Response to Reviewers' Critiques

1. A *Hybrid Type 2 design may be less appropriate for an intervention that already has been studied in a RCT and has significant supporting data. The proposal lacked details on the preliminary data presented from the RCT and how these data inform feasibility of the proposed study with regards to recruitment, site selection and retention.*

The design of the study is revised to Hybrid Type 3 in order to focus more on implementation issues, as recommended by the reviewers. Although the Home Safety Toolkit (HST) was tested in one individual RCT, the outcomes were significantly improved in the intervention group. In addition to strong efficacy data, there is strong indirect evidence of the consequences of delayed action from population studies of dementia, implementation momentum from recent caregiver legislation, and advocacy from patients and providers. The Type 3 Hybrid Design will allow us to study the conditions that will support and accelerate translation of the HST into every-day practice.

With a Hybrid Type 3 study design, we are no longer proposing a Cluster Randomized Trial (CRT), thus the issues regarding recruitment, site selection and retention are also revised. Nevertheless, the CONSORT table in Appendix 4 demonstrates the feasibility for conducting the study. The RCT was conducted in 3 specialty clinics – two at VAMCs and one at an NIA funded Alzheimer's Disease Center, where the population of patients that are seen in these clinics is smaller than PACT clinics, and where only Veterans with a diagnosis of probable dementia of the Alzheimer's type were included. In the proposed study, we will implement the HST in PACT clinics where the majority of Veterans with dementia receive care, and will include all ICD 9 diagnoses for dementia, not just Alzheimer's disease, because Veterans with other dementias are likely to benefit from the HST also.

In the RCT, 23% of subjects that were referred were subsequently considered ineligible or refused. At Bedford VAMC in FY 12, there were 832 unique patients with an ICD-9 dementia diagnosis living in the home and community. Using an estimate of 25% ineligibility, approximately 600 Veterans would be eligible to receive the HST. In the RCT, another 15% were excluded from the study after randomization due to a change in their eligibility status/inclusion criteria, e.g. unanticipated nursing home placement. Applying this rate of attrition to all patients in Bedford with an ICD-9 diagnosis of dementia would leave an estimated 530 potential recipients of the HST. The numbers of Veterans with an ICD 9 diagnosis of dementia is proportionally higher in the larger participating sites, such as VA Boston Health System, where there are 1739 unique patients with such a diagnosis. Applying the estimates of 25% ineligibility and 15% attrition to the population at VABHS leaves approximately 1100 Veterans/caregivers who could receive a HST. We expect similar numbers of eligible Veterans/caregivers at the remaining four participating sites.

2. *The effectiveness aim has major flaws that limit its ability to answer the key question about the intervention. The extent to which the study is conducted in specialized geriatric clinic settings severely limits generalizability.*

The effectiveness aim has been revised to be more appropriate for a Type 3 hybrid design and to answer the key question: Are Veterans with dementia receiving the HST? We use the RE-AIM evaluation model for Aim 2 of the study, in order to focus on understanding the conditions that are necessary to achieve the outcomes shown to be significant in the prior individual RCT, for example, are there subgroups of Veterans/caregivers who are more likely to receive a HST related to length of time since

diagnosis, number of co-morbidities, frequency of healthcare utilization, characteristics of the PACT where they receive care.

In addition, we will not use specialized geriatric clinics in the study. The original intent was to understand aspects of the "inner setting" that might influence implementation, but this is incidental to the major aims of the study and not needed in order to promote implementation in PACT/primary care settings where the majority of Veterans with dementia receive care.

3. *Reviewers had concerns about the cluster randomized design and randomization plan. It appears that caregivers were being selected differently at intervention and control sites.*

A different approach to the effectiveness aim is proposed in this revised study that is now using a Hybrid type 3 design without intervention and control sites. A CRT is no longer proposed because there is strong efficacy data from the individual RCT and a large CRT is unlikely to add more information about the primary outcomes of caregiver self-efficacy and strain, and Veteran risky behaviors and accidents. Further, the outcomes of import in the RCT are very difficult to measure in the sample size that is required for a CRT in order to account for intra-class correlations. There are no automated, routinely collected data on caregiver self-efficacy and caregiver strain, nor Veteran risky behaviors, making it resource-intensive to conduct a CRT where these repeated measures have to be collected for individual Veterans and Caregivers.

4. *Data analysis plan is lacking detail and specificity. The proposal was vague about the qualitative and quantitative analyses.*

Substantial detail has been added regarding the proposed qualitative and quantitative analyses. The methods for AIM 1 are guided by the PARIHS framework and definitions and measures of elements and sub-elements in seminal publications. We give examples of the interview schedules and expand on the analytic framework that will be used to understand the PARIHS elements of Context and Evidence, which is the first step to developing the Facilitation strategies that promote Successful Implementation. We also provide revised quantitative analyses for supplemental information from the Organizational Readiness to Change Assessment (ORCA) tool where we will compare scores across sites. We also provide statistical analyses for understanding characteristics of subgroups of Veterans/caregivers, i.e. those that receive a HST and those that do not.

5. *Budget seems high for the research question addressed. It is recommended that the PI focus on the implementation tasks and reduce resources devoted to the project.*

The budget has been adjusted, primarily for the percent of Research Assistant time, which is reduced with the elimination of the CRT and focus on implementation milestones as measured by the Stages of Implementation Completion (SIC) measure. The budgeted time for the project coordinator at VISN 6 is also reduced because there are no intervention and control sites. We continue to request a full-time project director at VISN 1 because the design of the study requires time for interviews, qualitative data analysis, facilitation strategies, and coordination between two VISNs and 6 sites. While the directly collected data is by site and therefore a smaller number than individuals in a CRT, the data are updated regularly for audit and feedback to the clinical providers. In addition, elements in the RE-AIM evaluation model as well as SIC rely on observation

and field notes that require someone who is familiar with clinical issues and comfortable in a clinical setting.

6. *The investigators are not collecting information on whether homes are safer after the intervention.*

As above, the individual RCT, with equivalence between the intervention and control groups, revealed significant differences in the degree of home safety in the group with the Home Safety Toolkit. As with measures of caregiver self-efficacy and strain, the measurement of home safety is not a routine, automated variable and thus collections of these data would require interviewing every Veteran/caregiver in the study. Instead, we accept the results of the RCT that the intervention group using the HST had significantly better home safety than the control group. In the redesigned Type 3 Hybrid study, we will focus on other conditions that might contribute to the successful acquisition and use of the HST in operational settings (PACT) e.g. time since diagnosis, number of co-morbidities, characteristics of the PACT team where the Veteran receives care.

With the redesign of the proposal to a Type 3 Hybrid design, and the elimination of the CRT, the quantitative analyses are also revised. We employ the Organizational Readiness to Change Assessment (ORCA) tool to enhance the qualitative analyses in Aim 1 in order to collect data from a large group of staff where a large number of individual interviews is both unrealistic and probably unnecessary. We use descriptive statistics to share results with individual sites to inform the facilitation strategies to promote implementation. We also can compare results of ORCA to examine patterns of facilitators and barriers across the six participating sites to supplement the selection of implementation strategies and to study patterns of unique site characteristics that suggest particular implementation strategies.

With the resign of the proposal to focus on implementation tasks, we are using the instrument Stages of Implementation Completion (SIC) to monitor the implementation plan and to measure effectiveness of implementation. Founded on the idea that implementation can be conceptualized as a recursive process, the SIC is a stage-driven assessment tool comprised of eight main stages, each with its own set of sub-activities.[37] While the posited eight stages are assumed to unfold within three phases of implementation (i.e., pre-implementation, implementation, and sustainability) and represent important milestones that are required for successful implementation, the sub-activities that correspond to each stage represent observable tasks that are required to complete each stage.[37,38] As a measure, the SIC is date-driven and involves the computation of three scores: (1) the number of stages completed (stage completion); the length of time spent in each stage (i.e., stage duration), and the proportion of activities completed in each stage (i.e., proportion score).

7. *The proposal would have been strengthened if publications reporting RCT findings were submitted as an appendix.*

The manuscript is in review and thus is not appended, however in response to Reviewer 2, analytic tables for MANCOVA (multiple analysis of covariance) and Means and Confidence Intervals are added to information about prior work in the Research Plan. These findings have been presented following peer review of abstracts and our study was selected for a plenary presentation at the HSR&D annual meeting in 2011.

1.0 Specific Aims

There are an estimated 333,105 Veterans with dementia of the Alzheimer's type or a related disorder enrolled in the Veterans Health Administration (VHA), of which 206, 006 are currently receiving services.[1] Persons with dementia are at greater risk of accidents and injury in the home because of the cognitive and functional impairments associated with the illness.[2,3] Hospitalization of a person with dementia can be catastrophic with a significantly greater risk of death, institutionalization or further cognitive decline.[4] During an illness trajectory that can last from 4 – 20 years, 80% of the person's care is provided by family and friends.[5] Family caregivers absorb the largest costs of care in both dollars and emotional distress, with caregiver burden and depression contributing to institutionalization of the person with dementia.[6]

An evidence-based intervention, the Home Safety Toolkit (HST), was tested in a randomized clinical trial (RCT) and demonstrated significant findings on both caregiver and care-recipient variables.[7] The HST consists of a learner-verified booklet, "Keep the Home Safe for a Person with Memory Loss" (Appendix 1) and frequently used home safety items (Appendix 2) for Veterans with dementia. Dissemination of findings from the RCT to clinical audiences have been received enthusiastically, with recommendations to include the Prosthetics & Sensory Aids Service and Caregiver Support Program as operational partners for implementation of the HST.

