effectiveness across two distinct specialties (mental health and primary care), which would be much more difficult in a multi-site study given resource limits. Second, given potential for differing appetites for intervention implementation across VHA sites, we agree on the need for a multi-site study, but see this as best pursued in a subsequent trial. Such a trial could be a multi-site hybrid type 2 trial[95] informed by the effectiveness (**Aims 2 and 3**) and pre-implementation data (**Aim 4**) from the current proposal to then evaluate multi-site effectiveness and implementation strategies. Third, our single site provides adequate power for our proposed analyses.

Modality of appointment reminder: We considered testing our interventions using phone, text messaging, or other technological-savvy reminder modalities. We opted not to test these approaches, particularly text messaging, in the current proposal because our conversations with VHA informatics and other leaders suggested feasibility of widespread implementation is still years away, largely because the VistA system for appointment scheduling and appointments remains in place. Nonetheless, we believe a text messaging intervention would be an ideal next step, particularly once intervention content and message wording is refined through results from **Aim 1**. We have ongoing conversations with the VHA Office of Connected Care, which has developed the text

messaging “Annie app,” and we anticipate the BE principles in this proposal could be evaluated in Annie’s text message-based appointment reminders, through VEText, or through MyHealtheVet upgrades that will allow appointment reminders through secure messaging.

Intervention content: We recognize there are numerous possible interventions, varying by BE principles and what personalization is included. We considered a factorial design whereby each possible combination is evaluated, but power constraints make that difficult. Ultimately, it was both scientific and pragmatic reasons that guided our selection of messages included in each intervention.

Contamination risk: We selected provider as the unit of randomization for pragmatic and statistical reasons. On a pragmatic level, individual patient randomization is not feasible for this intervention utilizing VHA’s appointment scheduling architecture in VistA. Statistically, provider randomization allows for enough clusters for statistical power. We understand there is contamination risk, as Veterans have appointments across providers. Our preliminary work suggests contamination risk is low.

Alternative plans for Aim 4 (pre-implementation study) if the intervention proves ineffective: In this case, we will change the content for interviews with VHA staff to obtain two types of data. First, we will conduct a detailed inquiry into the acceptability, feasibility, and desired features of enhanced appointment reminders delivered through different modes (e.g., text message, secure messaging, or automated phone reminders). This is because a reason for trial failure could be related to the use of letters and/or postcards as a mode of reminder delivery. Together with the validated reminder wording created from Aim 1, these new data from Aim 4 could provide preliminary support for a reminder intervention using a different delivery mechanism. Second, we will elicit suggestions on modifications to the intervention for particular subpopulations of interest. These subpopulations will be identified through Aim 2 and Aim 3 post-hoc analyses meant to identify groups of patients with evidence of intervention effectiveness (e.g., established patients on the VHA list of scheduled patients with a high probability of no-show).

M. PROJECT MANAGEMENT PLAN

This project will last for 3 years. Please see the Gantt Chart in **Table 5** for information on timing of study activities. The majority of project personnel will be located at the Center to Improve Veteran Involvement in Care (CIVIC). CIVIC will provide office space, equipment, and administrative research support to project staff. As PI, Dr. Teo will lead team meetings with co-investigators and the project manager at least monthly (biweekly during certain study periods such as intervention development and data analysis of trial

results) to discuss scientific issues. Dr. Teo will also have weekly meetings with other study personnel on operational and logistical issues. Drs. Zikmund-Fisher and Kaboli will fly to Portland to attend a study kick-off meeting. Subsequently, they will attend research meetings every two to four weeks via phone or videoconference. Dr. Zikmund-Fisher will participate in all research team meetings, as well as ad hoc one-on-one meetings with Dr. Teo, during Year 1 to assist with intervention development and refinement, and Year 3 to assist with interpretation of Aim 1 and Aim 2 results. Dr. Kaboli will attend team meetings throughout the study. Drs. Teo and Kaboli will supervise the study's project manager and analysts. Drs. Kaboli and Zikmund-Fisher will not have access to VA identifiable data.

