Abstract – Submitted With Grant Application
HTN-IMPROVE: Determining the Implementation Process
Funded by:
Veterans Affairs
Quality Enhancement Research Initiative/Health Services Research & Development
RRP 09-196

Anticipated Impacts on Veterans Healthcare:

Hypertension is the most widely recognized modifiable risk factor for stroke, myocardial infarction, peripheral vascular disease, heart failure, and end-stage renal disease. In the Department of Veterans Affairs health care system (VA), hypertension is the most common chronic condition with a prevalence of 37% among veterans. Results of the proposed project will provide lessons on organizational facilitators and barriers to implementing self-management support programs that have been shown to be efficacious in clinical trials in the "real world" setting of the primary care clinic, thereby extending the benefits of the programs to veterans who are treated at a variety of VA facilities. The potential is thereby to reduce the burden of hypertension and potentially other chronic illnesses among veterans.

Project Background:

We have previously demonstrated the effectiveness of a nurse-delivered tailored behavioral and educational intervention aimed at improving hypertension control (V-STITCH; HSR&D grant IIR 20-034) and have shown that the intervention improves patients' BP control by 15% at 24-months compared to usual care controls. In a non-VA setting, using a combined BP monitoring and nurse-delivered tailored behavioral and education intervention (TCYB; R01 HL070713), we have improved SBP by 5.7 mm/hg and DBP by 3.5 mm/hg relative to a control group over 24 months. The VA recently set a new target of 75% of hypertensive patients under control. To achieve this rate of BP control alternative interventions will be necessary. There has been a gap between knowledge and translation of effective hypertension interventions into practice despite having a solid evidence base for effective interventions. The proposed project seeks to evaluate the organizational factors associated with implementation of a proven behavioral intervention to improve BP control in a cost effective way among veterans with hypertension in a primary care setting.

Project Objectives:

The principal aim of the proposed study is to evaluate barriers and facilitators for implementing a previously studied behavioral intervention designed to improve hypertension self-management. This will be done prior to the implementation of the previously studied patient-tailored telephone hypertension self-management program at three VA Medical Centers.

Project Methods:

To address the study aims, the project will be conducted in three geographically diverse VA sites within three Veteran Integrated Service Networks (VISNs). Using Innovation and organization theory, we will conduct a needs assessment and evaluate barriers and facilitators for implementing the proposed behavioral intervention at each of the three intervention sites. We will 1) conduct a series of semi-structured qualitative interviews to assess aspects of the conceptual model and 2) survey members of the "core implementation team" (i.e. site champion and staff directly involved in planning for and implementing the intervention) and other primary care physicians, mid-level providers, and nurses who will potentially interact with the intervention. The surveys will include a newly developed measure of organizational readiness to change. In addition, staff members will be asked to complete the Assessment of Chronic Illness Care and a representative of each facility will be asked to complete the VHA Clinical Practice Survey.

Research Plan – Submitted With Grant Application

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A. RESEARCH OBJECTIVES

Hypertension is the most widely recognized modifiable risk factor for stroke, myocardial infarction, peripheral vascular disease, heart failure, and end-stage renal disease.[1] In the Department of Veterans Affairs health care system (VA), hypertension is the most common chronic condition with a prevalence of 37% among veterans.[2] Four decades of clinical trials have produced an enormous body of evidence that controlling hypertension improves cardiovascular and renal outcomes, and the mechanisms for achieving control (e.g., diet, exercise) are well known and widely accepted. However, despite the increased incidence of multiple hypertension-related diseases, the availability of respected evidence-based guidelines, and the availability of more than 100 antihypertensive medications, *only a third of all U.S. hypertensive patients have their blood pressure (BP) under effective control.*[1]

We have previously demonstrated the effectiveness of a nurse-delivered tailored behavioral and educational intervention (V-STITCH; HSR&D grant IIR 20-034) and have shown that the intervention improves patients' BP control by 15% at 24-months compared to usual care controls. In a non-VA setting, using a combined BP monitoring and nurse-delivered tailored behavioral and education intervention (TCYB; R01 HL070713), we have improved SBP by 5.7 mm/hg and DBP by 3.5 mm/hg relative to a control group over 24 months. The VA recently set a new target of 75% of hypertensive patients under control.[3] To achieve this rate of BP control alternative interventions will be necessary. There has been a gap between knowledge and translation of effective hypertension interventions into practice despite having a solid evidence base for effective interventions. The proposed project seeks to evaluate the organizational factors associated with implementation of a proven behavioral intervention to improve BP control in a cost effective way among veterans with hypertension in a primary care setting.