The purpose of this project is to study the processes necessary to make a Home Safety Toolkit for Veterans with dementia accessible to these patients and their caregivers; and to gather additional information about the effectiveness of the HST when implemented in VA Patient Aligned Care Team (PACT) clinics. The project is a Type 3 Implementation-Effectiveness Hybrid Research Design with strong support from operational partners: Prosthetics and Sensory Aids Service (P&SAS), Department of Social Work/Caregiver Support Program, Office of Geriatrics and Extended Care, and leaders in VISN 1 and VISN 6 facilities.

Aim 1: Conduct a diagnostic analysis of the mechanisms needed to make the Home Safety Toolkit (HST) available to Veterans with dementia and their caregivers.

1a. Use a developmental formative evaluation to describe the current processes by which Veterans receive home safety items, and identify the modifications necessary in order to provide a HST for Veterans with dementia seen in PACT clinics.

1b. Collect quantitative data from PACT clinics at the 6 participating sites using the Organizational Readiness to Change Assessment (ORCA; Appendix 5)[18] tool in order to enhance the diagnostic analysis in the formative evaluation.

1c. Design a tiered group of strategies to facilitate implementation of the HST in PACT clinics, as informed by the diagnostic analyses in Aims 1a and 1b.

Aim 2: Provide and evaluate the Home Safety Toolkit for Veterans with a diagnosis of dementia in PACT clinics in VA medical centers in two VISNs.

2a. Monitor implementation milestones at participating sites using the tool - Stages of Implementation Completion (SIC).

2b. Use the RE-AIM evaluation framework to assess the overall success of the implementation of the HST: extent of Reach, Effectiveness, Adoption, Implementation and Maintenance.

2a.1 Background

Dementia of the Alzheimer's type and related disorders is a growing public health problem. In the United States, an estimated 5.2 million people have dementia of the Alzheimer's type (DAT), a number that is projected to grow to 13.8 million by 2050.[8]

Other population studies estimate that 13% or 1 in 8 Americans suffers from this disease[9], the sixth leading cause of death in the United States for which there is no treatment or cure.[10] Among older Americans, dementia is the second largest contributor to death, affecting one out of three seniors. Persons with dementia are at greater risk of accidents and injury in the home because of the cognitive and functional impairments associated with the illness.[2,3] Moreover, if an accident leads to hospitalization of a person with dementia of the Alzheimer's type or related disorder, the experience can be catastrophic with a significantly greater risk of death, permanent institutionalization or further cognitive decline.[4]

In the Veterans Health Administration, there are an estimated 333,105 Veterans with dementia of the Alzheimer's type or a related disorder, of which 206, 006 are currently receiving services.[1] A person with dementia of the Alzheimer's Type or related disorder will live an average of four to eight years and as long as 20 years after the onset of symptoms.[8] During this illness trajectory, 80% of the person's care is provided by family and friends.[5] Family caregivers absorb the largest costs of care in both dollars and emotional distress. Because of the demands of caring for a person with dementia, family caregivers have negative health consequences and increases in health care costs for themselves.[5]

The importance of the family caregiver in maintaining Veterans' health and well-being and ability to live in the home environment has been underscored by the Caregivers and Veterans Omnibus Health Services Act of 2010.[11] The Act confirms the legitimacy of family counseling, education, and non-institutional services for Veterans of all eras. The family caregiver for a person with dementia becomes the Veteran's primary safety net, and their response to caregiving can directly influence the Veteran's ability to remain at home. Caregiver burden has been shown to be a predictor of institutional placement for a person with dementia of the Alzheimer's type or related disorder.[12] Reductions in caregiver strain and improvements in the caregiver's perception of social support have been shown to significantly delay permanent institutionalization of the person with dementia.[13,14]

The nature of the evidence-based Home Safety Toolkit reflects the clinical priorities of direct care providers and patients/families. The HST is a self-paced low-risk, low-tech educational intervention that was developed with attention to the practical realities of caregivers for a Veteran with dementia. The significant findings are for variables that have been shown in multiple and longitudinal studies to be important for caregiver and care-recipient well-being and delay of institutionalization. Dissemination of these findings to clinical audiences at conferences (e.g. National Caregiver Conference, August 2011), grand rounds presentations, and continuing education programs for caregivers (e.g. Spring Caregiver Training, Togus, ME May 22, 2012) have provided the same feedback: "How can we get this HST for our patients?" Because the HST includes concrete sample safety items, the implementation intervention requires budgetary and supply considerations that are atypical for conventional patient education resources and thus we enlisted support from our operational partners, in particular the Prosthetics and Sensory Aids Service. The importance of the caregiver outcomes in previous work - measures of strain, self-efficacy and social support - are recognized by the Caregiver Support Program, another of our operational partners, as important to maintaining the safety of the Veteran in the home and community.

Previous Work

Concerns by clinical providers and families about how to make the home safer for a Veteran with dementia provided the impetus for a program of research supported by HSR&D (NRI 97-030; NRH 05-056) and led to the development and testing of a

Home Safety Toolkit (HST) for Veterans with dementia.[15-17] Both providers and families were uncertain about where to begin and what were the essential components of home safety for dementia. The extant literature contained lists of general home safety recommendations, such as removing scatter rugs that can be tripping hazards, but many pragmatic details about what would work and where to begin were not studied. This left clinicians to make recommendations to address the safety concerns of family caregivers with no evidence base from which to draw.

The first series of studies developed the Home Safety Toolkit based on clinical concerns. A quasi-experimental design was used to answer the primary questions: What were the prevalent risks for injury to a Veteran with dementia living at home? What environmental modifications made the home safer and were acceptable to families? What educational approaches would activate the family caregivers to make home safety recommendations? The resultant Home Safety Toolkit (HST) has two components: the booklet "Keep the Home Safe for a Person with Memory Loss" which has been learner-verified for attractiveness, comprehension, self-efficacy, and persuasiveness (Appendix 1). The second component of the HST is a sample of low-cost safety items that are acceptable to families and proven effective to reduce risky behaviors, accidents and injuries, e.g. motion sensors and stove knob covers (Appendix 2).

The Home Safety Toolkit was tested in a randomized clinical trial (RCT; NRH-05-056). The sample was typical of care dyads for people with dementia of the Alzheimer's type seen in VA Patient Aligned Care Team (PACT) clinics (Appendix 3). The care recipients with dementia are an older group with a wide range of disease severity. The caregivers are somewhat younger as a group, reflecting some primary caregivers who were adult children. Because two of the recruitment sites were Veteran's Administration facilities, the care-recipients are more likely to be male with female caregivers.

There were no significant differences between the intervention and control groups on demographic and disease severity measures in the randomized controlled trial and the CONSORT table in Appendix 4 demonstrates the randomization of the sample and progress of the groups through the study. Testing of the hypotheses demonstrated that the intervention group had significant improvement in important variables for both the informal caregiver and Veteran care-recipient. Caregivers in the intervention group had higher home safety ($p =< .001$) and higher self-efficacy for injury prevention ($p =< .002$), and lower caregiver strain ($p =< .001$) than caregivers in the customary care group. Care recipients (Veterans) in the intervention group had fewer risky behaviors and accidents ($p =< .001$) than care recipients in the customary care group.

To demonstrate the strength of the evidence for the HST, we present the analytic tables for the randomized controlled trial (the manuscript for the RCT is in review and therefore not appended). Table 1 presents the results of the MANCOVA (multiple analysis of covariance), used in order to test all variables simultaneously. Means and Confidence Intervals for the significant variables in the RCT are displayed in Table 2.

Table 1 Corrected Model MANCOVA – Tests of Between Subjects Effects

	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
CG Self Efficacy	2633427.731	45	58520.616	2.189	.002	.614	98.508	.999
CG Strain	904.965	45	20.110	2.976	.000	.684	133.936	1.000
Home Safety	28004.977	45	622.333	2.537	.000	.648	114.177	1.000
CR Risky Behaviors and Accidents	97564.778	45	2168.106	4.504	.000	.7666	202.686	1.000
Social Support	16325.316	45	362.785	3.450	.000	.715	155.243	1.000

Table 2 Means and Confidence Intervals

	Control Group (N = 48)		Intervention Group (N = 60)		Significance
	Mean (SD)	95%CI	Mean (SD)	95%CI	*p* value
Caregiver Self-Efficacy	1305.646 (203. 36)	1248.12 – 1363.18	1350.300 (197.18)	1300.41 – 1400.19	.002*
Caregiver Strain	6.958 (3.864)	5.868 – 8.048	5.950 (3.175)	5.15 – 6.75	.000*
Home Safety	133.583 (20.145)	127.88 – 139.283	129.316 (20.022)	124.25 – 134.38	.000*
Social Support	73.292 (16.303)	67.63 – 78.95	75.050 (13.194)	71.71 – 78.39	.000*

Care Receiver Risky Behaviors and Accidents	37.438 (37.041)	26.96 – 47.92	33.950 (32.573)	25.71 – 42.19	.000*

An unexpected finding was an increase in social support in the intervention group, which is of special interest to the Caregiver Support Program, one of our organizational partners. In the hypotheses for the RCT, social support was tested as a covariate, but in the RCT, *with equivalent comparison groups*, it did not co-vary but we noticed that social support increased significantly in the intervention group at the end of the 3 month study period. We conclude that the HST had apparently increased the intervention group's perception of tangible support from the social network. In a long-standing program of research on caregivers of persons with dementia, the research team at the New York University Alzheimer's Disease Center has reported perceived quality of social support as the mediating variable for delayed institutionalization of the person with dementia.[13,14,18] With increased self-efficacy in the intervention group, the caregivers appear to have activated their social support network as well, suggesting that caregiver self-efficacy increases perceived social support, which mediates time to institutionalization.