Table 5. Gantt Chart

Project Activities	Year 1				Year 2				Year 3			
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Study start-up (hiring, training, SOPs)	■											
Recruit participants (Aim 1)		■										
Conduct interviews/design sessions & analyze (Aim 1)		■	■									
Finalize intervention content (Aim 1)			■									
Finalize data extraction procedures/coding (Aims 2 & 3)		■	■									
Prepare for and conduct randomization (Aims 2 & 3)				■								
Revise appointment letter templates in VistA (Aims 2 & 3)					■							
Collect longitudinal data (Aims 2 & 3)					■	■	■	■	■			
Analyze quantitative data (Aims 2 & 3)									■	■	■	
Finalize interview guides and pre-testing (Aim 4)						■	■					
Recruit and conduct interviews (Aim 4)								■	■			
Analyze interview data (Aim 4)									■	■		
Disseminate study results (All Aims)				■							■	■

INFORMED CONSENT

Patients: For Aims 1 and 4, we will seek Waivers of Authorization and Informed Consent Process for Screening/Recruitment Purposes. For Aim 2 and Aim 3, we will request a Waiver of Informed Consent Process.

For Aim 1, the Waiver of Authorization and Informed Consent Process for Screening/Recruitment Purposes will allow us to review patients' medical records, CDW, and VSSC data to identify potential patients for recruitment for interviews. After identifying a pool of potentially eligible subjects (Veterans), the potential subjects will be stratified along several criteria to promote purposive sampling based on: number of scheduled appointments in the prior 12 months (both primary care and mental health), number of scheduled appointments attended vs. no-showed in the prior 12 months, new vs. established patient, service era, and gender. After a potential subject is identified, we will send information about the study and an invitation to participate or opt-out. These letters will be sent out in batches to 50 patients at a time. Patient who do not opt-

out will be contacted via their preferred method of communication (mail, phone, or email) to arrange an in-person study meeting at VAPORHCS. Consent and enrollment will take place at the same time during the in-person visit. Participants who enroll in the study will be involved for just one day for the completion of an interview, but data can be retained for the duration of the study. During the in-person study visit, we will review the Informed Consent Sheet and HIPAA Authorization. We will provide a copy of the Study Contact Sheet. After signing the Informed Consent and HIPAA Authorization, a member of the study team will conduct the interview with the Veteran. We will audio record the interviews. Audio recordings may also be sent to the VHA Salt Lake City (VHASLC) Centralized Transcription Services Program (CTSP) for transcription services. After the completed interview, the Veteran will receive an incentive of either a gift card or cash voucher of equivalent value for their participation. We can contact the Veteran after the interview to follow-up after the visit. We might call him/her on the phone to follow-up from the study visit. We might need to ask a clarifying question or to fill in any missing data.

For Aim 2 and Aim 3, the Waiver of Authorization and Informed Consent Process will allow us to review administrative databases (CDW and VSSC) to identify potentially eligible patients for inclusion in the intervention. The waiver of informed consent process is the only feasible method to accomplish the objective of this part of the project, which is to analyze associations between appointment reminders and appointment outcomes for large groups of patients at VAPORHCS. Importantly, there will be no interaction between the research team and patients in Aim 2 and Aim 3; no patients will be contacted in any way. As part of the intervention, appointment reminder templates, which contain no personally identifying information about the patient, will be modified. Appointment reminders containing basic appointment information are routinely and automatically mailed to patients with scheduled individual outpatient mental health and primary care appointments. Wait time data from SHEP will be linked with CDW data at the patient level.

For Aim 4,

Patients: The Waiver of Authorization and Informed Consent Process for Screening/Recruitment Purposes, will allow us to review patients' medical records, CDW, and VSSC data to identify potential patients for recruitment for interviews. Patients will be stratified along several criteria to promote purposive sampling based on: number of scheduled appointments in the prior 12 months (both primary care and mental health), number of scheduled appointments attended vs. no-showed in the prior 12 months, new vs. established patient, service era, and gender. After a potential subject is identified, we will contact the patient via mail with information about the study and an invitation to participate or opt-out. Patients who do not opt-out will be contacted

via their preferred method of communication (mail, phone, or email) to arrange a time for their informed consent and interview. Interviews will occur in one of three ways: 1)in-person at VAPORHCS; 2) over the phone; or 3) over a video conferencing application.