A.1. Principal Aims

The principal aim of the proposed study is to evaluate barriers and facilitators for implementing a previously studied behavioral intervention designed to improve hypertension self-management. This will be done prior to the implementation of the previously studied patient-tailored telephone hypertension self-management program at three VA Medical Centers. The project will involve two primary components:

1. **Qualitative interviews** with core implementation team staff and a sample of primary care providers (i.e. physicians and mid-level providers with a panel of assigned primary care patients) and primary care nurses. These interviews will be guided by an organizational model of innovation (described in detail below).

We will examine whether the successful implementation of the intervention (e.g., consistent, high-quality, appropriate intervention delivery) will be associated with higher levels of: 1) organizational readiness for change; 2) quality of the implementation policies and practices that the clinic puts into place; 3) adaptations that the clinic makes to increase the fit of the intervention with clinic operations; 4) climate for implementation that results from these policies, practices, and adaptations; 5) extent to which intended users (e.g., physicians, nurses) perceive that the intervention reflects their values (e.g., professional autonomy, practice

boundaries); and 6) extent to which clinic-level and organizational changes reinforce or reduce the climate for implementation (e.g., users' perceptions that intervention use is rewarded, supported, and expected).

2. **Surveying** all primary care providers and nurses regarding:
    a. Organizational Readiness for Change/implementation of the nurse-directed self-management support intervention.
    b. Organization of the system for providing hypertension care as related to the Wagner Chronic Care Model.[4]

We will also examine whether these surveys are valid instruments for measuring readiness to implement chronic illness care interventions and the organization of primary care programs in which these innovations are being implemented.

B. BACKGROUND

B.1. Context-Evidence for the Intervention being Implemented

Evidence for the nurse-directed hypertension self-management intervention is based on three clinical trials led by Dr. Bosworth. In all the three prior studies involving over 2000 hypertensive patients, funds were included to cover the cost of a research nurse to provide the intervention. A significant component of the proposed study involves examining the implementation of V-STITCH using local resources and staff not covered by a research grant. Understanding how local resources are configured to implement the proposed hypertension intervention is paramount before the study can be implemented across the VA.

Table 1: Progression of Our Recent Hypertension Studies

Study Name (sample size)	**Veteran Study to Improve the Control of Hypertension – V-STITCH (n=588)**	**Take Control of Your Blood Pressure – TCYB Study (n=699)**	**Hypertension Intervention Nurse Telemedicine Study – HINTS (n=588)**
Current Status	Completed	Enrollment completed & patients followed for up to 24 months	Enrollment completed & and follow-up for 18 on-going
Study Sample	•Hypertensive Veterans •Enrolled from primary care clinics	•Hypertensive community patients •Enrolled from a University clinic and community clinic	•Hypertensive Veterans with inadequate BP control •Enrolled from VA primary care clinics
Intervention Components	• 9 tailored behavioral, educational modules •Provider decision support (ATHENA)	• 11 tailored behavioral, educational modules • Home BP monitoring	•11 tailored behavioral, educational modules •Medication Management via decision support system •Home BP tele-monitoring
Intervention Frequency	Every 2 months for 24 months	Every 2 months for 24 months	Every 2 months, when BP is out of control, for 18 months
Outcome	BP control obtained from all primary care clinic visits	BP control obtained by RA at 6 month intervals (5 measurements)	BP control obtained by RA at 6 month interval (4 measurements)

B.1.a. *Veteran – Study To Improve The Control of Hypertension (V-STITCH) study (Bosworth, Oddone).* Recently completed, the V-STITCH study (VA HSR&D IIR 20-034), was a randomized controlled trial that tested whether a patient intervention, a provider intervention, or combination of the two is more effective in improving BP control. In V-STITCH, providers were randomized to receive or not receive a hypertension decision support intervention. A sub-sample of the providers' patients were then randomized to receive the patient intervention or not. This study was conducted in three VA primary care clinics. The V-STITCH sample was composed of patients with a diagnosis of hypertension that had filled a prescription for hypertensive medication in the previous year. Patient enrollment was independent of prior BP control; 816 eligible patients were approached and 588 were enrolled and randomized to receive the nurse intervention or usual care (76% recruitment rate). The mean age of the sample was 63 years and 41% were African American. Most were of low SES and 23% reported

having inadequate income. Participants had relatively poor health behaviors; 54% did not report any exercise in the last week and 30% reported they currently smoke. Only 43% of the sample had adequate BP control at baseline.

