

Protocol:
Video Enhanced Care Management for Medically Complex Veterans

ClinicalTrials.gov ID: NCT02962687

Most recent updates approved by IRB: 10/5/2017
Most recent Continuing Review approval: 10/8/2018

B. BACKGROUND

B.1. Unrecognized CI is common, especially among older adults with chronic medical illness. Cognitive impairment that does not meet the threshold of dementia affects approximately 22% of the adults older than 70, in the United States.⁸ The diagnosis of cognitive impairment is often missed in primary care clinics.^{9,10} This may be due, in part, to the high prevalence of co-existing medical conditions that compete for a provider's time and attention. Among VA primary care users ≥ 65 , who have lower health status and higher comorbidity compared to age-matched counterparts who don't receive VA care, 42.5% of primary care users ≥ 65 were found to have previously unrecognized cognitive impairment (total $n=630$; $n=21$ with dementia, $n=247$ with cognitive impairment, no dementia [CIND]).² In a recent study of Veterans with heart failure, a prevalent condition associated with high self-care needs, the prevalence of unrecognized CI was 58%.¹¹ Although universal screening for CI is not recommended, a targeted case-finding approach in groups with higher-than-average risk is widely cited as a good strategy.¹² Older adults with medical complexity certainly constitute such a high risk group.

B.2. CI is directly related to acute care use and adverse health outcomes. In a recent study in the VA system, patients who screened positive for CI had twice the number of hospitalizations and their mean length of stay was nearly four times as long as those who screened negative.¹³ Patients with CI are more likely to have functional impairments; in a national sample, 45% of individuals with CI were found to have one or more impairments in an instrumental activity of daily living.¹ Moreover, patients with CI develop dementia at a greater rate than those with normal cognition.⁸ Dementia is well-known to be associated with higher health care costs and increased severity of co-morbid illnesses and potentially avoidable hospitalizations.¹⁴ Hospitalizations are not only costly; they also constitute a significant burden on patients and families. A large proportion of chronic illness care relies on principles of self-management and patients with CI likely need increased support in order to comply with complicated medication and care regimens, and avoid subsequent unnecessary emergency department (ED) and hospital use.

B.3. Unmet needs and opportunities for intervention.

B.3.a. Poorly coordinated care. Patients with medical complexity and CI receive care that often is fragmented, inefficient, and ineffective. For example, the risk of potentially avoidable inpatient admissions or preventable complications in an inpatient setting increases dramatically with the number of chronic conditions among older adults.¹⁵ People with multiple chronic conditions (MCC) are seen by health care providers frequently and in multiple settings (hospitals, EDs, outpatient and specialty clinics, nursing homes, home health care providers). The need to receive, process, and integrate information from multiple settings and providers is especially difficult for patients with CI. Thus, *care coordination*, which recognizes the diversity of the full spectrum of disease burden in older adults, rather than trying to manage each condition in isolation, is an essential component of improving care in this population.¹⁶ Care coordination directly addresses medical complexity through reducing workload burden.⁴

B.3.b. Risk of progression to dementia. CI progresses to dementia at an annual rate of 12%.⁸ Thus, *protecting cognitive health* is an essential goal in this population. The Institute of Medicine recently endorsed three evidence-based strategies for promoting cognitive health: 1) increasing physical activity; 2) reducing cardiovascular risk factors including hypertension, diabetes, and smoking; and 3) managing medications and health conditions that could affect cognition.⁶ Interventions to promote cognitive health directly address complexity through enhancing capacity.³

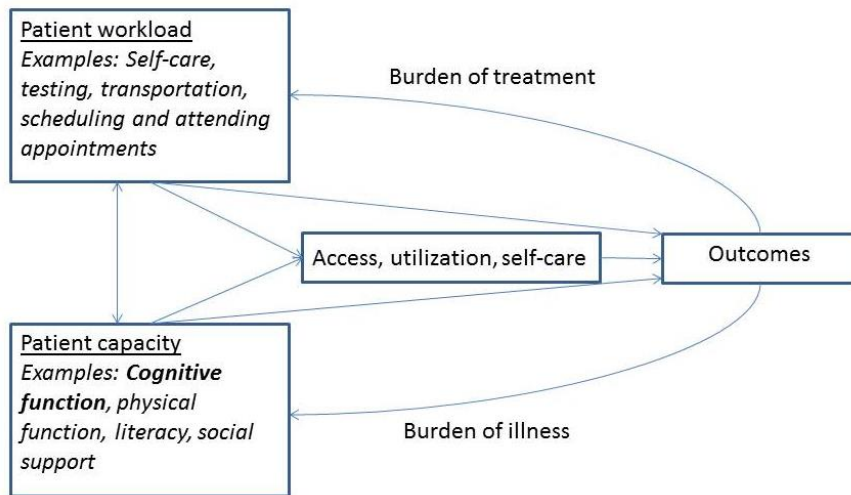
B.3.c. New care models need to be integrated with primary-care and scalable. Given the increasing number of affected individuals, specialized medical homes for complex-needs patients in communities throughout the U.S. are not likely to be feasible.¹⁷ In VA, the majority of patients with MCC are cared for in traditional PACTs; thus it is essential to develop care models that are integrated with primary care. The geographic dispersion of Veterans receiving care throughout VHA makes it imperative to develop care models beyond traditional face-to-face encounters.

B.4. Previous studies of interventions for patients with medical complexity and CI. A recent review highlighted the fact that few dementia care management programs have targeted patients with mild cognitive deficits; the majority of interventions have focused on caregivers and none specified reducing hospitalizations as a primary aim, although reducing hospitalizations among older persons with CI is an explicit goal of Healthy People 2020.¹⁸

B.4.a. Rising rates of internet use and video visits with older adults. Among older adults who use the internet, 71% go online every day or almost every day, and an additional 11% go online three to five times per week. These older internet users also have strongly positive attitudes about the benefits of online information in their personal lives. Rates of internet use among older adults are rising rapidly, at an annual rate of 6-10% per year.¹⁹ A 2013 study compared video visits to in-person visits in patients with Parkinson's disease (mean age 67, 22% female) and found them to be feasible (93% completed as scheduled) with no difference in clinical outcomes between the groups.²⁰ Video visits on mobile devices afford the opportunity to assess a patient's environment, thereby replicating certain aspects of home visits, and are currently used to provide clinical care for geriatric populations within VA, such as Home Based Primary Care.

Key conclusions from evidence review

1. CI is prevalent and often unrecognized among medically complex patients.
2. There is a need for new interventions aimed at reducing acute care utilization among patients with CI.
3. Increasing numbers of older adults use the internet and are open to technology-enhanced interventions.
4. There is some evidence supporting the feasibility of video visits in older adults; but it is uncertain whether video visits offer advantages over telephone-based care management in this population.