Current Practices for Home Safety for Veterans with dementia: All enrollees in the Veterans Health Administration (VHA) are eligible for a home safety assessment by an Occupational Therapist if a consultation is ordered by the primary care provider with justification to promote function and mobility. The Prosthetics & Sensory Aids Service (P&SAS) can supply safety devices such as grab bars, a tub bench, and/or a walker.[19] Although these items might also be needed by a Veteran with dementia, the home safety needs for someone with progressive memory loss in addition to physical impairments require additional considerations. For example, a Veteran with intact cognition would benefit from easier access to medications so the person would not have to reach or use a step stool. In contrast, the goal for a person with dementia is to prevent accidental dosing mistakes by making medications inaccessible. Similarly, use of common household items such as coffee makers and microwaves can be dangerous for someone with cognitive impairment when they might enhance functional independence for another patient without dementia.

There is currently sparse and unsystematic education for home safety for Veterans with dementia. Prior to the recent randomized controlled trial (RCT), an earlier version of the home safety booklet was distributed through websites and presentations in Veterans Health Administration (VHA). Titled "Worksheet for Making the Home Safer for a Person with Memory Loss"), the information was accurate and reading literacy was at the recommended 5th – 6th grade level, however other dimensions of health literacy principles were not addressed, such as the use of pictures, white space and testimonial statements from other patients.[20] In the RCT, the Worksheet was used as "customary care" because the Institutional Review Board (IRB) at the primary site, Bedford VAMC, was concerned about participants in the control group being at greater risk without home safety information, however this level of patient education is not customary practice in most clinics serving Veterans with dementia. Unfortunately, there is no way to easily measure whether home safety education for dementia is being conducted at VA clinics, in contrast to a medication or lab test being ordered. On the basis of conversations in many VHA meetings and conferences the past several years, we conclude that are few standardized approaches to improve home safety for Veterans with dementia.

Governmental and not-for profit organizations such as the Alzheimer's Disease Education and Referral Center (ADEAR; National Institute of Aging) and the Alzheimer's Association, respectively, have developed informational booklets about home safety[21] , but it is unknown whether these patient education materials are used in VHA clinics. In addition, while the information is accurate, recommendations are often stated in general terms that family caregivers find hard to actualize/implement. For example, "Secure exits." Families ask us, "With what? What is safe? What if there is a fire and we need to get out quickly?"[16] Or a recommendation viewed as not realistic for a family caregiver who needs to be able to conveniently manage household tasks. For example, "Lock all medicines". Older family caregivers in particular are worried about misplacing a key and need regular access to medicine several times a day. Instead, we found that "out of sight, out of mind" is a very safe principle to make the home safer for a person with dementia.[17]

Conceptual Framework: The Promoting Action on Research Implementation in Health Services (PARIHS) framework will be used to guide the implementation strategies in the project.[22] The PARIHS framework proposes that Successful Implementation (SI) is a function of the nature and quality of the Evidence (E), characteristics of the Context (C), and Facilitation (F) strategies. It is best employed as a two-stage process where the elements of Evidence and Context, and the respective sub-elements, are assessed in order to design the most appropriate Facilitation strategies. This project has a strong task orientation in order to implement an evidence-based practice previously tested in a randomized clinical trial, and thus we use reference tools developed by Stetler and colleagues.[23]

The second phase of the project, to provide and evaluate the HST in facilities in two VISNs, will be guided by the RE-AIM Evaluation Model.[24] RE-AIM is designed to improve the chances of adoption and sustainability of a program in real world settings. The elements in the RE-AIM model (Reach, Effectiveness, Adoption, Implementation, and Maintenance) are used to evaluate program design at both the participant level and the setting level and emphasizes both external validity (Reach and Adoption) and internal validity (Effectiveness and Implementation).[25]

Complementary Efforts: The VA Caregiver Support Program (CSP) was developed In response to Public Law 111-163 Caregivers and Veterans Omnibus Health Services Act of 2010 Title I – Caregiver Support.[26] This program describes services for Veterans of all eras, reinforcing the elements that were included in the Millennium Bill of 2000. The CSP re-confirms the services that are available to older Veterans, in particular caregiver education and training and counseling; durable medical equipment, prosthetics and sensory aids to improve function; and financial assistance with home modifications to improve access and mobility. In presentations of the HST, Caregiver Support Coordinators have been enthusiastic about having this resource available to support older Veterans with dementia and their family caregivers. Implementation of the HST will both support and further the goals of the Caregiver Support Program.

The Tampa VA HSR&D/RR&D Center of Excellence (COE), Maximizing Rehabilitation Outcomes, and the Center's Patient Safety Center, are well known for serving as a national resource for Veterans with disorders of mobility and immobility. The COE has been a leader for programs on preventing falls and serious injury from falls, and in more recent years, has begun work on safe locomotion for Veterans with dementia who wander. The COE is currently a recipient of a T21 clinical demonstration grant to develop care plans for safe locomotion for use by VHA staff and family caregivers. Dr. Horvath, the PI for the current proposed QUERI study is an original

member of the Wandering Consortium launched by the VISN 8 COE and a colleague of the T21 project director, Dr. Helen Moore. As the VISN 8 COE tests wandering technologies, there are questions raised regarding how their findings can be sustained in everyday practice, for which our proposed QUERI study will provide some guidance. In fact, some of their initial findings are already integrated into our HST and we will continue to collaborate with Dr. Moore who has communicated interest in being another site for implementation of the HST in our dissemination plans.

2a.2 Significance

Implementation of evidence-based interventions that enable vulnerable populations such as Veterans with dementia to live safely at home are urgently needed. Since the passage of the Millennium Bill, VHA has made a commitment to improve the ability of Veterans to live in the preferred setting of the home and community. With subsequent initiatives, such as the recent Transformation 21 funding for Non-Institutional Long Term Care projects, this commitment has been confirmed and extended. Reception to presentations of the HST by staff and family caregivers has been unequivocally positive, thus confirming the strength of the evidence and the momentum for implementation.

Successful implementation of the HST would enhance and accelerate the efforts of the VA Dementia Steering Committee to improve care of the Veteran with dementia. Since the sobering projections of the prevalence of dementia in VHA, there has been a consistent effort to improve care of the Veteran with dementia. The VA Dementia Steering Committee is charged with the implementation of the recommendations in the 2008 report that was accepted by the Chief Consultant for Geriatrics and Extended Care, Office of Patient Care Services. The recommendations include structural changes to establish VISN-level and facility-level dementia committees at all VA medical centers. Processes of care recommendations include assessment for safety and risky behaviors of dementia. To date, the focus has been on primary care providers and the tools necessary for early identification of cognitive changes and differential diagnosis of delirium, dementia and depression. However, other providers, such as nurses and social workers, are concerned about the perennial management issues for a Veteran living with dementia and the Dementia Education and Training subcommittee of the Dementia Steering Committee is developing a comprehensive curriculum of patient care resources.

This study also has implications for implementing other evidence-based practices in PACT clinics. Measurement of PACT implementation has been consistent since 2009, beginning with the Medical Home Builder and continuing with PACT Compass.[27] We will test measurements of targeted PACT functions, e.g. Continuity and Telephone Ratio, as potential influential variables in the successful implementation of new practices.

2a.3 Research Design and Methods

The project is a mixed method Type III Hybrid Implementation – Clinical Effectiveness study.[28] The intention is to simultaneously test an implementation strategy (Aim 1) and study further the conditions associated with the effective utilization of the HST (Aim 2). While accelerating translation of evidence-based findings into every day practice, the study of implementation conditions also can provide a better understanding of clinical effectiveness. The study meets the recommended conditions for this design: there is strong face validity for both the clinical and implementation strategies that will support generalizability to PACT settings; there is strong indirect evidence from the RCT with the same patient population; there is minimal risk associated with the clinical and

the implementation strategies and no potential risk from displacing other adequate interventions; and strong implementation momentum from recent caregiver legislation, and advocacy from patients and providers.[28]

Aim 1: Conduct a diagnostic analysis of the mechanisms needed to make the HST available to Veterans with dementia and their caregivers.