For in-person interviews, consent and enrollment will take place at the same time during the in-person visit. Participants who enroll in the study will be involved for just one day for the completion of an interview, but data can be retained for the duration of the study. During the in-person study visit, we will review the Informed Consent Sheet and HIPAA Authorization. We will provide a copy of the Study Contact Sheet. After signing the Informed Consent and HIPAA Authorization, a member of the study team will conduct the interview with the Veteran.

For interviews conducted over the phone, once a Veteran has expressed interest in the study, the Veteran will be mailed copies of the informed consent document and HIPAA Authorization with a return envelope. Research staff delegated to obtain informed consent will set up a time to speak with the Veteran over the phone, explain the study, walk them through both documents and answer questions. If the Veteran chooses to participate, they will be asked to sign the informed consent document and HIPAA Authorization and mail them back to the research team in the provided envelope. The research team will then schedule a second phone call with the participant to complete the interview at least two weeks in advance to allow time for mailed documents to be received and processed. The research staff will document consent in CPRS. Once the research team receives the consent and HIPAA Authorization in the mail, the person who obtained consent will sign the forms and add an additional note in CPRS to explain the date discrepancy. Research staff will make copies of the forms and mail copies back to the participant. Interviews will only occur after signed and mailed consent and HIPAA documents have been received by the research team. Participants who enroll in the study will be involved for one day for completion of the interview, and data will be maintained for the duration of the study.

For interviews that are conducted over a video conferencing application, the consent process will be similar to participants consented over the phone. Once a Veteran has expressed interest in the study, the Veteran will be mailed copies of the informed consent document and HIPAA Authorization with a return envelope. Research staff delegated to obtain informed consent will set up a time to speak with the Veteran over an agreed upon and VA-approved video conferencing application (i.e. VA Video Connect, although in specified circumstances other video conferencing applications such as Apple Facetime, Facebook Messenger, Skype, Zoom, Cisco WebEx, or Google Hangouts may be used. Public facing applications will not be used). Patients will be informed that certain third-party video conferencing applications may introduce additional privacy risks. Research staff will use all available encryption and privacy modes. During the first video conference meeting, the delegated research staff will

explain the study, go through the documents, and answer questions. If the Veteran chooses to participate, they will be asked to sign the informed consent document and HIPAA Authorization and mail them back to the research team in the provided envelope. The research team will then schedule a second video visit with the participant to complete the interview at least two weeks in advance to allow time for mailed documents to be received and processed. The research staff will document consent in CPRS. Once the research team receives the consent and HIPAA Authorization in the mail, the person who obtained consent will sign the forms and add an additional note in CPRS to explain the date discrepancy. Research staff will make copies of the forms and mail copies back to the participant. Interviews will only occur after signed and mailed consent and HIPAA documents have been received by the research team. Participants who enroll in the study will be involved for one day for completion of the interview, and data will be maintained for the duration of the study.

We will audio record the interviews using a handheld VA audio recorder. Audio recordings may also be sent to the VHA Salt Lake City (VHASLC) Centralized Transcription Services Program (CTSP) for transcription services. After the completed interview, the Veteran will receive an incentive of either a gift card or cash voucher of equivalent value for their participation. We can contact the Veteran after the interview to follow-up after the visit. We might call him/her on the phone to follow-up from the study visit. We might need to ask a clarifying question or to fill in any missing data.

Staff: We will seek a Waiver of Authorization and Informed Consent Process for Screening/Recruitment Purposes and a Waiver of Consent Documentation for this study population. VHA staff will be recruited with the assistance of our operational partners. These partners will identify specific staff at VHA sites and services, and national leadership at VHA offices working on access, no-shows, and appointment reminders (e.g., OVAC, NIRMO, and the Office of Connected Care). The research team will contact potential subjects via email, phone, or mailed letter, and provide a description of the study. Staff who express interest in participating will be scheduled for a phone or video conference (on applications such as Zoom, Cisco WebEx, or Skype) meeting to discuss and obtain informed consent (including consent to be audio-recorded) and to conduct an interview. After expressing interest, we will ask if they would prefer to be interviewed on VA time or non-VA time. If they would prefer to use VA time, we will ask for their supervisor's information and explain that we will be emailing him/her to obtain permission to conduct the interview during his/her VA Tour of Duty. We will obtain permission from their supervisor prior to conducting the interview on VA time. We will send them the research information sheet via email for them to review. After we allow them time to ask questions, we will ask if they would like to schedule the interview. These interviews will be audio recorded. Before the interview, we will obtain and record a verbal consent for recording. Audio recordings may also be sent to the VHA Salt Lake

City (VHASLC) Centralized Transcription Services Program (CTSP) for transcription services.