B.5. Conceptual Framework. The conceptual model by Shippee and colleagues provides the theoretical framework for designing the care management program to support patients with medical complexity and CI (illustrated in Figure 1).³ Patients with chronic conditions face many treatment demands, including managing appointments and advice from multiple treating providers, following medication schedules, self-monitoring their condition, and practicing proactive health behaviors. These constitute a patient's **workload**. Other demands/factors that may **limit capacity** include financial

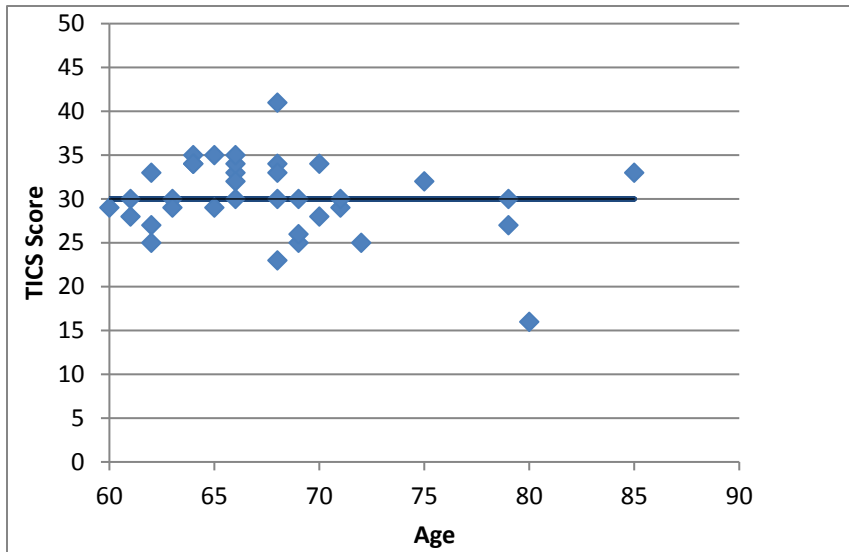
concerns, access (transportation) problems, low health literacy, lack of social support, and prevalence of mental health disorders like depression and CI.⁴ **We will target patients with high cumulative complexity by enrolling older patients with high Care Assessment Need (CAN) scores and identifying those with the additional, significant capacity-limiting factor of CI.** Our intervention will focus on both pathways that interact to lead to poor health outcomes: healthcare workload demands, and factors that limit patient capacity. Consistent with the model's emphasis on social support as an essential factor in overall complexity, we will engage and incorporate a Care Partner (friend, family member, or caregiver) as a critical member of the patient care team.

B.6. Alignment with VA Goals and Objectives. The study directly addresses a major priority for VHA as outlined in the VHA Blueprint for Excellence, *Transformational Action 1.2.a. Enhance Coordination-of-Care and the use of Patient-Aligned Care Teams (PACT) for Veterans with the Most Complex Care-Needs* and *Transformational Action 3.2.d. Proactively identify individual patients at risk for undesirable outcomes such as death, hospitalization, or preventable medical complications and identify specific interventions that are most likely to reduce risk.*⁷

B.7. Preliminary studies led by research team members.

B.7.a Studies of nurse-led interventions in high-risk populations and studies enrolling dyads. Together the team has extensive experience conducting trials of nurse-led care management and transitional care interventions. Dr. Hastings leads Discharge Information and Support for Patients Receiving Outpatient Care in the Emergency Department (DISPO ED; HSR&D 12-052, PI Hastings), an ongoing clinical trial examining a nurse-led telephone care program for Veterans treated and released from the ED who are at high risk for repeat ED visits.²¹ To date, the study has enrolled 490 of 514 Veterans, ahead of the planned enrollment schedule, with 96% of patients completing all follow-up measures. Dr. Van Houtven leads and Dr. Hastings is a key co-investigator of an ongoing RCT testing an innovative informal caregiver support training program aimed at

increasing days at home for Veterans referred for home-based care services (Helping Invested Families Improve Veterans' Experiences Study (HI FIVES)).²² Practical, feasible, IRB-approved procedures were established for enrolling the dyads and to date HI-FIVES has successfully enrolled 230 patient/caregiver dyads. The V-STITCH study (VA HSR&D IIR 20-034, Co-PI Oddone) was an RCT conducted in the Durham



VAMC's primary care clinics (N=588) that tested a behavioral intervention involving a nurse contacting patients by telephone every 2 months for 24 months. HINTS (VA HSR&D IIR 04-426, Co-Is Oddone and Van Houtven) was a 4-arm RCT with a nurse telephone intervention component aimed at improving BP control (N=591). Dr. Hendrix led a study to train informal caregivers of hospitalized Veterans (VA HSR&D PPO 09-272, Co-Is Hastings, Van Houtven) that included a telephone call from a nurse within 24-72 hours of hospital discharge. The post-discharge telephone call was successfully delivered to 94% of subjects. Thus, the proposed team has broad experience delivering nurse-led

interventions, including recruiting and enrolling dyads of medically complex Veteran patients.

B.7.b Estimates of cognitive impairment in patients with multiple chronic conditions (MCC). In order to collect preliminary data for the current proposal, we administered the Telephone Interview of Cognitive Status, modified version (TICS-m) to 35 participants in DISPO ED, a clinical trial that enrolls patients with a history of high health care utilization and MCC.²¹ Figure 2 displays TICS-m score, according to age. **Overall 34% of respondents scored in the range of 20-29, suggestive of mild CI.**²³

B.7.c. Acceptability of Video-Enhanced Intervention: Survey of Veterans with MCC and Caregivers. As part of Dr. Hastings' DISPO ED study and Dr. Van Houtven's HI-FIVES study we examined prevalence and characteristics of internet use, and attitudes about new technology in Veterans and caregivers aged 65 and over (n = 59; see Table 1). We found that 58-75% of Veterans and caregivers aged 65 or over had used the Internet in the last year, and both groups indicated a high level of comfort with it (mean 4.2 on 5-point scale). A key finding was that Veterans ages 65 and over indicated high levels of willingness to communicate with a health team using videoconferencing software on a cellphone, tablet or laptop (mean 4.3 on 5-point scale).