Using the Promoting Action on Research Implementation in Health Services (PARIHS) framework and associated tools and instruments, the goal of Aim 1 is to assess the nature of Contextual factors and characteristics of the Evidence that will guide the Facilitation strategies needed for Successful Implementation.

Aim 1a Use a developmental formative evaluation to describe the current processes by which Veterans receive home safety items, and identify the modifications necessary in order to provide a HST for Veterans with dementia seen in PACT clinics.[29]

Sites and Participants: The formative evaluation will be conducted at 6 **sites** that represent different geographical areas in order to study the factors that will contribute to generalizability: Bedford VAMC, VA Boston Health System, Manchester VAMC, VA Maine Health System, Durham VAMC, and Asheville, VAMC. We will use qualitative methods to identify the salient aspects of the process for **participants**: key stakeholders and Veterans/Caregivers.

Stakeholders include: Prosthetics and Sensory Aids (P&SAS) managers (one at each of the facilities N=6), Sensory and Physical Rehabilitation Service (S&PRS) Line Leaders (N=6), Primary Care clinical staff (at least one MD, NP, RN and OT from each of the participating facilities, N=24). These staff members are the most involved with the: (1) assessments of the patient's needs and home safety, (2) prescription of P&SAS items, (3) maintenance of the facilities' home safety items inventory, (4) delivery of home safety items to patients, and (5) patient education about home safety for Veterans with dementia.

Key informant participants will be stakeholders who are purposively sampled.[30,31] That is, persons we anticipate who will have best knowledge of Contextual and Evidence sub-elements related to providing home safety items to Veterans will be interviewed. In addition to the P&SAS managers and S&PRS line leaders, who are inherently involved with home safety assessment and provision of safety devices, we will identify primary care providers who have prescribed home safety items for Veterans with dementia within the past 6 months. The VISN 1 P&SAS manager has confirmed that he has records of consults from staff members who have prescribed general safety items such as walkers, safety rails, and wheel chairs in the past six months to specific Veterans. These providers at the participating sites will be invited to participate in an interview, after review and approval of all procedures by the pertinent Institutional Review Boards.

Veterans and caregivers will also participate in the developmental formative evaluation. We will identify key informants through P&SAS records of Veterans/Caregivers who had a recent (within 6 months) experience with receiving home safety items. We will conduct semi-structured interviews by phone or in person (at the caregiver's request) with 2 – 3 Veteran/Caregiver dyads at each facility (N= ~ 15 interviews).

Data Collection and Analysis: Data collection will be organized using the PARIHS framework. The PARIHS framework describes Successful Implementation (SI) as a function of the nature and quality of the Evidence (E), characteristics of the Context (C), and Facilitation (F) strategies. It is best employed as a two-stage process where the elements of Evidence and Context, and the respective sub-elements, are assessed in order to design the most appropriate Facilitation Strategies.[29]

We will conduct semi-structured interviews to elicit **narrative data** using qualitative techniques of theoretical sampling and a schedule framed by the PARIHS elements to elicit concrete experiences with providing home safety items for Veterans with dementia. The Context element includes the sub-elements of Leadership Support, Culture, Evaluation Capabilities and Receptivity to the targeted EBP/change. The Evidence element of PARIHS includes the sub-elements: Research and published guidelines; Clinical experience; Patient experiences, needs and preferences; Local practice information; and Other characteristics of the targeted EBP. Associated reference tools for the Context and Evidence sub-elements provide definitions, observations, and questions that are recommended in order to analyze the facilitators and barriers related to these sub-elements.[29] For example, an interview with the P&SAS might begin with a broad survey question such as: Please think about a Veteran for whom you had a recent safety device prescription experience. Probes: What went well about the experience? What could have gone better? What would you wish you could do differently? In what ways does support from leadership influence the process? Now tell me about an experience where a new product was first introduced to P&SAS. What helped you to make this change? What barriers did you have to overcome? What kinds of information do you receive about the evidence which led to the new item/practice? What kinds of data are available to you that assist with your decision making? To what extent does implementation of evidence based practices such as a HST for dementia fit with organizational priorities?

As another example, one Evidence sub-element is whether PACT providers consider: (1) whether there is value in prescribing a HST, and (2) whether the prescription of a HST to all eligible Veterans is feasible. An interview with a PACT provider might begin with a broad survey question such as: Please think of a Veteran in your panel who has dementia. Please tell me about your assessment of how safe Mr./Ms. ___ is at home. What sorts of advice have you given to help Mr./Ms. ___ to be safe at home? Are there devices you think would be helpful for Mr./Ms. _'s home safety? Are these available to you to provide? Do you think you could provide such devices to all of the Veterans with dementia in your panel? If so, how would you do this? If not, why not?

The initial analytic framework displayed in Table 3 will look for themes that are related to activities that were essential for the HST effectiveness in the randomized controlled trial (rows) and the Facilitators and Barriers to those activities that are revealed in narrative data regarding Context and Evidence elements of the PARIHS framework (columns).

Table 3 Diagnostic Formative Evaluation Schema

HST Effectiveness	**Context sub-elements**		**Evidence sub-elements**	
Successful Stocking and Delivery of HST	Facilitators	Barriers	Facilitators	Barriers
-Procuring sample safety items				

-Assembling safety items into kit				
-Maintaining print booklet				
-Mailing kit to Veterans				
Successful Prescription of HST by PACT Staff	Facilitators	Barriers	Facilitators	Barriers
-Positive Staff attitudes towards the usefulness of the intervention, home safety, family caregivers				
-Positive Staff knowledge of recognition and diagnosis of dementia				
-Positive Processes (e.g., clinical reminder system)				
-Phone call initiated by nurse/provider to family caregiver				
-Phone call response to family caregiver initiated call				
Successful Utilization of HST by Patients and Caregivers	Facilitators	Barriers	Facilitators	Barriers
-Knowledge of benefits of safety kit (knowledge)				
-Knowledge of appropriate use of safety kit				
-Skills needed to use safety kit				
-Acceptability of use of safety kit				
-Delivery of safety kit to home				

The **analysis of the narrative data** will proceed with audio-recording and transcribing the interviews verbatim and the transcriptions will provide the narrative data for analysis. Previously collected narrative data will be analyzed in order to guide the collection of subsequent interview data. As a result, we expect that the initial semi-structured interview schedule will evolve based upon previously collected data so that

Context and Evidence sub-elements that were not evident during the RCT but are evident to the stakeholders can be theoretically sampled in subsequent interviews.

The narrative data will be content analyzed as organized by elements of the PARIHS framework.[32-34] First, each interview transcript will be read in total. Segments of data will be categorized into the relevant cells of the analytic matrix as exemplified in Table 3. Data segments within each cell will be compared and contrasted for similarities and differences. Data segments that no longer fit within a cell will be resorted. New cells may be labeled with new categories based upon the analysis of the narrative data, and the interview schedule and the matrix subsequently refined. Newly collected data will be compared with subsequently collected data to assure homogeneity of data in each cell of the analytic matrix. Relevance to Facilitation Strategies will be described in analytic memos.

The completed analysis will comprise the Context and Evidence sub-categories relevant to the successful implementation of the HST. Differences between two VISNs and the respective facilities and differences between stakeholder roles will be highlighted to enhance strategic understanding. We will use the *developmental* formative evaluation findings to tailor implementation strategies to each setting in conjunction with findings from the Organizational Readiness to Change Assessment (ORCA; See Aim 1b. below.)

Aim 1b. Collect quantitative data from PACT clinics at the 6 participating sites using the Organizational Readiness to Change Assessment (ORCA; Appendix 5)[35] tool in order to enhance the diagnostic analysis in the formative evaluation.

The ORCA tool is recommended by Stetler and colleagues[23] as one instrument that can be used to evaluate Context, Evidence and Facilitation components that can influence Successful Implementation. While the qualitative analysis in Aim 1a will provide a deep understanding of processes that are essential for HST implementation, the ORCA instrument is a realistic approach to evaluate PARIHS elements more broadly among a large number of staff.

Participants include all stakeholders in the 6 participating sites, including PACT teamlet members (PCP, RN, Clinical Associate, NP/PA) and second tier resources (Rehabilitation Services and Social Services). Based on the number of PCPs at the participating sites (N= 228 PCPs X 3 average size of teamlet = 684 primary care staff + average 2 OTR and 5 SW in primary care = approximately 726 eligible participants. Primary care leadership will lend support by encouraging completion of the ORCA (either on-line or paper – if requested), but respondents will be voluntary and anonymous as typically required by Institutional Review Boards.

ORCA has 74 total items and takes approximately 15 minutes to complete (some items are organized under an overarching question and thus can be scored quickly). Reliability and factor analysis testing supports 3 primary scales related to the 3 Elements of PARIHS: Context, Evidence, Facilitation. Each item is scored in a Likert fashion from 1 (very weak) to 5 (very strong).

Descriptive analysis: First, baseline scores for each primary scale will be summed and displayed graphically by site. At initial meetings with clinic staff, we will review the site's ORCA scores and discuss the implications for successful implementation, in particular notable strengths and actionable barriers. The ORCA results will be used to enhance/confirm tailored implementation strategies with clinical staff.

