**Optimizing Function and Independence Through iHI-FIVES – Protocol**

**NCT03474380**

**IRB Approval Date: July 6, 2023**

***DVAHCS REQUIRED ELEMENTS AND PROTOCOL TEMPLATE***

**PROTOCOL TITLE:** Optimizing Function and Independence QUERI

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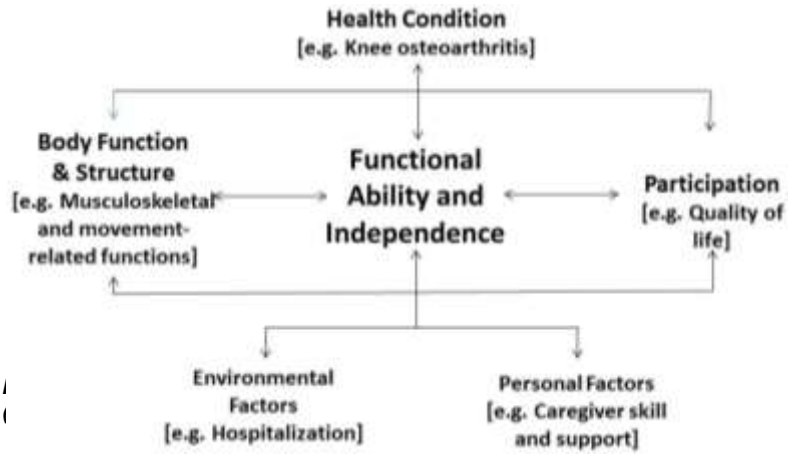
**VERSION NUMBER AND DATE:** AMD 23 5.17.2023

**SPONSOR/FUNDING SOURCE:** VA QUERI

## BACKGROUND

**Clinical Framework and Introduction of Individual Projects**

Function QUERI will support implementation of 2 new clinical programs. These were selected on the basis of alignment with national VA strategic goals, those of our operational and clinical partners, and potential impact for Veterans. The underlying clinical framework for our projects is the **International Classification of Functioning, Disability and Health** (ICF, Figure 1), a biopsychosocial model of disability that conceptualizes a person's level of functioning as a multidimensional and dynamic interaction between her or his health conditions, environmental factors, and personal factors. An individual's functional status is dynamic, with stressors such as hospitalization or development of a symptomatic chronic illness being important tipping points into disability.[1] Each clinical program directly addresses known stressors and/or contextual factors that influence functional ability and independence. STRIDE is a supervised walking program for hospitalized older Veterans. STRIDE focuses on maintaining musculoskeletal strength and mobility (body function and structure) during hospitalization (environmental factors), a highly vulnerable time for development of disability.[2] HI- FIVES, is a multimodal, evidence-based skills training program for caregivers of Veterans with cognitive and/or functional limitations who have recently been referred to home and community-based services. HI-FIVES promotes function and independence through caregiver skill training and support (personal factors). The ICF also provides guidance for selecting relevant Veteran-centered outcomes (e.g. quality of life, days in the community) and important patient-level covariates. Details of the three clinical programs are provided in separate sections below, following our description of the implementation core.




**Implementation Framework and Strategies**

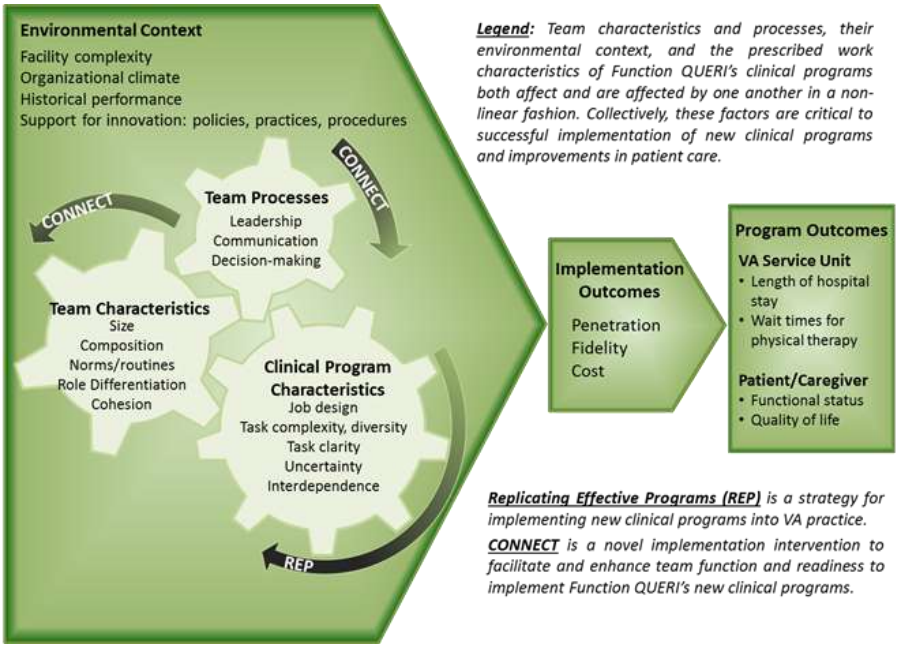



***Figure 2. Nested model of team function and performance in implementation***

**Implementation Strategies.** Guided by our implementation framework (Figure 2), preliminary evaluation of barriers to implementation for each project and input from clinical and operational partners, we have selected Replicating Effective Programs (REP) as the overarching implementation strategy for incorporating new clinical programs into routine practice. Half of participating sites will receive REP paired with CONNECT, a teamwork training intervention that focuses on optimizing team readiness and function.

Replicating Effective Programs. REP has been described both as an implementation framework[12] and strategy.[13] Herein we refer to REP as an implementation strategy because we will use it as an integrated bundle or package of discrete, standardized activities selected to address identified barriers to implementation success.[14] REP is appropriate for Function QUERI projects for three reasons. First and most importantly, REP addresses the major barrier to adoption of new clinical programs for Veterans at risk for functional decline identified by our partners in GEC: limited clinical resources. REP is designed to promote flexibility in the delivery of clinical programs, and Function QUERI will use this to provide options for program designs that can be implemented using existing clinical resources. Second, REP has been empirically tested and validated through randomized controlled trials and shown to be effective in promoting uptake and fidelity of clinical interventions in various healthcare organizations, including VA.[12,13,15,16] Third, REP is pragmatic in its emphasis on creation of user-friendly clinical program implementation packages that can be used for large scale roll-outs with relatively low need for additional implementation resources (distinct from clinical resources), an important consideration for any large organization such as VHA.

*REP Implementation Activities*. REP is designed for roll-out of new programs through four phases: pre-condition, pre-implementation, implementation, and maintenance. Across these phases, REP is delivered through a combination of standardized activities as displayed in Figure 3. Each Function QUERI project has initiated the REP pre-condition phase, by identifying needs and gaps in clinical care resulting in loss of function and independence and the clinical programs that will be used to fill these gaps. Pre-implementation phase activities that project teams have already begun include identifying barriers to implementation and clinical program delivery. Implementation phase activities will include drafting clinical program implementation packages, with input from stakeholder groups. Packages include standardized program materials for clinical staff to implement the program (e.g. training manuals, procedures, competencies, etc.) and guidance on core elements of the program and options for customization. Following clinical training, project teams provide technical assistance and support. The final step in REP is refining clinical program implementation packages in preparation for dissemination at additional sites (Section *2.6*).

REP has many advantages as an implementation strategy; there are limitations to its use as well. An often noted barrier to adoption of new clinical programs is a focus on the clinical program content while ignoring the organizational learning context and processes needed to successfully implement change[17] and REP offers no activities specifically designed to prepare clinical teams for program uptake. Function QUERI addresses this challenge and potential limitation of REP by proposing to pair REP with CONNECT to facilitate the readiness of teams to adopt new clinical programs.[17,18]

CONNECT is a bundle of interaction-oriented activities designed to supplement implementation efforts by promoting team function and readiness for change, as a critical precondition of effective implementation of Function QUERI's clinical programs. CONNECT has been used successfully in other clinical settings[17-19] and is associated with improvements in communication and participation in decision-making among clinical staff and in

patient outcomes.[18] CONNECT activities include group storytelling, role play to improve daily interactions between providers, relationship mapping of communication patterns, strategies for creative problem solving, and individual mentorship to sustain new interaction behaviors.

**Function QUERI Clinical Program 1: Optimizing Function and Independence through STRIDE**

More than one-third of adults over the age of 70 are discharged from the hospital with a major new disability that was not present before the onset of acute illness.[2] At least half of the time the associated illness is not a disabling condition like hip fracture or stroke, but rather a medical condition such as pneumonia or heart failure. Moreover, one year following discharge, more than half of older adults with hospital-associated disability do not recover to their pre-illness functional status, resulting in higher rates of nursing home placement and death.[20] A key contributor to hospital-associated disability is immobility during hospitalization.[21] While fewer than 5% of patients have physician orders for bed rest, hospitalized older adults spend only 3% of their time standing or walking.[22] The hazards of immobility in the hospital have been recognized for more than 2 decades,[23] but there are currently no VA-system wide approaches to address this important gap in clinical care.

STRIDE is a supervised inpatient walking program developed by an interdisciplinary team of investigators, clinicians and administrators at the Durham VA and funded by the VHA Office of GEC. STRIDE consists of a one-time gait and balance assessment conducted by a physical therapist, followed by daily supervised walks by a recreation therapy assistant for the duration of the hospital stay. Program evaluation has demonstrated high satisfaction among Veteran participants and reduced need for post-acute institutional care.[24] As a result, the Durham VAMC funded STRIDE as a permanent program that currently serves over 650 Veterans annually, and the VHA Office of GEC funded a dissemination grant to launch the program at another medical center. The STRIDE program has generated inquiries from many VA and non-VA healthcare systems interested in improving mobility among hospitalized patients; however an important challenge and consideration for provider organizations is the optimal method to disseminate and spread this promising clinical model into practice more widely and in a sustained way. Our initial experience with STRIDE implementation suggests inter-professional relationships and team dynamics are key determinants to the success of a new hospital-based clinical program that requires collaborative processes involving multiple disciplines.

**Rationale**

Hospitalization is a highly vulnerable time for loss of function and independence**.** An insidious and common complication associated with hospitalization for older adults is loss of independence due to inability to perform self-care functions.[25] This loss of independence often has serious implications, including increased risk of long-term care in a nursing home, repeat hospitalization, and death.[1,2,26] Loss of independence often begins with weakness and deconditioning that accompany onset of the illness itself, which then leads to disability that fails to improve or worsens during hospitalization.[20] Even in healthy older adults, bedrest leads to significant loss of muscle mass (1 kg) and strength (16% decline at knee extensors) within 7-10 days.[27]

Functional decline and loss of independence can be mitigated by inpatient walking programs. Increased time spent walking during hospitalization has been associated with reduced length of hospitalization, less need for institutional post-acute care, improved physical functioning at 30 days post-discharge, and reduced 2-year mortality.[28,29] In a group-randomized randomized controlled trial (RCT) conducted in 3 non-VA hospitals, a supervised walking program was found to reduce hospital length of stay (mean 5.8 days for program participants vs. 6.9 days for usual care; $p< 0.05$).[30] A systematic review of early physical rehabilitation programs for hospitalized older adults concluded they were safe and participants demonstrated improvements in physical functional status and reduced likelihood of discharge to a nursing home.[31]

Clinical demonstration of STRIDE at Durham VA. STRIDE is a supervised walking program for older Veterans admitted to the hospital with medical illness, modeled on the aforementioned RCT.[30] Daily supervised walking is the core element of the program. Patients are eligible for STRIDE if they are age 60 or older and admitted to the General Medicine Service of the Durham VAMC. Veterans with admitting conditions that limit their ability to ambulate safely (e.g. new neurological deficit, unable to follow one-step commands) are excluded. Patients are referred to STRIDE by their treating physician. Next they are evaluated by a physical therapist who assesses their safety for walking and provides an assistive device (e.g. walker) if needed. After the physical therapist evaluation, patients begin daily supervised walks that continue for the duration of the hospital stay (goal 20 minutes divided into 2 sessions).[30] Daily walks are supervised by a recreation therapy assistant that works with

each patient's nurse to determine the best timing for the walk and follows established protocols for offering rest breaks as needed and monitoring vital signs.

A significant proportion of STRIDE patients had functional deficits at baseline; 50% used an assistive device for walking, and 45% reported at least 1 fall in the past 3 months. STRIDE walks lasted 10 minutes on average, and 90% of patients reported feeling better after their walk. Overall 92% of STRIDE participants were discharged to home compared to 74% from a clinically similar group of patients receiving usual care ($p$=0.007); the remainder went to skilled nursing or rehabilitation facilities.[24] Based on the cumulative evidence, and positive staff and Veteran feedback on the program, Durham VAMC made STRIDE a permanent clinical service.

Dissemination of STRIDE is a high priority for VHA program offices and clinical and executive leadership. Two of Function QUERI's national program office partners, VHA Office of GEC and Office of PM&R Services, share common goals that are directly addressed by this project: increasing independence and improving quality of life for Veterans, and promoting the Veteran's ability to remain in the most independent and least restrictive living environment. Both offices strongly support STRIDE dissemination as directly responsive to these shared goals and strategic objectives.

Barriers to STRIDE implementation that our implementation strategies will address**.** In preparation for the current study, we evaluated barriers to STRIDE implementation in Durham and the Baltimore VAMC, which developed a GEC-funded STRIDE program in FY15. Key challenges identified by clinicians and program leaders included: 1) differing availability of staff resources and 2) lack of communication and teamwork among front-line providers of multiple disciplines (e.g. physicians, nurses, physical therapists) around the issue of patient mobility. In Durham, clinical leaders assigned recreation therapy assistants to supervise walks; however limited resources in Baltimore compelled their programs' use of nurse aids to supervise walks. Providers at both sites reported a lack of understanding of the roles of individual providers (i.e. whose job it is to walk patients) was an impediment to promoting patient mobility. Moreover, poor communication produced a "silo effect" that prevented sharing relevant clinical information to other providers and, in extreme cases, resulted in conflicting instruction to patients about mobility. These experiences were a key factor in selecting REP as an implementation strategy, given its focus on tailoring clinical programs for local environments, and our interest in augmenting REP with CONNECT to improve team-based interaction strategies to promote optimal program effectiveness.