No compensation will be provided.

We can contact Staff after the interview to follow-up after the visit. We might call them on the phone to follow-up from the study visit. We might need to ask a clarifying question or to fill in any missing data.

Provider Clinic Information: Although providers are not subjects in this study, provider clinic information will be used to assign patients to study arms, and appointment letters or postcards will be changed, which may impact appointment attendance rates. Therefore, the request in our waiver of authorization and informed consent process for screening/recruitment will include provider-level data. There will be no interaction between the research team and providers; no providers will be interviewed or otherwise contacted in any way, and individual provider data will not be reported. We will also inform providers of this study via emailed announcements describing the study. Providers will have the opportunity to opt-out from having their patients included as subjects via an email reply to the study team.

RISK AND SIDE EFFECTS

Because the intervention in this study does not involve any direct contact with subjects, this study is highly unlikely to involve risks to patient. Nonetheless, it will be the responsibility of the project manager to monitor the progress of individual participants and report any concerns to the PI during regular study meetings. Interviewers and anyone else who has contact with study participants during study activities have the responsibility to monitor for any potential patient safety issues and report any concerns to the PI. The balance of risk to benefit will be continuously monitored by the PI, and the study may be modified or terminated if risks begin to outweigh benefits.

Potential Risk

For all study activities involving administrative data extraction (i.e., screening and recruitment for all Aims, and data analysis for Aim 2 and Aim 3), the risk to subjects is minimal. The primary risk is breach of confidentiality via inadvertent disclosure of personal health information (PHI). For study activities involving direct contact with subjects (i.e., Aim 1 and Aim 4 activities), the risk to subjects is also minimal due to the nature of the interaction. The primary risks are breach of confidentiality via inadvertent disclosure of personal health information (PHI) and discomfort during interviews or other contacts.

Protection Against Risk

Numerous efforts will be made to minimize the likelihood of the risk of a breach of confidentiality. No personally identifying information will be released outside of VHA. All subjects will be assigned a coded study ID number with password secure cross-walk located behind the VA firewall on a secure server or in locked file cabinets, separate from other study data. Identifying information will be removed from datasets prior to statistical analyses. CDW, VSSC, and SHEP databases are accessed only within the secure VHA electronic environment. We will analyze and report subject data in aggregate form only, and no PHI will be reported for any subject. All investigators and team members who will have access to personal identifiers or cross-walks linking data to identifiers will have received appropriate VHA background checks as part of VHA hiring and/or credentialing and will have completed Data Security Training within the prior 12 months.

All information linking study data to PHI will be kept within VHA electronically in secure computer files stored behind firewalls requiring password access, or in hardcopy form in locked file cabinets in locked offices. All patient identifiers will be removed prior to analysis. All investigators and team members who will have access to the data will have received appropriate background checks as part of hiring and/or credentialing, and will have completed Data Security Training within the prior 12 months.

For Aim 1 and Aim 4, individual interviews with Veterans will be digitally audio-recorded. After interviews, digital recordings will be uploaded directly to a network folder on a password secure server behind the VA firewall. Recording will then be deleted from the audio recorder. All audio recordings will be destroyed when analyses are complete. Filenames of digital recordings will not include participant names; only a unique study ID number will be listed in filenames. Transcriptions will be de-identified during the transcription process by personnel who have training and experience in transcription. Only study personnel will have access to de-identified transcripts. Any hardcopies made of transcripts will be kept in locked files in investigators' offices. We will ensure that any quotations used in manuscripts or reports do not contain identifying information.

For Aim 4, interviews with Staff will be digitally audio-recorded. After interviews, digital recordings will be uploaded directly to a network folder on a password secure server behind the VA firewall. Recording will then be deleted from the audio recorder. Audio recordings will not be destroyed since they will contain the verbal consent for the recorded interviews. Filenames of digital recordings will not include participant names; only a unique study ID number will be listed in filenames. Transcriptions will be de-identified during the transcription process by personnel who have training and experience in transcription. Only study personnel will have access to de-identified transcripts. Any hardcopies made of transcripts will be kept in locked files in investigators' offices. We will ensure that any quotations used in manuscripts or reports do not contain identifying information.