Secondly, total scores and subscale scores will be compared between sites and between facility-based PACT teams and CBOC teams in order to identify patterns in the

scores that will inform implementation efforts. The unit of analysis is the site. We will obtain descriptive statistics on all items and baseline scores for each primary scale will be summed. This will include the means, medians, standard deviations and 95% confidence limits. We will compare the distributions of the scores between sites graphically and with appropriate statistical tests. As appropriate, group differences will be tested using chi-square test of independence (categorical variables), t-test/ANOVA (continuous variables) or the equivalent non-parametric tests. A two-sided p-value <0.05 will be considered significant.

Aim 1c. Design a tiered group of strategies to facilitate implementation of the HST in PACT clinics, as informed by the diagnostic analyses in Aims 1a and 1b..

In the PARIHS framework, *Facilitation* is an interactive process of problem solving and support that has two sub-elements: the role of a facilitator, and other implementation interventions conducted by the facilitator and/or members of the study team. The diagnostic analyses in Aims 1a and 1b are critical to determine the appropriate role, purpose and skills of the facilitator, and the other types of implementation interventions that will promote successful implementation.

The expected variability in the PARIHS elements of Context and Evidence in the 6 participating sites will be used to plan for appropriate facilitator roles. The facilitator is an explicit change agent for implementation of the HST and it is possible that an individual within a facility will assume the role of Internal Facilitator, but unlikely that such a person will be sanctioned for most of the facilities. Therefore we expect that the project staff will often serve as an External Facilitator. The initial reliance on external facilitation is a common approach in Hybrid 3 Type studies where both implementation interventions and clinical effectiveness are being evaluated. We will be evaluating the degree to which similar external facilitation is needed for all sites or where specific strategies will be needed for individual sites.

In addition to the nature of the facilitator role, the second sub-element in the Facilitation component of PARIHS includes other types of implementation interventions. The following well-known types of interventions will be incorporated as indicated to further tailor implementation strategies.[36]

- Targeted dissemination to Email User Groups such as primary care leaders and members of facility Dementia Committees;
- Didactic Education through grand rounds and audio-conferences;
- Academic Detailing with 1:1 interaction;
- Technological support such as an alert or clinical reminder in the Electronic Medical Record;
- Advocacy through individual site champions (distinct from facilitator role);
- Audit and Feedback of performance measures and/or HST prescriptions

Table 4 demonstrates an analytic matrix that will inform facilitation strategies. The left column represents **"C" Contextual sub-elements** and **"E" Evidence sub-elements** that require one or more facilitation strategies as derived from the diagnostic analysis in Aims 1a and 1b. Some examples are given based on our experience with the HST randomized controlled trial and associated interactions with leadership and clinic staff.

Table 4 Facilitation Sub-Elements

	Facilitator role	Other Interventions	Fn
C1 P&SAS	Study team	DSS coordinator at	

managers perceive a need for additional data on eligible Veterans with dementia in order to budget for HST	member as Facilitator assists P&SAS manager to acquire needed data from DSS coordinator	Bedford VAMC "walks" other DSS coordinators through the process of pulling data on Veterans with ICD 9 diagnosis of dementia	
C2 PACT PCPs are worried about adding another task to a clinic appointment that already is hard to complete with medication reconciliation and management of co-morbid conditions.	Study team member as Facilitator explores use of PACT efficiency principles such as group education for similar patient cohorts who can benefit from the HST.	Facilitator explores roles of PACT team members where RN case manager or clinical associate can pre-screen daily appointments for Veterans with dementia and integrate HST into clinic instructions.	
Cn			
E1 Clinical provider accepts strength of RCT evidence but is unfamiliar with range and frequency of home safety issues for dementia.	Study team member presents the HST to providers with sample booklets and items with an interactive educational approach.	Facilitator identifies an early adopter or champion who will serve as a model to others in the PACT for HST prescription to Veterans with dementia.	
E2 Clinical providers perceive the HST as complex and requiring extensive patient education.	Study team presents the procedures in the RCT that used a self-directed approach; aspects of health literacy principles are emphasized that include reading, comprehension, self-efficacy.	Aggregate data from Veteran/Caregiver interviews is shared with providers to demonstrate their readiness and preferences to use the HST.	
En			

Aim 2: Provide and evaluate the HST for Veterans with a diagnosis of dementia in PACT clinics in VA medical centers in two VISNs.

Aim. 2a. Monitor implementation milestones at participating sites using the tool - Stages of Implementation Completion (SIC).

We plan to monitor implementation using the Stages of Implementation Completion (SIC)[37] as a means to gauge progress towards achievement of a series of implementation milestones indicative of Successful Implementation. Founded on the idea that implementation can be conceptualized as a recursive process, the SIC is a stage-driven assessment tool comprised of eight main stages, each with its own set of sub-activities. While the posited eight stages are assumed to unfold within three phases of implementation (i.e., pre-implementation, implementation, and sustainability) and represent important milestones that are required for successful implementation, the sub-activities that correspond to each stage represent observable tasks that are required to complete each stage.[37,38] As a measure, the SIC is date-driven and involves the computation of three scores: (1) the number of stages completed (stage completion); the length of time spent in each stage (i.e., stage duration), and the proportion of activities completed in each stage (i.e., proportion score). As in analysis of ORCA scores, we will compare scores between the 6 facilities and between facility-based primary care teams and CBOC teams in order to explore differences in implementation completion that will inform future dissemination of the HST.

Table 5 represents the HST implementation monitoring plan with the eight SIC stages and descriptions of the implementation activities that comprise each stage. The last column in the table lists other complementary data that we will collect as part of each stage. While the SIC activities that we propose to measure will be instrumental for gauging progress towards implementation goals, this complementary data will be important for providing more nuanced insights into the experiences of teams implementing the HST, and the facilitators and barriers to Successful Implementation.

Table 5 Implementation Monitoring Plan

Phase	Stages		SIC Activity Description	Other Data Collected
Implementation Planning	1	Engagement	- Date site is informed of HST availability - Date of interest indicated	- Observation and field notes generated during study team and site meetings
	2	Consideration of Feasibility	- Date of first contact for implementation planning - Date first in-person meeting held - Date ORCA questionnaire completed -Date ORCA results discussed with team	- Observation and field notes generated during meetings with regard to leadership responsiveness and individual team members' as champions or internal facilitators. - Number and disciplines of staff attending the meeting
	3	Readiness Planning	- DATE CPRS order set is ready - Date of team review of eligibility criteria for HST - Date of interactive education on HST booklet and safety	- Analysis of ORCA results with implications for facilitation strategies and other implementation interventions.

			items	
Implementation	4	Staff Roles defined	- Date facilitator roles are identified - Date of PACT roles identified: PCP, RN care manager, Clinical Associate - Date second tier PACT roles identified: OTR, social worker(s) - Date implementation plan is described with staff roles integrated	- Observation and field notes generated during facilitator and clinical team member training sessions - Brief questionnaires and semi-structured interviews with each internal facilitator and some clinical team members to gauge perceptions; sense of preparedness following training
	5	Adherence Monitoring Processes in Place	- Date baseline # of potential eligible Veterans with dementia are reported - Date plan is in place to cross-reference eligible Veterans with P&SAS records to distinguish those who did and did not receive a HST.	- Observation and field notes generated during relevant meetings - Document analysis for reports; reporting procedures
	6	Services Begin	- Date first order for HST is sent to P&SAS - Date first HST sent to eligible Veteran/caregiver - Date first telephone encounter with family caregiver	- P&SAS records - P&SAS records
	7	Ongoing Services, Fidelity Monitoring and facilitation	- Date of first site visit after distribution of HST begins - Date of first implementation review - Date of corrections/additions to implementation plan - Date of second implementation review	- Field Notes - Usage reports regarding number of HST distributed - Brief email query to all clinical team members to assess "ongoing" experience
Sustainability	8	Competency	- Date facilitators formally "end" their work - Date of final program assessment	- Brief email query to all clinical team members to gauge knowledge of HST Presentation of RE-AIM evaluation to facility leadership

Aim 2b Use the RE-AIM evaluation framework to assess the overall success of the implementation of the HST: extent of Reach, Effectiveness, Adoption, Implementation and Maintenance.

The RE-AIM framework is used for implementation studies sponsored by the Administration on Aging and has been found useful to evaluate implementation research studies.[24,25] In this Hybrid Type 3 study, we are especially concerned with external validity, represented by Reach and Adoption in the RE-AIM model. The important measurement for our study is whether the HST reached the intended recipients– Veterans with an ICD 9 diagnosis of dementia. We will first report the percentage of eligible Veterans who received the HST in the 6 participating facilities. Data for FY 12

from DSS for 3 of the participating facilities in VISN 1 indicate a total of 3, 127 unique Veterans with an ICD 9 diagnosis of dementia (Bedford = 832; Manchester = 556; VA Boston = 1739). Applying ineligibility (25%) and attrition (15%) rates from the RCT, we estimate that these three facilities will have 1993 eligible Veterans. We expect similar numbers from the remaining 3 participating sites, with over 3500 Veterans with an ICD 9 diagnosis of dementia who are potential participants in the study, a sufficient number for all analyses. Numbers for individual facilities will allow for analysis at the setting level.