	DISPO ED: Veterans Age ≥65, n=40	HI-FIVES: Caregivers Age ≥65, n=19
Age, mean (SD)	69.6 (5.1)	72.4 (5.4)
Gender (% male)	97.5%	0%
% White	70.0%	60%
% African American	30.0%	45%
Education ¹ (% w/ HS or less)	27.5%	36.8%
Economic Situation ² (% insecure)	37.5%	31.6%
Used internet in last year (% yes)	75%	57.9%
If yes, Comfort level with using internet (1 – 5 scale; mean)	4.2	4.2
Frequency of internet use (% once per week or more)	63.4%	100%
Cell	32.5%	5.3%
Tablet	27.5%	21.1%
Laptop	32.5%	21.1%
Other computer in home	40%	42.1%
Computer outside home	5%	10.5%

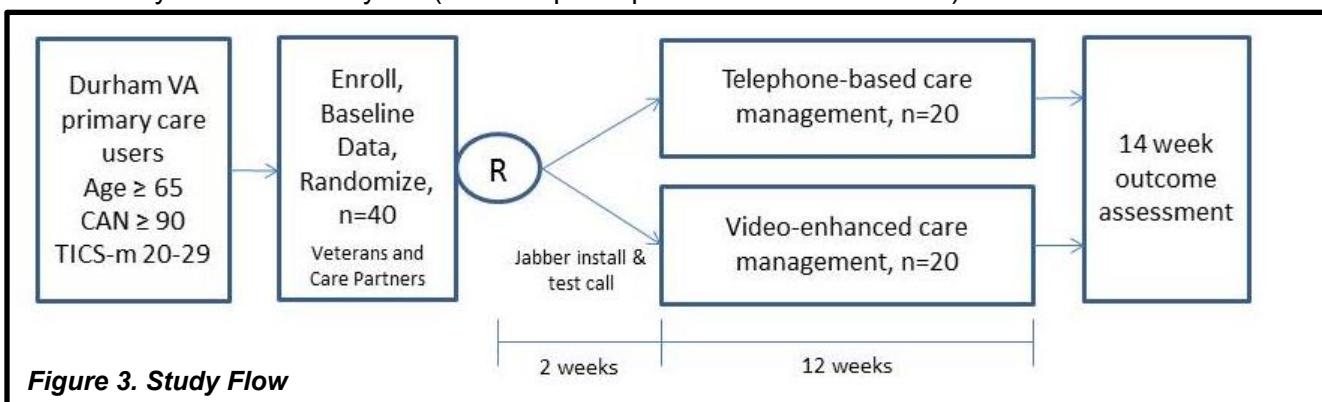
Use of Skype/FaceTime/ videoconferencing software (% yes)	40%	26.3%
Willingness to videoconference with health team (1 – 5 scale; mean):		
Using a cellphone/smartphone	4.3	3.7
Using a tablet	4.3	3.8
Using a laptop	4.3	4.4
Using another computer in the home	4.1	4.2
Using a computer outside the home	3.2	2.7

C. SIGNIFICANCE

This pilot study will provide important information about the feasibility, acceptability and

usability of a novel care management program for a large and vulnerable group of Veterans, who are high utilizers of the health care system and at risk for adverse health outcomes. In 2012, over 52% of the 6.2 million Veterans receiving primary care in VA were age 65 years or older; thus, if proven effective, the care management program for medically complex Veterans with CI could have a direct impact on the way care is delivered to a large number of Veterans. This study is extremely timely and innovative in its use of a population-based screening approach to identify patients for a multi-faceted, non-disease based intervention, and its exploration of video visits in patients with CI and a self-identified Care Partner.

D. APPROACH
D.1. Overview of Study Design. We propose a pilot study to test a 12-week video-enhanced nurse care management program for medically complex older Veterans with CI, delivered via telephone or through video visits. This study will test a 12-week intervention; in a larger RCT, we plan to continue the intervention for 12-months. Veterans aged 65 or older with Care Assessment Need (CAN) scores ≥ 75 will be contacted by phone and screened for CI using the TICS-m. Respondents with scores in the range of 20-29 (predictive of cognitive deficits in the mild range)²³ will be invited to participate in the study. Following informed consent and baseline data collection, participants will be randomized (1:1) to receive the intervention via *telephone* or through *video visits on iPads*. The program will consist of monthly telephone or video calls enabled by the Pexip Infinity application (version 12.2) on iPads, with the goal of providing structured information and support in two key areas: (1) care coordination (reduce workload) and (2) protecting cognitive health (build capacity). All subjects will participate in an outcome assessment call at week 14, consisting of survey items and a semi-structured interview. Study team will also conduct qualitative interviews with participants and their care partners after the 14 week assessment. These calls will be recorded and transcribed. At the beginning of each call, study staff will capture each patient's and care partner's assent to record the phone call. Study flow is illustrated in Figure 3. The study will enroll 40 dyads (Veteran participants and Care Partners).



D.2 Participant eligibility criteria.

D.2.a. Inclusion Criteria (Veteran). To be included in the study, patients must meet **all** of the following:

1. Receive primary care from a Durham VAMC affiliated primary care clinic (≥ 1 visit within the previous 12 months)
2. Age ≥ 65
3. CAN score ≥ 75
4. Participant must have a valid email address
5. Valid telephone number in the medical record
6. Identifies a friend or family member that we may contact for study participation as the Care Partner
7. TICS-m score 20-31

D.2.b. Rationale for targeting patients age ≥ 65 years with high CAN score. As a validated tool that has been successfully implemented throughout VHA nationally, CAN risk scores provide an ideal way to identify a medically complex population. The CAN score (v. 2.0) is derived using predictive analytics from 36 input variables captured from various Corporate Data Warehouse (CDW) domains.²⁴ CAN scores provide an estimated probability of hospital admission or death within a specific time frame (either 90 days or 1 year). The score is expressed as a percentile and is reflective of how a given patient compares with other VA patients in terms of probability of hospitalization or death. For this study, we will use the model calibrated for predicting hospitalization within 1 year, and focus on Veterans with CAN score of ≥ 75 . We target individuals 65 and older due to higher prevalence of CI in this population.

D.2.c. Cognitive Screening Procedures. The TICS-m (9-11 min administration time) is a 50-point global cognitive screening tool that has been well-validated for use in multiple populations and was specifically designed for use over the telephone (i.e. no visually mediated items). TICS-m scores in elderly populations have been shown to be normally distributed and without evidence of a ceiling effect which limits the ability of other instruments to detect early CI.²⁵ TICS-m has been used as a reference standard for telephone-based detection of cognitive impairment.^{26,23} Participants with score between 20 and 31 (education-adjusted) will be eligible for the study, because scores in this range have been shown to correlate with cognitive impairment in the mild range²³ and to differentiate normal from impaired individuals when adjustment for education level is included. The small number of patients who scored in the 30-31 range and did not initially meet criteria for eligibility in the first months of study enrollment (original TICS criteria range = 20-29) will be re-contacted by study staff and offered participation. The VHA "Screening for Cognitive Impairment" directive does not recommend screening for cognitive impairment in asymptomatic older adults. The directive also states clinicians should be alert to early signs or symptoms of cognitive impairment and evaluate as appropriate. Therefore, at each nurse encounter, participants will have a note entered into the electronic health record (CPRS) notifying the patient's primary care team of any relevant clinical issues. If symptoms of cognitive impairment are noted by either the nurse manager or care partner an alert notifying the team of the noted symptoms will also be included in the CPRS progress note.

