A. Cover Page

1. Title: **MyHealtheVet to Enable Shared Decision Making (SDM) Regarding Menopausal and Associated Symptoms (MAS) in Postmenopausal Women Veterans**
   Request ID: **15911255**
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2. **Abstract:**

The overall goal of this project is to determine the effectiveness of the **MEANS** (**MyHealtheVet** to **E**nable **A**nd **N**egotiate for **S**hared decision making) intervention in improving women's self-reported knowledge and rates of diagnosis and appropriate management of Menopause Associated Symptoms (MAS). The proposed intervention is an educational and Shared Decision Making (SDM) platform for MAS to enhance communication between patients and their providers regarding MAS. *MEANS* incorporates educational secure messages via the Veterans Affairs comprehensive online Personal Health Record called MyHealth*e*Vet (MHV), along with face-to-face and print interventions.

MEANS will be implemented in target population comprising postmenopausal women Veterans ages 45 to 60 who receive primary care at the Miami Veterans Affairs Healthcare System. This project will enroll women in MHV, develop a library of MAS material for dissemination, and assess feasibility of MVH use for educating and tracking women regarding MAS. We will evaluate the impact of *MEANS* interventions among women Veterans at the Miami VAHS who receive the *MEANS* intervention on women's self-reported knowledge on MAS and MAS treatment (a) before and after the intervention, and (b) compared to a control group of eligible women patients between 45-60 years who do not receive the *MEANS* intervention 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 preparation, 12 months for implementation of the *MEANS* intervention, and 6 months for program evaluation and submission of reports.

MyHealtheVet to Enable Shared Decision Making (SDM) Regarding Menopausal and Associated Symptoms (MAS) in Postmenopausal Women Veterans

C. 1. Overall Goal & Objectives: The overall goal of this project is to determine the effectiveness of the **MEANS** (**MyHealtheVet** to **E**nable **A**nd **N**egotiate for **S**hared decision making) intervention in improving women's self-reported knowledge and rates of diagnosis and appropriate management of Menopause Associated Symptoms (MAS). The proposed intervention is an educational and Shared Decision Making (SDM) platform for MAS to generate enhanced communications between patients and their providers regarding MAS. It will be implemented in perimenopausal women Veterans ages 45 to 60 who receive primary care at the Miami Veterans Affairs Healthcare System (VAHS). The *MEANS* intervention is theoretically based on the SDM model for clinical practice. *MEANS* consists of a series of educational secure messages that use the Veterans Healthcare Administration's (VHA) established comprehensive online *Personal Health Record (PHR)* called MyHealth*e*Vet (MHV), face-to-face, and print interventions. To accomplish our goal, we will identify all women Veterans age 45 to 60 in the Miami, West Palm Beach and Orlando VAHS. Our Specific Aims are to:

<u>Aim 1</u>. Enroll women Veterans in MHV and compare the proportion of eligible patients in the Miami VAHS who are registered and authenticated in the PHR MHV before and after the intervention at the Miami VAHS. We hypothesize that the proportion of eligible women patients in the Miami VAHS who are enrolled and authenticated in MHV will increase by 20% after the *MEANS* intervention.

<u>Aim 2.</u> Develop a library of MAS material, links and information suitable for dissemination weekly via MHV as educational and SDM tools to enable women Veterans age 45-60 to discuss with HCP regarding MAS.

<u>Aim 3.</u> Assess feasibility of MVH use for educating and tracking women regarding MAS: We will send weekly MHV messages regarding MAS, and ask women to report their MAS via secure messaging (SM). Among women in the Miami VAHS who enroll in *MEANS* project, we will track (a) the number of times they use the weekly information sent via MHV (b) the proportion of times they respond to the Women's Health Questionnaire (WHQ) sent via MHV.