**Clinical Program Procedures**

STRIDE implementation will occur in two stratified blocks (4 VAMCs per block) with two waves per block (2 VAMCs per wave), with each wave corresponding to a different 3 month implementation period for the intervention rollout (Figure 4). The timeline for STRIDE will be approximately 18 months in which pre-implementation (control) and post-implementation (treatment) data will be collected. In this stratified design, each cluster (VAMC) provides some before (control) and after (intervention) observations, and every cluster (VAMC) switches from control to be exposed based on their randomly assigned implementation start date within their stratified block (step) during recruitment months of the study. Further, transition to intervention condition will occur at approximately 3-month intervals. The pre-implementation period will occur from time 0 (stratified block 1) or time 6 (stratified block 2) to the beginning of implementation at each VAMC.

| | | Recruitment months | | | | | |
|---|---|---|---|---|---|---|---|
| Stratified Block | Wave | 1-3 | 4-6 | 7-10 | 11-12 | 13-15 | 16-18 |
| 1 | 1 | | 1st | | | | |
| 1 | 2 | | | 2nd | | | |
| 2 | 1 | | | | 3rd | | |
| 2 | 2 | | | | | 4th | |
| | pre-implementation implementation post-implementation administrative data collection only | | | | | | |

***Figure 4: Stepped wedge design for the 8 participating STRIDE VAMCs (4 per stratified block, 2 per wave), with a 3-month period to implement training for each site***

Randomization procedure. For each stratified block, we will have two randomizations due to the stepped-wedge design and comparison of two implementation strategies. First, in each stratified block, the 4 VAMCs will be randomized to either wave 1 or wave 2, then within wave each VAMC will be randomized to either REP alone or REP + CONNECT. Within each block and wave combination, one VAMC will use REP alone and the other will use REP + CONNECT for STRIDE implementation. In each stratified block, the four VAMCs will be in the pre-implementation period during the first 3-month recruitment window. There will be a 3-month interval implementation period in each block where the intervention is rolled out.

STRIDE Participating sites. We will recruit sites in blocks of 4 based on our stratified design described above for a total of eight sites for participation. With assistance from our operational partners (Dr. Kenneth Shay from GEC and Dr. Joel Scholten from PM&R), we will recruit the sites on a volunteer basis to complete the cohort of eight. To ensure that sites are similar enough to compare between arms, sites are required to have a minimum average daily census of 20 general medicine patients per day. We will conduct site visits at all participating sites prior to implementation to obtain additional important contextual information and baseline data for analyses.
Implementation activities. *REP*. Drafting the STRIDE intervention package will include identifying core elements of the program and those that can be modified to fit local conditions. The core program element is daily supervised walking; this will be critical for evaluating implementation fidelity to the program. The intervention package will provide options for sites to determine the type of provider who provides the supervision, using input from the team and other stakeholders. Based on our experience to date, we anticipate that these options will include the following models: dedicated rehabilitation assistants (physical therapy or recreation therapy) or nurse aids to supervise walks; nurses are trained on use of gait aids and dedicated equipment is made available on each floor; volunteers complete competencies for gait training, with supervision from other clinical staff.
*CONNECT*. For sites randomized to REP + CONNECT, CONNECT training will occur prior to orientation and clinical training for STRIDE. All staff with a relevant role in promoting (or hindering) mobility in the hospital setting will participate in CONNECT training. This will include nurses, physical therapists, therapy assistants, nursing aids and physicians. These will be the same at all sites, regardless of how sites choose to tailor the program (i.e. who supervised walks). We anticipate that the CONNECT activities that will be most relevant to STRIDE include learning protocols that bring together interdisciplinary groups to discuss and role-play local interaction strategies and problem-solving. In this way, all team members are empowered to recognize and share barriers to optimal program delivery and work together to find solutions.

All activities related to implementation of STRIDE as described above are non-research operations activities, as defined in VHA Handbook 1058.05. These programs are designed to support VHA's mission of delivering health care to the Nation's Veterans.

**Please see letter from Richard M. Allman, MD, Chief Consultant, Geriatrics and Extended Care Service (10P4G) providing certification of non-research operations activities status (Appendix A).**

Upon further evaluation, it was determined that Function QUERI, STRIDE, and CONNECT were not designed with an explicit focus on racial health equity. In order to address this, a QUERI Advance Diversity in Implementation Leadership (ADIL) project will quantify disparities in hospitalization outcomes and access to care among older adult Veterans in the STRIDE program trial and to integrate a health equity focus into the Function QUERI. Increasingly, evidence demonstrates racial and ethnic disparities in discharge and function post-hospitalization. It is unclear to what extent these disparities are due to unequal access to care or due to cumulative effects of structural racism and other social determinants of health. There is a critical need to understand systemic inequities in access to and benefits from programs that improve hospitalization outcomes and to design equity-driven implementation strategies for programs that could mitigate disparities.

## Function QUERI Project 2: Maximizing Veteran Independence through Informal Caregiver Support (iHI FIVES)

Over 5 million Veterans receive informal care in their homes from family and friends. Whereas caregivers (CGs) allow Veterans to avoid or delay nursing home entry,[35] caregiving comes at a cost to CGs through high rates of depression, and potentially to Veterans if CG depression/burden prevents Veterans from receiving high quality informal care. CG training programs can enhance CG skill and reduce negative consequences of caregiving and thereby increase quality of care and optimize patient independence.[36-41] However, CGs who care for Veterans report unmet need for training.[42]

Implementing helping Invested Family Members Improve Veterans Experiences Study (iHI-FIVES) is a clinical program that has been adapted from the HI-FIVES randomized controlled trial to be delivered in the field by existing clinical teams. iHI-FIVES will deliver an evidence-based skills training program to CGs of Veterans who have recently been referred to Veteran-directed care or home and community-based services (home-based primary care, homemaker home health aide services, adult day health care, respite care). Topics address tools for

increasing Veteran function and independence, CG injury prevention and self-care, communication with providers, and navigating the VHA. iHI- FIVES aims to improve support to CGs and patients through reductions in CG burden and depressive symptoms, increases in caregiver satisfaction with VHA health care the patient receives, and increases in the number of days that functionally and/or cognitively impaired Veterans spend safely at home.

The VA Caregiver Support Program (CSP) considers iHI-FIVES to be a clinical program that has strong potential to fill a critical gap in VA CG training. To adapt iHI-FIVES for successful implementation, our partners and our team will directly address known capacity constraints to deliver iHI-FIVES. Specifically, our implementation strategy will adapt iHI-FIVES for ease of delivery using stakeholder input (REP), and half of the sites will also form and train cross-service teams and promote inter-service and inter-professional relationships (CONNECT). In close partnership with the VA CSP Office, we will implement iHI-FIVES in eight VAMCs to compare the effectiveness of implementation using REP alone versus REP + CONNECT and to examine the impact of iHI-FIVES on key patient and caregiver outcomes.

**Rationale**. Although VHA has the most extensive system of home and community-based services of any health care system in the U.S., the majority of patients who need help in the home receive it exclusively from family members or friends. These CGs often lack the training and support needed to provide high quality care to Veterans. Despite significant expansion in front-line staff to meet the growing demand for CG services, with 224 Caregiver Support Coordinators (CSCs) now working at 122 VAMCs nationally, critical gaps in CG training remain.[42,43]

Prior CG support programs have overwhelmingly focused on psycho-educational support for CGs of dementia patients. By contrast, the iHI-FIVES curriculum addresses caregiver skills needed to care for a heterogeneous patient population, and thus addresses the needs of a broader population of CGs in VHA. Importantly, the timing of iHI-FIVES - after referral to home and community-based services - represents a 'crisis point' in a patient's ability to remain independent. Thus, iHI-FIVES is designed for key tipping points into disability (Figure 1): 1) to promote patients' functional recovery through CG training; and 2) to optimize patient functioning and independence at specific time points when patients face longer episodes of disablement and are less likely to recover.

Our implementation strategies address barriers to expanding CG training and support. Our overarching implementation strategy REP is expected to address key factors leading to gaps in CG training: (1) low levels of awareness of the CSP and its mission among PACT and specialty providers: we will educate PACT and other providers about the CSP. (2) CG support is often fragmented or duplicative because many services offer ad hoc training: we will train CSCs and their partner trainers to reach across services to help deliver iHI-FIVES and streamline CG support efforts. (3) limited resources and support for CSCs to sufficiently provide direct support to CGs or increase their services for general CGs: sites will be able to select from curriculum delivery options as well as what additional resources to provide based on their perceived capacity.[44] We will test the ability of the CONNECT implementation intervention to augment team formation and team processes across services (e.g. Social Work Service (SWS), PACT team members, Geriatrics) and thereby improve HI-FIVES implementation (Figure 2).

iHI-FIVES is a clinical intervention with strong potential for high impact in VA. iHI-FIVES is a clinical program that delivers evidence-based skills training program to family or friend CGs of Veterans with cognitive and/or functional limitations who have recently been referred to Veteran directed care, home-based primary care, homemaker home health aide services, adult day health care, or respite care (see overview in Table 5).

***Table 5. HI-FIVES Curriculum***

CORE: *4 IN-PERSON WEEKLY GROUP CLASSES*
- Session 1: Introduction, frustrations and rewards of CG
- Session 2: Clinical issues, increasing independence, prevent injury
- Session 3: Caring for the caregiver, communication, depression, burnout
- Session 4: Navigating the VHA, planning for future, services for CGs

*OPTIONAL: 1-3 PHONE TRAINING CALLS, caregivers choose topics, action items*

Patient-oriented topics
- a. Disease information
- b. Safety issues such as falls
- c. Safe home environment, driving
- d. Managing symptoms at home
- e. Planning for future (directives)
- f. Sleep hygiene for patient

Caregiver-oriented topics
- a. Management of stress
- b. Caring for self
- c. Asking for help
- d. Sleep hygiene for self
- e Coping with frustrations
- f. Relaxation techniques

*OPTIONAL: 1-2 BOOSTER CALLS, after group classes, general check-in and follow up on any action items*

**Clinical Program Procedures**.

*Overview*. Similar to Project 1, this project is a hybrid type III effectiveness-implementation design using a stepped-wedge design and mixed methods evaluation. We will test two implementation strategies, REP alone versus REP+CONNECT for implementation of iHI-FIVES.[45] The type III design was selected for three reasons: the implementation strategy REP and implementation intervention CONNECT have strong preliminary evidence;[24,44] iHI-FIVES shows promise in evaluations of 'value' to CGs through increasing caregiver perceived quality and satisfaction with VHA care the Veteran receives; and the VA Caregiver Support Program views iHI-FIVES to hold great promise to fill critical gaps in training for CGs of cognitively or functionally impaired Veterans. To improve the evidence-base for iHI FIVES across multiple sites, we will carefully track both patient-level clinical effectiveness and site-level implementation outcomes.

The participants in the iHI-FIVES clinical program will be CGs of Veterans who had a recent referral (3 months or 6 months) to receive Veteran directed care or home and community-based services (home-based primary care, homemaker home health aide services, adult day health care, respite care). [110] In addition, sites will use their discretion to recruit other caregivers who may benefit from their program, after receiving training in the REP process on the targeted caregivers of interest (e.g., those CGs helping functionally or cognitively impaired Veterans who are at high risk of nursing home entry).

Implementation activities. The pre-implementation activities as specified by REP will include preparing the package for training and delivery using a stakeholder panel. As a part of the stakeholder activities of REP, core elements and optional components of iHI-FIVES will be established for evaluating implementation fidelity to the program. The core program element is group classes, which will not be optional given their critical role in reducing CG isolation; however, the stakeholder panel may opt to include phone training sessions (Table 5 shows topics based on materials already developed for the RCT). The intervention package will provide options for stakeholder panels to determine who will deliver the curriculum (trainers can teach alone or with other co-teachers from their own or other service lines), as well as what additional local resources to provide in the training materials. During orientation and program training (delivered by Function QUERI at sites), CSCs will receive facilitation guides and instruction on curriculum delivery as well as options for potential recruitment CG strategies and discuss how to work across services to form their own site-specific teams. For example, other services that support caregivers may be included (e.g., PACT, Spinal Cord Injury service, Geriatrics, traumatic brain injury (TBI) clinic, PTSD clinic, Occupational Therapy/Physical Therapy (OT/PT), and volunteers from VA Volunteer Services). As a result, there will be variation among REP and REP + CONNECT sites in team composition and service reach (e.g., across services or housed solely within the CSP). We will evaluate team characteristics and their processes for both strategies. In summary, participating sites will have options for implementation throughout the REP process, such as 1) whether to offer optional phone training; 2) who will deliver the curriculum and

will they teach it alone or with other service lines; 3) how to recruit beyond the list of potential eligibles, and 4) how to form teams to deliver the clinical program.

*CONNECT.* For sites randomized to REP + CONNECT, sites will receive explicit training and instruction prior to iHI-FIVES program delivery targeted to CSCs and other services about the benefits of interacting together to improve CG support. Currently there is sub-optimal information flow directly between providers (social workers, CSCs, PACT nurses) that is then communicated back to patients and their CGs. We anticipate CONNECT to facilitate more direct information flow between the diverse providers that serve CGs and their Veterans with cognitive and/or functional impairment, which will thereby improve the success of iHI-FIVES implementation. Because the potential team members in iHI-FIVES (e.g. VAMC personnel who support caregivers) often work in different locations without regular opportunities for frequent communication, the Group and Individual Mapping components of CONNECT will likely be the focus of their team training (Relationship Mapping, Table 1). Landscape site-visits and close coordination with the implementation core will be used for optimal adaptation of CONNECT for iHI-FIVES.

All activities related to implementation of iHI-FIVES as described above are non-research operations activities, as defined in VHA Handbook 1058.05. These programs are designed to support VHA's mission of delivering health care to the Nation's Veterans.

| | | Recruitment months | | | | |
|---|---|---|---|---|---|---|
| Stratified Block | Wave | 1-6 | 7-12 | 13-18 | 19-24 | 25-30 |
| 1 | 1 | | | | | |
| 1 | 2 | | | | | |
| 2 | 1 | | | | | |
| 2 | 2 | | | | | |

pre-implementation ■ post-implementation ■ administrative data collection only

***Figure 5: Stepped wedge design for the 8 participating VAMCs***

Study timeline. In this stepped-wedge design, iHI-FIVES implementation will occur in two stratified blocks (4 VAMCs per block) with two waves per block (2 VAMCs per wave), with each wave corresponding to a different 6 month period to begin offering the iHI-FIVES training to CGs in each study site (Figure 5). The timeline for HI-FIVES will be 30 months in which pre-implementation (control) and post-implementation (treatment) data will be collected. In this design, each cluster (VAMC) provides before (control) and after (intervention) observations and every cluster (VAMC) switches from control to be exposed based on their randomly assigned post-implementation start date (step) during recruitment months of the study. Transition to intervention condition will occur at 6-month intervals. The pre-observation period occurs from time 0 (stratified block 1) to the beginning of post-implementation at an individual VAMC. Each site will provide at least two rounds of iHI-FIVES training in each 6-month period (the basic iHI-FIVES training, e.g., core component, means that "one round" is defined as "4 weekly classes") covering core sessions listed in Table 5. Ideally, each class in a round would be offered on consecutive weeks, but the sites will have discretion on scheduling around holidays. The National Director of Caregiver Support felt that offering 2 rounds of iHI-FIVES in a 6-month period (total of 8 hours instructional time, and additional recruiting and recording keeping time) is reasonable for CSC workload.

2.5.3.c. Randomization procedure. Similar to implementation Project 1, there will be two randomizations due to the stepped-wedge design and comparison of two implementation strategies. First, in each stratified block, the 4 VAMCs will be randomized to either wave 1 or wave 2, then within wave randomized to REP alone or REP + CONNECT for iHI-FIVES implementation. In each stratified block, the 4 VAMCs will be in the pre-implementation period during the first 6-month recruitment window. Within each block, sites will begin offering iHI-FIVES training to CGs during the first post-implementation period and will continue for the remaining post-implementation 6-month intervals.

