

## **Technology and collaborative care improve the use of hormone therapy in Postmenopausal Women Veterans**

**C. 1. Overall Goal & Objectives:** The overall goal of this proposal is to determine the effectiveness of the VA-STEAM (VA Strategies To Educate and Address Menopause) intervention in improving the management of vasomotor symptoms (VMS) and vulvovaginal atrophy (VVA) in postmenopausal women Veterans age 45 to 60 who receive primary care at the Miami Veterans Affairs Healthcare System (VAHS). The VA-STEAM intervention is theoretically based on the Reasoned Action Model/Theory of Planned Behavior and consists of a series of information technology, phone, face-to-face, and print interventions that use the established technology and model of collaborative care in the Veterans Healthcare Administration (VHA). VA-STEAM will include the creation of a Menopause Clinical Reminder linked to a clinic note template in the Miami VAHS electronic health record (EHR). To accomplish our goal, we will identify all women Veterans age 45 to 60 at three VHA facilities and then compare the impact of VA-STEAM on primary care providers and patients at the Miami VAHS, to a control group of primary care providers and patients at the West Palm Beach and Orlando VAHS who will not receive the intervention. Our Specific Aims are to:

Aim 1: Establish and compare the proportion of eligible patients in the Miami VAHS who have ICD9 codes for VMS and VVA in their EHR (a) before and after the intervention, and (b) compared to those who receive usual care at the West Palm Beach and Orlando VAHS, before and after the intervention at the Miami VAHS.

We hypothesize that the proportion of eligible patients in the Miami VAHS who have ICD9 codes for VMS and VVA in their EHR will increase by 30% after the VA-STEAM intervention.

Aim 2: Establish and compare the proportion of eligible patients with menopausal ICD9 code in the Miami VAHS who receive hormone therapy (HT) (a) before and after the intervention, and (b) compared to those who receive usual care at the West Palm Beach and Orlando VAHS, before and after the intervention at the Miami VAHS.

We hypothesize that the proportion of eligible patients in the Miami VAHS who receive HT will increase by 20% after the VA-STEAM intervention.

Aim 3: Track the data entered and the number of times the Menopause Clinical Reminder in their EHR is opened by primary care providers at the Miami VHAS when caring for women Veterans age 45 to 60 years.

Aim 4: Establish and compare in eligible patients, the self-reported knowledge on menopause symptoms and management, degree of personal involvement in menopause management, and satisfaction with menopause care in the Miami VAHS (a) before and after the intervention, and (b) to the women who receive usual care at the West Palm Beach and Orlando VAHS, before and after the intervention at the Miami VAHS.

This 2-year project includes 6 months of preparations, 12 months for the implementation of the VA-STEAM interventions and 6 months for program evaluation and submission of reports.

**c. 2. Technical Approach**

**G. 2. a. Current Assessment of need in target area**

1. **Needs Assessment - Baseline Data** The number of women cared by the VHA has nearly doubled in the past decade, reaching 292,921 in 2009; 44% of female Veterans receiving care in VHA are 45 to 64 years of age, with the tallest peak at age 47, and few of them receive HT, as described below.

A large number of menopausal women receive care at VHA. In 2009, women Veterans visited VHA primary care clinics an average of 3.5 times; 15% of women had at least 6, and 90% had at least one primary care visit. Primary care is provided at the Primary Care Clinics or at the VHA’s Women’s Health Clinic.

In calendar year 2012, 2712 women had at least one primary care visit at the Miami VAHS, (Miami and Broward Clinic), 2203 at the West Palm Beach VAHS and 3482 at the Orlando VAHS. Of those, 1310, 1067, and 2113 were age 45-60 in Miami, West Palm Beach and Orlando, respectively.

Few postmenopausal women Veterans receive ICD 9 menopausal codes. The VHA’s Corporate Data Warehouse is a national repository of data from VistA and several other VHA clinical and administrative systems and is available to VA physicians and researchers (see below). We queried the VA Data Warehouse for female Veterans ages 45 to 60 who in calendar year 2012 had at least one primary care outpatient visit at three large Florida VHA facilities and their satellite outpatient clinics, Miami, West Palm Beach. Among them, we identified those who had an ICD9 code for menopausal symptoms and those who were receiving oral, dermal or vaginal estrogens. Overall, 30% of women in that age group had a menopause ICD9 code, 23% in Miami, 14% in West Palm Beach, and 43% in Orlando (Table 1).

<b>Table 1. Women age 45-60 at three VA facilities</b>			
	<b>Miami</b>	<b>WPB</b>	<b>Orlando</b>
<b>Women age 45-60 receiving primary care</b>	<b>1310</b>	<b>1067</b>	<b>2113</b>
<b>Total women with menopause ICD9 codes</b>	<b>305</b>	<b>152</b>	<b>918</b>
Symptomatic climacteric symptoms (ICD9 627.2)	264	111	696
Postmenopausal atrophic vaginitis (ICD9 627.3)	32	27	332
Symptomatic states/ artificial menopause (ICD9 627.4)	5	9	10
Other specified menopausal disorders (ICD9 627.8)	17	8	25
Unspecified menopausal disorder (ICD9 627.9)	22	8	32
<b>Total women on estrogen</b>	<b>94</b>	<b>289</b>	<b>323</b>
Women on estrogen, oral or patch	10	12	16
Women on vaginal estrogen	7	44	45
Women on vaginal estrogen plus estrogen oral or patch	77	233	262

Few postmenopausal women Veterans are prescribed HT. VMS are the most commonly reported and bothersome of menopausal-related symptoms. VMS occur in approximately 65-80% of women in the menopause transition [1,2], with increasing frequency and severity in the late perimenopause and early postmenopause. VMS generally persist for several years after the final menstrual period, although 10-20% of women continue to experience VMS for decades. VMS are associated with decreased physical, emotional, and social quality of life, as well as sleep disturbance and depressed Mood [3-5].