D.2.d. Exclusion criteria (Veteran). Patients will be excluded if they meet **any** of the following:

1. CI or dementia (identified via ICD diagnosis codes or PCP note in previous 2 years)
2. Enrolled in or have an active consult for a special population PACT (e.g. GeriPACT, Home Based Primary Care, Mental Health, Post-Deployment, etc.)
3. Are enrolled in a study that prohibits participation in another study
4. Serious mental illness defined as diagnosis of psychosis of any type, schizophrenia, bipolar disorder, psychiatric hospitalization in the previous year or current high-risk suicide flag in their CPRS medical record
5. Are currently hospitalized or incapacitated for any reason
6. Active substance abuse, documented in the medical record within the previous year
7. Eligible for hospice, palliative care, or prognosis of less than 6 months to live
8. Lack decision-making capacity, documented in the medical record
9. Referred to institutional care or residing in nursing home
10. Unable to communicate on the telephone, or no telephone access for duration of study
11. Care Partner fails six-item screener or has no access to phone, and no other Care Partner available

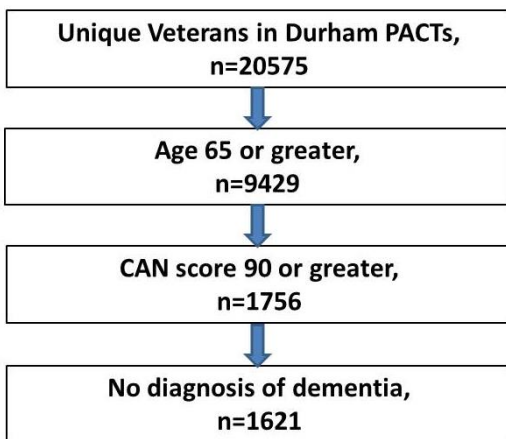
At the clinical discretion of the study physician (PI), subjects may be enrolled in the study with an exclusion criteria if the clinical criteria (#1, 4, 7) is determined not to affect eligibility (for example, a previous dementia diagnosis in a patient whose clinical record notes do not indicate evidence of dementia).

D.2.e. Care Partners. The Veteran participant will identify their Care Partner of choice. Care Partners must be aged 18 or older, able and willing to provide informed consent for study participation (must score 5 or higher on a brief and reliable 6-item cognitive screen),²⁶ and able to communicate by telephone. In order to serve as the Veteran's Care Partner, an individual must be willing to join the Veteran for telephone or video calls and participate in outcome assessment calls. We propose to enroll dyads for three key reasons. First, the study focuses on older Veterans with CI; the participation of a partner can help the Veterans to understand and implement care recommendations, as well as access the technology required for video visits. Second, in our pilot studies, many Veterans expressed to us that their usual and preferred manner of receiving health information is through a spouse or adult child.²¹ Third, this is consistent with the growing literature about the

important role of companions in medical care, and expert recommendations that care be better integrated with family and caregivers.^{16,27}

D.2.f. Recruitment Pool. The number of Veterans who would have been eligible for this study in March, 2015 based on age, CAN score ≥ 90 , and no pre-existing diagnosis of dementia is listed in Figure 4. In our pilot work, we examined the prevalence of other eligibility criteria and found that 1.3% did not have a valid telephone number, 1.7% were nursing home residents, and 1.9% were unable to talk on the telephone. Therefore, taking additional exclusions into account and anticipating 34-40% will score between 20 and 29 on the TICS-m, we project that 475-600 Veterans will meet all study eligibility criteria. It is anticipated that because the population of patients selected for this study will have at least a CAN score > 75 , they may seek additional medical care for events related to their diseases (and care may involve hospitalizations). They may also experience seasonal health issues such as flu or allergies. It is also anticipated that during study participation, they may seek medical assistance to recover from accidents or planned surgical procedures.

D.3. Enrollment Procedures. Using an automated data pull, study staff will first identify the patients who meet criteria for age and CAN score and apply exclusion criteria based on clinic stop and diagnosis codes available in CDW. Study staff will then conduct a brief medical record review to check for exclusions that are not readily available in CDW (e.g. residential status). During the medical record review study staff will determine if the patient has “decision-making capacity” by searching the medical record notes section using the key term “capacity”. The patient will be considered initially eligible if study staff finds that the patient has decision-making notated in the medical record. The patient will not be initially eligible if the term or similar term “lack of decision-making capacity” is found in the record. If term “capacity” is not found, study staff will assume decision-making capacity is intact. Of those eligible, we will mail introductory recruitment letters signed by the PI (see Sample Letter; Appendix). Patients will be provided a toll-free number to



contact if they do not wish to be contacted further. Starting about one week after mailing recruitment letters, a member of the study staff will call patients to ascertain eligibility and obtain informed consent from the Veteran participant and Care Partner. During the phone screen process, study staff may use their discretion with the input of the Care partners to further determine whether the patient’s decision-making capacity is intact. For the Care Partner, the Six Item Screener (SIS), a cognitive assessment instrument, will be administered by trained study staff prior to Care Partner consent. If there is any question as to whether or not a potential adult subject has decision-making capacity, study staff will consult with a qualified practitioner (i.e., the study physician or study RN) about the individual’s decision-making capacity before proceeding with the informed consent process. Because the screening and enrollment is entirely telephone based, we will seek a waiver of documentation of informed consent, as approved by the Durham VAMC IRB in our ongoing studies using similar recruitment methods.

Figure 4. Study Recruitment Pool

D.3.g. Rationale for Enrollment and Screening over the Telephone. We have opted not to enroll Veterans at a primary care visit or other in-person visit for a number of reasons. First a telephone-based strategy expands the reach of the intervention by allowing enrollment from multiple community-based outpatient care clinics and not just the main hospital clinic. Most importantly this strategy mimics more closely how this intervention would be implemented if effective. We will track number of attempts to contact, and examine differences between patients who enrolled or refused and those we were unable to contact to inform future implementation efforts.