Participating Sites. With our partners in the VA CSP, we will recruit sites in blocks of 4 based on our stratified stepped wedge design for a total of 8 volunteer VAMC sites for iHI-FIVES implementation (see letter of support from National Director Meg Kabat). To ensure sites are similar enough to compare between arms, sites are required to implement at least two rounds of iHI-FIVES training every six months. The full standard curriculum of HI-FIVES (e.g. if the sites choose all core and optional items to deliver) is 12 weeks in duration; delivering only the core curriculum would take four weeks of group classes. We anticipate some potential volunteer sites will be high functioning and primed for more successful implementation at baseline (i.e., based on their past performance in training and other performance metrics). Thus, we will work with our operational partners to review the volunteer pool to obtain diversity of sites based on a priori ease of implementing a new clinical program

(e.g. high performing, late adopter). We will explore with the implementation core the need to stratify by 'baseline site performance'. Eligible sites will need to have at least 50 recent referrals to Veteran directed care, home-based primary care, homemaker home health aide services, adult day health care, or respite care in a 3 or 6-month period to provide enough patient and caregiver volume to offer training (and for evaluation purposes). We are designating 3 or 6 months because, although we prefer a shorter window of 3 months, feasibility of site volume may lead us to use a 6-month period. Thus, we will assess the referrals on each interested site to make sure there is sufficient volume. We will conduct site visits at all participating sites prior to implementation to obtain additional important contextual information and baseline data for analysis.

**Please see letter from Margaret Kabat, National Director, Caregiver Support Program (10P4C), providing certification of non-research operations activities status (Appendix B).**

## STUDY DESIGN

Overview. We will conduct a **mixed methods evaluation** to address the aims specified below for the STRIDE and iHI-FIVES programs. All evaluation activities involving human subjects will be carried out by employees of the Durham VA. Only Durham VA employees will have access to and conduct analyses from collected data. Clinical site personnel who participate in STRIDE or iHI-FIVES will participate in clinical program duties only; no employees of other VAMCs implementing STRIDE or iHI-FIVES will participate in research activities.

STRIDE Aims

Specific Aim 1: To evaluate **implementation** of STRIDE at REP alone versus REP + CONNECT sites.

Key questions: Are implementation penetration and fidelity higher at REP + CONNECT sites? Do team processes improve more at REP + CONNECT sites, compared to REP alone sites? How do providers experience implementation at REP alone vs. REP + CONNECT sites?

Specific Aim 2: To examine the **impact** of STRIDE on patient outcomes.

Key questions: Do STRIDE participants have fewer discharges to skilled nursing facilities and shorter lengths of stay? Do STRIDE participants have better physical function and higher health-related quality of life at 30 days post-discharge? What is the value of STRIDE from the Veteran's perspective?

Specific Aim 3: To determine the **conditions** under which STRIDE implementation is most successful.

Key questions: Are higher implementation fidelity and penetration associated with better team processes, as measured by the Team Development Measure (TDM©)? If REP+CONNECT has better implementation fidelity and penetration, do team processes moderate or mediate this effect? What contextual factors are associated with higher implementation fidelity and penetration? What contextual elements do providers and leaders report to be vital contributors to implementation success?

QUERI ADIL Aims

Specific Aim 1: Quantify disparities in hospitalization outcomes (length of stay and discharge to home) prior to STRIDE implementation among older adult Veterans based on social determinants of health (Black race, Latino/a ethnicity, history of housing insecurity, rurality, and neighborhood deprivation).

Specific Aim 2a: Quantify disparities in access to STRIDE (proportion of eligible Veterans with any program activity and fidelity of program delivery) based on social determinants of health.

Specific Aim 2b: Determine whether and to what extent social determinants of health are associated with disparities in STRIDE program effects on length of hospital stay and discharge to home.

Specific Aim 3: Create the CONNECTED (CONNECT for Equity and Diversity) implementation package and equity-relevant implementation outcomes. We will use implementation mapping (a 5-step process for development of implementation strategies) to include an explicit health equity focus and representation from racially diverse Veterans, staff, and operations partners.

iHI-FIVES Aims

Specific Aim 1: To evaluate **implementation** of iHI-FIVES at REP alone versus REP + CONNECT sites.

Key questions: Is implementation penetration and fidelity higher at REP + CONNECT sites? How do providers experience implementation at REP alone vs. REP + CONNECT sites? Do team processes improve more at REP + CONNECT sites?

Specific Aim 2: To examine the **impact** of iHI-FIVES on key patient and caregiver outcomes.

Key questions: Do iHI-FIVES patients have more days in the community at six months? Do HI-FIVE caregivers have higher satisfaction with VA care, lower depressive symptoms and lower burden? What is the value of iHI-FIVES from the Veteran and caregiver's perspective?

Specific Aim 3: To determine the **conditions** under which iHI-FIVES implementation is most successful.

Key questions: Are higher implementation fidelity and penetration associated with better team processes, as measured by the TDM®? If REP + CONNECT has better implementation fidelity and penetration, do team processes moderate or mediate this effect? What contextual factors are associated with higher implementation fidelity and penetration? What contextual elements do providers and leaders report to be vital contributors to implementation success?

Understanding the relationships between uptake of new clinical programs and teams' contexts is critical to designing, evaluating, and realizing the effectiveness of implementation efforts. We will use mixed qualitative and quantitative methods to evaluate implementation processes, outcomes, and context. Evaluation will focus on evaluating implementation processes, program impact, and the conditions under which program implementation, regardless of implementation strategy, is most successful. An overview of mixed method designs that will be used to meet these aims in diverse clinical settings is described below.

To evaluate implementation, we will use a quantitatively driven simultaneous design (QUAN + *qual)* in which quantitative data constitute the core component and are collected in parallel with qualitative data.[47,48] These two methods will be used to answer related questions, in that quantitative data will be used to evaluate implementation effectiveness (i.e., outcomes of penetration and fidelity) and qualitative data to understand how implementation processes (including team processes) and environmental context relate to implementation outcomes. Data integration will involve embedding qualitative process data within the quantitative outcomes data (for example in a matrix format in which program sites are arranged from high to low penetration) to evaluate the relationship between implementation outcomes and process for both implementation strategies (e.g. REP alone vs. REP + CONNECT).

Pre-implementation landscape assessment at participating sites. Function QUERI personnel will conduct site visits at all participating sites to conduct baseline assessments of clinical needs, clinical and administrative processes, teams, and environmental context before clinical programs are formally introduced. During these visits, data will be drawn from multiple sources, including semi-structured interviews with service line administrators, clinical providers anticipated for program delivery, local policies and procedures (e.g., directives, protocols), surveys to assess team development and function for program delivery, and process mapping with key informants. Additional informants relevant to each program and site will be identified through snowball purposeful sampling.[48] Information within and between participating sites will be used to inform refinements to clinical program implementation packages and obtain baseline data for analyses of context sensitivity.

Common Measures and Data Sources. Guided by our nested model of team function and performance in implementation (Figure 2), the implementation core will utilize common measures and data sources to evaluate team processes and characteristics, program characteristics, environmental context, and implementation outcomes; sample measures and associated data sources are displayed in Table 2.

*Team characteristics and processes*. Features of team characteristics and processes will be assessed using the Team Development Measure (TDM©), a 31-item questionnaire, which characterizes the degree to which groups have the characteristics of highly effective teamwork in place.[49,50] The TDM© is ideally suited for Function QUERI's evaluation of teams for several reasons. First, the instrument has been tested in a variety of healthcare settings (e.g., administrative, inpatient and outpatient) and maintains psychometric strength when applied to

group size ranging from 3 to 43 members. Second, the TDM©'s validated instrument design measures team functioning from the perspective of individual members of teams, allowing for data collection and analysis at the individual and team-level.

Although TDM© responses generate a summative score describing overall team development, items from the TDM© also cluster to reflect the four key dimensions of team function: communication, role clarity, cohesion, and goal and means clarity.[49] This will enable the implementation core to 1) assess baseline and post-implementation changes in dimensions of team function, 2) identify variations in team strengths and weaknesses within and across clinical programs at participating sites, and 3) assess the dimensionality (e.g., one summative measure of team function or multiple measures of team function) and predictive power of team function on implementation and program outcomes to inform future implementation efforts.

The implementation core will examine other important features of teams, including size, composition and the degree to which team membership spans boundaries (e.g., clinical, professional, etc.) by supplementing the TDM with additional survey items. For example, we will also describe team communication channels (internal, external), decision-making, and establishment of routines (Table 2). The team survey will take roughly 15-20 minutes to complete.

*Clinical program characteristics* include the components and processes that each site chooses for program delivery. Each site will be provided with clinical program implementation packages that outline both the core and optional elements of each program. We will carefully track how each site decides to structure their program, and also assess other important elements associated with delivering the program such as task complexity and uncertainty, and dependence on other teams or clinical units within the organization.

## Provider data collection

Pre-implementation provider interviews.

For STRIDE, we anticipate interviewing approximately 5-10 providers (clinicians and administrators) per ward at each site (n=8 sites) for a total of approximately 50-100 subjects, or until we reach theoretical saturation. For iHI-FIVES, we anticipate interviewing approximately 5-10 providers (CSCs, administrators, and staff from other services that support caregivers) at each site (n=8 sites) for a total of approximately 50-100 subjects, or until we reach theoretical saturation. Interviews will take place at participating sites or over the phone, 2-4 months prior to program implementation. After obtaining verbal informed consent, interviews will be conducted over the phone or in person by Function QUERI staff. See Appendix for a copy of the provider interview guide. We will seek a waiver of documentation of informed consent and HIPAA so that we may offer study participation to subjects over the phone. Subject eligibility criteria will include:

- Willing and able to provide informed consent
- Knowledge of local context as described above

Post-implementation provider interviews

For STRIDE, approximately 3-4 months after STRIDE implementation we will conduct interviews with approximately 5-10 providers per ward at each site (n=8 sites) for a total of approximately 50-100 subjects, or until we reach thematic saturation, to understand their experience with the program. For iHI-FIVES, we will conduct approximately 5-10 providers (CSCs, administrators, and staff from other services that support caregivers) at each site (n=8 sites) for a total of approximately 50-100 subjects, or until we reach thematic saturation, to understand their experience working on caregiver support at their VAMC. After obtaining verbal informed consent, interviews will be conducted over the phone or in person by Function QUERI staff. Subject eligibility criteria will include:

- Willing and able to provide informed consent
- Participation in STRIDE or iHI-FIVES program

Enrollment Procedures. We will obtain the appropriate collective bargaining unit (CBU) approvals before enrolling providers and conducting interviews. Once the VAMC has been confirmed to be a STRIDE or iHI-FIVES site, we will contact key informants for interviews. Using snowball sampling from these initial interviews, we will identify other involved individuals on the ward to approach and offer participation in an interview. The study team will initially contact the provider via email (Appendix C for STRIDE, Appendix 16 for iHI-FIVES) and invite him/her to participate in the interview. When providers respond to the invitation email and state that they want to

participate, study staff will send them information about the interview, including information about their rights as study participants from the verbal informed consent script (Appendix D for STRIDE, Appendix 13 for iHI-FIVES). Telephone interviews and/or in-person interviews will then be scheduled. At the beginning of the conversation, the study interviewer will confirm that the participant received and read the information about the study and consent process. Then the study interviewer will reiterate key parts of the informed consent information that had been sent via email when the interview was scheduled (e.g. purpose of the study, the key informant's rights as a study participant, the confidentiality of the interview), ask if there are questions, and ask for verbal consent. The interviewer will ask permission to audio-record the interview. Interviewers will use the script contained in the Appendix to review participant rights and obtain verbal consent in cases where consent information was emailed prior to a scheduled phone interview.
If providers cannot be reached via email, they may be called by study staff or study interviewers before being considered unreachable. If a provider is reached via phone, study staff will explain the study and invite that person to participate using the verbal informed consent script. If the person verbally consents, the interview can be conducted at that time or scheduled for another time. Study interviewers will keep an electronic verbal consent log. The telephone interviews will be audio-recorded using a secure system (Sparky) behind the VA firewall and transcribed using a secure VA transcription service (Salt Lake City) or by staff.

Pre-implementation provider surveys

For STRIDE, we plan to survey a maximum of 100 providers (e.g. physicians, nurses, physical therapists, etc.) in each ward at each site (n=8 sites) for a maximum total of 800 subjects. We will administer the survey 2-4 months prior to STRIDE implementation (see Appendix for full instrument). For iHI-FIVES, we plan to survey a maximum of 10-20 providers (e.g., social workers, CSCs, PACT nurses, etc.) at each site (n=8 sites) for a maximum of 80-160 subjects.

After obtaining informed consent, surveys will be administered in one of two ways: 1) email via link to secure Illume survey; or 2) in-person on paper hardcopy of survey. Further details of enrollment procedures are provided below. We will seek a waiver of documentation of informed consent and HIPAA so that we may offer study participation to subjects via email. Participation is voluntary. Subject eligibility criteria will include:

- Willing and able to provide informed consent
- Hospital staff member working in inpatient setting

Post-implementation provider surveys

Using the same procedures and eligibility criteria, as well as implementation records, we will also survey providers 3-4 months after STRIDE or iHI-FIVES implementation. We will attempt to survey all providers who participated in the pre-implementation survey as well as others who have joined the staff, were unavailable, or chose not to participate in the first survey. Providers who participated in CONNECT training and those who participate directly in delivery of the clinical program will be asked additional questions about these experiences.

Enrollment Procedures. We will obtain the appropriate collective bargaining unit (CBU) approvals before enrolling providers and collecting survey data. Once the VAMC has been confirmed to be a STRIDE or iHI-FIVES site, we will contact program leadership (e.g. program champion) and/or the appropriate service line leaders to identify individuals to approach and offer participation. The study team will initially contact the provider via email (Appendix) and invite him/her to participate in the survey. The email will include all elements of informed consent (Appendix) and include a VA-intranet-secured link that the provider should use to begin the survey if they agree to participate. If the participant agrees to participate in the survey, they will be directed to click on a VA-intranet secured link to complete and submit the confidential survey to our VA-secure-networked server. Two brief follow-up email reminders may be sent as needed to encourage providers to complete the survey. If there is no provider response and the subject has primary non-VA email, a message may be sent to that email asking the participant to respond to the link in their VA email.
In the event that providers cannot be reached by email or do not complete the survey through email, personnel will be approached during the clinical program site visit by study staff and invited to participate and complete the survey in-person on paper. If the providers agree, study staff will provide the informed consent script and if they

are willing to participate, they will be asked to complete a paper copy of the survey. The completed survey will be scanned on an approved VA mobile scanner by study staff and transmitted securely to the Durham HSR&D secure network, restricted-access Function QUERI study folder. In the event that the scanner is not available, the surveys will be returned to Durham VA HSR&D in a pre-addressed, business reply envelope. Similar email procedures will be followed for the post-implementation survey. In addition, participants who do not respond to the secure email link will be mailed a paper copy of the survey and consent with a pre-addressed, business reply envelope to return it. In order to increase survey participation, we may offer incentives such as an entry into a raffle for small prizes.