In the US, <25% of women are receiving treatment for their menopausal symptoms [6]. Our data shows this proportion is as low in women Veterans receiving care in Florida VHA

facilities, as shown in Table 1. In Miami, 30% of women in this age group with menopausal symptom ICD9 code were on some form of estrogen, 35% in Orlando. Remarkably, in West Palm Beach, twice as women were on estrogen than those with ICD9 codes for menopausal symptoms. These data suggest that there is substantial variability across VA facilities in management of menopausal symptoms which may be due to inconsistent or absent processes with regard to the alignment of assessment, diagnosis, coding and discussion of treatment options.

## 2. Target for the Intervention

*VA-STEAM* (VA Strategies To Educate and Address Menopause) is a series of information technology, print, face-to-face, and print interventions that will be compiled from existing materials (North American Menopause Society, Australian Government National Health and Medical Research Council, etc., see Appendix) to improve rates of screening for menopausal symptoms and increase awareness and rates of appropriate use of HT, other drug therapies and lifestyle modalities to treat these symptoms. *VA-STEAM* interventions will be targeted to (1) women Veterans who receive primary care at the Miami VA Medical Center (VAMC) and Broward Clinic, and (2) the primary care providers at those facilities. Female patients in this age group and their providers at the West Palm Beach and Orlando VAHS' will serve as controls.

In calendar year 2012, 2712 women had at least one primary care visit at the Miami VAHS, (Miami and Broward Clinic), 2203 at the West Palm Beach VAHS and 3482 at the Orlando VAHS. Of those, 1310, 1067, and 2113 were age 45-60 in Miami, West Palm Beach and Orlando, respectively.

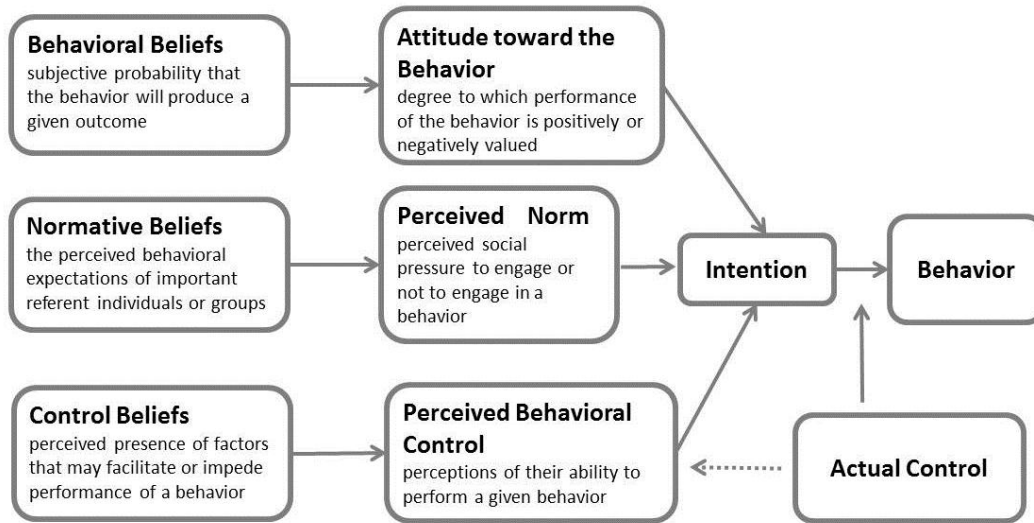
The Miami VAHS consists of the Miami VA Medical Center and 6 Community –Based Out Patient Clinics that are located from Key West to Deerfield Beach, a range of over 200 miles. The Broward Outpatient Clinic is located 40 miles north of the Miami VAMC and is its largest satellite clinic. Each facility has a designated Women's Health Liaison who is proficient in caring for women and coordinates the services for women Veterans. There are 15 Primary Care/ Patient-Aligned Care Teamlets (PACT) in the Miami facility, 15 teamlets at the Broward Clinic, 37 teamlets in the West Palm Beach VAHS and 34 teamlets at the Orlando VAHS (see below for a detailed description of teamlets and PACT).

## **C. 2. B. Intervention Design and Methods**

The intervention is theoretically based on the Reasoned Action/ Theory of Planned Behavior Model and will leverage the collaborative care principles and robust information technology already in place at VHA [7]. The Theory of Reasoned Action suggests that a person's behavior is determined by his/her intentions to perform the behavior and that this intention is, in turn, a function of his/her attitude toward the behavior, subjective norm, and perceived behavioral control (Fig. 1). It has been used to understand and influence health behaviors and outcomes. This theory will be applied to both patient and provider *VA-STEAM* interventions, which will be delivered to both target groups via information technology, print, face-to-face, or in print. The wide variety of *VA-STEAM* interventions will allow patients and providers to utilize the information in the format of their preference.