We are interested in identifying variables that influence whether or not a Veteran receives a HST, thus we will group Veterans with an ICD 9 diagnosis of dementia into those that received a HST and those that did not. We will collect the following data to explore potential variables: time since diagnosis of dementia; number of contacts with the VA health care system (clinic encounters, ER visits, hospitalizations); # of co-morbidities; and characteristics of PACT setting (staffing ratio; continuity with PCP; Telephone ratio of encounters).

REACH	*Did the program reach the intended audience?* Percent of Veterans who received HST of those Veterans diagnosed with one of the ICD 9 codes for dementia; Distinguishing characteristics of subgroups: time since diagnosis; Contacts with VHA in previous 12 months; # of co-morbidities. Qualitative data regarding facilitators and barriers to reach target population.
EFFECTIVENESS	*How do we know the program was effective?* Analysis of Stages of Implementation Completion measure: (1) the number of stages completed (stage completion); the length of time spent in each stage (i.e., stage duration), and the proportion of activities completed in each stage (i.e., proportion score).
ADOPTION	*How was the organization developed or supported to implement the intervention?* Policy and procedures to use P&SAS as a mechanism to stock and mail HST to Veteran/Family member; Facilitation strategies in PACT clinics; PACT metrics that influence whether a Veteran receives a HST.
IMPLEMENTATION	*How did we ensure the intervention was properly implemented?* Audit of P&SAS records; field notes and observations during site visits. Facilitation strategies used to promote implementation.
MAINTENANCE	*How do we incorporate the intervention so it is effective long-term?* Modifying CPRS functionality and P&SAS policies/procedures to include the HST prescription as a component of standard care for Veterans with dementia living in the home setting; integration with Dementia Steering Committee clinical recommendations

Sample: The target population is Veterans with one of the ICD-9 codes for dementia, including but not limited to dementia of the Alzheimer's type. We will limit the sample to Veterans who have a caregiver living with them but will not specify a minimum number of caregiving hours. The amount of time spent in caregiving is a function of the care-recipient's dependency and disease severity, but to date we have not seen a direct correlation between these variables and risky behaviors. For example, a person with early cognitive changes who has maintained some independence can be a safety risk using a car or other motorized equipment. However, in Aim 2 we will explore further whether time since diagnosis and co-morbidities have a relationship to the likelihood that a Veteran with dementia receives a HST. *Inclusion criteria* are: Veteran has one of the ICD – 9 codes for dementia, is expected to be living in the community for the next 6

months, and a family caregiver can assist with home safety modifications. *Exclusion criteria* are: Veteran is admitted to residential care or caregiver cannot provide informed consent.

Descriptive analysis: Our unit of analysis is the individual patient. We will obtain descriptive statistics on all measures. This will include the means, medians, standard deviations and 95% confidence limits. Parametric or nonparametric tests will be used depending on the distribution of the variables. We will explore the relationship among the covariates and their associations with the outcome variable (receiving HST) by conducting binary analysis relating the response measures to our full set of independent and dependent variables. As appropriate, group differences will be tested using chi-square test of independence (categorical variables), t-test/ANOVA (continuous variables) or the equivalent non-parametric tests. A two-sided p-value <0.05 will be considered significant.

Multivariable analysis: Furthermore, we will obtain odds ratios and 95% confidence intervals from a logistic regression model that will evaluate the factors associated with veterans with dementia receiving HST or not adjusting for all other variables. We will use Generalized Estimating Equations to adjust for clustering of patients at the site level.

While we add quantitative analyses in Aim 2b, results from the qualitative analyses will be integrated in the RE-AIM framework for a comprehensive summary of the program evaluation.

2a4. Dissemination Plan

With support from Co-I Schlosser and VISN 1 and 6 Leads for Sensory & Rehabilitation Service Line and Prosthetics & Sensory Aids Service, we will share successful approaches to stocking and sending the HST to Veterans with dementia in other VISNs. We also will make available to all Clinical Applications Coordinators any tools in CPRS that are found to be facilitators for HST implementation, e.g. a clinical reminder linked to Veterans with a dementia diagnosis.

Both Drs. Horvath and McConnell, and co-investigator Hancock serve on their VISN-level dementia committees, with Hancock named to chair the VISN-6 committee beginning in 2012. As active and well-respected members, they are well-poised to lead dissemination efforts at the regional level, and use that experience to generate new insights into dissemination strategies at multiple levels.

As a GRECC Associate Director for Education/Evaluation, Dr. Horvath is involved with several national initiatives that provide opportunities for dissemination. Dr. Horvath chairs the Dementia Education Workgroup, a special interest group comprised of 4 additional GRECC host facilities: VA Puget Sound Health System, Minneapolis VAMC, Palo Alto VAMC, and Gainesville VAMC. Dr. Horvath will enlist the support of the respective AD/EE at these facilities to discuss implementation strategies for both the host facilities and non-host facilities in the associated VISNs.

Dr. McConnell, co-investigator at Durham VAMC chairs the Dementia and Training Sub-committee of the VA Dementia Steering Committee, and Dr. Horvath is a member of this subcommittee. The Subcommittee has been charged with a task to develop a comprehensive curriculum for care of the Veteran with dementia, and the HST can be incorporated into the resources associated with the curriculum. Dr. McConnell and Dr. Horvath are also members of their VISN Dementia Committees and can use the national conference call for all VISN Dementia Committee chairpersons, with support by Dr. Susan Cooley, Chief Consultant for Dementia Initiatives, Office of Geriatrics and Extended Care.

Recent communications with the VA National Center for Patient Safety confirm that there are no directives or other guidelines that are available nationally for home safety for dementia. They are very interested to disseminate an evidence-based practice once the steps to implement the HST have been determined and will post implementation guidance for the HST on the website for the National Center for Patient Safety.

2a5. Project Management Plan

This will be a 36- month project conducted at VISN 1 and VISN 6 facilities. Dr. Horvath is Project PI and has a leadership role in VISN 1, and previous collaboration with the VISN 6 Co-I Dr. McConnell. The local service line managers for primary care, geriatrics, and sensory/physical rehabilitation at the participating sites have expressed their enthusiastic support for the project, as documented in the letters of support. A careful project management plan has been developed to complete all program activities, monitor and evaluate continuous progress of the study, and ensure high quality of data collection and data analysis. Table 6 outlines the roles and responsibilities of the research team members and the timeframes for program activities. We believe that 36 months is a reasonable timeframe within which to conduct the study based on our experience in recruitment and data collection in the previous home safety studies, and through the inclusion of a second VISN site to increase available sites.

The Project Management Plan has several structural features to assure a well-coordinated study: 1) weekly telephone conferences are held that alternate between VISN specific facilities and all-group calls for the 6 sites. These conference calls include the PI, Co-investigators, Project Staff, and consultants as indicated. The alternating weekly conference calls will be used to track the progress of the study, discuss issues related to specific project activities, and assure the quality of the data. Mechanisms for data security, issuing of subject codes, and maintenance of the master code list of participants will be discussed. Minutes of the investigator meetings describing issues discussed and decisions made will be maintained by the Project Director (VISN 1) and the Project Coordinator (VISN 6) to compile a paper trail for future audits should they be requested.

Face-to-face meetings are scheduled at the start of the study to discuss fully the data quality control measures related to the study design, and the training of project staff. Subsequent all-team in-person meetings are scheduled at key junctures in the study to ensure full understanding of the study protocol, data collection strategies, and interpretation of the findings.

TABLE 6: PROGRAM ACTIVITIES, RESPONSIBLE PERSONNEL, AND TIME FRAMES (ALSO SEE GANTT CHART)

Program Activities	Person(s) Responsible	Time Frame[1]
Start up activities:		
▪ Recruit project staff.	K. Horvath; E. McConnell	3 months
▪ Develop flier to request key informant interviews	S. Trudeau and E. McConnell	1 month
▪ Submit to Central IRB	K. Horvath; S. Trudeau;	3 months

[1] These timeframes overlap. Refer to GANNT Chart for depiction of these timeframes over the study period.