Rationale for Enrollment We have opted to enroll providers primarily by email or in-person for logistical reasons. An email or paper-based strategy greatly expands the reach of the evaluation by allowing enrollment from multiple VAMCs. We will track number of attempts to contact, and examine differences between providers who enrolled or refused and those we were unable to contact to inform future implementation efforts. Tracking individual responses will also allow the study team to examine within person differences in team characteristics, processes, and satisfaction that contribute to team performance and outcomes.

## PROGRAM-SPECIFIC METHODS: STRIDE

*Implementation Outcomes.* **Penetration** of STRIDE will be assessed by the percentage of eligible patients with any documented walking during hospitalization. In a sub-sample of patients, we will assess total daily minutes of activity and distance walked (if any), and the percentage of eligible patients who report their providers wanted them to walk while they were in the hospital. **Fidelity** will be assessed via the percentage of STRIDE participants with at least two documented supervised walks, or one walk > 5 minutes per hospital business day (excluding day of consult, admission days pre-consult, discharge day, weekend days and holidays).

These data will be obtained from patient survey, review of electronic medical records via VistaWeb or Joint Legacy Viewer JLV, and through a CDW datapull of health factor data.

*Patient Outcomes.* Our primary patient-level outcome of interest is **discharge from the hospital to a skilled nursing facility**. This could be considered a service-level outcome as well given the important financial implications for VHA; however we feel it's most relevant as a patient-centered outcome given the overwhelming data that patients prefer home to institutional care.

*Service Outcomes.* Primary service outcome is hospital **length of stay** (LOS). Patients value shorter hospitalizations as well; however we include it here due to its implications for overall facility efficiency and performance reporting (e.g., SAIL measures).[43]

These data will be obtained from VA administrative records (e.g. Corporate Data Warehouse), VA/CMS Repository Data, and confirmatory chart review through VistaWeb or JLV.

### Patient data collection

Representative measures include the following instruments. Physical function will be assessed with subscales of the Function and Disability Instrument (LL-FDI). The Life Space Assessment (LSQ) will assess the extent of mobility in the person's environment. The LSQ is a reliable measure and has construct and criterion validity in samples of older adults. Health-related quality of life will be assessed via the ICE-CAP A and the Euroquol (EQ-5D). The Euroquol has been widely used and well-validated, including for telephone administration. It features relevant questions on mobility and has been mapped to health utilities providing additional data for understanding the program's overall value.[52] The full patient survey is shown in the Appendix.

Key covariates. Patient-level covariates will be identified based on the ICF (Figure 1) and other factors known to assess functional outcomes and recovery after hospitalization,[54] such as age, living arrangements, social support, baseline health (e.g. functional status, chronic health conditions, use of sedative medications, nutritional status, depression), severity of acute illness, and delirium on admission. Site-level covariates will include facility size and complexity, staffing ratios (nursing and PT), average daily census, and academic affiliation. Data sources will include CDW, Pharmacy Benefits Management (PBM), Inpatient Evaluation Center (IPEC), VHA

Support Services Center (VSSC), Strategic Analytics for Improvement and Learning (SAIL), Geriatrics and Extended Care Data Analysis Center (GECDAC) and the medical record.

Patient surveys

We plan to survey approximately 30 patients per 3-month period (16 3-month periods across 8 sites) for an approximate total of 960 subjects (150 subjects per VAMC in stratified block 1 and 90 subjects per VAMC in stratified block 2). For all VAMCs, patients will not be surveyed if they were admitted and discharged in the 3-month window of the implementation rollout. Surveys will be collected via telephone at 30 days following hospital discharge. We will seek a waiver of documentation of informed consent and HIPAA given that recruitment and data collection is entirely telephone based and minimal risk. Participation is voluntary. Subject eligibility criteria includes:

- Able and willing to provide informed consent (does not lack decision-making capacity)
- Discharged from a participating hospital within the preceding 30 days
- Age >= 60
- Index admission for medical illness
- Community-dwelling (i.e. not in a nursing home or institutional care) prior to hospital visit
- Ability to ambulate safely and independently (does not need help walking across a small room)
- Valid telephone number in the medical record
- Admitted to a medical service and discharged from a medical service
- Index hospital stay was in a ward identified to participate in the STRIDE program

Exclusion Criteria:

- Patient deceased
- Index hospital stay was ≤ 2 business days (48 hours), including any observation days
- Currently hospitalized
- Current high-risk suicide flag in medical record
- Diagnosis of cognitive impairment or dementia
- Difficulty with or unable to communicate on the telephone, or no telephone access
- Discharged to another hospital or acute care setting
- Transferred into index hospital from another hospital
- Bedrest order that was not lifted for at least ≥2 days of the index hospitalization

Patient Interviews

We plan to interview approximately 5-10 patients from each STRIDE site (n=8 sites) for a total of 40-80 subjects. Interviews will be conducted approximately one week post-discharge for patients participating in the STRIDE program. The interviews include 5-10 questions and are projected to take 10-20 minutes to administer. The interviewer will ask permission to audio-record the interview, invite the participant to ask any questions and request verbal consent to proceed with the interview. The telephone interviews will be audio-recorded using a secure system (Sparky) behind the VA firewall and transcribed using a secure VA transcription service (Salt Lake City) or by study staff. Data collection and audio recording of interviews concluded on 1.22.20.
The verbal informed consent script (see Appendix) will include language mentioning the potential interview and audio-recording and that patients have the option to decline the interview and audio-recording.

Enrollment Procedures. An automated CDW datapull and/or VistaWeb/Joint Legacy Viewer as appropriate will first identify the patients who meet criteria for age, index admission and discharge status. Study staff will then conduct a brief medical record review to check for eligibility criteria 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 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/opt-out 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. See Appendix for the patient informed consent script and screening script. Because the screening and enrollment is entirely telephone based, we will seek a waiver of documentation of informed consent and of HIPAA, as approved by the Durham VAMC IRB in our ongoing studies using similar recruitment methods.

Rationale for Enrollment and Screening over the Telephone. We have opted not to enroll Veterans during a hospital admission or other in-person visit for logistical reasons. A telephone-based strategy makes the evaluation possible by allowing enrollment of patients from multiple VAMCs across the country. 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.

PROGRAM-SPECIFIC METHODS: QUERI ADIL

**Aims 1 and 2: Data Source**

Aims 1 and 2 will utilize existing data from the Function QUERI STRIDE implementation trial, which includes nearly 15,000 Veterans across 8 VA facilities who met inclusion criteria for the stepped-wedge trial. Sites were randomized to one of two implementation programs: Replicating Effective Programs (REP) or REP + CONNECT (a supplement to REP that consisted of interaction-oriented staff training activities designed to promote clinic teamwork and readiness to implement new practices). Veteran criteria for STRIDE participation were as follows: ≥ 60 years of age, admitted for medical illness, community-dwelling, able to follow one-step commands, and able to ambulate safely. Veteran-level data was collected pre- and post-implementation.

**Aim 1 Measures**

The goal of Aim 1 is to quantify pre-implementation disparities in hospitalization outcomes. Main outcomes include: length of hospital stay and discharge from the hospital to a skilled nursing facility. Key social determinants of health include: CDW race and ethnicity data, positive EHR screen for housing and food insecurity within the past 5 years, census tract Rural-Urban Community Area (RUCA) code, and census tract Neighborhood Deprivation Index (NDI). Housing insecurity, food insecurity, and NDI from approved CDW data sources have not previously been analyzed as predictors of hospitalization outcomes for the parent project. Covariates will be similar to the parent project, and will include: (patient-level) age, baseline health, severity of acute illness, and delirium on admission; and (site-level) facility size/complexity, staffing ratios, average daily census, and academic affiliation. Using race as a stand-in for systemic inequity may reify the myth of biological race and runs the risk of glossing over racism as a causal factor in inequity. However, given the absence of existing measures of systemic racism, race and ethnicity variables will be included in analysis. To avoid using whiteness as a norm, effects coding of race (i.e., quantifying the extent to which each racial group varies from the grand mean) will be used. Additionally, a new algorithm for race/ethnicity coding in CDW will provide more precision in these measures.

**Aim 2 Measures**

The goal of Aim 2 is to quantify disparities in access to STRIDE and disparities in STRIDE program effects. Access to STRIDE (2a) will be assessed by the percentage of all eligible patients with documented walking during hospitalization, the percentage of STRIDE participants with documented supervised walking, and the percentage with ≥ 10 minutes of daily walking. STRIDE program effects (2b) will be measured by the difference in pre- and post-implementation patient-level length of hospital stay and discharge from the hospital to a skilled nursing facility. Key social determinants (2a and 2b) will be identical to those of Aim 1.

**Aim 1 Analysis**

We hypothesize that social determinants of health (i.e., Black race, Latino/a ethnicity, history of housing insecurity, rurality, and neighborhood deprivation) will be significantly associated with hospitalization outcomes. We will model patient-level outcomes of discharge and length of stay via generalized linear mixed models with a random intercept for cluster. Models will also account for multiple hospitalizations per patient. We will estimate the association (e.g. odds ratio, incidence rate ratio) of the social determinant with the outcome and the associated 95% confidence intervals.

**Aim 2 Analysis**
We hypothesize that social determinants of health will be associated with STRIDE access. The modeling approach for Aims 2a/2b will be similar to Aim 1. In Aim 2b, 1) we will additionally account for within- and between-period effects, and 2) address heterogeneity in STRIDE program effects on patient-level outcomes attributed to each social determinant through estimation and testing of pre-specified interaction terms between social determinants and STRIDE indication. Models will adjust for REP vs. REP + CONNECT and patient characteristics.

**Aim 1 and 2 Power Calculation**
With a cohort of nearly 15,000 patients, we are confident that we will be adequately powered to detect clinically meaningful differences in patient-level outcomes. Clinically meaningful differences will be pre-specified by study clinicians to minimize spurious findings.

**Aim 3: Overview**
We propose to use implementation mapping methodology to incorporate a greater focus on racial equity within the CONNECT implementation package. Implementation mapping includes a 5-step process for strategy development. CONNECT is an appropriate foundation for this work because it has been used successfully in multiple clinical settings and has been associated with improvements in staff communication.

**Aim 3: Recruitment & Participants**
We will convene a Function QUERI Equity Working Group monthly for 6 months to use implementation mapping to develop/adapt implementation strategies that focus on health equity for staff receiving the CONNECT implementation package. The working group will include the mentoring team, and will consist of 12-15 end-users; it will also include the Function QUERI leadership team and experts on health equity. Dr. Wilson will facilitate the group. End-user group members will include: Veterans over the age of 60, general medicine inpatient services staff, Veteran caregivers, geriatricians, and operations partners. Effort will be made to include end-users who are Black, Indigenous, or People of Color, while recognizing that it is not the default responsibility of those who experience oppression to address disparities.

**Aim 3: Procedure**
We will present workgroup members with findings from Aims 1 and 2 (i.e., equity needs assessment). At meeting 2, the group will identify matrices of change (e.g., reduce staff authority bias, reduce staff implicit racial bias, improve housing security). Dr. Wilson and Function QUERI collaborators will then select implementation strategies based upon the matrices of change, the Expert Recommendations for Implementing Change (ERIC) taxonomy, and the Health Equity Implementation Framework. At meetings 3 through 6, the working group will collaboratively revise and refine the proposed implementation strategies.

**Aim 3 Deliverables**
Although final content of the CONNECTED implementation package is dependent on the implementation mapping process, some potential strategies might include: equity training for clinical teams, audit and feedback of equity metrics, and/or coalition building with local clinical/community partners. At the project's conclusion, the team (led by Dr. Wilson) will propose a QUERI- or HSR&D-funded project to test CONNECTED.

## PROGRAM-SPECIFIC METHODS: iHI-FIVES

*Implementation Outcomes.*

**Penetration** will be measured using caregiver-level and provider-level measures at each site. *Caregiver-level*. We will measure penetration of the program at each site by assessing the number of caregivers "reached" by iHI-FIVES in a 6-month interval out of the total number of caregivers "eligible" during the same interval. *Provider-level*. Penetration at the provider-level will be measured as the number of providers who refer caregivers to participate in iHI-FIVES in a 6-month interval out of the total providers involved in caregiver support. *Site level.* Penetration at the site-level will be measured as the number of caregivers registered into the Caregiver Application Tracker (CAT) out of the number registered in the prior 6-months.

**Fidelity** will be measured as follows: 1) the number of 6-month intervals in post-implementation in which a site delivered at least two rounds of iHI-FIVES trainings out of the total number of 6-month intervals in post-implementation; 2) the number of rounds of training in which the full iHI-FIVES core curriculum topics were covered out of the total number of rounds of training offered.

These data will be obtained from review of electronic medical records via VistaWeb or Joint Legacy Viewer JLV, CDW data pull of health factor data, training records and attendance logs for each site, POC-reported data on instructors involved, and caregiver participant interviews.

*Patient Outcome:* Our primary individual-level outcome for iHI-FIVES is a patient-level outcome. Veteran **independence** (i.e., days spent alive and at home over the 6-month outcome period). This will be calculated as 180 days after the data pull date for that specific 6-month interval minus the total number of days **in an Emergency Department (ED) setting, an inpatient setting, or in a post-acute facility in the 6 months after the study start date (e.g., 6 months post-data pull).**

*Caregiver Outcomes: **Function.*** Our primary caregiver-level outcome of interest is **function** which includes depressive symptoms, as well as subjective **burden** (or the level of stress felt by CGs), and global **satisfaction** with VA health care quality measure as perceived by the caregiver. Caregiver outcome data will be obtained from surveys.

**Patient data: Definition of the Primary Outcome**

To create the primary outcome, measures from administrative data and VA/CMS Repository data will be created that include patient ED days, inpatient days, post-acute facility days, and residential nursing home stays. These are all defined below, along with contextual utilization variables. We examine whether patients had a residential nursing home stay because we do not include those types of stays in our primary outcome and because patients who have transitioned to residential care of this type are no longer considered to be "independent" or living at home. As such, any days occurring in a visit of these types, will be censored and not included in the analysis as a day not at home. The outcome period is defined as from the mid-point of each 6-month block forward 6 months (e.g., the last day of month 3 in a block).

*Emergency Department (ED) Days.* We will count an emergency department encounter occurring on one day (two days, etc.) as one day (two days, etc.) not at home. For any ED visit that results in an inpatient admission on the same day as the ED visit, we will count the first day as being an ED day. Days thereafter that are spent in the inpatient setting, defined as there being a record of a hospital admission within one day of their ED visit, will be counted under the inpatient variable, described below.

*Inpatient Days*. We will use the admission date and the discharge date to calculate days spent in an inpatient stay. Inpatient hospice stays will be not included in the Inpatient Days count. Residential Psychiatric Inpatient Days will not be counted in the Inpatient Days count. See below for definitions of each of these. We will cross reference Inpatient Days against ED Days and Post-Acute Facility Days to prevent double counting.