After 6 months of preparations, the *VA-STEAM* interventions will be delivered over the following 12 months. Data analysis and generation of reports will occur in the last 6 months.

**Figure 1.** Reasoned Action Model/ Theory of Planned Behavior as framework for the interventions.



**Preparations** will consist of: (1) submission to the Miami VAHS IRB, (2) patient focus groups, (3) provider focus groups, (4) patient survey, (4) design of the interventions based on data obtained from focus groups and survey.

**Patient survey.** The project will begin with a survey mailed to women Veterans age 45 to 60 years who had at least one primary care visit in the previous 12 months at the Miami, West Palm Beach and Orlando VAHS. Patients from each facility will be sent surveys printed in paper of a different color. Otherwise, all surveys will be anonymous. Surveys will be mailed out with a self-addressed and stamped return envelope. The survey will assess sources of information on menopausal health, knowledge, symptoms and satisfaction with care of menopausal symptoms at VHA. The data obtained will be utilized to tailor pre-existing tools to create the VA-STEAM tool kit. At the end of the 12-month intervention, a similar survey will be mailed to the women in the target group at the three facilities who had one primary care visit in the 12 months preceding the second survey.

**Focus groups.** Patient and provider focus groups will be conducted at the Miami VAMC and the Broward clinic. These will take place while surveys are mailed and the responses compiled. We will conduct 3 patient focus groups of 5 - 10 participants per group at the Miami VAMC (n=2) and the Broward clinic (n=1). Female patients in the target age group attending the primary clinics at these two facilities will be approached to participate. The focus groups will assess values, perceptions and barriers to HT, views about self-management and use of technology. One provider focus group will be conducted at each facility, Miami VAMC and Broward. We will solicit voluntary participation for a one-hour session during their lunch hour.

**Hormone Therapy Information and Content.** Key to the success of the intervention will be developing and tailoring content that women will find appropriate, helpful and easy to understand regarding HT as part of patient-centered care. As information about HT is often difficult to understand for lay audiences due to the medical terminology used as well as the complexity of the topic, the focus groups with women Veterans will help us understand their perceptions, attitudes, self-management and information needs to tailor both content and

delivery of the intervention (e.g., flyers, handouts and website content). Specifically, focus group guide questions will be open-ended and will draw upon previous research on communicating HT to lay audiences, self-management of care and the theoretical framework of the Reasoned Action Model/Theory of Planned Behavior to include questions asking about attitudes, norms, values and beliefs regarding HT. These questions will help assess the different perceptions about HT and key concerns that may be influencing HT decisions for women. Questions will also ask how they would like this information delivered, as well as their use of technology. Answers will inform the appropriate content needed to communicate with women about HT and the corresponding technology, or communication channel, which women would prefer to receive such information. Understanding women's technology preferences, and tailoring our content and technology use preferences in this way, will help us incorporate a patient-centered care perspective that is emphasized in the VA PACT initiatives. In addition, focus group questions will assess women's health literacy levels to ensure content is written at an appropriate reading level that would be easy to understand.

To further inform our information and materials for providers, two provider focus groups will be conducted to understand their perceptions on patients HT decision-making and develop appropriate resources and support materials to assist providers in discussing HT with patients. Drawing upon the Reasoned Action Model/Theory of Planned Behavior, focus group guide will ask providers open-ended questions asking about the perceived norms and beliefs about HT. In particular, we will ask providers to discuss the challenges in addressing HT in their clinical settings and their beliefs and perceptions in being able to talk with patients about HT and prescribe HT. We will also ask their perceptions about the patients' priorities and needs for HT. Additionally, we will ask providers their thoughts on how best to receive resources and information. It will be important to garner these perceptions and thoughts to inform the intervention materials and the use of appropriate technologies to use in the intervention.

Focus Group Analysis. Focus groups will be audio-recorded and transcribed. A brief analysis will be conducted to identify common themes among participants' responses to questions. Analysis will help us select key words and phrases that should be included in the content to enhance the appropriateness of the materials for both audiences.

## **Intervention**

The behavioral constructs and corresponding intervention strategies for patients are listed in Table 2 and those for providers in the PACT teamlet are listed in Table 3. The Project Manager will work with the PACTs to implement the interventions during individual patient visits, group patient visits, video-telemedicine visits and telephone consultations.

Collaborative care is a scalable strategy for delivering evidence-based interventions for common health problems where trained providers provide proactive, patient-centered care and management to a large caseload of patients [8]. The primary care Patient Aligned Care Teams (PACTs) recently implemented throughout VHA is a form of collaborative care and will greatly facilitate the implementation of the proposed VA-STEAM intervention. Primary care at VHA is organized around PACT principles. Based on the patient-centered medical home, delivery of care through PACT has the goal of improving healthcare delivery through increasing access, coordination, communication, and continuity of care. Each teamlet consists of a primary provider (physician, advanced registered nurse practitioner (ARNP) or physician assistant (PA)),

a registered nurse (RN), a licensed practical nurse (LPN) and a program support assistant. In addition to the core teamlet staff, every two to four teamlets are supported by a pharmacist, a dietitian, social worker, case manager and behavioral health staff. PACT provides accessible, coordinated, comprehensive, patient-centered care, and is managed by primary care providers with the active involvement of other clinical and non-clinical staff. PACT allows patients to have a more active role in their health care, which is associated with increased patient satisfaction.