D.3.h. Randomization Procedure. Once patients and Care Partners have provided verbal consent and completed the baseline measurement battery, study staff will randomize the Veteran to Telephone-Based Care Management (Section D.4) or Video-Enhanced Care Management (Section D.5). Randomization assignments will be performed by the study statistician and the entire study randomization will be done before patient enrollment begins. We will stratify randomization based on whether or not patients are ‘experienced with relevant technology’. Participants will be considered ‘experienced with relevant technology’ if they indicate use

of a tablet to regularly access the internet OR experience using videoconferencing/videochat platforms. This definition was based on review of prevalence data in an ongoing RCT.

D.4. Arm 1: Telephone-Based Care Management Intervention. The core components of the intervention (delivered to both arms) are listed in Table 2. Based on a strong conceptual framework,¹² the care management program features monthly calls to deliver information related to improving care coordination²⁸ (e.g. assistance with medication and appointment management) and protecting cognitive health¹³ (e.g. promoting physical activity and smoking cessation). Consistent with the literature on the most effective care coordination models, the study nurse will also accompany patients to one PCP visit (for those who have one scheduled during the study period), and provide additional calls and support after any ED visits or hospital admissions. For patients randomized to Arm 1: Telephone-Based Care Management Intervention all study contacts (excepting the PCP visit) will occur over the telephone.

Table 2. Summary of Core Components of Care Management Intervention and Related Evidence		
Care Coordination⁵		
Evidence-based Recommendation	Core Components of Care Management Program	Additional Strategies in Video-Enhanced Intervention
Supplementing telephone calls to patients with in-person meetings	N/A	Supplementing telephone calls to patients with video calls allows for eye contact, reading facial expressions, improved ability to assess patient comprehension of new information
Occasionally meeting in person with providers	Accompanying patient to a PCP visit	N/A
Acting as a communications hub for providers	Notes in CPRS to communicate with PACT team	N/A
Delivering evidence-based education to patients	Strong emphasis on physical activity promotion	Ability to demonstrate recommended exercises and environmental assessment for potential hazards
Medication management	Medication reconciliation and providing medication adherence aids	Direct observation of patient performing tasks such as filling pill box, using Metered Dose Inhalers, etc.
Providing transitional care after hospitalizations	Telephone and/or video call with patient, Care Partner, and PACT after hospitalizations or ED visits , available by telephone for “acute health events”	Visual assessment of health condition following acute events
Protecting Cognitive Health, from Institute of Medicine⁶		
Encourage physical activity.	Strong emphasis on physical activity promotion and referrals to exercise programs, c/w evidence-based benefits to physical and cognitive health	Assess physical abilities to tailor program referrals
Reduce and manage cardiovascular disease risk factors (including hypertension, diabetes, and smoking).	Individualized education for chronic disease management ; smoking cessation counseling and referral to programs to support cessation	Direct observation of patient or Care Partner checking BP, measuring blood glucose, administering insulin
Review medications that might influence cognitive health	Patient education about potentially risky medications; note in CPRS to provider when potentially inappropriate medications (PIMs, according to Beers’ criteria) are identified	Visual inspection of over the counter medications and those prescribed by outside providers as possible PIMs

D.4.a. Structure and timing of nurse contacts. Scheduled calls with the study nurse will begin 2 weeks after randomization (to reflect the time needed for the Pexip test call, Section D.5.a), and occur every 4 weeks thereafter. Beyond having a more sustained intervention period, we anticipate that more frequent contacts may be beneficial; however, in this feasibility pilot we will limit the intervention to a total of 4 scheduled calls. We will explore the potential benefits of more frequent calls in the qualitative interviews post-study completion (Section D.6.b). The Care Partner will be encouraged to participate in all calls. Also as noted in Table 2, the nurse will make additional telephone calls to patients as needed for acute events (e.g. ED visits), and will accompany the patient to a PCP visit, for those patients who have one scheduled during the intervention period.

D.4.b. Content and delivery of nurse calls. Following procedures in use in HI-FIVES, intervention content will include both core and tailored content, selected according to participants' individual needs.²² Core topics delivered to all participants will include medication management (medication reconciliation, adherence counseling and aids if needed, and physical activity promotion (education about recommended physical activity levels and walking, personal goal-setting and program referrals (e.g. Silver Sneakers, MOVE, Gerofit). In addition, the nurse will conduct a medication review and provide a report to PCPs when potentially inappropriate medications are identified. The medication review will utilize explicit criteria (Beer's) updated by the American Geriatrics Society in 2015 focusing on medications that worsen cognition.²⁹ We focus on medications and physical activity given the evidence of both physical and cognitive benefits of improving care in these domains. The study nurse will select the topic for the 3rd call, based on needs and preferences expressed by the participant and Care Partner Consistent with our conceptual framework (Section B.5) and guiding principles for the intervention content (Table 2), other potential topics include smoking cessation, blood pressure management, diabetes care, informal care support programs, sleep patterns, and falls prevention.

Following each telephone or video visit, the study nurse will enter a note in CPRS documenting the information reviewed and referrals made. All notes will be copied to the patients' PCP and PACT Nurse. Following procedures in use in DISPO ED, the study nurse will enter unsigned orders, if needed, for the PCP to review and accept (sign). Examples include orders for exercise program referrals. This approach has been used successfully with very high uptake of recommendations (93%) in a previous VA study.²⁹

The study nurse will use software already developed for previous Durham HSR&D Center of Innovation (COIN) studies including DISPO ED, to guide content delivery during calls, including scripts and questions for patients. This software adheres to current VA information security standards, and will be linked with a secure SQL Server database, following procedures developed by COIN IT staff and used successfully by numerous COIN investigators. Patients are offered printed and mailed information about the topics discussed if they desire, including how to reach the study nurse for additional questions or issues. Each call will end with open-ended questions, allowing Veterans to describe additional needs that were not addressed. In order to understand staff time needed for the full intervention, we will carefully track interventionist time spent on calls (including attempted and incomplete calls), reviewing medical records, and documenting and making referrals.

D.5. Arm 2: Video-Enhanced Care Management Intervention. Patients randomized to Arm 2: Video-Enhanced Care Management Intervention will receive the same number of contacts delivered on the same schedule and focused on the same key components as the telephone-based program. The primary difference in the video-enhanced intervention is that the nurse will communicate with the patient and Care Partner using video visits in secure Virtual Meeting Rooms, facilitated through the Pexip Infinity applications (version 12.2) on iPads. We will use tablets (instead of desktop or laptop computers) so that participants can move them around easily if needed to facilitate observation of the Veteran or some aspect of their home environment; iPad is a tablet approved for use with the Pexip Infinity application (version 12.2). Table 2 summarizes the supplemental strategies that may be used in the video-enhanced intervention. Any scheduled video visits not able to be completed due to a technology problem will be conducted over the telephone. The nature and type of any technology limitations will be closely tracked.