*Post-acute Facility days*. We will also use admission and discharge dates to measure days in a post-acute facility setting. We will include Community Living Center, Community Nursing Home, and private or Medicare nursing home (e.g. not reimbursed by the VA) days directly following an inpatient stay. Specifically, a post-acute facility stay is defined as nursing home stay of 100 days or fewer immediately following discharge from an inpatient stay (on the same day or day before). For community-dwelling patients, if a patient has a long-stay nursing home stay following immediate discharge from the hospital, we will count the first 100 days as post-acute days and then thereafter the days will be censored. For patients who are identified as living in a nursing home (e.g. they have a nursing home stay for at least 101 days), being discharged from the hospital into a nursing home upon immediate discharge from the hospital will not be counted as post-acute care. This will be considered residential nursing home care and the days will not be included in the count of post-acute facility days. Chart review will confirm identification of community residence or nursing home residence if deemed necessary. We will cross reference against ED days and Inpatient Days to prevent double counting. If

a patient begins at a facility stay as a post-acute facility episode as defined above, but does not leave the facility by day 100, that is considered a transition to a 'residential nursing home stay'. Thus, the first 100 days of that post-acute episode will be counted as "100 days" not at home but then thereafter the patient will be censored.

Measures that will be created to help with censoring decisions:

*Residential Nursing Home Stays.* A binary outcome of "any residential nursing home stay", defined as an episode of 101 or more days in a nursing home setting (CLC, CNH, VA and non-VA locations), will also be constructed and explored descriptively and as exploratory analysis. An episode of 101 days or more in our preliminary analysis of local GeriPACT patients and 100 HI-FIVES patients, pooled and not by arm, indicates a permanent move to a nursing home. We view this cut-off to help distinguish between post-acute skilled facility care and longer term residential custodial care. For comparison, in Medicare in 2016, mean length of stay for post-acute care was 30 days [32] and 97% of discharges from Medicare post-acute care facilities (SNFs) occurred by 90 days. Thus, it is likely that stays in a VA nursing home for less than 101 days can also be considered post-acute care and that days over this threshold will be considered residential. Additionally, since a "Residential Nursing Home Stay" represents a more permanent transition from the home environment, the patient will then be censored at the time of that transition from the primary outcome. Specifically, days after the admission date for a stay which lasted longer than 100 days will be removed from the "denominator" of the outcome, such that those days do not count as either at home or not at home because this measure is no longer considered applicable after the transition. In addition, for the rare cases in which patients living in a nursing home (e.g. they have a nursing home stay for at least 101 days) are then admitted and then discharged from the hospital back into a nursing home, these days following the discharge will also be counted as "residential nursing home days". We will examine the binary outcome of any residential nursing home stay as "the patient had a long stay nursing home stay ≥101 days in the 6 month outcome period across VA and VA-purchased stays" versus no long-stay nursing home stay.[33]

Finally, for descriptive purposes, the team will define other utilization types: any adult day health care use, any respite care, and any short-term nursing home stays will also be described. A short-term custodial nursing home stay, which is one that is 1) not within one day of an inpatient discharge and 2) less than or equal to 60 days, is not counted as a day not at home and patients will not be censored. This will be examined in descriptive analyses.

Key covariates. Patient-level covariates will be identified based on the ICF (Figure 1) and other factors known to assess independence including age, race, ethnicity, marital status, service connection, urban/rural status, NOSOS score from year prior to start date. Site-level covariates to explore will include presence of a Geriatric Research Education and Clinical Center, rural status, and academic affiliation. Data sources will include CDW, Inpatient Evaluation Center (IPEC), Strategic Analytics for Improvement and Learning (SAIL), Geriatrics and Extended Care Data Analysis Center (GECDAC) and the patient medical record.

*Sample of Patients.* Administrative data and VA/CMS Repository data will be used to construct the primary patient outcome. Analysis will be performed on a sample of Veterans from a 3 or 6-month repeated automated CDW data pull and/or VistaWeb/Joint Legacy Viewer as appropriate. This data pull will occur at a uniform time period (e.g., 2 weeks) of each 3 or 6-month interval for the duration of the 30-month study.

Patient eligibility criteria includes a consult or referral in the past 3 or 6-months from the date of the data pull to the following VA services:

- H/HHA (homemaker home health aide services)
- Home based primary care (HBPC)
- Adult day health care
- Respite care
- Veteran directed care

and meet none of the exclusion criteria:

- Consult or referral to hospice care.

We anticipate that there will be between 15,000 -18,000 total Veteran patients meeting these criteria. We will require sites have a minimum of 50 recent referrals to HCBS (recent is defined as within a 3 or 6-month interval) to be an eligible site.

*Sample of Caregivers.* Survey data will be used to construct secondary caregiver outcomes.

*Enrollment procedures.* Of the Veteran patients identified from the repeated automated data pull described above to create the administrative primary outcome, we will mail introductory recruitment/opt-out letters signed by the PI (see Sample Letter for iHI-FIVES; Appendix). Patients will be provided a toll-free number to opt out. Starting about one week after mailing recruitment letters, a member of study staff will call patients and describe that we would like to conduct a brief survey with their family or friend caregiver by phone. If they do not have a caregiver, contact will cease. If they do, study staff will ask the Veteran patient for permission to contact the caregiver, and if allowed, will confirm contact information for the caregiver. The patient's interaction with the study team is limited to agreeing or declining to give the study team permission to contact their caregiver.
See Appendix for the iHI-FIVES patient screening script.

Because the Veteran patient contact screening is entirely telephone based and minimal risk, we will seek a waiver of informed consent and of HIPAA, as approved by the Durham VAMC IRB in our ongoing studies using similar recruitment methods (Appendix).

For eligible Veteran patients who gave permission to the study team to contact their caregiver, a member of the study team will call the caregiver to describe the survey, answer questions, ascertain eligibility, and obtain informed consent. It will be common based on our experience with the RCT of HI-FIVES for the caregiver to answer the Veteran's phone. If this is the case, we will proceed to the caregiver informed consent and screening script (Appendix).

For caregiver surveys, we will seek a waiver of documentation of informed consent and HIPAA given that recruitment and data collection is entirely telephone based and minimal risk (Appendix). Participation is voluntary. The caregiver survey exclusion criteria by phone screening include:

- Unwilling to complete baseline survey and 3-month follow-up survey
- Not able to communicate via telephone
- Of minority age
- Caregiver is a professional without a pre-existing personal relationship with the Veteran and receives payment for caregiving services
- Caregiver is a member of the Durham HSR&D Veteran and Family Input Initiative (VAFII), where members have advised and provided input towards the development of iHI-FIVES intervention materials (will apply to the Durham VAMC site only, study staff have a list of VAFII caregiver members).
- Informs us Veteran is currently in hospital or institution
- Informs us Veteran is currently receiving hospice care

The goal is to collect 120 surveys from caregivers in the pre-implementation period and 200 caregivers in the post-implementation period (n=320). All caregivers will fill out a baseline survey upon consent and 2-3 months later complete a follow-up survey. Both surveys take approximately 20-30 minutes to complete. The primary analysis approach for the caregiver outcomes (satisfaction with VA care, subjective burden, depressive symptoms), will be performed on these 320 caregivers.

For an "as treated" analysis, there will be an additional pool of caregivers recruited into the study among those participating in the iHI-FIVES clinical program. We expect that not every caregiver participating in the clinical program will consent to be a research subject, thus, with a conservative estimate of a 50% enrollment rate from the pool of participating caregivers (n=320), the minimum number of participating caregivers in the "as treated"

analysis is expected to be 100. Prior to the start of the first iHI-FIVES training, a member of the study team will call caregivers to ascertain eligibility and obtain verbal informed consent from the caregiver. Study team members will describe that participation in the study is completely voluntary and will not impact the caregiver's invitation to attend the iHI-FIVES training. Caregivers will be provided a toll-free number to contact if they do not wish to be contacted further. See Appendix for the caregiver informed consent script and screening script.

Rationale for Caregiver Enrollment and Screening over the Telephone. We have opted not to enroll caregivers of Veterans during the Veteran's hospital admission or other in-person visit to their VAMC for logistical reasons. A telephone-based strategy makes the evaluation possible by allowing enrollment of caregivers from multiple VAMCs across the country. To inform future implementation efforts, we will track number of attempts to contact and examine differences between caregivers who enrolled or refused and those we were unable to contact.

Caregiver Interviews.
We will not be conducting qualitative interviews with caregivers in the pre-implementation period. In the post-implementation period, we plan to interview by telephone approximately 5-12 caregivers who participated in iHI-FIVES training and consented to be part of the study for a total of approximately 40-96 subjects across 8 sites, or until we reach thematic saturation. The interviews will take approximately 15-20 minutes to administer. The study team interviewer will ask permission to audio record the interview, and invite the caregiver to any questions and request verbal consent to proceed with the interview. The telephone interviews will be audio-recorded using a secure system (Sparky) behind the VA firewall and transcribed using a secure VA transcription service (Salt Lake City) or by study staff. In addition, we plan to share site-level summaries of the qualitative interviews with individual sites for implementation and quality improvement purposes.

For the caregiver qualitative interviews, we will seek a waiver of documentation of informed consent and HIPAA given that recruitment and data collection is entirely telephone based and minimal risk. Caregivers who are enrolled in the study will be mailed a written statement regarding the research that contains key elements of the informed consent. The verbal informed consent script (see Appendix) will include language mentioning the potential interview and audio-recording that caregivers have the option to decline the interview and audio recording. Participation is voluntary. The caregiver interview exclusion criteria by phone screening include:

- Not able to communicate via telephone
- Participated in less than 50% of the iHI-FIVES group training program sessions
- Of minority age
-
- Caregiver is a member of the Durham HSR&D Veteran and Family Input Initiative (VAFII), where members have advised and provided input towards the development of iHI-FIVES intervention materials (will apply to the Durham VAMC site only, study staff have a list of VAFII caregiver members).

Enrollment Procedures. We will first identify the caregivers who have participated in the iHI-FIVES training program using an LSV report of iHI-FIVES caregiver attendance developed for sites. We will compare this list with caregivers identified for the study sample (see procedures above). We will confirm eligibility via VistaWeb/Joint Legacy Viewer review of the Veteran/caregiver records. We will mail introductory recruitment/opt-out letters signed by the PI (see Sample Letter; Appendix). Caregivers 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 caregivers to ascertain eligibility and obtain informed consent from the caregiver. See Appendix for the caregiver informed consent script and screening script. Because the screening and enrollment is entirely telephone based, we will seek a waiver of documentation of informed consent and of HIPAA, as approved by the Durham VAMC IRB in our ongoing studies using similar recruitment methods.

Rationale for Enrollment and Screening over the Telephone. We have opted not to enroll caregivers during an iHI-FIVES training session or other in-person visit for logistical reasons. A telephone-based strategy makes the evaluation possible by allowing enrollment of caregivers from multiple VAMCs across the country. We will track number of attempts to contact, and examine differences between caregivers who enrolled or refused and those we were unable to contact to inform future implementation efforts.

**RISK/BENEFIT ASSESSMENT**

Providers. There is no patient involvement in the provider survey or interview process. The benefits of these interviews far outweigh any minimal risk that may be involved.

Patients. The evaluation is minimal risk and does not involve an intervention. For the STRIDE program, we will ensure that patients are willing and able to provide informed consent and will not enroll patients who have evidence of dementia, cognitive impairment or lack of capacity. For the iHI-FIVES program, there will be no survey questions or interviews asked of the patient.

Caregivers. The evaluation is minimal risk and does not involve an intervention. For the iHI-FIVES program, we will ensure that caregivers are willing and able to provide verbal informed consent and will not enroll caregivers if they are not able to provide informed consent and will not enroll caregivers if they are under 18 years of age or if their Veteran patient is in hospice or currently in the hospital or other institution.

Protection of Data from Improper Use or Disclosure

There is a slight risk of breach of privacy resulting from unauthorized use, loss, or disclosures of PHI. However, if such an event occurs, the Durham local site PI and staff will follow the Durham VA Medical Center's procedures. The lead principal investigator will work closely with the IRB, the ISO, and Privacy Officer if notification to individuals is necessary.

Through their VA training, all staff are familiar with the Durham VA Medical Center's procedure for reporting loss or theft of computer devices, unauthorized use, loss, or disclosures of PHI, or violations of information security requirements is to report the incident immediately (within 1 hour of discovery) to the VA Police, the employee's Supervisor, ISO, and Privacy Officer. Loss or theft of computer devices or PHI will also be reported to the Durham VA IRB as an adverse event.

**Data Management**

The Durham HSR&D COIN 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 COIN policies. Utilization data will be downloaded directly from national files to the Durham HSR&D COIN servers or stored in the secure VINCI environment. Of study personnel, only the study Statisticians and Economist will have access to the utilization 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.

Additional Safeguards for Provider Interviews and Surveys. The information gained during the interviews and surveys will not be used to evaluate quality of care. Neither the provider's supervisors nor the provider's peers

or patients will have access to the data. Data will remain confidential. No individually identifiable information will be published or disclosed, unless required by law.

In order to protect participants' privacy, we will avoid the use of names during the audiotaped interview. To protect participants against risk after interview data have been collected, we will take a variety of measures to ensure confidentiality. In all records, participants will be assigned unique identifiers. The key linking unique identifiers to participants, the verbal consent log, as well as all interview recordings and transcripts will be stored electronically in a restricted-use folder on a VA server, and hard copies of any of these files will be stored in a locked file cabinet in the locked office of study personnel.

We will guard against the individual identification of participants in transcripts and research reports by using study IDs and by not identifying specific research sites. These data will be accessible only to the PIs, study staff and the appropriate data management personnel in Durham. We are outsourcing transcription of recorded interviews to the VA Salt Lake City's Professional Transcription Service in order to ensure timely availability of qualitative data for the purposes of qualitative analysis. The audio recordings to be transcribed will be placed in a dedicated sub-folder of the study's shared folder on the Durham HSR&D P Drive, and approved VASLC Transcription staff will access files and complete tasks within this folder. No data will leave the Durham VAMC.
Electronic data will only be stored and accessed through secure VA servers and other VA information systems. Access to primary data will be restricted to those members of the research team with specific need to perform their duties. Data will not be removed from designated VA computer systems, except for archiving at study completion.

## DATA AND SAFETY MONITORING PLAN

This study carries minimal risk of unexpected or adverse events. The patient and provider data will remain on secure VA servers. Any paper copies of data will always remain in locked cabinets. All aspects of this study are of minimal risk. Unexpected or adverse events are highly unlikely in this study. In the highly unlikely event that a study-related serious adverse event should occur, it will be reported per Durham VA Medical Center IRB requirements. Any other adverse events, serious adverse events and protocol violations will be reported at Continuing Review per Durham IRB requirements.