<b>Table 2. PATIENT - Behavioral Constructs, Intervention Strategies, and Corresponding Program Components</b>		
<b>Behavioral Construct</b>	<b>Intervention Strategies</b>	<b>Program Component</b>
<b>Behavioral Beliefs</b>	Fact-finding to tailor interventions	Focus groups
<b>Attitude toward Behavior</b>	Fact-finding to tailor interventions	Focus groups
<b>Normative Beliefs</b>	Social references to legitimize recommendations	Simplified version of medical guidelines (website, flyer, handout)
<b>Perceived Norm</b>	Peer support	Group visits/Group telephone education
<b>Control Beliefs</b>	Information about VMS/VVA, options for therapy (medication and lifestyle)	Mail flyer/Handouts in clinics Website Telephone education
<b>Perceived Behavioral Control</b>	Ongoing support to patient	Develop personal menopausal health goals Access to PACT members Twitter messages

<b>Table 3. PROVIDERS - Behavioral Constructs, Intervention Strategies, and Corresponding Program Components</b>		
<b>Behavioral Construct</b>	<b>Intervention Strategies</b>	<b>Program Component</b>
<b>Behavioral Beliefs</b>	Fact-finding to tailor interventions	Focus groups
<b>Attitude toward Behavior</b>	Fact-finding to tailor interventions	Focus groups
<b>Normative Beliefs</b>	Professional references to legitimize recommendations	Medical guidelines (CPRS links, website) Lecture
<b>Perceived Norm</b>	Individual and group performance ICD9 coding and HT prescriptions	Almanac: monthly report to all providers
<b>Control Beliefs</b>	Fact-finding to tailor interventions	Focus groups
<b>Perceived behavioral control</b>	Facilitate VMS and VVA management	CPRS links to guidelines Point of care CMEs Panel management tools Motivational interview video Consultation with specialists

1) VA-STEAM for Patients. The following *VA-STEAM* interventions will be targeted to female Veterans who had a at least one primary care visit at the Miami VAMC or Broward Clinic in the previous 12 months:

- Flyers. Flyers will be mailed to target females at months 1, 5 and 9. The flyers will encourage discussion of menopausal symptoms with PACT members at the next visit, provide guidance on how to develop personal health goals, and list the *VA-STEAM* website address, Twitter account, and VANTS number and schedule of phone sessions. These flyers will also be distributed in the waiting areas of the primary care clinics at the two target facilities.

- Phone sessions. For those who may have limited resources, every other month we will offer an educational phone session via a toll-free number. About 20-30 minutes of education on menopausal symptoms, lifestyle modifications and HT will be provided, followed by an interactive Q&A session. The goal is to offer an alternative option for interacting with clinical staff instead of just the mailed materials. VHA utilizes the Veterans Affairs Nationwide Teleconferencing System (VANTS) for audio and video teleconferencing. This system provides ready access for individuals to call in and listen to educational presentations and/or to fully participate in interactive discussions. The system can be configured for a specific number of lines/participants as well as the functionality to provide calls in "lecture" mode such that all other lines are muted so to reduce interruptions or background noise. Teleconferencing can be opened up to full participation at any time during the call. Teleconferencing provides a convenient way for patients to access informational services, especially when no identifying information is shared during the call. VANTS is increasingly being used to supplement self-management programs (weight management) offering Veterans the option of getting social support and educational information in a convenient, patient-centered modality. In order to address the needs of Veterans who are not computer/web/twitter literate, we will conduct monthly or every other month VANTS phone session that could be accessed by women who aren't the above and who may have difficulty accessing group.

- Website. A website will be created to provide information on menopausal symptoms, HT and other drug therapies, healthy lifestyle, medical society guidelines, and links to other websites that provide relevant information. The website content will be updated monthly during the 12 months of the intervention. The site will also serve as a reference point for the other interactive interventional elements (i.e., telephone education, group visits, twitter).

- Twitter messages will be sent periodically with positive and supporting messages that provide general lifestyle advice to manage menopausal symptoms (layered clothing, hot drinks, alcohol intake, exercise, etc.)

- Video to educate patients on HT. This original video will be produced and played in the TV monitors in the patient waiting areas, along with other educational and informational videos.