The project manager will conduct a review of study files every six months to assure compliance with approved procedures. The research team will work closely with the VAPORHCS Information Security Officer and Contracting Officer to ensure that any data transfer, storage, and handling by non-VA entities adhere to VA security policies.

PARTICIPANT SAFEGUARDS:

The risk to participants is minimal and participation is entirely voluntary. Participants may withdraw from the study at any point without repercussion. Participants also have the choice to not answer interview questions or other study activities if they choose. This study will not include vulnerable populations and will only enroll participants with apparent capacity to give consent.

SUICIDALITY:

If concerns arise about a participant being at significant potential risk for suicide, the PI or his designee will be notified. Study team members conducting video, telephone, and in- person visits will have emergency contact information available at all times for the PI or designee and emergency services (e.g. VA National Veterans Crisis Line). All study team members will receive training and supervision on suicide risk assessment and suicide crisis procedures. These procedures include reporting these incidents to the PI and initiating appropriate emergency response interventions as indicated.

If a participant appears to be at potentially elevated risk of suicide, a study team member will contact the PI or his designee to further review risk potential. This may involve medical record review, speaking with the patient directly, or contacting the participant's mental health or primary care provider to facilitate ongoing care as indicated. Additional care options in the case of more urgent circumstances may include clinical evaluation by the study PI or his designee, contacting the local suicide prevention coordinator, escort to the Portland VA Medical Center Emergency Room, or "warm-transfer" to the Veteran's Crisis Line (http://www.portland.va.gov/research/documents/hrpp/warm-transfer.doc).

BENEFITS:

For Aim 1, patient participants will receive a $20 stipend for time and transportation costs associated with participating in interviews. Members of the Veteran Engagement Group will also participate and they will be compensated with a $25 stipend for their participation ($25 is the standard per hour compensation for VEG members). For Aim 4, patient participants will be compensated with a $20 stipend for time and transportation costs associated with participating in interviews. Otherwise, there will be no direct benefit to other subjects (patients, providers, staff). However, patients, providers, and staff in the future may benefit as per below. This information is also included in the Informed Consent Forms.

This study has the potential to considerably improve patient care experiences by reducing no-show rates, reducing wait times, and increasing VHA healthcare access. In addition, results and products of this study may also help VHA providers and staff by reducing healthcare inefficiencies associated with patient no-shows, cancellations, and rescheduling. The risk to Veterans, as described above, is low relative to the potential benefit to VHA and Veterans.

PROTECTED HEALTH INFORMATION:

All information linking study data to PHI will be kept within VHA electronically in secure computer files stored behind firewalls requiring password access, or in hardcopy form in locked file cabinets in locked offices. Patient identifiers (i.e., names, address, SSN) will be removed prior to analysis.

The identifiers and health information collected and used during analysis are the minimum necessary needed to conduct the research and cannot be further reduced. For patients in Aim 1 and Aim 4, as well as VHA staff in Aim 4, name and contact information (address, telephone, and email in the case of VA employees and Veterans who opt for a video conferencing modality for their interview) are essential to contacting subjects about their enrollment in the study. For patients in Aim 1 and Aim 4, participants social security number will be used to link locally obtained data with those accessible in the CDW as necessary for completion of these aims, including checking medical records to assess study eligibility. For patients in Aim 2 and Aim 3, dates related to appointments are essential to analyzing the intervention outcomes.

All investigators and team members who will have access to the data will have received appropriate background checks as part of hiring and/or credentialing, and will have completed Data Security Training within the prior 12 months.

MULTI-SITE STUDY CONCERNS

N/A - All study recruitment and data analysis for this study is being conducted entirely at the VA Portland Health Care System.