Analyses

*Aim 1: To evaluate **implementation** of STRIDE and iHI-FIVES at REP alone versus REP + CONNECT sites.*

We hypothesize that sites randomized to REP + CONNECT will have higher **penetration** (for STRIDE that is the proportion of eligible patients with ≥ 1 documented walk during hospitalization, higher total daily minutes of activity and distance walked, and higher proportion of eligible patients who report their providers wanted them to walk while they were in the hospital; and for iHI-FIVES that is the proportion of eligible caregivers reached by iHI-FIVES in a 6-month interval and the proportion of providers involved in caregiver support who refer caregivers to participate in iHI-FIVES in a 6-month interval) and **fidelity** (higher proportion of STRIDE participants with ≥ one documented supervised walk, and with ≥ 10 minutes of daily walking); for iHI-FIVES proportion of sites that delivered at least two rounds of iHI-FIVES trainings in a 6-month interval during post-implementation and the proportion of training rounds from the total number offered in which the full iHI-FIVES core curriculum topics were covered). For Aim 1, outcomes are defined in the post-implementation period only and the primary analyses will be for the outcomes in the first post-implementation 3-month period so that analysis will not be confounded with time since implementation. For the dichotomous outcomes, we will use logistic regression models[55-57] where the main predictor of interest will be REP vs. REP + CONNECT adjusting for clustering of VAMC with either a random effect or by conditioning. For continuous outcomes, we will use linear mixed regression models.[58] Adjustments for patient characteristics and a random effect for hospital ward may also be added. In hospitals that have multiple post-implementation 3-month measurement times, we will examine how fidelity and penetration outcomes change over time using descriptive methods (e.g. plots, descriptive statistics, subgroups).

In addition to testing the above quantitative hypotheses, we will use semi-structured interviews with providers to elicit their experience with implementation process and evaluation of outcomes. Specifically, we will ask providers questions about team processes, for example, *How do team members communicate with each other*

*and how are decisions collectively made?*, as well as questions about effectiveness of implementation strategies. We will code interviews using both *a priori* labels of team processes and implementation outcomes and data derived labels to reflect respondent description of implementation. We will aggregate this individual-level data into site-level case memos, structured according to interview questions and *a priori* measures. We will then develop a matrix to compare reports of implementation processes and outcomes between REP and REP + CONNECT sites. The rows of the matrix will reflect *a priori* implementation measures and the columns will reflect whether responses are from REP or REP + CONNECT sites. Coded data within each matrix cell will reflect description of the implementation process or outcome, coded with descriptive labels (e.g., regular, in-person meetings), and we will assign valence to indicate whether data indicate facilitators or barriers to implementation. At least two researchers will independently code transcripts and assign valence to data and then will meet to compare codes and resolve discrepancies.[59]

*Aim 2a: To examine the **impact** of STRIDE on patient outcomes.*

To address Aim 2, we will utilize quantitative and qualitative methods with simultaneous collection of and equal weight given to both data types (QUAN + QUAL) to evaluate impact of program on patient outcomes.[48] These two approaches will be used in a complementary way to answer related questions, in this case how STRIDE impacts patients. We will merge the two analyses together to present an in-depth assessment of program impact, both in terms of clinically relevant measures as well as from patient priorities, which may or may not match *a priori* clinical measures.

Quantitative analyses for Aim 2 will be conducted at the level of the patient, utilizing all available data to evaluate STRIDE effectiveness on defined dichotomous, count and continuous outcomes. The overall anticipated sample size of eligible STRIDE patients during pre- and post-implementation periods is 2000. The anticipated maximum sample is 16,000. Only a subset of STRIDE eligible patients will receive survey measures in both the pre- and post-implementation periods. We will use random effect linear (continuous outcomes), negative binomial (count outcomes), or logistic (dichotomous outcomes) models appropriate for the stepped-wedge design which account for the correlation of patients within the same VAMC.[34,60] For example with a continuous outcome, I VAMCs, T time points, N individuals per VAMC per time interval, the model is: $Y_{ijk} = \mu + \alpha_i + \beta_j + X_{ij}\theta + e_{ijk}$, where $\alpha_i$ is the random effect for the ith VAMC, $\beta_j$ is a fixed effect that captures time trends, and $X_{ij}$ is an indicator of the intervention mode for the ith hospital at time j (=0 prior to intervention and =1 post intervention), and $\theta$ is the measure of the effect of the intervention. Adjustments for patient characteristics and a random effect for hospital ward may also be added.

Qualitative data will be collected via 30-45 minute semi-structured telephone interviews with a sample of patients in STRIDE. Interviews will be audio recorded. We will ask patients about whether they found STRIDE to be helpful for them and in what ways and if they have suggestions for improvement. We will analyze data using conventional content analysis, in which we will transcribe interviews and then code text with descriptive labels that are developed as we read through transcripts. Data will be coded by a team process as described in Aim 1. Findings from Aims 1 and 2 will be supplemented by **budget impact analyses**

*Aim 2b:* To examine the **impact** of iHI-FIVES on key patient and caregiver outcomes.

To address the impact of the iHI-FIVES program, we will use quantitative methods to examine the effect on patient outcomes. The overall anticipated number of eligible Veteran patients in the iHI-FIVES study will be 15,000-18,000 total patients. The analysis plan of our primary outcome is to examine days at home for the patient over a 6-month interval and will be defined as the total number of days not in the emergency department, nursing home, or inpatient ward. The start date for each patient, or the day of the automated data pull, will be “day 0” for all patients, and the maximum total possible number of days at home will be 180 for all patients. To make this outcome variable easier to deal with analytically, our first step will be to calculate each patients' days not at home by subtracting their number of days at home from 180, converting the “stack” of days at 180 to a “stack” at zero. For days not at home outcome, we anticipate, that it may have an excess of zeros and larger variance than what is to be expected from either a Poisson or Negative Binomial process. Common approaches for analyzing this type of data are the zero-inflated Poisson (ZIP) model and the zero-inflated negative binomial (ZINB) model[116] or two-part models.[117,118] Consequently, we will explore the distribution that best fits this outcome: Poisson, Negative Binomial, ZIP, ZINB, or a semi-continuous distribution such as a two-part gamma.[119]

To address if caregivers who participate in iHI-FIVES have higher satisfaction with VA care, lower depressive symptoms, and lower burden, analysis will be conducted at the level of the patient or caregiver utilizing all available data to evaluate iHI-FIVES effectiveness versus control condition on defined count and continuous outcomes. The overall anticipated sample size of eligible caregivers in the iHI-FIVES study will be 320. We will

use random effect linear (continuous outcomes), negative binomial (count outcomes), or logistic (dichotomous outcomes) models appropriate for the stepped-wedge design which account for the correlation of patients within the same VAMC.[34,60] For example with a continuous outcome, I VAMCs, T time points, N individuals per VAMC per time interval, the model is: $Y_{ijk} = \mu + \alpha_i + \beta_j + X_{ij}\theta + e_{ijk}$, where $\alpha_i$ is the random effect for the ith VAMC, $\beta_j$ is a fixed effect that captures time trends, and $X_{ij}$ is an indicator of the intervention mode for the ith hospital at time j (=0 prior to intervention and =1 post intervention), and $\theta$ is the measure of the effect of the intervention. Adjustments for patient characteristics and a random effect for VAMC site may also be added.

*Sensitivity analysis.* In addition to the primary analysis of the primary and secondary outcomes described above, we will perform an "as treated" analysis focused on the outcomes of Veteran patients from caregivers in the post-implementation period exclusively. This will show us whether there is benefit conferred upon those caregivers/Veterans in the iHI-FIVES program compared to similar caregivers/Veterans not in the program. The treated caregivers will be all caregivers who meaningfully participated in the iHI-FIVES training (e.g., attended at least one class). The comparison caregivers will be selected from the full set of caregivers referred to iHI-FIVES using n:1 matching on key baseline covariates of the patient and caregiver. The rationale for matching on key Veteran baseline covariates is to ensure that we have similar Veteran acuity in both groups, because the training may be differentially effective for caregivers by level of Veteran disability. Candidate matching variables for the patient include:

- Patient age bands
- Patient Jen Frailty Index Score (0-10)
- Patient CAN scores (1 year inpatient use version)
- Dementia status based on ICD9 codes in the past 6 months
- Documentation of incontinence in the past 6 months

Based on the sample size, we may use only a subset of these matching variables, and use exact and distance-matched methods. Candidate matching variables for the caregiver will include: age, race, employment status, education, and caregiver relationship to the Veteran. We will use the same analysis techniques for the "as treated" analysis as described above. Or we may simply use regression adjustment if sample size is too low, from the candidate set of covariates described here.

To address the value of iHI-FIVES from the caregiver's perspective, qualitative data will be collected via 15-20-minute semi-structured telephone interviews with a sample of caregivers who participate in iHI-FIVES. Interviews will be audio recorded. We will ask patients about whether they found iHI-FIVES to be helpful for them and in what ways and if they have suggestions for improvement. We will analyze data using conventional content analysis, in which we will transcribe interviews and then code text with descriptive labels that are developed as we read through transcripts. Data will be coded by a team process as described in Aim 1. Findings from Aims 1 and 2 will be supplemented by **budget impact analyses.**

*Aim 3: To determine the **conditions** under which STRIDE implementation is most successful.*

As described for Aim 1, Aim 3 outcomes are defined in the first post-implementation 3-month period so that analyses will not be confounded with time since implementation. To examine the relationship between team function and dichotomous implementation outcomes, we will use logistic regression models[57] where the main predictors of interest will be the baseline TDM© scores (e.g., overall, and team dimensions such as cohesion and role clarity) adjusting for clustering of VAMC with either a random effect or by conditioning.[55,56] Other responses from the provider survey instrument may collectively reflect other dimensions of team function. Using exploratory factor and cluster analysis methods, the implementation core will determine the appropriateness (i.e., with our operational partners) and reliability of constructing other composite measures of team function that will be incorporated in quantitative analysis to examine teams' mediating/moderating effects on implementation outcomes. For continuous outcomes, we will use linear mixed regression models.[58] In VAMCs that have multiple post-implementation 3-month measurement times, we will examine how fidelity and penetration outcomes change over time by TDM© scoreteam function using descriptive methods (e.g. plots, descriptive statistics, subgroups). Adjustments for covariates and a random effect for VAMC ward may also be added. If scores of team function are associated with implementation outcomes, we will explore whether they differentially affect implementation outcomes by patient and facility characteristics. If we find in Aim 1 that the implementation strategy REP + CONNECT improves implementation outcomes compared to REP alone, we will examine whether team function mediates or moderates this effect following methods of MacKinnon[52] and Kraemer.[61,62] These quantitative findings from Aim 3 will be complemented by additional **analyses of context sensitivity** as described earlier.

Sample size estimate. For STRIDE, sample size calculations were conducted for patient-level analyses evaluating impact of STRIDE on discharge to skilled nursing facility. The sample size calculation was done based on a complete stepped-wedge design using Hussey and Hughes (2007) method.[60] The sample size is based on the following assumptions for the discharge to skilled nursing facility outcome: 1) base discharge rate to skilled nursing of approximately 20%; 2) 10% drop in discharge rate after STRIDE, determined as a clinically significant gain in the outcome; 3) intracluster correlations (ICC) ranging from 0.02 to 0.6 for patients within the same hospital; 3) 8 hospital sites with 5 3-month assessment periods; and 4) alpha=0.05, power>80%. A total sample of 2000 patients (~250 per hospital, 50 per 3-month interval) will result in ≥80% power to detect a 10% reduction in discharges to skilled nursing facilities. The anticipated maximum sample is 16,000. For iHI-FIVES, the sample size calculation was done based on a complete stepped-wedge design using Hussey and Hughes (2007) method.[60] The overall anticipated number of Veteran patients will be 15,000-18,000 with a minimum sample size of 400 subjects (at least 50 per VAMC, 20 per 6-month interval). The power calculation for this sample size is based on the following assumptions for days not at home: 1) 8 is the baseline mean number of days not at home over 6 months; 2) 2-day reduction in days not at home over 6 months; 3) coefficient of variation (CV) ranging from 0.3 to 0.5 for assessments on participants within the same VAMC; 4) 8 VAMCs with five 6-month assessment intervals; and 5) alpha=0.05, power>80%. A minimum sample of 400 Veterans will result in at least 80% power to detect a mean reduction of 2 days not home assuming variance equal to the mean (Poisson distribution).

Impact. Prevention of hospitalization-associated disability is an urgent clinical priority for VHA and Veterans. By implementing STRIDE in eight VAMCs, this project will fill this key gap in inpatient care for the more than 30,000 Veterans hospitalized in these facilities annually. In addition to important positive effects on Veterans' health and satisfaction we anticipate important budgetary impact through reduction in non-VA care costs for hospitalizations at non-VA facilities due to diversion status and reduced direct costs for post-acute institutional care. Finally, testing REP alone and REP + CONNECT will inform dissemination efforts. If the lower budget impact strategy of REP alone has the equivalent impact on individual outcomes, it may be preferred over REP + CONNECT.

Implementation of iHI-FIVES is expected to increase quality of care for vulnerable Veterans by better supporting the caregivers who care for them. In turn, better supporting caregivers can avoid costly nursing home placements. Importantly, the implementation of iHI-FIVES targets a prevalent, heterogeneous patient population at high risk of nursing home entry—keeping these vulnerable patients independent meets the definition of patient-centered care.[121] Further, the focus on CONNECT and team-building aims to improve information flow about high-risk patients through the creation of new, cross-service teams. Increased information flow may enhance targeting of services to patients at highest risk of negative outcomes. And yet, if REP has similar impact on individual outcomes, it provides a lower budget impact option to CONNECT and will inform dissemination efforts. The project may also create positive practice spillovers by increasing provider knowledge about VA Caregiver Support Program.

The QUERI ADIL project will maximize impact based on the QUERI ACTION Framework. **Alignment**: This project aligns with both Veterans' Health Administration's priorities (i.e., "improve the uptake of strategies to address health disparities and Veteran social determinants of health") and QUERI's Strategic Plan ("integrating health equity as a core component to implementation science initiatives"). **Informing the field**: Findings will be disseminated to local Veteran advisory groups, groups of under-represented Veteran groups, operations partners, national health services conferences, media outlets, and implementation science peer-reviewed scientific journals. **Observing healthcare changes and generating new questions**: This project is anticipated to lead to at least one new QUERI or HSR&D project application.

*Environmental context* is an important consideration in our evaluation. Clinical programs and their teams operate within the broader context of local VAMCs that vary by facility complexity, organizational climate, presence of policies and practices to support innovative practices, and historical performance. These factors may work individually or in combination to support or challenge a team's ability to accomplish intended goals.

*Implementation outcomes* are the intermediate result of deliberate action in implementing new practices/services.[44] They serve as indicators of implementation processes that are the precondition for attainment of intended clinical and system-level change (i.e., program outcomes such as reductions in admission to nursing homes).

This distinction is important, as it provides more specificity of the mechanisms underlying implementation successes or failures.[44] Given the overall goals of Function QUERI and the goals of our operational partners, we will focus on 3 main types of implementation outcomes: **penetration**, **fidelity**, and **cost** (see bottom of Table 2).