- Individual Clinic visits in Primary Care

- Shared Medical Appointments. In 2005, VHA mandated group or shared medical appointments (SMAs) as a means to improve clinic efficiency and quality of care. SMAs offer an opportunity to utilize physician and non-physician providers to their fullest potential. Based on the chronic care model, SMAs are patient medical appointments in which a multi-disciplinary/multi-expertise team of providers sees a group of patients (8-20) in a 1.5 to 2 hour visit. Chronic illnesses such as diabetes lend themselves to this approach. SMAs are frequently utilized for conditions which require education and support of patients while they develop and implement

self-management skills. SMAs are particularly appropriate for chronic conditions in which the symptom profile may change over time. The benefits of SMAs include dissemination of provider expertise among staff members and patients and a strong sense of teamwork among different providers who contribute to the care patients. In addition to improved clinical outcomes, after participation in SMAs, challenging or high-risk patients usually become better self-managers, teachers, and motivators for other patients. SMAs offer an effective way to engage patients in educating other patients, consolidating their own learning and understanding complex medical issues. Patients benefit from the accessibility to multiple disciplines or areas of expertise (e.g., disease and medication management, behavioral/ motivational experts). They also benefit from the experience of other patients participating in the group (peer support). With team guidance, patients learn from each other about solutions to tackle the day-to-day challenges in a way that is impossible to achieve in traditional clinic visits. Finally, the patients gain a sense of control and usually experience improved health and greater satisfaction with care. In the current proposal, we will offer 90-minute SMAs which will focus on raising awareness of menopausal symptoms, impact of symptoms on quality of life, treatment options, and factors which may influence women's decision to use or refuse HT (i.e., risks and benefits). The group approach will be similar in format to our ongoing Cardiovascular Risk Reduction groups in which Framingham Risk scores are used to help patients understand the benefits and risks associated with disease processes and treatment. The *VA-STEAM* Group Clinic will similarly utilize educational materials and visual aids to facilitate understanding of health factors for Veterans with varied degrees of health literacy and numeracy.

2) *VA-STEAM for Providers*. The tool kit will consist of education materials and, benefiting from the advanced and widespread use of technology throughout VHA, will also include provider support and assistance with decision making incorporated in the Miami VAHS electronic health record system (EHR).

- Lecture on Menopause Management to primary care providers by Neil Goodman, MD (CME 1 hour). Dr. Goodman has an appointment as Voluntary Professor of Medicine at the Univ. of Miami. He is a reproductive endocrinologist in private practice in Miami.

- Video to train providers. As part of the proposed project, we will develop a script and brief educational video for use with primary care staff which utilizes Motivational Interviewing (MI) skills in discussing the risks and benefits of HT. Such videos are frequently used in training of MI skills and is perhaps best exemplified by the success of the Effective and Ineffective Physician series which target tobacco cessation (<http://www.youtube.com/watch?v=URiKA7CKtfc> and <http://www.youtube.com/watch?v=80XyNE89eCs>, respectively). Use of a video in training activities serves many purposes including use of role models with whom staff can identify, demonstration of MI skills (e.g., open ended questions, reflection, summaries, and affirmations), and illustrating a format for facilitating a dialogue about changing health behaviors. Ambivalence related to medical adherence, obtaining screening and diagnostic tests, increasing exercise, quitting tobacco, and changing nutritional patterns is common and proves to be a significant barrier to implementing prevention/treatment measures. Originally conceived as a treatment for alcohol use disorders, MI has become widely recognized as a brief, evidence-based intervention applicable for a range of psychiatric and medical conditions as it assumes that ambivalence in the face of changing problematic behavior is normal and expected



in consultation and treatment settings [9]. MI strategies have been shown to significantly impact the provider's ability to connect and mobilize the patient's own motivational resources to increase self-management and disease prevention making MI strategies ideally suited to the primary care environment. There appears to be strong evidence that MI is an effective approach focusing on eliciting a person's intrinsic motivation for change of behavior.

- Menopause Clinical Reminder in Miami VAHS. Technology at VHA provides a unique setting for novel interventions and measurement of outcomes. CPRS (Computerized Medical Record System) is the electronic health record used throughout VHA. CPRS is a Veterans Health Information Systems and Technology Architecture (VistA) software application. CPRS enables clinicians, nurses, clerks, and others to enter, review, and continuously update all information connected with any patient. It supports ambulatory and inpatient care and has allowed VHA to achieve a pharmacy prescription accuracy rate of 99.99%. With CPRS, care providers can quickly flip through electronic "pages" of the chart to add new orders, review or add problems, write progress notes, or see results. Alerts, notifications, cautions, warnings, advanced directives, future appointments, demographic data, medications, and orders are all available. CPRS gives providers the ability to create document templates to make writing or editing progress notes, completing consults, or writing discharge summaries quicker and easier. The Clinical Reminders and Clinical Reminder Dialogs and Reports in CPRS are templates that help caregivers deliver higher quality care to patients for both preventive health care and management of chronic conditions, and helps ensure that timely clinical interventions are initiated. Reminders assist clinical decision-making and also improve documentation and follow-up, by allowing providers to easily view when certain tests or evaluations were performed and to track and document when care has been delivered. They have prompts for ordering tests, prescribing medication or other evaluations that enhance the quality of care for specific conditions. The clinicians can then respond to the reminders by placing relevant orders or recording clinical activities on patients' progress notes. Clinical Reminders may be used for both clinical and administrative purposes. However, the primary goal is to provide relevant information to providers at the point of care, for improving care for Veterans. The package benefits clinicians by providing pertinent data for clinical decision-making, reducing duplicate documenting activities, assisting in targeting patients with particular diagnoses or site-defined criteria, and by assisting in compliance with VHA performance measures and with Health Promotion and Disease Prevention guidelines. The Menopause Clinical Reminder will be built to facilitate the assessment of menopausal symptoms during clinic visits. It will incorporate the Women's Health Questionnaire and will contain links to medical society guidelines, point-of-care CMEs (short paragraphs of information with questions linked to CME credits provided by the Miami VAHS) , and handouts for patients to be printed at the clinic site. An example of the Osteoporosis Consult Clinical Reminder can be found in the Appendix. It was developed by Dr. Levis (PI) for optimal management of osteoporotic patients. This Reminder is currently in use for all osteoporosis consults at the Miami VA.