The behavioral intervention involved a nurse contacting patients by telephone every 2 months for 24 months. At each call, the nurse delivered information in nine educational and behavioral modules. The information was both standard and tailored to patients' needs. Of the 294 patients randomized to the nurse intervention, 84% of the sample received all 12 intervention telephone calls. The average length of time to administer the intervention call was 3.7 minutes (SD=2.5 minutes). After 24 months of follow-up, BP control increased from 44% to 65% in the nurse intervention group compared to the control group from 44% to 53% (p=.03; an absolute difference of 12.6%). The mean annual cost of implementing the intervention was estimated to be $112 per patient (range $61-$259). [5] The intervention did not lead to significant increases in overall observed inpatient or outpatient costs. There was no difference in the number of primary care visits over the 2 years.[6, 7]

V-STITCH *informs the current proposed study in multiple ways: 1) We demonstrated an effective behavioral/educational intervention that we believe can be easily implemented and is cost effective. 2) We have been able to successfully retain these individuals for up to 24 months.*

B.1.b. ***Take Control of Your Blood Pressure Study (TCYB) (Bosworth, Oddone).*** The TCYB study is a randomized clinical control trial of hypertensive patients occurring in two Duke University-affiliated clinics. The focus of TCYB is behavior modification through self-management based on home BP monitoring.[8] Patients were randomized to one of four groups: usual care; a nurse-administered behavioral intervention; home BP monitors alone; or, a combination of the behavioral intervention and home BP monitors. We enrolled 636 hypertensive adults in 12 months; 28% are functionally illiterate, 51% are minority. Our retention rate for the 24-month study was 91%. Patients given a brief explanation of how to use the home BP monitor were able to use the devices effectively and accurately when assessed at a follow-up visit. Most of the planned behavior intervention was delivered (the average number of encounters completed for the 318 in the nurse arm was 11 out of 12 over 24 months). Patients randomized to the combined behavioral/home BP monitor group showed the greatest BP control improvement (70.4% at baseline to 83.2% at 24 months). The largest sustained improvement in SBP was observed in the combined intervention group (SBP improved from 126 mm Hg at baseline to 120 mm Hg at 24 months). The average phone call was 15 minutes per encounter (180 minutes over 24 months) and the cost of the combined intervention was $416 over 24 months. *TCYB informs the proposed study in multiple ways: 1) We demonstrated that patients could successfully measure their home BP over 24 months. 2) The study provides further argument for proposing a two arm study (e.g., combined intervention versus an education control).*

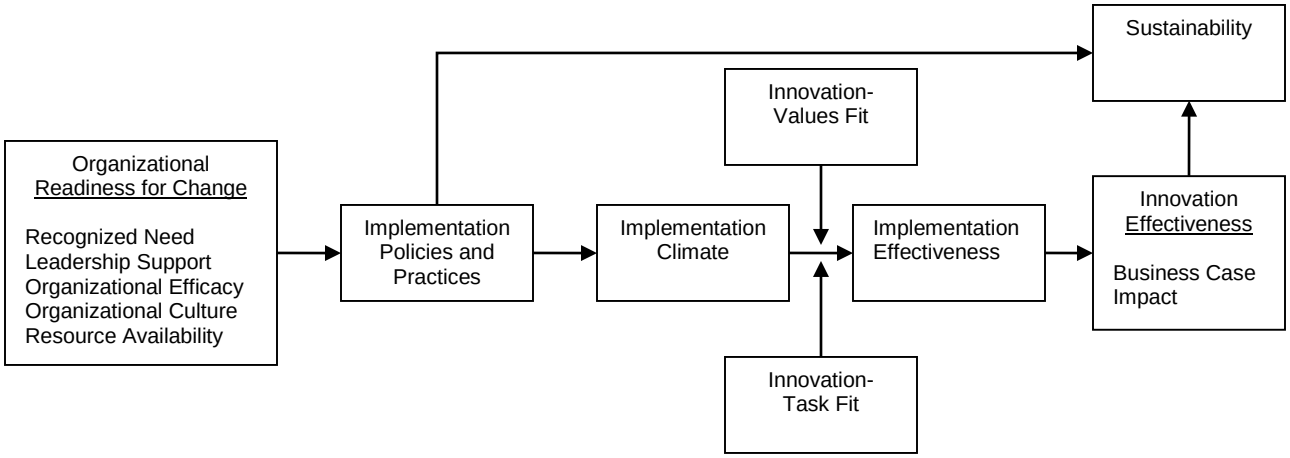
B.1.c. ***Hypertension Intervention Nurse Telemedicine Study (HINTS) (Bosworth, Oddone).*** The VA-funded HINTS study involves a sample of hypertensive veterans with poor BP control at baseline enrolled in three VA primary care clinics.[9] Enrollment was 588 hypertensive adults; 38% are functionally illiterate, 51% are minority, 43% have diabetes. Participants are randomly allocated to one of four arms (usual care, tailored nurse- administered behavioral adherence intervention, medication management, and a combined behavioral adherence and medication management intervention). For each patient, the nurse-administered intervention is activated only when home BP monitoring indicates inadequate BP control (non-diabetics >135/85; diabetics >135/80 based on VA guidelines). Patients assigned to the behavioral intervention receive a nurse-administered tailored self-management intervention to promote adherence with medication. Patients randomized to the medication management arm have their hypertension regimen changed by a nurse using a validated hypertension decision support system.