***Table 2. Sample Measures from Nested Model of Team Function and Performance in Implementation***

| Measure | Definition | Data Sources |
|---|---|---|
| **Team Characteristics** | | |
| Team size | Number of members of team for clinical program delivery | Program design<br>Semi-structured interview |
| Team composition | Diversity of members within team to accomplish tasks (e.g., expertise and skill set) | Program design<br>Semi-structured interview |
| Role Clarity | Extent to which roles among team members are clearly defined and supersede individual members' professional roles | TDM© composite |
| Cohesion | Commitment in working as a collective unit to accomplish the work of the team | TDM© composite |
| **Team Processes** | | |
| Communication | Open communication and participation in handling conflict and solving problems as a collective unit | TDM© composite |
| Communication structure | Standardization and centralization of conveying key information within team and externally to related clinical units | Semi-structured interview |
| Goal and Means Clarity | Collective understanding of the work of the team and its goals, and agreement on how their goals are reached | TDM© composite |
| Decision-making | Manner in which information is exchanged and decisions are made within teams (e.g., member involvement, techniques of decision-making) | Semi-structured interview |
| Task interdependence | Degree of dependence of tasks between members within a team (team- and individual-level measures) | Program design<br>Semi-structured interview |
| Satisfaction/experience | Employee satisfaction with the outcomes of the team's work, to date. | TDM survey items #21, 23, |
| **Program/task characteristics** | | |
| Complexity | Degree to which tasks require diverse operations and skills | Program design<br>Semi-structured interview |
| Diversity | Number of different patient subpopulations served (e.g., clinical conditions) | |
| Uncertainty | Predictability in the work processes; presence of standardized processes and protocols for different clinical scenarios | |
| Program interdependence | Degree of dependence of tasks on other clinical units or departments | |
| Task interdependence | Degree of dependence of tasks between members within a team | |
| **Environmental context** | | |
| Facility complexity | Operational complexity of VAMC (e.g., patients served, case-mix, intensive care unit level, etc.) | Administrative data |
| Climate | Share perception on the degree to which clinical program is supported, rewarded, and expected within VAMC | Provider Survey<br>Semi-structured interview |
| Policies, practices, and procedures | Organizational effort to support innovative practices within VAMC (e.g., performance monitoring) | Provider/Admin Survey<br>Semi-structured interview |
| Historical performance | Prior organizational performance on related clinical metrics (e.g., adjusted length of hospital stay) | Provider Survey<br>Semi-structured interview<br>Administrative data |
| **Implementation outcomes** | | |
| Penetration | Integration of program within VAMC's relevant clinical units<br>• Similar to "reach" (e.g. number of eligible persons who receive a service, divided by the total number of persons eligible for the service) | Chart review<br>Patient/Provider Survey<br>Administrative data |
| Fidelity | Degree to which program is implemented as intended<br>• Adherence to protocol (e.g., % patients who received core elements of program)<br>• Dose and quality of program delivered<br>• Participant engagement | Chart review<br>Semi-structured interviews<br>Administrative data |
| Cost | Total implementation cost = ∑ program-related + implementation strategy + resource utilization costs | Project records, VHA salary data, managerial cost accounting data |

Analyses of context sensitivity. Organization-specific contextual characteristics are likely to affect both implementation and program outcomes, thus we will perform analyses of context sensitivity for both of Function QUERI's multi-site implementation projects (Project 1, STRIDE and Project 3, iHI FIVES). We will examine context via simultaneous collection of quantitative and qualitative data. We describe the qualitative methods for context analyses for both implementation projects here, as we will use similar techniques. Qualitative data will

be obtained through semi-structured interviews with clinical program personnel and administrative leadership. These interviews will provide rich contextual data regarding clinical program implementation, team function, and organizational context that are otherwise unobservable in clinical or administration data. For example, respondents will be asked about their VAMC's organizational climate; the importance of the clinical program to their facility; key conditions for successful implementation at their facility; their perceptions of their team's function and readiness for change; the impact of the clinical program on their workload; interactions with providers and patients; changes made to care delivery and content; barriers to implementation; satisfaction with the process; and recommended changes to the clinical program. Responses will be coded and analyzed at individual and team-levels to develop facility-level summaries of contextual factors, indicating where there is divergence in responses at the team or site-level. From this coded data, we will identify and visually display emergent themes in a matrix, with columns reflecting implementation outcomes (i.e., fidelity and penetration) arranged from high to low, to illustrate patterns in contextual factors according to implementation outcomes.

Budget impact analyses (BIA). Utilizing a similar approach across projects, we will perform BIA to frame affordability to the VHA.[73] We will calculate the budget impacts of the clinical programs and compare them to each program's value. Value will be defined in light of all of the evaluation evidence. For example, value may be framed as total budget impact per unit gain in patient function or as total budget impact compared to the clinical team's narrative on how a program benefited patients. We will also consider framing budgetary impact against different domains, such as total costs by site or costs per Veteran participant. The clinical program leads will work with the implementation core to develop appropriate comparisons.

For the BIA we will consider three cost categories: (1) program-related implementation costs; (2) implementation strategy costs; and (3) resource utilization costs. We will not consider the fixed labor costs of implementation planning (e.g. stakeholder committee time) because these are one-time costs that would not occur if the clinical programs were implemented nationally. First, for **program-related costs**, we will measure personnel time and labor costs associated with preparing for and delivering the clinical programs using micro-costing. Clinical program trainer time and clinical delivery team time (including donated FTE) will be collected through personnel time logs and periodic time studies. Personnel time will be valued using VA Human Resources salary data. In addition to labor costs, we will consider program-related capital costs such as purchased durable equipment (e.g., walkers, measuring wheels, stop watches and portable pulse oximeters). Second, we will track **implementation strategy costs,** which includes REP and CONNECT training time, training materials, and site-visit travel. Travel costs will be measured using accepted per diem reimbursement, and the cost of personnel time will be measured as described above. Third, for **resource utilization costs** we will examine patient-level utilization pre-and post-clinical program by treatment and control subjects, to understand marginal costs/savings associated with the clinical programs.

Depending on the evaluation results of implementation Projects 1 and 2, the BIA will particularly focus on comparing total costs by the implementation method of REP vs. REP + CONNECT. Since CONNECT is expected to be more time-intensive and expensive than REP, it is critical to consider the relative gains (if any) to both team function and patient outcomes from adding CONNECT training to REP. For these projects we will also consider variability in budgetary impact by site (e.g. costs may differ by low versus high penetration sites or by team composition). Thus, we will examine costs by different measures of context at each site.

**Implementation Products and Dissemination.** The development and evaluation of strategies to build and support team readiness for implementation is a unique departure from currently funded QUERI program projects and this focus promises to make significant contributions to the field of implementation science. Mapping implementation techniques to team-based constructs will inform our development of a Team Building and Readiness Toolkit for Implementation that provides guidance to practitioners on tailoring implementation strategies to care teams within local settings. Also ultimately, discoveries from our implementation of clinical programs for vulnerable Veterans at high risk for disability will be valuable to VHA for realizing priority goals of improving patient access to care, supporting employee engagement, and creating a culture of high performance; thus synthesis and dissemination of our findings in the manner most useful to VHA is a high program priority. The Durham COIN has developed dissemination strategies based upon prior experience with conception, implementation, and reporting of innovations in VA healthcare delivery; we will build on this collective experience to inform strategies for Function QUERI dissemination activities. Stakeholders play a key role in maximizing Function QUERI's value and impact. Stakeholders will have direct involvement in and across projects, setting the stage for rapid, widespread acceptance and dissemination throughout VHA clinical practice. In addition to traditional strategies for

disseminating findings, Function QUERI will provide two types of products based on project activities and evaluations.

Clinical Program Implementation Packages. Clinical program packages will be developed and refined throughout the duration of each Function QUERI project. Findings from our evaluations of the clinical impacts of STRIDE, Group PT for Knee OA, and iHI-FIVES programs' packages will prompt further refinement at the conclusion of each project. Packages will include information including: provider training manuals/materials, information sheets for referring providers to facilitate consults to the program, lessons learned, suggested administrative strategies (e.g., scheduling), strategies to promote referrals and patient/caregiver adherence to program curricula, forms/templates for documenting patient status and outcomes, recommended exercises/lecture materials, templates for clinical assessments, patient educational materials and instructions. In close collaboration with our national operational partners, polished Clinical Program Implementation Packages will be developed and disseminated to guide program implementation efforts at other VA facilities.

Team Building and Readiness Toolkit. Function QUERI will serve a unique opportunity to evaluate the value of CONNECT for enhancing implementation efforts. A shortcoming in the field of implementation science is that implementation strategies are often not specified with sufficient detail for others to replicate them in research or practice. We will translate implementation findings across the 3 projects to identify the contextual factors and components from CONNECT that improve team function and optimize effectiveness of implementation of VA clinical programs. Applying the recommended guidelines for specifying discrete implementation techniques to this synthesis,[74] we will develop a Team Building and Readiness Toolkit to prepare teams for uptake of new clinical programs. Function QUERI personnel with relevant experience in toolkit development (Mahanna, Sperber, Wang) will work closely with investigators to synthesize project findings and develop format and content for the drafted toolkit. Revisions and refinement of the toolkit will occur through two stages of review from our expert panels (Sections *2.7.2* and *2.7.3*) to ensure the toolkit is readable, comprehensive, and meets the needs of the intended audiences. We will work closely with QUERI and our operational partners to ensure presentation and dissemination of the Team Building and Readiness Toolkit to all relevant audiences in VA Central Office in the final year of Function QUERI. We will also present results at annual research and dissemination and implementation science meetings and selected online portals such as the VA QUERI webinar series, VA Pulse Implementation Research Group and the VHA CommSite. Last, we will present our findings in relevant publication venues.

## Management and Partnerships

### Key Personnel

The Function QUERI team is comprised of an interdisciplinary group of investigators and clinicians with expertise in all aspects of the proposed project. Dr. Hastings, a geriatrician, is the Corresponding PI for Function QUERI. In her roles as Director of the Durham VAMC Geriatrics Clinic, leader of GEC and Office of Rural Health (ORH)-funded T21 programs and HSR&D funded clinical trials, she has substantial expertise in local and national geriatric clinical practice, evaluation of models of care, and partnered research. Dr. Hastings has extensive clinical and research experience with Veterans with functional limitations. Dr. Hastings (Project 1), Dr. Allen (QI project and co-PI), and Dr. Van Houtven (Project 3 and co-PI) will lead Function QUERI's three clinical program projects. Dr. Allen, health services researcher and exercise scientist, examines care delivery and outcome improvements for patients with OA and other musculoskeletal conditions. Dr. Van Houtven, health economist, evaluates long-term services and supports delivery, including interventions to support informal caregivers. Dr. Wang (Co-PI) will lead the Function QUERI implementation core. With expertise in organizational behavior, Dr. Wang assesses managerial and organizational influences on healthcare service provision, care coordination, and patient outcomes. The multiple PI plan provides more detail on the roles and responsibilities of the project leaders.

The Function QUERI team has substantial experience in the following critical areas for our proposed program of work:

- **Implementation Science and Quality Management** Dr. Wang; Dr. Jackson, epidemiologist and Director of Durham COIN Implementation Science Laboratory; Dr. Sperber, public health, health behavior, and mixed qualitative and quantitative methods and member of Durham COIN Implementation Science Laboratory; Dr. Damush, health psychologist and PI of PRISM QUERI Program at Indianapolis COIN; Drs. Crevensten and Price, hospitalists and Co-Directors of Quality Management at San Francisco VAMC; Dr. Colon-Emeric, co-developer of CONNECT implementation intervention.

- **VA Operations and QUERI-Partnered Evaluation** Dr. Hastings, implementation of the STRIDE and EQUiPPED T21 QI demonstration projects, GEC and ORH; Dr. Wang, Office of Specialty Care Services, Dialysis Workgroup's National Dialysis Pilot Study, and National VA Kidney Program; Dr. Van Houtven, Director, partnered evaluation of the VA Caregiver Support Program, VA CSP; Dr. Jackson, PI of VA Chaplain Mental Health Quality Improvement Project; Drs. Jackson and Sperber, VA Lung Cancer Screening Clinical Demonstration Project, VHA National Center for Health Promotion and Disease Prevention; Drs. Sperber and Oddone collaborated on the Telephone Lifestyle Coaching (TLC) project funded by the VA National Center for Health Promotion (Damschroder, PI).
- **Quantitative and Qualitative Methodology** Dr. Coffman, biostatistician and trials methodologist; Dr. Sperber, public health and mixed qualitative and quantitative methods; Dr. Van Houtven, economic evaluation, budget impact analysis; Drs. Wang, Hastings, Allen, VHA administrative and utilization data.
- **Clinical and Functional Assessment** Dr. Hastings, mobility measures, physical function; Dr. Allen, pain and physical function measures (general and for OA); Dr. Oddone, primary care physician, interventionist and Director of Durham HSR&D COIN; Dr. Hoenig, geriatrician and rehabilitation researcher and Durham VAMC; Chief of Physical Medicine and Rehabilitation; Dr. Colon-Emeric, geriatrician researcher at Durham VAMC.

Together, the team has the necessary expertise, relevant experience, and analytic techniques required to successfully accomplish the aims of Function QUERI.

**Collaboration with National Partners.** This QUERI program will be conducted in concert with key support, feedback, and engagement with our VA operational partners (see Letters of Support). These partnerships reflect more than four years of ongoing collaboration with VA Operations, which has been instrumental in defining the gaps in clinical care and resultant clinical programs to address them: STRIDE, Group PT for Knee OA and iHI FIVES. Their continued engagement in the Function QUERI demonstrates interest and commitment to support their continued expansion across VAMCs nationwide.

Office of Geriatrics and Extended Care (GEC) funded development and dissemination of STRIDE, investing more than $350,000 to date in the program. STRIDE was developed with support from VHA Office of GEC, as part of its Transformation to the 21st Century Non-institutional Long Term Care (T21 NILTC) initiative. As part of its evaluation of the NILTC program, GEC identified limited clinical resources and difficulty hiring new clinical staff as the major barriers to implementation of new programs. Thus this partnership was very influential in Function QUERI's choice of implementation strategies that focus on providing options for tailoring clinical programs and providing options for using existing clinical resources. A major priority for GEC is disseminating programs that have been developed through the T21 NILTC initiative; thus the knowledge gained about implementation strategies will be of immediate use and value to GEC. GEC will assist Function QUERI in recruiting sites for STRIDE participation, and also providing access to data through the GEC Data Analysis Center.

VA Caregiver Support Program (CSP) is committed to the implementation of iHI-FIVES and advising on all program projects. This partnership is critical to perform the work, because Ms. Kabat will seek volunteer sites from the field, and will also provide data on caregivers enrolled in the CSP. Importantly, the CSP is dedicating tangible support of a 1.0 FTE Caregiver Support Coordinator (Josh D'Adolf) for four years to aid in Project 3 for training the team to deliver HI-FIVES, strategizing with sites on recruitment preferences, and providing ongoing phone and in-person support (see letter of support from Meg Kabat). Findings from HI-FIVES in Project 3 are critical to CSP, as the Office considers further expansion of HI-FIVES caregiver training programs and foci.