- Professional detailing of PACT providers by investigators and PACT pharmacist.

- Telehealth Services. VHA uses new technology to change where healthcare has traditionally been provided. The expansive use of Telemedicine throughout VHA facilitates the delivery of collaborative care to Veterans at their homes or local clinics. Specialist consults will be provided as requested, in person at the Miami VAMC or via a telehealth visit with patients or providers at

the Broward clinic. Specialty Care Access Network-Extension for Community Healthcare Outcomes (SCAN-ECHO) has been established by VHA to increase access to specialty care services for Veterans in rural and medically under-served areas through the use of videoconferencing equipment. It enables specialty care teams in areas such as diabetes, pain management, and Hepatitis C to use videoconferencing equipment to connect with Veterans' local PACTs. During a scheduled SCAN-ECHO clinic, the PCP presents a patient's case and the specialty care team recommends a treatment plan. In addition to case presentations, formal clinical education is also provided.

Almanac. Primary Care Almanac is a tool available in CPRS to facilitate the management of high risks populations. The Almanac allows a PACT members to mine the data of patients in their own panel and identify those who may need improved control of a medical condition by identifying those patients by diagnosis, abnormal tests or vital signs and those who do not have appointments. A typical use is in the management of diabetics and hypertensives, identification of frequent Emergency Room users, and medication position ratios. The Almanac provides extensive demographics on the patients on the panel. The data can be exported as an excel spread sheet and arranged according to levels of the parameter being looked at (see Appendix). Each provider will receive a monthly report of the number and proportion of women in the target age group who have menopause ICD9 codes and are who are on HT, for their panel and the average for the group of providers.

### **C. 2. c. Evaluation Design**

#### *i. Assessment Metrics. How it will be determined if practice gap was assessed*

This is a pre-post study design with a control group that will target the Miami VAHS primary care providers and their female patients age 45 to 60. Primary care providers at the West Palm Beach and Orlando VAHS' and their patients will serve as the control groups.

Baseline data will consist of 12-month retrospective data collection of women Veterans who had  $\geq 1$  primary care visit at the Miami, West Palm Beach and Orlando VAHS' to determine the number and proportion of those who had an ICD9 code reflecting menopausal symptoms (627.2, 627.3, 627.4, 627.8, 627.9) and those who were on an estrogen preparation (oral, dermal, vaginal). Demographic data, as well as number of primary care and other medical visits, other diagnostic codes and medications received during those 12 months will also be obtained. Diagnostic codes will serve to explain outcomes and contraindications for HT, such as breast cancer or history of deep-vein thrombosis. Patients with menopausal ICD9 codes and/or on HT who receive care at these facilities by other specialties but not by primary care will not be included in the database. Retrospective data gathered from all patients cared for by the providers at the three VHA facilities for the 12-months will be compared to data obtained from these same providers during the VA-STEAM intervention period. Data will be retrieved at the end of the 12-month intervention.

#### Primary Outcomes

Aim 1: Establish and compare the proportion of eligible patients in the Miami VAHS who have ICD9 codes for VMS and VVA in their EHR (a) before and after the intervention, and (b) compared to those who receive usual care at the West Palm Beach and Orlando VAHS, before and after the intervention at the Miami VAHS.

Aim 2: Establish and compare the proportion of eligible patients with menopausal ICD9 code in the Miami VAHS who receive hormone therapy (HT) (a) before and after the intervention, and (b) compared to those who receive usual care at the West Palm Beach and Orlando VAHS, before and after the intervention at the Miami VAHS.

Aim 3: Track the data entered and the number of times the Menopause Clinical Reminder in their EHR is opened by primary care providers at the Miami VHAS when caring for women Veterans age 45 to 60 years.

Aim 4: Establish and compare in eligible patients, the self-reported knowledge on menopause symptoms and management, degree of personal involvement in menopause management, and satisfaction with menopause care in the Miami VAHS (a) before and after the intervention, and (b) to the women who receive usual care at the West Palm Beach and Orlando VAHS, before and after the intervention at the Miami VAHS.

### Secondary Outcomes

1. Physician satisfaction and recommendations assessed by survey at the end of the trial.
2. Understand the reasons why *clinical reminders* were opened but no action taken. A representative sample of electronic records (n= 50) will be reviewed by two of the co-investigators to help explain why action was not taken after opening the Menopause *Clinical Reminder* (i.e. acute medical illness, family history of breast cancer, etc.).