B.2. Conceptual Framework

We will use innovation and organization theory to inform our investigation. [10-13] An innovation is a technology or practice that an organization uses for the first time, regardless of whether other organizations have previously used the technology or practice.[14-16] In this case, this will be the behavioral intervention tested in V-STITCH, and refined in TCYB, and HINTS (e.g., approximately 2000 hypertensive patients). The behavioral intervention is a highly specified innovation whose implementation requires systemic organizational changes in structure, staffing, workflows, and policies. Implementation refers to the transition period, following a decision to adopt a new technology or practice, during which intended users actually put the new technology or practice into use.[14, 15] Like other promising innovations in health care, the behavioral tailored intervention is a dynamic innovation whose meaning and use evolves over time.[17]

To guide the project, we have adapted an organizational model of innovation implementation that Dr. Weiner and others have refined in prior work[14-16] (see Figure 1). Briefly, the model posits that the effective implementation of the innovation (the intervention) is a function of the various VA clinics' readiness for change, the quality of the implementation policies and practices that it puts into place, the climate for implementation that results from these policies and practices, the extent to which intended users of the innovation (e.g., physicians and nurses) perceive that innovation use fosters the fulfillment of their values, and the extent to which the innovation fits with task requirements (e.g., feasibility). The organizational benefits of an innovation (e.g., improved patient care) depend on how well and how consistently intended users use the innovation. Sustainability, which refers to the capacity of organizations to maintain innovation use over time, needs to be considered. For the VA, sustainability of the intervention depends on innovation effectiveness, continued acquisition of resources from the environment (e.g., funding, patients), and ongoing investment of resources in implementation policies and practices (e.g., training, rewards, communication systems).[18] Lastly, the staffing and health care costs of implementing the intervention also need to be considered.

Figure 1. Conceptual Model



Implementation Policies and Practices are the strategies that an organization employs to put into use the innovation, and the actions that follow from those strategies. Examples include education and training, communication and coordination, recognition and rewards, and time to experiment with the innovation.[19] Implementation policies and practices are cumulative, compensatory, and equifinal.[20] This means that, in general, more policies and practices supporting implementation are better; yet, some high-quality policies and practices may compensate for the absence or low quality of other polices and practices. Also, organizations can achieve the same level of implementation with differing mixes of policies and practices.[21, 22]

Implementation Climate refers to organizational members' "shared summary perception of the extent to which their use of a specific innovation is rewarded, supported, and expected within their organization".[20, p. 1060] Implementation climate emerges from shared information about, observations of, and experiences with the organization's implementation policies and practices. Organizations can create a strong implementation climate by making use of a variety of policies and practices designed to enhance organizational members' means, motives, and opportunity for innovation use.[21, 22]

Implementation Effectiveness refers to the consistency and quality of innovation use [20, 22-26]. Although individuals can vary in innovation use, implementation effectiveness is conceptualized here as an organization-level construct that describes the pooled consistency and quality of innovation use (i.e., intervention activity). Implementation effectiveness is necessary, but not sufficient for innovation effectiveness. [19, 20, 22, 27] Implementation effectiveness is operationally defined as accrual, or the enrollment of new patients into clinical trials.