Physical Medicine and Rehabilitation (PM&R) Services are provided in a variety of settings including acute medical, surgical, and psychiatric units, and community living centers (CLC), with a goal of facilitating Veterans' ability to remain in the most independent and least restrictive living environment through therapeutic interventions. PM&R operates from a physician directed, interdisciplinary team-based model of care designed to increase independence and improve quality of life for Veterans with disabilities, which is directly aligned with the goals and focus of Function QUERI. PM&R leadership will provide important clinical and operational input on STRIDE and Group PT and will assist in recruiting sites for STRIDE.

Office of VA Voluntary Services (VAVS) coordinates activities for more than 140,000 volunteers who provide more than 11 million hours of service to America's Veterans. Ms. Sabrina Clark, National Director, will serve on the Advisory Board for Function QUERI. She is actively working with Dr. Hastings and Ms. Ronni Miller, Director of Voluntary Services at the Durham VAMC to develop a volunteer-based walking program in Durham that will serve as a model for other facilities that want to use volunteers.

VA Mid-Atlantic Healthcare Network (VISN 6). Network Director Mr. Hoffman has directed all medical centers in VISN 6 to develop a STRIDE program and has asked Dr. Hastings and the Function QUERI team to lead this

effort. Drs. Hastings, Wang, and Jackson have experience working with VISN 6 leadership and medical centers conducting quality improvement projects.
With our Partners' input, we will seek commonality in the service delivery challenges facing VA providers' ability to serve vulnerable Veterans with impaired function and will work collaboratively to address these gaps. We will keep our national partners notified bi-annually regarding progress toward mutual implementation goals. We will also convene 3 in-person meetings in which national stakeholders and the QUERI program will share information to actively develop a short- and long-term vision of clinical and managerial processes in VHA to restore and sustain patient function and independence.

**Program and Implementation Advisory Board.** Function QUERI has formed an Advisory Board consisting of clinical and operational leaders from national partner program offices, experts in implementation science and Veterans. The Advisory Board will ensure that the proposed program activities are responsive to clinical needs for rigorous information and that results are disseminated effectively and fully. Specifically, the Advisory Board will assist with oversight and decision-making about implementation strategy development, individual project design, evaluation, and dissemination of implementation activities across clinical programs. It will also keep the team abreast of anticipated changes at VA that might influence implementation activities, provide input on the development of intervention packages for each clinical program, and advise on the Team Building and Readiness Toolkit and other dissemination strategies most useful for VA policy and operations. Program investigators will convene with the Advisory Board in-person during the first year of the program, to kick-off implementation activities and evaluation plans. We will then meet with the Advisor Board semi-annually, by telephone, for review and assessment of: research implementation and evaluation plans, interpretation of results, and materials prepared for dissemination.

The Function QUERI Advisory Board includes key members from each of our national partner program offices, as described above. These will include **Kenneth Shay (GEC**) Director of Geriatric Programs, **Karen Massey (GEC)** Chief, GEC Strategic and Transformational Initiatives, **Margaret Kabat (CSP)** Director, Caregiver Support Program Office, **Joel Scholten (PM&R),** Director, Office of Physical Medicine and Rehabilitation, and **Sabrina Clark (VAVS),** Director, VA Voluntary Service. In addition, the Function QUERI will receive ongoing consultation and guidance from leading experts in various aspects of Implementation Science, including:
**Laura Damschroder, MS, MPH**, a research scientist at the Ann Arbor VA and University of Michigan. She led development of an implementation framework, the Consolidated Framework for Implementation Research, which is being used in studies around the world. She is currently and has been on several invited national expert panels related to implementation and sustainability of evidence-based practices. Other Advisory Board members are:
**Ruth Anderson, PhD, RN, FAAN**, is Associate Dean for Research in the UNC School of Nursing. Together with Dr. Colon-Emeric (study Co-I) she developed and tested the CONNECT for Quality intervention to reduce falls in nursing homes (NIH/NINR; R01NR003178).
**Hector Rodriguez, PhD**, Associate Professor in Health Policy and Management and Co-Director of the Center for Healthcare Organizational Innovation Research at the University of California Berkeley School of Public Health, is a medical and organizational sociologist who conducts organizational and outcomes research on enhancing teamwork and team effectiveness to improve the quality of care for chronic illness in medical groups, community health centers, and the VHA.
**Byron Powell, PhD**, Assistant Professor in Health Policy and Management at the UNC Gillings School of Public Health, is an implementation scientist who conducts research on the strategies and organizational factors that facilitate the implementation of evidence-based practices in community-based behavioral health and social services.
**Morris Weinberger, PhD**, Core Investigator with the Durham HSR&D COIN and Distinguished Professor in Health Policy and Management at the UNC Gillings School of Public Health, is a health services researcher who develops and evaluates innovative strategies within health care systems to improve the process and outcomes of care for medically vulnerable patients, including Veterans.
**Bryan Weiner, PhD**, Professor in Health Policy and Management at the UNC Gillings School of Public Health, is an organizational psychologist who conducts research on the adoption, implementation, and sustainability of innovations and evidence-based practices in health care organizations. Dr. Weiner is also the UNC Director of the Consortium for Implementation Science, fostering collaborations in research, practice, policy, and training to advance theory (e.g., organizational readiness for change), methods, and measures in dissemination and implementation research.

**Veteran and Caregiver Engagement Panel**. In addition to our close partnerships with clinical and operations stakeholders, the Function QUERI will engage a group of Veterans and caregivers throughout the projects. Our COIN has recently begun a Veterans Engagement Panel (co-led by Dr. Allen), and we have developed specific processes for identifying and involving Veterans meaningfully in this panel. The Function QUERI Panel will be based on those processes, as well as the experiences of the project leads with other patient stakeholder groups. The panel will have representation from key groups relevant to each of the projects (e.g., older Veterans with recent hospitalization, Veterans with knee OA, Veterans with recent referrals to home care services and their caregivers), as well as representation of women and minority Veterans. We expect the full panel will include about ten individuals. We will aim to convene the full panel twice annually (including one meeting during the first month of the funding period), and smaller panels will meet more frequently to advise on each specific project. The perspectives of this panel will be instrumental for bringing the Veteran and caregiver perspectives to all phases and aspects of the projects, including patient-centered outcomes (e.g., satisfaction measures), logistics of the clinical programs, and patient characteristics to include in analyses.

**Program Timeline and Metrics**. We propose a 5 year program of work for Function QUERI. Specific project and implementation core activities are outlined below. Key metrics will include initiation of Implementation Project 1 (STRIDE) and Local QI project 2 (Group PT for Knee OA) in Year 1, completion of a white paper on CONNECT and completion of Local QI project in Year 2, completion of implementation project 1 (STRIDE) in Year 4 and implementation project 3 (iHI FIVES) in Year 5. In Year 5 we will also synthesize and dissemination findings via a Team Building and Readiness Toolkit.

| | YEAR 1 Quarter | | | | YEAR 2 Quarter | | | | YEAR 3 Quarter | | | | YEAR 4 Quarter | | | | YEAR 5 Quarter | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| **Implementation Project 1: STRIDE** | | | | | | | | | | | | | | | | | | | | |
| Train staff, draft intervention package, landscape site visits | | | | | | | | | | | | | | | | | | | | |
| Baseline data collection | | | | | | | | | | | | | | | | | | | | |
| STRIDE implementation | | | | | | | | | | | | | | | | | | | | |
| Evaluation: surveys, interviews, and medical record review | | | | | | | | | | | | | | | | | | | | |
| Analyses, reports to partners, manuscripts | | | | | | | | | | | | | | | | | | | | |
| **Local QI Project 2: Group PT for Knee OA** | | | | | | | | | | | | | | | | | | | | |
| Group PT for Knee OA implementation | | | | | | | | | | | | | | | | | | | | |
| Evaluation: surveys, interviews | | | | | | | | | | | | | | | | | | | | |
| Analyses, reports to partners, manuscripts | | | | | | | | | | | | | | | | | | | | |
| **Implementation Project 3: HI FIVES** | | | | | | | | | | | | | | | | | | | | |
| Train staff, draft intervention package, landscape site visits | | | | | | | | | | | | | | | | | | | | |
| Baseline data collection | | | | | | | | | | | | | | | | | | | | |
| iHI FIVES implementation | | | | | | | | | | | | | | | | | | | | |
| Evaluation: surveys, interviews, and medical record review | | | | | | | | | | | | | | | | | | | | |
| Analyses, reports to partners, manuscripts | | | | | | | | | | | | | | | | | | | | |
| **Implementation Core** | | | | | | | | | | | | | | | | | | | | |
| Adapt CONNECT and prepare white paper | | | | | | | | | | | | | | | | | | | | |
| Implementation evaluation and analyses | | | | | | | | | | | | | | | | | | | | |
| Develop and disseminate Team Building and Readiness Toolkit | | | | | | | | | | | | | | | | | | | | |

**Privacy, Confidentiality, and Information Security**

**1. Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:**

The Personal Health Information that will be obtained, used, and/or shared for this study includes:

| Identifier(s) | Source(s) of Health Information |
|---|---|
| ☒ Names | ☒ Medical history & physical exam information |
| ☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: addresses to mail patient and caregiver opt-out letters and written statement regarding the research. Zip code used to determine rural-urban community area (RUCA) code and census tract will be used to determine Neighborhood Deprivation Index (NDI). | ☒ Photographs, videotapes, audiotapes, or digital or other images |
| ☒ 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, Describe: birth date, admission and discharge dates, referral dates, ED visit dates, date of enrollment | ☐ Biologic specimens (e.g., blood, tissue, urine, saliva). Describe: |
| ☒ Telephone numbers | ☒ Progress notes |
| ☐ Fax numbers | ☐ Diagnostic / Laboratory test results |
| ☒ Electronic mail addresses (to email providers study information and a survey link) | ☐ Operative reports |
| ☒ Social Security Numbers | ☐ Imaging (x-ray, CT, MRI, etc.) |
| ☒ Medical record numbers | ☒ Discharge summaries |
| ☐ Health plan beneficiary numbers | ☒ Survey / Questionnaire responses |
| ☐ Account numbers | ☐ Billing records |
| ☐ Certificate and/or license numbers | ☐ HIV testing or infection records |
| ☐ Vehicle identifiers and serial numbers, including license plate numbers | ☐ Sickle cell anemia information |
| ☐ Device identifiers and serial numbers | ☐ Alcoholism or alcohol use information |
| ☐ Web Universal Resource Locators (URLs) | ☐ Drug abuse information |
| ☐ Internet Protocol (IP) address numbers | ☐ Mental health (not psychotherapy) notes |
| ☐ Biometric identifiers, including finger & voice prints | ☐ Psychological test results |
| ☐ Full-face photographic images and any comparable images | ☐ Genetic testing |
| ☒ Any other unique identifying number, linked study ID, characteristic, or code, describe: Study ID numbers | ☐ 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.

**2. Data and/or Specimen Acquisition:**

Data for this study will be collected through (*check all that apply*):

☒ Prospective data and/or specimen collection obtained from participants. Provide description of processes:

Please see p. 11-14 in the protocol for a description of the data collection process for STRIDE. Please see p. 11-12 and p. 15-20 in the protocol for a description of the data collection process for iHI-FIVES.

☒ 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 protocol p.12-14 for a description of CDW, VistaWeb and medical chart review data collection for STRIDE and p. 15-19 for iHI-FIVES. Utilization data will be downloaded directly from national files to the Durham HSR&D COIN servers or the secure VINCI environment.

☐ 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: .

*Note: for data and/or specimens obtained from a VA approved data repository, a Data Use Agreement (DUA) must be executed prior to obtaining data and/or specimens. See VHA Handbook 1200.12 for further information.*

**3. 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:

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

A. Data and/or Specimen Location: OITDURSQLRESCH.VA.GOV (SQL database server), \\OITDURHSMSMB601.va.gov\Durham_HSRD_R (shared document folder), and vhadurhsrd-sas1.v06.med.va.gov (SAS server temporary storage).

Data will be stored electronically - See above. Data that will be stored electronically include - See protocol p. 10-19.

Paper records of data include participant study folders with records of enrollment dates, informed consent and any data collection instruments administered in paper form; will be stored in locked file cabinets (#129 6th floor), Legacy Tower.

☒ Data will also be placed at the VA Informatics and Computing Interface (VINCI; http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx). The VA Informatics and Computing Infrastructure is a partnership between the VA Office of Information Technology and the Veterans' Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).

B. Data Retention Plan

☒ Research records will be maintained and destroyed according to the National Archives and Records Administration, Records Schedule Number: DAA-0015-2015-0004. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Currently, destruction of research records (see DAA-0015-2015-0004, section 7.6 "Research Investigator Files" for materials included in research records) is scheduled for 6 years after the cut-off (the cut-off is the completion of the research project) and may be retained longer if required by other federal agencies. Records will not be destroyed without pre-notification to the facility records manager. .

☐ Other data retention plan, describe:

**5. Data Access and Data Recipients**

All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. 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.

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

**I.** ☐ Data and/or specimens will <u>not</u> be transported or transmitted outside of Durham VAMC environment.

**II.** ☐ Data and/or specimens will be transported BETWEEN sites that are under the auspices of the Durham VA Medical Center.

a. ☐ Local DVAMC memorandum "Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities" has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials.

b. ☐ Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container):

<u>NOTICE!!!</u>

<u>Access to these records is limited to: AUTHORIZED PERSONS ONLY.
Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.</u>

**III.** ☒ Data and/or specimens will be transmitted to <u>other VA sites</u> 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 securely from other VAs to the Durham VA using a VA-approved travel scanner, scanned as an image file on a QUERI staff member's VA-issued, FIPS 140-2 encrypted laptop. The file will be uploaded to a HSR&D secure server when back in Durham. If the VA network is available at the participating VA and QUERI staff laptops can successfully access the network, the file will be uploaded while at the site. If wi-fi is available at the site or the hotel where QUERI staff are staying, the file will be uploaded securely through VPN to the Durham VA HSR&D server. If the travel scanner and secure transmission is not available, the paper data will be sealed in a in a VA business-reply envelope and sent to the Durham VA.

☐ 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:

**IV.** ☐ 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 > 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.

**7. 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 subjects' 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 Illume survey databases on server OITDURSQLRESCH.VA.GOV, project shared document folder OITDURHSMSMB601.va.gov\Durham_HSRD_R and vhadurhsrd-sas1.v06.med.va.gov (SAS server temporary storage).Access to database and file systems is granted to research personnel via membership in Active Directory security groups created by OI&T and 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 that will be temporarily stored on a VA-issued laptop will be stored in a FIPS-140-2 encrypted hard-drive. 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:

**8. 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).

**9. 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:

***10.*** **Future Use of Data:**

☐ Data will be retained for future use. This is described elsewhere in the protocol and is noted in the HIPAA authorization.

☐ Future Use of data is optional (i.e., not required by the research subject).

☐ Future Use of data is required for participation in the study.

☒ No future use of data is currently planned.

**11.** Use of Mail Merge Technology N/A
☒ Mail merge programs will be used to generate letters and/or address labels for mailings to potential or already enrolled research subjects. The study team is aware that to reduce risk of mail merge related privacy

incidents, use of mail merge programs requires a 25% accuracy check to verify that (potential) research subject name and mailing address are properly “matched”.  If discrepancies are found, a 100% accuracy check is required before letters may be mailed.

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Provide references, if applicable.

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