### Baseline Characteristics

1. Socio-demographics: age, race, ethnicity, frequency of primary care and specialty visits
2. Clinical: height, weight, BMI, tobacco and alcohol, comorbidities, concomitant medications

- How results will be collected, analyzed, and interpreted. The following data will be extracted from the EHR: problem list entries, diagnostic codes, demographics, vital signs (including height and weight), selected laboratory results, medication list, and orders for selected procedures (i.e., bone density, mammogram). Chi-square tests will be used to compare the differences in proportions (observation vs. intervention periods) between the Miami VAHS and West Palm Beach and Orlando facilities. Logistic regression analysis will be used to adjust for demographic (age, race, ethnicity) and clinical factors (body mass index, medications, prior fractures, comorbidities, etc.).

We plan to include women of all races and ethnicities and believe that we will have an adequate sample size to analyze the data by age groups (i.e. 45-49, 50-54, 55-60), race, and ethnicity. However, as few people of American Indian and Asian origin reside in South Florida, and therefore few attend the local VAHS, subanalyses will only include Blacks, Hispanic Whites and Non-Hispanic Whites.

Richards et al. [11], using an intervention specific to osteoporosis (i.e., a checklist of risk factors for osteoporosis) at another VHA facility, showed that the proportion of clinical encounters with appropriate practice behavior (ordering a bone density test and/or prescribing an FDA-approved medication for osteoporosis) doubled, from 14% to 29%. A separate article on computerized decision support to reduce potentially inappropriate prescribing to older adults in the emergency department (ED) provides some insights on a similar approach as this proposal, but using a different setting: a randomized clinical trial [12]. The physicians who were

randomized to the intervention and received the decision support prescribed inappropriate medications during 2.6% of the visits of elderly patients to the ED, while control physicians who did not receive computerized decision support prescribed inappropriate medications during 3.9% of the visits (OR= 0.55, 95% CI 0.34 – 0.89, p= 0.02). These findings imply that a computerized decision support leads to a reduction of approximately 45% in the inappropriate medication management of elderly patients in the ED (i.e., leads to an increase by 1.8 times (almost double) in the proportion of appropriate medication management of these patients). Based on these studies showing changes in physician practices after patients completed an osteoporosis checklist and improved practices with computerized decision support, we expect that this study will have enough power to detect a difference in the proportion of patients with a menopause ICD9 code or prescribed HT before and after the *VA-STEAM* intervention, and between the intervention (Miami VAHS) and control groups (West Palm Beach and Orlando). We expect a >30% increase in ICD9 codes in the target population, from 30% to 40%, and 20% increase in the proportion of women with menopause symptom ICD9 codes who receive HT. Without accounting for race differences, a sample size of 120 in each group (intervention and control) will provide 80% power to detect a difference in the proportion of tests ordered (25 vs. 32%), assuming a significance level of 0.05. For a comparison between Blacks, the sample size would be 81 in each group, while for a comparison between Non-Hispanic Whites a total of 212 in each group would be needed. Therefore, to address differences across race groups, this study will require a sample size of approximately 300 in the intervention group and 300 in the comparison group.

- Sources of Data. (1) VHA Corporate Data Warehouse (CDW). CPRS (Computerized Medical Record System) is the electronic health record used throughout VHA. CPRS is a Veterans Health Information Systems and Technology Architecture (VistA) software application. CDW is a relational database organized into a collection of data domains. Domains represent logically or conceptually related sets of data tables. Domain themes generally indicate the application in the VistA electronic health record system from which most of the data elements in the domain come (e.g., vital signs, mental health assessment). Data are available from October 1999 to present. Availability varies by domain. CDW's SharePoint site provides an up-to-date list of available domains with some structural documentation in the Metadata Reports section. CDW data domains are classified as either production or raw. VistA is the primary source of CDW data. No filtering of records, editing of content or business rules have been applied to these data. Raw data domains reflect the source system structure (VistA) and are not modeled, standardized, or indexed. Tables in production domains have been structured to support flexibility of queries. We have queried CDW to obtain our preliminary data and will conduct comparable queries to obtain baseline and end-of-study outcomes. ( 2) The Almanac feature allows providers to check performance of their patient panel in real-time. A monthly report will be generated for each provider's panel and for the provider group overall, that will identify the patients in the target group without menopause ICD9 codes and/or not on HT. (3) VIReC: The VA Information Resource Center is one VHA's Health Services Research and Development Service resource centers. Its mission is to improve the quality of VHA research that utilizes databases and information systems.

- How data will be collected and reported. Completed surveys will be scanned utilizing scanning software already available in Dr. Levis' office computers that captures the information entered in the documents and exports it into an Excel table. This recognition technology avoids time-consuming and error-prone data entry, allowing for manual editing before the data is stored in the database. ICD9 and HT data will be collected by conducting queries in the CDW. Report templates will be created by the Health Informatics Specialist and tested during the preparation phase. Dr. Rodriguez will create the monthly Almanac reports.

- Control group. Women in the target age group and their primary care providers at West Palm Beach and Orlando VAHS will not receive the intervention and will serve as the control group.

*ii. Change expected from the intervention*

We hypothesize that the proportion of eligible patients in the Miami VAHS who have ICD9 codes for VMS and VVA in their EHR will increase by 30%, and the proportion of those who receive HT will increase by 20% after the *VA-STEAM* intervention while remained unchanged at the West Palm Beach and Orlando facilities.