Innovation-Values Fit refers to the extent to which intended users perceive that innovation use will foster the fulfillment of their values. [20, 21, 23, 28] Values refer to "generalized enduring beliefs about the personal and social desirability of models of conduct or 'end-states' of existence."[29, p.1076] Individuals vary in their values, but emphasis here is given to values shared by groups (e.g., physicians).[30] Innovation-values fit moderates the relationship of implementation climate and implementation effectiveness. Even in the context of a strong implementation climate, innovation use could range from non-use to compliant use to committed use depending on innovation-values fit.[20]

Innovation-Task Fit refers to the extent to which the innovation is compatible with task demands, work processes, and organizational capabilities. Innovation-task fit moderates the relationship of implementation climate and implementation effectiveness. Even if a VA clinic builds a strong implementation climate, implementation effectiveness (accrual) will suffer if the clinical interventions' design characteristics (e.g., patient eligibility restrictions, data collection requirements) do not fit the organization's task performance capabilities (e.g., patient populations, workflow).

Innovation Effectiveness refers to the organizational benefits that accrue from innovation use (i.e., the intervention). [20, 23] Innovation effectiveness depends on how well and how consistently intended users use the innovation (implementation effectiveness). From an organizational standpoint, innovation effectiveness exists if a cost effectiveness case exists. Innovation effectiveness also exists if the investing entity perceives that innovation use has a positive indirect effect on organizational function. From a VA perspective, innovation effectiveness exists if evidence-based clinical services more rapidly diffuse among clinics than among clinics not using the intervention. This would indicate that innovation use resulted in more evidence-based clinical care even for non-trial patients.

Sustainability refers to the capacity of organizations to maintain innovation use over time. For the VA, sustainability of the intervention depends on innovation effectiveness, continued acquisition of resources from the environment (e.g., funding, clinical trials, and study participants), and ongoing investment of resources in implementation policies and practices (e.g., training, rewards, communication systems).[31, 32]

C. SIGNIFICANCE

The hypertension related outcomes of renal disease, CHF, and CHD-related mortality, have increased significantly in the last decade.[33] Moreover, the prevalence of hypertension itself has increased to 29.3% in 2003-2004[34] resulting in 65 million Americans with hypertension (>8 million veterans), which will likely lead to an even greater burden of stroke and CVD outcomes.[34] With the increasing prevalence of hypertension and subsequent secondary diseases, and the overall poor rate of BP control in treated patients, it is more important than ever to improve control of this prevalent disease.

The VA has set a national goal of 75% of hypertensive patients reaching BP control and this study will provide important information that will help meet these goals.[3] Given that the national prevalence of hypertension among the adult U.S. population has increased to 31%,[34] intensive, but easily translated and disseminated interventions are required to treat this epidemic. If the proposed implementation intervention is able to achieve levels of BP control similar to those set by national VA goals (or higher), information from this study could directly impact clinical practice in the VA system.

There is a large gap between what we know and what we need to know about how to promote the use of evidence-based guidelines and practice within primary care. The proposed project will significantly advance scientific knowledge about models for disseminating and implementing hypertension guidelines by testing theoretically informed empirically grounded organizational models of implementation processes that are adapted to the context of clinical practice. The models will not only identify the key organizational factors associated with implementation effectiveness, but also describe the interplay of these factors both in start-up and early implementation as well as in later, mature implementation.

C.1. Benefits to the VA

Despite knowledge of the risks of poor BP control and evidence for efficacious treatments, a majority of veterans still do not have adequate BP control. Hence, the VA considers the reduction of hypertension an important goal and has elevated it to the level of a VISN Director Performance Standard. This study will be an important step in providing additional scientific evidence concerning detailed organizational characteristics that may be associated with successful intervention of an evidence-based intervention into primary care settings and assessing facilitators and barriers to its implementation. In addition, it is anticipated given current quality of care requirements, the proposed study will expand understanding of organizational factors involved in providing care given that care will be provided by telephone where more patients could be followed versus in-person. Translation of our findings into practice will be enhanced by the identifying key organizational factors associated with implementation of a pragmatic intervention. Information obtained from this work will impact the implementation of other interventions to reduce the impact of stroke among veterans. Lessons learned from the evaluation of the implementation of this program will inform the development of an implementation 'tool box' and packaging the components for wider distribution to the VA.