D.5.a. Installing software for video calls. Participants who have their own iPad will be able to utilize it for the study. Patients who do not have access to an iPad will be loaned one for use during the study. All participants will be provided with detailed instructions for installing the Pexip Infinity application (version 12.2) application or have the application pre-installed on their device) and will have access to IT support over the telephone or in-person at the Durham VA with a study staff member and the facility telehealth coordinator if needed.

Consistent with current clinical policy for video visits, study staff will collect participant emails addresses to send an encrypted email to facility telehealth team for scheduling purposes. Emails addresses will not be stored in VA research databases. Research staff will not directly send or receive any emails to patients. All patients will participate in a test call with facility telehealth staff before scheduling their first study nurse call. We allot 2 weeks from the time of enrollment for the Pexip installation and completion of a test call. If the patient cannot complete the Pexip Infinity application (version 12.2) installation within this 2-week time frame (for any reason), the intervention will continue using telephone calls only. All patients in the Video-Enhanced Care Management Program (Arm 2) will be provided with an iPad cover with built-in stand and keyboard to make logging into Pexip easier and quality of video interaction better.

D.5.b. Technology solution for video calls. We have selected the Pexip Infinity application (version 12.2) for the video calls for several key reasons: 1) this technology meets all VA security standards and is currently in use

for in-home video telehealth encounters throughout VHA (FaceTime, Skype, etc. are not approved for use by VA clinicians); 2) facility telehealth coordinators can provide ongoing IT support (see Telehealth Coordinator letter of support); and 3) use of a tablet (iPad) enables mobility of the device to expand the applications of the video link to viewing aspects of the users home environment.

D.6. Measures and Data Sources

D.6.a. System Usability Scale. We will use the simplified language version of the System Usability Scale (SUS; see Appendix) to measure usability of video visits via iPad. The SUS is a widely-used, simple but reliable method to evaluate the usability of new technologies.³⁰ The SUS is well-validated and consists of 10 Likert-scaled items with scores ranging from 0 to 100.³¹

D.6.b. Participant and study staff feedback. Patients and Care Partners will participate in semi-structured interviews regarding perceived benefits and challenges of the care management program. Interviewer scripts will include open-ended questions about barriers and facilitators of success in the program, including technology-related, and as well as more specific questions to elicit stakeholder perspectives on intervention content, and recommendations for improvement (see Evaluation Table; Appendix). We will also seek feedback from primary care providers and study staff.

D.6.c. Measures of intervention effectiveness. In preparation for a future RCT, we will collect outcome measures we anticipate using to test intervention effectiveness. Patient reported outcomes will be examined at baseline and the 14-week follow-up call (immediately following completion of the 12-week intervention period that begins at week 2; Figure 3). Consistent with our conceptual framework, the balance of workload demands and capacity directly affect utilization and outcomes; thus we plan to focus on hospitalizations, ED visits, and patient-reported outcomes recommended for use in patients with MCC,¹⁶ that may be responsive to the intervention.

Hospitalizations and ED visits. To calculate this outcome, we add the total number of days a patient is in the emergency department (ED), or hospital. In order to avoid double-counting events, we only count ED visits as a discrete day if the ED visit did not lead to hospital admission. We include observation stays as hospital days. Data from the outpatient and inpatient files from the CDW will be used to generate counts of days associated with emergency care (treat and release), observation stays, and inpatient care, over the 14 week observation period. ED visits will be identified through the outpatient files according to clinic stop codes (130, 131, 102130 and 102131).³² Inpatient encounters will include total days in the hospital (DISDAY minus ADMITDAY).

PROMIS-29. The Patient-Reported Outcomes Measurement System 29-item Health Profile (PROMIS-29) has good evidence of reliability and responsiveness, and is suitable for telephone administration. PROMIS has published its results in 20000+ adults, many with MCC, and has been recommended by the Working Group on Health Outcomes for Older Persons with Multiple Chronic Conditions, an expert panel convened by the National Institute of Aging in collaboration with Agency for Healthcare Research and Quality.¹⁶ The tool has also undergone extensive valuation work enabling translating PROMIS-29 responses into quality-adjusted life-years.³³

Physical Activity Scale for the Elderly (PASE). The PASE is a self-report, 12-item scale that measures occupational, household, and leisure activity during a one-week period.³⁴ This scale was developed for use among older adults and has been validated for use via telephone.

Medical Outcomes Study: Short Form Social Support Survey Instrument. This 8-item measure reflects how often a person looks to others for companionship, assistance, or other types of support, and is well-validated.³⁵

Depression and anxiety. It is important to note that eligibility for the current study depends on the results of a cognitive screener administered on one occasion and this does not constitute a formal diagnosis of any cognitive disorder. Nevertheless, we expect that some participants will be referred for further testing and may receive a diagnosis in a clinical setting. There have been no studies reporting harm related to receiving a diagnosis of CI; however, some groups have raised concerns about this possibility. Thus we will measure symptoms of depression (Patient Health Questionnaire [PHQ]-9) and anxiety (General Anxiety Scale [GAD]-7) at baseline and the 14 week follow-up call. The PHQ-9 is a nine item depression scale that is well validated and documented in a variety of populations including a geriatric populations and primary care settings.³⁶ The GAD-7 is a 7-item anxiety scale with good reliability, as well as criterion, construct, factorial, and procedural validity.³⁷ We will utilize a safety protocol to address suicide risk identified during the administration of study measures (Appendix).

Other Measures. We will collect information on patient socio-demographics, chronic medical conditions, self-rated health, health literacy, and sleep questions. We will review patient medical records to determine actions taken by the PCP as a result of the TICS-m score progress note (e.g. Geriatrics, Neurology referrals, Neuropsychology testing, scheduling a follow-up visit, etc.) and new diagnoses of CI or dementia.

D.7. Analyses

D.7.a. Aim 1: Examine the *feasibility* and *acceptability* of a 12-week care management program for medically complex Veterans with CI, delivered via telephone or through video visits. Feasibility will be examined by calculating overall rates of eligibility and enrollment, as well as rates of attrition, adherence to nurse calls or video visits, and interview completion. Clinical and personal characteristics associated with enrollment and study completion will be explored as well via contingency tables and regression analyses. Acceptability will be assessed using in-depth interviews with study participants (Veterans and Care Partners), primary care providers, and study staff (Section D.6.b.). We will conduct a formative evaluation of the intervention in order to elicit information about ways to enhance acceptability and effectiveness of the intervention in anticipation of testing it in a larger study.³⁸ Collecting qualitative data from relevant stakeholders including study participants, PCPs and study staff, will provide additional rich context for interpreting other quantitative study results.³⁹ Tasks and methods for each evaluation stage are described in the Appendix.