RESOURCES AVAILABLE

The study will take place at the VA Portland Health Care System (VAPORHCS) in Portland, Oregon. VAPORHCS is the fastest growing unique population amongst 1A facilities in 11 primary care clinics. Ambulatory primary care clinics are located at the main hospital in Portland, on the Vancouver, Washington campus, and at nine additional community based outpatient clinic sites; VAPORHCS serves both urban and rural areas and represents a diverse population of Veterans. The VAPORHCS HSR&D Center of Innovation is the Center to Improve Veteran Involvement in Care (CIVIC) is

where the science of this research study will take place, in collaboration with other CIVIC investigators, staff, and the CIVIC Veteran Engagement Group.

The majority of project personnel will be located at the Center to Improve Veteran Involvement in Care (CIVIC). CIVIC will provide office space, equipment, and administrative research support to project staff. Dr. Teo and his research staff retain private office space in CIVIC. CIVIC has approximately 4,500 square feet of office space, which includes the second and third floors of VAPORHCS Building 6. This contiguous space allows extraordinary opportunities for collaboration and synergy. All necessary equipment including computers, printers, copiers, and scanners are available to the research team. Dr. Teo will devote 3/8 time to this study, and his study coordinator will be devoting 8/8 time to this study.

COST TO SUBJECTS

There are no costs to subjects in the proposed study.

SUBJECT COMPENSATION

For Aim 1, patient participants will receive a $20 stipend for time and transportation costs associated with participating in interviews. Members of the Veteran Engagement Group will also participate and they will be compensated with a $25 stipend for their participation ($25 is the standard per hour compensation for VEG members). For Aim 4, patient participants will be compensated with a $20 stipend for time and transportation costs associated with participating in interviews. Otherwise, there will be no direct benefit to other subjects (patients, providers, staff). However, patients, providers, and staff in the future may benefit as per below. These payments are reasonable and commensurate with the expected contributions of the subjects. Payments are fair and appropriate and do not constitute undue pressure or influence on, or coercion of, the prospective research subjects to volunteer for participation in this study.

PRIVACY AND CONFIDENTIALITY

Numerous efforts will be made to minimize the likelihood of the risk of a breach of confidentiality. No personally identifying information will be released outside of VHA. All subjects will be assigned a coded study ID number with password secure cross-walk located behind the VA firewall on a secure server or in locked file cabinets, separate from other study data. Identifying information will be removed from datasets prior to statistical analyses. CDW, VSSC, and SHEP databases are accessed only within the secure VHA electronic environment. We will analyze and report subject data in aggregate form only, and no PHI will be reported for any subject. All investigators and team members who will have access to personal identifiers or cross-walks linking data to identifiers will have received appropriate VHA background checks as part of VHA hiring and/or credentialing and will have completed Data Security Training within the prior 12 months.

All information linking study data to PHI will be kept within VHA electronically in secure computer files stored behind firewalls requiring password access, or in hardcopy form in locked file cabinets in locked offices. All patient identifiers will be removed prior to analysis. All investigators and team members who will have access to the data will have received appropriate background checks as part of hiring and/or credentialing, and will have completed Data Security Training within the prior 12 months.

For Aim 1 and Aim 4, individual interviews will be digitally audio recorded. After interviews, digital recordings will be uploaded directly to a network folder on a password secure server behind the VA firewall. Recording will then be deleted from the audio recorder. All audio recordings will be destroyed when analyses are complete, except for audio recordings of interviews with VA staff, which will include the staff member's consent for audio recording. Filenames of digital recordings will not include participant names; only a unique study ID number will be listed in filenames. Transcriptions will be de-identified during the transcription process by personnel who have training and experience in transcription. Only study personnel will have access to de-identified transcripts. Any hardcopies made of transcripts will be kept in locked files in investigators' offices. We will ensure that any quotations used in manuscripts or reports do not contain identifying information.

Audio recordings may also be sent to the VHA Salt Lake City (VHASLC) Centralized Transcription Services Program (CTSP) for transcription services.

For Aim 1, a personal smartphone with a camera will be used to capture photographs of the cards laid out on the table from the pile sorting task, but the participant will not be included in the photograph. Photographs will be emailed from the interviewer's personal email on her smartphone to the research coordinator's VA email, uploaded to a network folder on a password secure server behind the VA firewall, and labeled using a unique study code. No personally identifying information will be included in the photographs or their labels.