D. METHODS

D.1. Methods Summary

To address the study aims, the project will be conducted in three geographically diverse VA sites within three Veteran Integrated Service Networks (VISNs). Using innovation and organization theory,[10-13] we will conduct a needs assessment and evaluate barriers and facilitators for implementing the proposed behavioral intervention at each of the three intervention sites. We will 1) conduct a series of semi-structured qualitative interviews to assess aspects of the conceptual model and 2) survey members of the "core implementation team" (i.e. site champion and staff directly involved in planning for and implementing the intervention) and other primary care physicians, mid-level providers, and nurses who will potentially interact with the intervention. The surveys will include a newly developed measure of organizational readiness to change. In addition, staff members will be asked to complete the Assessment of Chronic Illness Care[35] and one representative from each facility will be asked to complete the VHA Clinical Practice Survey.[36]

D.2. Facilities

The project will be conducted at three facilities in three separate VISNs that agree to implement the V-STITCH nurse-directed hypertension self management project. Facilities must agree to have a goal of delivering the program to at least 500 individuals who will be enrolled over a one-year period. These patients will be contacted monthly for one year. In order to do

this, the facility must agree to provide 0.5 full time equivalent employees (FTEEs) of nursing time to conduct the intervention. While access to the computerized software and related technical assistance will be provided by the Durham team, the individual facilities and their site champions will be responsible for ensuring the program is implemented (e.g. determining ways in which patient referrals occur; working with information technology to ensure nurse interventionist needs are met). As a result, we propose to study barriers and facilitators to this true facility-level intervention before the project has happened.

D.3. Qualitative Interview Sample

Semi-structure interview methods are well-suited for studying implementation processes, which tend to be fluid, non-linear, and context sensitive.[37, 38] In addition to permitting in-depth analysis of individual cases, case study methods offer analytic strategies for systematically comparing patterns observed across cases.[39] The sample will consist of core team members (i.e. site champions, nurse-interventionists, other key personnel involved in implementing the project) and other key primary care personnel. At each study facility, this includes: 1) core-team (5-10 individuals); 2) 8-10 physicians/health care providers, 3) 2-5 nurses, and 4) 1-3 IT personnel per VA site (N = 48-84 total). Sample size will vary somewhat across VA sites due to organizational differences in the number of individuals directly involved in the core implementation and staff members in the primary care program.

D.4. Quantitative Survey Sample

The quantitative survey will be administered via the VA Intranet (i.e. within the protected VA computer environment) to all physicians, mid-level providers with an assigned panel of primary care patients, and all nursing staff members within the primary care program at facilities implementing the intervention. These individuals will be identified with the assistance of the facility champion.

D.5. Qualitative Interviews

We will use a semi-structured interview guide to gather data on organizational readiness for change, implementation policies and practices, implementation climate, user-values fit, inter-organizational relationships, and environmental conditions. Team members will alternate conducting the interviews by telephone. Interviews will last between 30 minutes and one hour. They will be digitally recorded on a VA computer and later transcribed verbatim. Specifically, we will use pattern-matching logic, where an observed pattern is compared to a predicted one [40]. In pattern-matching, an observed pattern is compared to a predicted one (e.g., hypothesized relationships described in the study's conceptual model). If the patterns match, the predicted pattern is said to receive support. If they do not, the investigator reformulates the predicted pattern by developing and investigating alternative predictions. Analysis will involve three procedural steps: coding, within-case analysis, and between-case analysis.[39, 41]

Separate interview guides will be used for 1) administrators; 2) clinical application coordinators; 4) information technology personnel; 4) nurses; and 5) physicians/mid-level providers. Covered domains will include: 1) organizational readiness to change; 2) implementation policies and practices; 3) innovation-task fit; 4) implementation climate; 5) innovation-values fit; and 6) perceived implementation/innovation effectiveness.

D.6. Survey Measures

In order to assess the organizational functioning within intervention facilities and identify potential barriers to implementation, all primary care physicians, mid-level providers, and nurses will receive the **Assessment of Chronic Illness Care (ACIC)**. The 34-item ACIC was developed to allow healthcare teams to evaluate the degree to which their organization has implemented practices suggested by the Chronic Care Model (CCM). It has been used by many organizations participating in chronic illness quality collaboratives and as a basis for surveys of community primary care providers. The ACIC uses a 12-point Likert scale to ask respondents to rate the degree to which the organization has implemented 34 aspects of the CCM. These 34 items are grouped into seven subscales at correspond to the Wagner Chronic

Care Model: 1) overall organization of health system; 2) community linkages; 3) self-management support; 4) decision support; 5) delivery system design; 6) clinical information system; and 7) integration of CCM components.[35] Dr. Jackson was part of the initial team that developed the ACIC. The ACIC has been shown to be responsive to quality improvement efforts. Assessment of the instrument with 90 teams participating in chronic illness improvement collaboratives found significant improvement in chronic illness care components ($p < 0.05$) for all six subscale scores among both diabetes and congestive heart failure (CHF) focused teams in the collaboratives.