Program Activities	Person(s) Responsible	Time Frame[1]
▪ Submit to local R&D Committees	K. Horvath; E. McConnell; K. Hancock; Project staff	1 month
▪ Train PM, PC & RA in interview protocol and qualitative data analysis	R. Elwy; L. Radwin	3 months
▪ Development of quantitative data base	S. Rao; S. Zhao	1 month
▪ Conduct key informant interviews	PM; PC; RA	2 months
▪ Concurrent qualitative data analysis	PM; PC; Horvath; Trudeau; Radwin; Schlosser	4 months
▪ Collect and summarize responses to ORCA at all sites	PM; PC; RA; Rao; Zhao	2 months
▪ Develop and implement facilitation strategies for participating sites	Horvath; Elwy; Trudeau; McConnell; Hancock; Schlosser; PM; PC; RA	18 months
· Research Team Calls to track progress; weekly alternating between VISN calls and all-team calls	RA-organize calls; PM/PC-develop agenda and progress reports.	Weekly
▪ Collection and data entry for RE-AIM evaluation	PM; PC; RA; Rao; Zhao	21 months
· Collection and data entry for Stages of Implementation Measure	PM; PC; RA; Rao; Zhao	21 months
· Preliminary Data Analysis for Interim Reports	Horvath; Trudeau; Radwin; McConnell; Rao; Elwy; PM; PC	Annually
· Final Data Analysis	Horvath; Trudeau; Radwin; McConnell; Rao; Elsy; PM; PC	2 months
· Final Report, Manuscripts	PI, co-investigators, PD, PC, RA	4 months
▪ Dissemination Strategies	Horvath; Trudeau; McConnell; Schlosser; Sargent; Imbruno	2 months

Key: PD = Project Director (To be Named); PC= Project Coordinator (TBN); RA = Research Assistant (TBN)

Roles of the Research Team: This is an experienced research team that has worked together on other projects. The role of each of the investigators is briefly described with their expertise and accomplishments.

Kathy J. Horvath, PhD, RN (Principal Investigator). Dr. Horvath was the Principal Investigator for the previous two Home Safety studies supported by the Nursing Research Initiative (NRI 97-030; NRH 05-056)). She has a special interest in health literacy and clear language initiatives to support consumer advocacy, and methods such as self-efficacy enhancement to promote health-related behaviors. She obtained supplemental funding to strengthen the Home Safety Toolkit intervention by applying a learner verification method to test the new educational booklet for reading level,

comprehension and persuasiveness. She is a frequent speaker for interdisciplinary educational programs and presentations to community groups. She is a co-author, with Dr. Trudeau, on two publications on home safety for persons with dementia. A third manuscript reporting the results of the recently completed RCT is currently in the review process. Building on her experience in conducting the preliminary studies, Dr. Horvath will assume overall responsibility for the study.

***Horvath KJ**, Hurley AC, Duffy M, Gauthier MA, Harvey R, **Trudeau SA**, Cipolloni PB, Smith SJ. Caregiver competence to prevent home injury to the care-recipient with dementia. Rehabilitation Nursing 2005; 30(5): 189-196.*

*Hurley AC, Gauthier M, **Horvath KJ**, Smith SJ, **Trudeau** S, Cipolloni PB, Hendricks A, Duffy M. (2004). Promoting safer home environments for persons with Alzheimer's Disease: The Home Safety/Injury Model. Journal of Gerontological Nursing, 30 (6), 43-51.*

Scott A. Trudeau, PhD, OTR/L, Co-Investigator has extensive experience in dementia care practice, research, and policy and served as project director for the recent randomized clinical trail of the HST. Dr. Trudeau will provide expertise in processes related to the role of occupational therapists in promoting home safety for Veterans with dementia, interactions with the Prosthetics and Sensory Aids Service, analysis of qualitative data, and interpretation of findings from the analyses using the RE-AIM evaluation model.

TABLE 7: GANTT CHART

	Year 1				Year 2				Year 3			
QTR	1	2	3	4	1	2	3	4	1	2	3	4
Start-up activities: Recruit project Staff; Submit to Central IRB and local R&D Committees	X	X										
In Person Team Meetings and trainings		X		X		X			X		X	
Collect ORCA data		X	X									
Develop quantitative database and data entry		X	X			X	X	X	X	X		
Developmental formative evaluation: Recruit and interview Key Informants		X	X									
Concurrent qualitative data analysis and reliability checks		X	X	X		X	X	X				
Develop and Implement facilitation strategies				X	X	X	X	X	X			
Collect data on Stages of Implementation Completion (SIC) measure				X	X	X	X	X	X	X		
Collect quantitative data for RE-AIM evaluation; data entry and analysis				X	X	X	X	X	X	X		
First Interim Report				X								
Second Interim Report								X				
Final Data Analysis										X	X	

Final Report and Manuscripts												X
Dissemination to other sites and other stakeholders											X	X

Rani Elwy, PhD Co-Investigator is a Research Health Scientist at Center for Healthcare Organization and Implementation Research (CHOIR; formerly Center for Health Quality Outcomes and Economics Research - CHQOER) at Bedford VAMC. Dr. Elwy is the Co-Implementation Research Coordinator for HIV/Hepatitis QUERI. Dr. Elwy will serve as an expert in implementation science to provide guidance on the execution of the proposed project and assist with training of the project staff for the qualitative methods.

Laurel Radwin, PhD, RN, Co-Investigator is a nurse researcher at Manchester VAMC and an expert in qualitative research methods. Dr. Radwin is a professional colleague of Dr. Horvath for more than 15 years and participates in research development at CHOIR. She will oversee the collection and analysis of qualitative data.

James Schlosser, MD MBA, Co-Investigator is the Director of the VISN Improvement Resource Office, and the VISN Systems Redesign Point of Contact, VA New England Healthcare System (VISN 1). The New England Veterans Engineering Resource Center (VERC) reports to Dr. Schlosser and he will facilitate involvement of the VERC as indicated.
Dr. Schlosser is a nationally-recognized expert in quality improvement.

Jane A. Driver, MD, Co-Investigator is a geriatrician and physician/scientist at New England GRECC, VA Boston Health System division. Dr. Driver has worked with Dr. Horvath previously on research and educational initiatives and is available to assist with medical issues pertaining to identification and diagnosis of dementia.

Eleanor McConnell, PhD, RN, GCNS-BC, Co-Investigator, has served as a Clinical Nurse Specialist in Geriatrics and a Core Investigator at the Durham VA's Geriatric Research, Education and Clinical Center (GRECC) since 1988. She has served as a principal investigator or co-investigator on six separate VACO-funded clinical demonstration projects or research projects, 4 of which involved collaboration with the other VAMCs in VISN-6, including the recently completed HSR&D project EDU-08-417, for which Asheville VAMC served as a site.
Dr. McConnell also serves as principal co-chair of the VA's Dementia Education and Training Committee, and has collaborated with Dr. Horvath on educational innovations since 2007.

Tracey Holsinger, MD, Co-Investigator is a gero-psychiatrist and staff physician at Durham VAMC and a colleague of Dr. McConnell. Dr. Holsinger is available to assist with medical issues pertaining to identification and diagnosis of dementia for the team in VISN 6.

Sowmya Rao, PhD, Statistician is Senior Statistician with the Center for Health Care Organization and Implementation Research (CHOIR) at the Veteran's Administration in Bedford, Massachusetts and has a joint appointment as an Associate Professor in the Quantitative Methods Core in Quantitative Health Sciences Department at the University

of Massachusetts Medical School. Dr. Rao has over 15 years of experience in applying statistical techniques to the fields of epidemiology and health services research, and to topics within each of these, including measurement/surveillance of disease outcomes, disparities in health care, adoption of Electronic Health Records, impact of clinical tools, and survey research.

Stephen Imbruno, VISN 1 Prosthetics Manager will serve as a consultant (donated time) for the formative evaluations of the policy and procedures under which the Prosthetics &Sensory Aids Service (P&SAS) operates, and the modifications that are necessary in order to provide a Home Safety Toolkit to Veterans with dementia. Mr. Imbruno is an experienced P&SAS manager with a deep understanding of the processes through which Veterans can receive aids to maintain their safety and mobility in the home environment. He is the VISN 1 Lead for P&SAS and will facilitate communications with the other P&SAS managers in participating facilities. Mr. Imbruno works closely with Mr. Sargent.

Erik Sargent, VISN 1 Lead, Sensory & Rehabilitation Service Line Manager will serve as a consultant (donated time) for the formative evaluations to identify the modifications necessary to implement a Home Safety Toolkit intervention. Mr. Sargent is a licensed physical therapist and directs rehabilitation services that include occupational therapists who are often requested to do a home safety assessment.

Partnerships with VA Operations and Program Offices

Preliminary work has already established strong support from operational partners, in particular the Sensory and Physical Rehabilitation Service Line Managers and Prosthetics and Sensory Aids Service (P&SAS) in VISNs 1 and 6. In addition, the Office of Geriatrics and Extended Care and the Department of Social Work/Caregiver Support Program have expressed strong support and assistance as needed. The service line, network and VACO leaders have already supported the project by identifying key stakeholders and endorsing the importance of the HST implementation.

The Office of Geriatrics and Extended Care (OGEC) has pledged support to assist the study team with contacts and coordination at the VACO inter-departmental level. Dr. Susan Cooley, Chief Dementia Research and Initiatives, has facilitated contacts between Dr. Horvath and program managers for the Caregiver Support Program under the Department of Social Work. Margaret Campbell-Kother, MPH, RN, manager, Caregiver Education and Training has expressed enthusiastic support for the project and has the concurrence of her immediate supervisor, Laura Taylor, Director, Caregiver Support Program. The VISN 1 Directors for Geriatrics and Extended Care and Primary Care are in support of the project and will facilitate contacts and communication within their respective programs. The VISN 1 Director and Chief Medical Officer are committed to clinical research and implementation research in particular and will support the project as necessary through communications with VISN 1 facilities and operational staff. In VISN 6, the Director of the Geriatrics and Extended Care Service Line, who also co-chairs the VISN-6 Dementia Committee, has expressed his support for this initiative, and has been a key facilitator of VISN-6 multi-site research for prior projects. VISN 6 Prosthetics and Sensory Aid Services has likewise expressed strong support for this project.