Study data may also be stored in a designated study folder within VA Informatics and Computing Infrastructure (VINCI), a centralized data storage server. VINCI is a partnership between the VA Office of Information Technology (OI&T) and the Veterans' Health Administration Office of Research and Development (VHA ORD). VINCI provides the storage and server technologies to securely host suites of databases integrated from select national data. These servers reside at the Austin Information Technology Center (AITC), located in Austin, Texas. To ensure the protection of Veterans data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in

VHA Research and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO).

The project manager will conduct a review of study files every six months to assure compliance with approved procedures. The research team will work closely with the VAPORHCS Information Security Officer and Contracting Officer to ensure that any data transfer, storage, and handling by non-VA entities adhere to VA security policies.

CERTIFICATE OF CONFIDENTIALITY

N/A

DATA MANAGEMENT

This project will be housed at the VA Portland Health Care System (VAPORHCS).

All information linking study data to PHI will be kept within VHA electronically in secure computer files stored behind firewalls requiring password access, or in hardcopy form in locked file cabinets in locked offices. All patient identifiers will be removed prior to analysis. All investigators and team members who will have access to the data will have received appropriate background checks as part of hiring and/or credentialing, and will have completed Data Security Training within the prior 12 months.

For Aim 1 and Aim 4, individual interviews will be digitally audio-recorded. After interviews, digital recordings will be uploaded directly to a network folder on a password secure server behind the VA firewall. Recording will then be deleted from the audio recorder. All audio recordings will be destroyed when analyses are complete, except for audio recordings of interviews with VA staff, which will include the staff member's consent for audio recording. Filenames of digital recordings will not include participant names; only a unique study ID number will be listed in filenames. Transcriptions will be de-identified during the transcription process by personnel who have training and experience in transcription. Only study personnel will have access to de-identified transcripts. Any hardcopies made of transcripts will be kept in locked files in investigators' offices. We will ensure that any quotations used in manuscripts or reports do not contain identifying information.

The project manager will conduct a review of study files every six months to assure compliance with approved procedures. The research team will work closely with the VAPORHCS Information Security Officer and Contracting Officer to ensure that any data transfer, storage, and handling by non-VA entities adhere to VA security policies.

Transfer of Data Ownership

N/A

Data and Safety Monitoring Plan (DSMP)

Safety Monitoring: Because the intervention in this study does not involve any direct contact with subjects, this study is highly unlikely to involve risks to patient. Nonetheless, the PI or anyone else who has contact with study participants during study activities have the responsibility to monitor for any potential adverse events and protocol deviations. Any adverse participant event will be reported immediately to PI Dr. Teo, who will contact the participant and determine if additional intervention is needed to ensure participant safety. Protocol deviations will also be immediately reported to Dr. Teo who will ensure that adverse events deemed to be unanticipated problems and protocol deviations are properly reported to the IRB in a timely manner. Detailed written documentation will be kept for all adverse events that occur over the course of the study. PI Dr. Teo holds weekly meetings with his study personnel where they will discuss adverse events and protocol deviations associated with this project and ways to reduce repeat occurrences. Research staff will examine all cumulative adverse events quarterly to determine if there are any systematic problems and to implement protocol corrections as needed after receiving IRB approval.

Data Monitoring: We will use password protected excel documents to store study data, track data screening, enrollment and participation, create surveys, generate reports, and enhance project management. All information linking study data to PHI will be kept within VHA electronically in secure computer files stored behind firewalls requiring password access, or in hardcopy form in locked file cabinets in locked offices. All patient identifiers will be removed prior to analysis. All investigators and team members who will have access to the data will have received appropriate background checks as part of hiring and/or credentialing, and will have completed Data Security Training within the prior 12 months. The project manager will conduct a review of study files every six months to assure compliance with approved procedures. The research team will work closely with the VAPORHCS Information Security Officer and Contracting Officer to ensure that any data transfer, storage, and handling by non-VA entities adhere to VA security policies.

Per VHA guidelines, data resulting from this study will be stored locally on VHA password-secure folders until enterprise-level resources become available for long-term storage and access. Requests for data access will be considered and responded to within one month of the request and datasets will be made available electronically. Requests must be made in writing to the study PI and provide information on the purpose for accessing the data.

All data used in final, published results will be made available for sharing. Published data will be available upon request to any investigator in order to enable independent validation and interpretation of published data.

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