In order to assess the readiness of members of the primary care program at each intervention site to implement a change in the care process (i.e. the proposed intervention), we will administer the **Organizational Readiness to Change Survey** developed by Dr. Weiner (co-investigator). Twelve items assess perceived efficacy of the core implementation group to carry out critical implementation tasks effectively (e.g., coordinating implementation activities), perceived commitment of the core implementation group to implement the intervention, and perceived commitment of the user group to support and use the intervention. Additional items explore possible determinants of readiness.

Information on **respondent demographics** will also be collected. This includes age, race, gender, profession, years in the profession, years at the VA, and VA duties.

In order to control for overall facility characteristics (e.g. academic affiliation, size of the primary care program), we will administer the **VHA Clinical Practice Organization Survey-Chief of Staff and Primary Care Module** for all intervention facilities (one per facility) using strategies that achieved an approximately 90% response rate during national administration national administration done in 2006 and 2007 respective.[42, 43] We expect a higher response rate because of our collaboration with the smaller number of facilities.

D.7. Survey Process

Staff at the Durham HSR&D Center of Excellence will conduct all research. Staff at individual sites will not distribute the surveys, collect data, or analyze results. All we will ask from the facilities is to confirm the list of primary care physicians, mid-level providers, and nurses at their facility. The letter will include the signature of a facility clinical champion for the study. The following procedures will be used to collect survey data:

D.7.a. Staff Recruitment.

1. Clinic staff may refuse to complete the survey. If they refuse, staff will not be contacted again. Staff can refuse to complete the survey at any point during the recruitment process.
2. Each attending physician (including fellows), mid-level provider (nurse practitioners and physician assistants), nurse, and member of the "core implementation team" at the intervention primary care clinics will be asked to fill out the survey appropriate for their profession. If a staff member indicates that she or he does not wish to participate in the study, the provider will not be contacted again.
3. Staff members will receive an email message with a recruitment letter and link to the appropriate survey. If a staff member indicates that she or he does not wish to participate in the study, the individual will not be contacted again.
4. The recruitment letter text will explain the survey's purpose.
5. If providers/nurses do not complete the survey after a one-week period of time, a second email will be sent. If a provider indicates that she or he does not wish to participate in the study, the provider will not be contacted again.
6. If after the second email the providers/nurses do not return the survey, a hard copy will be sent. In addition to the survey and cover letter, this packet will include a stamped envelope for return and a pen to aid in completing the survey. If a provider indicates that she or he does not wish to participate in the study, the provider will not be contacted again.
7. Finally, if the providers/nurses do not return the survey after the second email and hard copy was sent, a RA may contact providers/nurses to ask if they would like to participate in the

study. If a provider indicates that she or he does not wish to participate in the study, the provider will not be contacted again.

8. There will be no exclusions based on provider race, ethnicity, or gender.

Extensive recruitment opportunities are required because clinical staff have a variety of schedules and work locations and receive a large volume of electronic and other mail making it possible that the may not receive information on the study in a way that makes it easily accessible to them without multiple contacts.

D.7.b. Survey Administration.

1. The survey will be administered using a VA intranet Web page (i.e. within the protected VA computing environment). It will allow answers to be entered into the electronic form and be recorded automatically in a database.
2. The computerized version of the survey will be linked to via a VA intranet page. Active Directory Authentication will be used to track responses from specific individuals and ensure that the person answering the questions is authorized to do so. Data will not be stored on individual computers used by individuals to complete the survey. Data will have at least 128 byte encryption during the transfer back to the Durham HSR&D server. This process will be conducted behind the VA firewall. Stored data will also have at least 128 byte encryption.

D. 8. Data Analysis

D.8.a. Qualitative Analysis. Qualitative analysis to examine the telephone interviews will involve three phases: data coding, within-case analysis, and between-case analysis. In the data coding phase, we will use qualitative data analysis software (ATLAS.ti 5.0) to code the study data. The conceptual framework will provide a starting list of codes, which we will supplement with emergent codes as analysis proceeds. Using a common codebook, two investigators will conduct a pilot test by independently coding five transcripts. Based on the pilot test, the investigators will sharpen the coding manual's definitions, decision rules, and examples. Research assistants will code the remaining documents.

In the second phase, we will conduct a within-case analysis of each VA using ATLAS.ti, generating reports of all text segments for each code. We will assess the degree to which the construct emerges in the data (its "strength"), the degree to which the construct positively or negatively affects implementation (its "valence"), and the degree to which relationships among constructs are consistent with the hypothesized model. We will assess support for the hypothesized relationships by using three criteria proposed by Trochim [44] and Miles and Huberman.[45] First, we will look for the overall covariance of the constructs (e.g., whether VA clinics exhibiting strong implementation climate have supportive administration). Second, we will look for explicit attributions or the identification of plausible mechanisms to link the two constructs (e.g., participants attribute a strong implementation climate to the deployment of appropriate implementation policies and practices).