1. Risks to human subjects

A. *Human Subjects Involvement and Characteristics*. This Implementation/Effectiveness hybrid study has two primary aims. In Aim 1, we conduct a series of semi-structured interviews with 4 or more clinical providers at the 6 participating facilities. PACT clinical providers who have had an experience with prescribing or educating patients/families about home safety items from the Prosthetics & Sensory Aids Service (P&SAS) in the past 6 months are invited to participate in a 30 – 40 minute semi-structured interview with the project staff. Clinical providers participate on a voluntary basis and are interviewed by project staff who do not have an ongoing relationship with them. Interviews are recorded and transcribed by a subject code that is kept separate from the data files. All research proposals that include VA employees are reviewed by the union representative to be sure there are no labor issues that have been overlooked. Most employees are non-Veterans and therefore this population will be included in the study.

   Aim 1 also includes administration of a standardized measure of implementation elements, the Organizational Readiness to Change Assessment (ORCA) too. Interviews are recorded and transcribed by a subject code that is kept separate from the data files. The questionnaire is sent to all primary care staff in the six participating facilities, N=700+. As with the qualitative interviews, the bargaining unit reviews the research protocol and staff participation is voluntary.

   AIM 1 also includes semi-structured interviews by telephone with caregivers of a Veteran with dementia of the Alzheimer's type or related disorder; or in person if requested by the caregiver. We invite 2-3 caregivers from each of the 6 participating facilities to participate who have recently (within 6 months) received a home safety item from the P&SAS. Veterans with early stage dementia may participate if they choose, but it is optional. Personal identifiable information is needed in order to mail an informational flier to the family, approved by the Central IRB and local Research and Development Committees. Interviews are recorded and transcribed using a subject code that is kept separate from the data files in a locked, secure file cabinet. Qualitative data and analyses are maintained on a secure research drive by subject code.

   Aim 2 is an evaluation of implementation effectiveness and overall success of the program in providing a HST to Veterans with an ICD 9 diagnosis of dementia and their caregivers. Inclusion Criteria: (a) Eligible recipients of a HST are Veterans with one of the ICD-9 codes for dementia who have an identified primary caregiver who lives with them; (b) expectation that the Veteran will remain living in the home and community for the next 6 months; and (c) caregiver can read and speak English. Exclusion Criteria: (a) Veteran or caregiver is currently in acute inpatient hospital setting; (b) plan is for Veteran to be admitted to residential long term care in less than 6 months; (c) primary caregiver unable to give knowledgeable informed consent or Veteran is unable to provide assent to participate.

B. *Sources of material.* Interview data for the formative diagnostic analysis is derived from the semi-structured interviews as described above. In addition, data will be obtained from administrative data in the Decision Support System (DSS) to the degree possible, e.g. Veterans with current diagnosis of dementia (inclusion criterion), time since diagnosis, # of co-morbidities, # of contacts with

the health care system in the preceding 12 months. We will obtain information about PACT performance measures from the PACT Compass, a dataset that is available on the VA intranet. Only aggregate data for a facility will be reported unless an individual primary care provider asks for a breakdown of Veterans with dementia who have or have not received a HST in their panel.

C. *Potential risks.* The HST is an educational intervention. The risks associated with the study are estimated to be minimal and not more than a Veteran or caregiver would experience in their usual daily activities. In fact, the HST has been shown to decrease risk in the randomized controlled trial (RCT) and there are no alternative interventions that would be delayed. In the recently completed RCT, adverse events were not related to the study but rather to the frail nature of an elderly Veteran population with multiple co-morbidities. No Veterans or caregivers chose to withdraw from the RCT; rather, Veteran/caregiver dyads had to withdraw due to hospitalization of one or the other for a medical problem unrelated to the study. It is possible that some caregivers may feel distressed by barriers to getting the home safety items they require for their Veteran, and/or are distressed by caregiving demands for a person with dementia. These risks will be detailed in the informed consent and the participants will be given names and contact information for further assistance. We anticipate no legal or social risks to the Veteran or caregiver.

2. Adequacy of Protection from Risk

Recruitment and informed consent. We will request a waiver of HIPAA authorization for recruitment purposes: (a) to screen P&SAS records to identify Veterans with dementia and a caregiver who recently received a home safety item from P&SAS, and (b) to identify clinical staff to participate in the qualitative interviews. Informed Consent Procedures: The choice to participate by either the VA staff or the patients/caregivers will be informed and voluntary. The participant should demonstrate the ability to: understand the nature of the research and participation, and the consequences of participation; have the ability to deliberate on alternatives; evidence the ability to make a reasoned choice; and comprehend that the intervention is research. Participants also must know that they can decide not to participate without jeopardizing their VHA care or employment. Decisions against participation or early withdrawal requests will be accepted without hesitation or consequence. Veterans/caregivers are given additional opportunities to decline to participate or to end their participation in the study. This aids in ensuring that a participant's continued involvement is truly voluntary by giving "permission" to leave the study. They are also informed that refusal to participate will be accepted without hesitation at any time and will not change their eligibility for VA services, treatment, disability payments, or other related VA benefits.

Patients with mild to moderate dementia show impairments of varying degrees in their memory, their

ability to manipulate information, and their ability to use spatial information (e.g., navigate a route).

Their ability to speak and comprehend language may be quite preserved. We do not wish to exclude

these patients because to date our research indicates that they are as much at risk for accidents as patients with moderate to severe dementia. The patient with mild – moderate dementia whom we recruit is often able to understand simple questions and respond appropriately. An example of such a question is: "Would you like to participate in a study about home safety for Veterans with memory loss?" Because these studies involve minimal risk (no medications, no radiation), we consider a patient competent to consent to the study if they are able to understand it.

One important measure we take with all participants with dementia who can understand verbal language and attend to a simple conversation is to have them summarize the study back to us at multiple points in the consent process. After giving the patient and their caregiver as much time as they would like to look at the consent form themselves, we ask if we may go over the consent form with them. At this point, we go through each paragraph, beginning with the Purpose, reading it to them. We then ask, "Can you summarize what I've just read in your own words?" We then ask if they agree to each part. The purpose in doing this is that the patient would have difficulty remembering all the parts by the time they reached the end of the consent.

We always explain the study to the patient's family member or legally authorized representative and we always have that individual sign the consent form as well—if he or she is convinced that the patient is interested in participating in the study. Usually, the legally authorized representative is also the primary caregiver who will be signing a consent form as well. At any time that the caregiver thinks the study is disturbing to the person with dementia, we end their participation. Without evidence that the study is disturbing to the person with dementia, we assume that he or she continues to consent to the study even as time passes and their dementia worsens, because they consented when they were able to understand and make a choice.

<u>Protection of risk to data security and confidentiality.</u> All study documents will be kept in locked file cabinets in a locked office in the secure CHOIR building at Bedford and at the GRECC offices at Bedford VAMC. De-identified study data will be kept on a VA server, under VA security measures, and will be password protected. Drs. Horvath and McConnell, as well as the program manager and research assistants at both sites will have access to identified data. Confidentiality safeguards will be strictly maintained to prevent violation of an

individual's privacy. When transcripts are received, the Veteran's name, address, and social security number will be immediately removed and replaced with their study ID number. As noted above, all study documents will be kept in locked file cabinets in a locked office in a secure building at the Bedford VAMC. In addition, all results will be reported in the aggregate so that no individual Veteran can be identified.

3. Potential benefits.

   We consider there to be potential benefits for study participation. Veteran/caregiver dyads who receive a HST will receive information about home safety and sample items to enhance caregiver self-efficacy for injury prevention. At the end of the study, all findings regarding facilitators and barriers to implementing a HST will be shared with other VA facilities to extend the benefits to as other Veterans with dementia.

4. Importance of knowledge to be gained.

   Risks are reasonable to participants relative to the importance of knowledge to be gained. We consider that the knowledge gained from the formative evaluations will be valuable for other implementations of evidence-based practices. Using PACT measures of team functioning to understand conditions that affect whether or not a Veteran receives a HST will provide new information on the degree to which PACT processes influence adoption of evidence-based practices. The study is conducted at 6 sites that are diverse in clinical services and geographic regions, providing strong support for generalizability of results.

5. Data and Safety Monitoring Plan.

   The PI, Co-Is, and all other study staff will monitor for adverse events. The first study staff member to take note of the adverse or serious adverse event will notify Dr. Horvath at Bedford VAMC and Dr. McConnell at Durham VAMC immediately. The study staff member and PI/Co-I will discuss the event in its entirety: (e.g. what happened, what caused it, if it was expected or unexpected, any ways to resolve or correct the issue, etc.). The PI will file a report of the event with the IRB the same day and when required to ORO. A copy of the report is kept on file in the project binder. At the acceptance of individuals to be members of the study, adverse and serious adverse events related to the study will be described. Individuals will be notified that if they are feeling distressed, they can exit and be removed from the study without repercussions.

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