D.7.b. Aim 2: Assess the *usability* and *perceived value* of video-enhanced care management, compared to telephone-based, among older Veterans with medical complexity and CI. We will administer the SUS at the 14-week outcome call to participants randomized to Arm 2 (video-enhanced.), care partners, and clinical staff. If any participants choose to withdraw from this Arm, we will administer this measure prior to withdrawal. We will examine overall sample mean, median, and distributions of scores according to established thresholds (e.g. >70 = excellent usability among those aged ≥65 years). Additionally, we will look at responses to individual items to see if certain items are more frequently endorsed (e.g. technical support item) to make refinements prior to a larger RCT. We will calculate means (or medians, as appropriate) and distributions of hospitalizations, ED visits, and patient-reported outcomes (PROMIS 29, PASE, MOS Social Support, PHQ-9, GAD-7) across time points, as well as changes between baseline and 14-week follow-up, as appropriate. Because of the small sample size, we will not conduct statistical testing. However, our descriptive analyses will allow us to evaluate whether there are clinically relevant differences in mean study outcomes between the two Arms (video-enhanced vs. telephone-based). Perceived value associated with each delivery method will be explored through questionnaires and in-depth interviews with study participants and study staff.

D.7.c. Sample size considerations. This is an exploratory pilot study that is not intended to test efficacy. While the sample size chosen must reflect the pragmatics of recruitment during a short enrollment period, we will have adequate sample size to provide meaningful confidence intervals for our estimates of feasibility, and comparisons between video and telephone delivery methods, and will have sufficient diversity of input on the intervention to plan refinements, if needed, prior to testing it in a larger RCT.

D.8. Dissemination and Implementation Plan

The results of this pilot study will provide essential information about the feasibility, acceptability, usability, and perceived value of a care management program for medically complex Veterans with CI, delivered via telephone or through video visits on iPads. By using these preliminary data to refine study methods and optimize the intervention protocol prior to conducting a large RCT, we will enhance the efficiency and overall value of the subsequent trial. Specifically this pilot study addresses the important question of whether providing care management via video visits is feasible in this population, and if so, whether it offers added benefits, compared to telephone. To examine video visits, we will use the Pexip Infinity application which is currently approved and in preliminary clinical use in VHA, making rapid implementation highly feasible, if proven effective.

D.9. Project Management Plan

D.9.a. Summary of Research Team Experience. The research team is comprised of investigators from the HSR&D COIN for Health Services Research in Primary Care; the Geriatrics, Research, Education and Clinical Center (GRECC) at the Durham VA, the Duke University Center for the Study of Human Aging and Development and Alzheimer's Disease Research Center. We have assembled a multidisciplinary study team with a track record of productive collaboration, as well as relevant experience with all the methodology, data sources and analytic techniques described in the current proposal.

D.9.b. Timeline. We propose a **1 year study**. As illustrated below, we expect to begin enrollment in month 4 and complete data collection by month 10. The remainder of the study period will be dedicated to analysis of the data, dissemination of study results, and preparation of an IIR to test the intervention in an RCT.

	Month											
	1	2	3	4	5	6	7	8	9	10	11	12
Project Start Up												
Finalize IRB	X	X										
Develop study database and procedures	X	X	X	X								
Intervention Implementation												
Enroll patients				X	X	X	X					
Intervention and outcome assessments					X	X	X	X	X	X		
Data Analysis												
Planning for data analysis									X	X	X	X
Data analysis and reporting/ Prepare IIR											X	X

D.10. Data Management

The Durham HSR&D CoE adheres to VA policy and Durham VAMC IRB requirements, but has also developed additional Standard Operating Procedures for data security which have been designed to ensure continued confidentiality, integrity, and availability of research data. These procedures, which protect both paper and computer based records, have been used successfully in many studies, and will be followed for the proposed study.

With respect to all data, these procedures mandate the following to ensure confidentiality and safe handling of all data: (1) Access to all participant data and information will be restricted to authorized personnel; (2) Participants will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred; (3) Each participant will be assigned an anonymous study ID which will be used on all study forms; and (4) All study personnel will maintain certification with the Durham VAMC IRB that they have completed training in research ethics and confidentiality.

With respect to paper based records, these procedures mandate the following: (1) All study records that contain participant information will be kept in secured locked areas when not in use; and (2) In addition, such materials, when in use, will be kept safe from public scrutiny. With respect to computer based records, the following practices are followed: (1) All research data are stored on VA-administered servers which are physically secured in a Durham VAMC server room; (2) Individual computer accounts, password protected, are issued to staff members; and (3) Access to computer data is granted by OI&T personnel after confirming appropriate documentation through the IRB, per CoE policies. Utilization data will be downloaded directly from national files to the Durham HSR&D CoE servers. Of study personnel, only the study Statisticians and Economist will have access to these data, which will not be moved from this secured environment.

The key linking the study ID numbers to the patients identifying information will be stored in a password protected electronic database and maintained on a password protected VA server, with access only available to approved study staff and investigators. The name and phone number of family members identified by the subject will also be recorded here.

D.10. a. Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:

The Personal Health Information that will be used or shared for this study includes:

Identifier(s)	Source(s) of Health Information
<input checked="" type="checkbox"/> Names	<input checked="" type="checkbox"/> Medical history & physical exam information
<input type="checkbox"/> All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code	<input checked="" type="checkbox"/> Photographs, videotapes, audiotapes, or digital or other images
<input checked="" type="checkbox"/> All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89	<input type="checkbox"/> Biologic specimens (e.g., blood, tissue, urine, saliva)
<input checked="" type="checkbox"/> Telephone numbers	<input checked="" type="checkbox"/> Progress notes
<input type="checkbox"/> Fax numbers	<input checked="" type="checkbox"/> Diagnostic / Laboratory test results
<input type="checkbox"/> Electronic mail addresses	<input checked="" type="checkbox"/> Operative reports
<input checked="" type="checkbox"/> Social Security Numbers	<input checked="" type="checkbox"/> Imaging (x-ray, CT, MRI, etc.)
<input checked="" type="checkbox"/> Medical record numbers	<input checked="" type="checkbox"/> Discharge summaries
<input type="checkbox"/> Health plan beneficiary numbers	<input checked="" type="checkbox"/> Survey / Questionnaire responses
<input type="checkbox"/> Account numbers	<input checked="" type="checkbox"/> Billing records
<input type="checkbox"/> Certificate and/or license numbers	<input checked="" type="checkbox"/> HIV testing or infection records
<input type="checkbox"/> Vehicle identifiers and serial numbers, including license plate numbers	<input checked="" type="checkbox"/> Sickle cell anemia information
<input checked="" type="checkbox"/> Device identifiers and serial numbers	<input checked="" type="checkbox"/> Alcoholism or alcohol use information
<input type="checkbox"/> Web Universal Resource Locators (URLs)	<input checked="" type="checkbox"/> Drug abuse information
<input type="checkbox"/> Internet Protocol (IP) address numbers	<input checked="" type="checkbox"/> Mental health (not psychotherapy) notes
<input type="checkbox"/> Biometric identifiers, including finger & voice prints	<input checked="" type="checkbox"/> Psychological test results
<input type="checkbox"/> Full-face photographic images and any comparable images	<input type="checkbox"/> Genetic testing
<input checked="" type="checkbox"/> Any other unique identifying number, characteristic, or code, describe: Study ID Numbers	<input type="checkbox"/> Other, describe:

All non-Veterans enrolled in this study will receive the VA Notice of Privacy Practices (NOPP) and are requested to sign the acknowledgment form. The signed acknowledgment form will be maintained with the research records.

1. Data and/or Specimen Acquisition:

Data for this study will be collected through:

- Prospective data and/or specimen collection obtained from participants. Please see section D.3 – D.6. for a description of the data collection process.
- Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.): Please see section D.3 – D.6. for a description of CDW data and medical chart review used to screen for eligibility, Utilization data will be downloaded directly from national files to the Durham HSR&D CoE servers..

Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number:

2. Level of Data:

The following level(s) of data will be acquired/maintained for this study (*check all that apply*):

- Identified (e.g., names, addresses or other identifiers included)
 Coded (direct and/or all identifiers removed, but study code/ID included)
 De-Identified (all HIPAA 18 and study ID/code removed):
 Verified Statistically
OR
 Verified by Absence or Removal of HIPAA 18 and study ID
 Limited Data Set
 Other: Describe:

3. Location of Data and/or Specimens, and Data Retention Plan:

A. Data and/or Specimen Location: VHADURSQLH5.v06.med.va.gov (SQL database server) and \\vhadurhsrdfile1.v06.med.va.gov\\$\projects\SECSI(shared document folder)

Data will be also be placed at the VA Informatics and Computing Interface (VINCI; <http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx>).

B. Data Retention Plan

Current VA regulations regarding research records retention does not allow for the discarding of records. After the close of the protocol if VA records and retention regulations allow for the destruction of paper research records, files will be shredded in accordance with VA records control requirements and information in electronic format will be deleted or purged from data files in accordance with VA records control requirements.

Other data retention plan, describe:

4. Data Access and Data Recipients:

Only VA research study personnel will have access to identifiers and coded data, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. This will only be done behind VA firewalls. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one's password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins). Access to study data will be removed for all study personnel when they are no longer part of the research team.

5. Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:

Data will not be transported or transmitted outside of the VA.

- I. Data and/or specimens will not be transported or transmitted outside of Durham VAMC environment.
- II. Data and/or specimens will be transmitted to other VA sites using the following method(s):

A. Data

- Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted disk (encryption is optional).
- Data are coded or contain identifiers and thus will be sent <chosed method of transfer such as: PKI or RMS encrypted e-mail, FIPS 140-2 encrypted disk (with VA-authorized carrier and tracking), or FIPS 140-2 encrypted external drive (with VA-authorized carrier and tracking). You may identify a primary and secondary method>.
- Other, describe:

B. Specimens

- Specimens are de-identified and thus will be sent via standard carrier (tracking is optional).
- Specimens are coded or contain identifiers and thus will be sent via VA-authorized carrier with tracking.
- Other, describe:

III. Data and/or specimens will be transported to non-VA/VHA sites (e.g., academic affiliates, laboratories, etc.) using the following method(s):

A. Data

- Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted CD.
- Data are coded or contain identifiers and thus will be sent via <chosed method of transfer such as FIPS 140-2 encrypted CD or FIPS 140-2 encrypted hard drive/flash drive> using VA—approved carrier with tracking.
- Data are coded or identified and will be uploaded to sponsor website using electronic case report form (eCRF)
- Other, describe:

B. Specimens

- Specimens are de-identified and thus will be sent via standard carrier (tracking is optional) or will be hand-delivered by research study personnel. Specify method of delivery:
- Specimens are coded and thus will be sent via VA-approved carrier with tracking or will be hand-delivered by research study personnel. Specify method of delivery:

In accordance with the HIPAA and the Privacy Act, for any coded or identifiable data or specimens released from the Durham VAMC (with the exception of Limited Data Sets), an Accounting of Disclosure (AOD) will be maintained (e.g., in a database or spreadsheet) that includes the participant’s name, date of the disclosure, description of the nature of the Individually Identifiable Information (III) disclosed, purpose of each disclosure, and the name and address of the person/agency to whom the disclosure was made.

6. Risk Mitigation Strategies:

- Data are fully de-identified (stripped of HIPAA 18 and study ID/code) before being shared outside of Durham VAMC.
- Specimens are fully de-identified (stripped of HIPAA 18 and study ID/code before being shared outside of Durham VAMC.
- Direct identifiers will be maintained separately from data and or specimens by using a code to “identify” subjects. In a separate database (i.e., a “linking” or “cross-walk” database) this code will be linked to identifying subject information.

The patients’ right of privacy and the confidentiality of the protected health information will be guarded through strict controls and safeguards for access of the data to members of the research team. All study data will be stored on VA servers maintained by OI&T staff to comply with VA information security requirements. This includes study tracking and Datstat Ilume survey databases on server VHADURSQLH5.v06.med.va.gov, and project shared document folder \\vhadurhsrdfile1.v06.med.va.gov\projects\SECSI (usually mapped on users’ systems as P:\SECSI). Access to database and file systems is granted to research personnel via membership in Active Directory security groups created by OI&T; limited to individuals on the IRB staff listing. Members are removed from the security group when they no longer require access to study data. Data will not be stored on desktop or laptop computer hard-drives. Only VA approved staff will have access to the data file for data analysis. The PI will have ultimate responsibility of access to the data. Furthermore, data will be kept in accordance with VA records control schedule.

- Other, specify:

7. Suspected Loss of VA Information:

Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

8. Reporting of Results:

- Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published.
- Other results reporting plan, describe:

Data Analysis and Statistical Considerations

Due to the small sample size, statistical analysis will not be performed on the sample.

References

Provide references, if applicable.

N/a