In the third phase, we will apply the same criteria across the cases to determine if cross-case variation in implementation is consistent with the hypothesized relationships in the model. Consistent with the organization-level focus of the model, we will aggregate and analyze quantitative data on implementation policies and practices (e.g. staffing levels) and other study constructs using simple statistics. In addition, we will create within-case and between-case data displays that cross-tabulate the quantitative and qualitative data in order to facilitate the use of pattern-matching logic. [45]

While not specifically part of the proposed grant, we will also use results from the qualitative interviews to examine organizational factors that may be associated with the clinical impact and long-term sustainability of the hypertension self-management intervention.

D.8.b. Quantitative Data Analysis. A primary goal of combining qualitative and quantitative data collection is to provide a cross validation between to two. At the facility level, we plan to link facility level scores on Organizational Readiness to Change Scale and coded responses in the area of organizational readiness to change from the qualitative interviews. While we have

only a limited number of facilities, this will provide us the opportunity to examine the face validity of the Organizational Readiness to Change Scale. Further, we will conduct a similar analysis comparing results of the Assessment of Chronic Illness Care to qualitative response regarding innovation-task fit and implementation policies and practices.

An additional primary goal will be to conducted analyses to validate the Organizational Readiness to Change Scale. We will measure constructs using multi-item scales to reduce the threat of mono-operational bias.[46] We will construct scales at the individual level based on exploratory principal factor analysis with orthogonal rotation. Items with factor loadings of 0.40 or more will be examined for inter-item consistency. Scale items with a Cronbach alpha coefficient of 0.70 or more will be averaged to construct individual-level scales.[47, 48]

While not specifically part of the proposed grant, we will also use results from the surveys to examine organizational factors that may be associated with the clinical impact and long-term sustainability of the hypertension self-management intervention.

E. ANTICIPATED PRODUCTS AND DISSEMINATION PLAN

The **final product** of the qualitative interviews will be a theoretically informed, empirically grounded model of organizational implementation adapted to clinical practice that will help facilitate the implementation of this and other interventions aimed at improving the care for patients with chronic illness.

We anticipate that a **final product** of the quantitative surveys will be validation of the Organizational Readiness to Change Survey. In addition, a validation analysis of the Assessment of Chronic Illness Care specifically within the VA will be done. An additional **final product** of the survey component of the study will be a survey tool made available to QUERI centers and VA facilities. After validation, we will make the survey administration tool available to QUERI centers and other VA facilities who wish to use it in the planning of innovations in the care of patients with chronic illness.

Immediately, results of this study will be used to aid facilities in the implementation of the nurse-direct hypertension self management program. In addition, a white paper on the model of organizational implementation will be prepared for all QUERI centers. Further, results will inform a tool kit for implementing the hypertension self-management intervention (not part of the proposed grant).

F. PROJECT MANAGEMENT PLAN

As PI, Dr. Jackson will be responsible for all aspects of the proposed study. Dr. Bosworth will serve as Co-PI and provide guidance as to implementation of the project. Dr. Damush (Co-I) will provide expertise on the process of VA implementation measurement. The project manager, Ms. Kaufman, will conduct day to day activities of the study. Dr. Weiner, developer of the Organizational Readiness to Change Scale, will provide consultation concerning the analysis of both qualitative and quantitative data. Finally, Ms. Smith, MS statistician, will conduct qualitative analysis and will be responsible for database administration. Weekly meetings will be conducted to ensure appropriate study progress.

F.1. Human Subjects Protection

Before the study commences, IRB/R&D Committee approval will be obtained from the Durham VAMC and each of the participating facilities. Data will be stored within the VA protected computer environment on Durham HSR&D computer servers physically located at the Durham VAMC.

F.2. Timeline

All aspects of the proposed project will be completed within one year.

Activity	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
IRB approval-Durham	X	X										
IRB approval-Other sites			X	X								
Development of interview guides	X	X	X	X								
Development of survey tool	X	X	X	X								

Qualitative interviews					X	X	X					
Staff surveys						X	X	X				
Qualitative interview analysis								X	X	X		
Survey analysis									X	X	X	
Prepare survey tool for distribution												X
Production of final report												X

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