We expect that the number of times the Reminder is opened and the amount of data entered in the Reminder will progressively increase over the 12 months of the *VA-STEAM* intervention as primary care providers become familiar with the new feature available to them in the EHR and that the *VA-STEAM* intervention will result in an increase in patient self-reported knowledge, personal involvement and satisfaction with menopause care at Miami VAHS, with no change at the West Palm Beach and Orlando facilities.

*iii. Audience engagement*

The RE-AIM framework will be used to understand the impact of the proposed health intervention. Examples of how the five RE-AIM components will be applied in the assessment of the overall impact of *VA-STEAM* are listed below.

Reach: From the pool exposed to recruitment (survey), how many responded. From the pool of eligible providers, how many utilized the Menopause Clinical Reminder. From the pool of patients having a visit with a Reminder, characterize age and race/ethnicity of those on HT.

Efficacy: will be determined by study outcomes.

Adoption: The proportion of providers using the Reminder, of patients attending SMAs and phone education sessions. Characterize providers who are not users of the Reminder (larger patient panel, sicker patients), and patients who do not participate in interventions.

Implementation: We will track usage of Reminders, SMAs and phone sessions over time. We will monitor if program is implemented as planned and adjust it as necessary.

Maintenance: at the individual and systems level will be tracked after this project is concluded.

*iv. Dissemination.*

VHA promotes best practices and disseminates and implements nationwide successful pilot programs. Facilities have comparable clinical operations and administrative structure, which will facilitate the implementation of this project. Veteran's healthcare in the US is separated geographically into 23 regions known as VISNs, or Veterans Integrated Service Networks. VISNs' administrations have a hierarchical structure. Each network or VISN's director

establishes policies and priorities for its region. VISN 8 includes Florida, south Georgia, Puerto Rico and Virgin Islands. VISN 8 is a system of 8 hospitals, 55 clinics, and 8 nursing homes. The leading medical centers in VISN 8 are Miami, West Palm Beach, Orlando, Bay Pines, Tampa, North Florida/South Georgia (Gainesville), and Puerto Rico. Each VISN supports a few clinical demonstration projects, one-year programs that, if successful, are implemented quickly and efficiently throughout the VISN. As an example, Dr. Dang's successful Telephone linked Care (TLC) demonstration project for Dementia piloted in Miami VAMC was later implemented in Pittsburg and Atlanta VAMCs.

The VHA has been fully committed to training providers to become proficient in women's health. It established a National Women's Health Mini-Residency program and trained over 800 primary care providers in basic and advanced women's health care. The SimLEARN partnership and the ED-WH curriculum are used to train and disseminate women's care procedures. SimLEARN, or Simulation Learning, Education and Research Network, is the VHA's program for simulation in healthcare training. It provides large body of curricula and best practices using innovative technologies to enhance diagnostic, procedural and communications skills and support quality care and best outcomes. In addition, the VHA, through a VA Health Services R&D grant has created a Cyber Seminar Spotlight on Women's Health education series which is offered to VHA facilities nationwide. The VA is also committed to advancing research on women health issues and has sponsored two national VA Women's Health research conferences.

The VA Women's Health Practice-Based Research Network Consortium's (PBRN) mission is to train and educate, foster research-clinical partnerships, technical consultation, mentorship, and dissemination of best practices. The VA Women's Health PBRN is a group of ambulatory practices within VHA that draws on the experience and insight of practicing clinicians to identify and frame research questions whose answers can improve practice. Its ready-to-use infrastructure facilitates multi-site interventions and implementations. Through Women's PBRN, VHA programs can be successfully disseminated to provide information and new approaches to enhance the delivery of health care for women Veterans. Dr. Levis is member of the VA Women's Health PBRN and Dr. Bastian serves on its Executive Committee.

The VA Reproductive Health Working Group consists of VA providers and scientists interested in Veteran women's health, particularly in issues that relate to the different stages of women's reproductive cycle. The group has monthly conference calls and presentations and is planning several pilot projects to be tested at selected VHA facilities. Dr. Levis is a member of the group.

### ***3. Detailed Workplan and Deliverables Schedule:***

The workplan and schedule of deliverables is listed in Table 4, after the Budget Justification. The first 6 months will be dedicated to prepare all *VA-STEAM* interventions. After submission and approval of the project by the Miami VAMC IRB, we will mail the survey and conduct focus groups with patients and providers. The data obtained from these activities will assist the team in preparing the *VA-STEAM* tool kit for the intervention. Baseline data from CDW regarding menopause ICD9 codes and estrogen prescriptions will be obtained just before starting the intervention. As described above, the *VA-STEAM* tool kit includes print, phone, face-to-face, and IT activities. The *VA-STEAM* interventions will be delivered over 12 months. It will begin with training of the PACT members which will include a 50-min lecture by a menopause expert and training during the weekly staff meeting the Menopause Clinical Reminder and

Motivational Interviewing using videos created for this purpose. Flyers will be mailed to patients and placed in the clinic waiting areas, where TV monitors will show the videos created for patients. After the conclusion of the intervention period, another survey will be mailed to patients and final data from CDW will be retrieved. The last 6 months will be dedicated to analyzing data and preparation of manuscripts and reports.