<u>Aim 4.</u> Evaluate the impact of *MEANS* interventions among eligible women Veterans age 45 to 60 years at the Miami VAHS who receive the *MEANS* intervention on women's' self-reported knowledge on MAS and MAS treatment (a) before and after the intervention, and (b) compared to a control group of eligible women patients between 45-60 years and their HCP who do not receive the *MEANS* intervention at the West Palm Beach and Orlando VAHS, before and after the intervention at the Miami VAHS, using data from VHA's Corporate Data Warehouse, CDW, a relational database organized into data domains. We hypothesize that self-reported knowledge scores of enrolled patients before and after will increase by 20% after the *MEANS* intervention.

<u>Secondary Aims</u>: 1). Evaluate impact of MHV on rates of "shared decision making" (SDM); 2) Rates of diagnosis and appropriate management of MAS, and use of Hormone Therapy (HT); 3) Qualitative assessment of *MEANS* via focus groups, and 4) Provider satisfaction.

This 2-year project includes 6 months of preparation, 12 months for implementation of the *MEANS* intervention, and 6 months for program evaluation and submission of reports.

C. 2. Technical Approach:

 C. 2. a. Current Assessment of need in target area

  i. Current Needs Assessment and Ongoing Projects in Target Area

<u>A large number of menopausal women receive care at VHA.</u> The number of women Veterans has doubled in the last decade. There were 552,662 unique women Veterans enrolled in VHA in Fiscal Year 2011, of which 235,297 (43%) were between the ages of 45 and 64 years, which is the fastest growing and largest group of female VHA users. In 2012, women Veterans had primary care visits an average of 3.5 times; 90% had at least one visit and 15% at least 6. In calendar year 2012, 2712 women had at least one primary care visit at the Miami VAHS, 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. At the Miami VAHS, 3600 women have received care in 2013; 44% (n= 1584) were between the ages of 45 and 64*.*

<u>Women have little information about MAS and its treatment options.</u> Our team (Levis/Dang) has conducted focus groups and surveyed women Veterans ages 45 to 60, who had at least one primary care outpatient visit in the previous 12 months at the Miami VAHS to inform us in the design of interventions to improve menopause management.

Focus Groups: Three focus groups were conducted (n=35, 8-12 women Veterans per group) with eligible women Veteran patients in 2014 in the Miami VAHS. The focus groups assessed values, perceptions, and barriers to hormone therapy, views about self-management and use of technology. Focus groups results indicate that women Veterans had a number of unanswered questions about menopause and menopausal symptoms and the management of menopause.

<u>Focus group data supported the idea of receiving menopausal information from knowledgeable physicians, support groups, the internet, and monthly newsletters.</u> Women Veterans stated that they were not open to using hormone replacement therapy, but were more open to using alternative and complimentary medicines.

Patient survey: In June 2014, an anonymous survey was mailed to 1369 women Veterans ages 45-60 receiving primary care at the Miami VAHS. The survey assessed sources of information on menopausal health, knowledge, symptoms, satisfaction with care of menopausal symptoms at VHA, and use of technology for menopause symptom management. Up to the date of this submission, a total of 339 surveys were received (24% response rate). Below we summarize the responses relevant to this application from the 25 initial surveys that have been analyzed.

- When asked to rate their general knowledge of MAS, the replies were evenly distributed from "little" to "very good" knowledge; however, 56% of the women responded they had "little" to "fair" knowledge of MAS treatment options.
- Among the women with menopausal symptoms, 68% responded that they had not utilized any health services in the previous 12 months for MAS management.
- Although >50% of the women reported use of MHV to check appointments and renew medications, only 20% use its secure messaging (SM) feature. Among those who do not use secure messaging, 80% would like to use it to communicate with their doctor or nurse about menopause symptom management.
- *Only 40% had discussed menopause treatment options with their HCP.*

<u>Few women Veterans utilize MHV and Secure Messaging (SM) feature:</u> **MyHealth*e*Vet (MHV)** is the VA's comprehensive Personal Health Record (PHR) website, which offers Veterans and caregivers Internet access to VA health care information and services. MHV is a free,

secure, Internet-based PHR by which patients may view and update portions of their medical record. MHV empowers Veterans to become informed partners in their health care and is easy to use. Moreover, it has secure messaging (SM), track health, personal diary, and goal setting functions, and ability to renew prescriptions. It also has educational materials. The **Secure Messaging (SM)** function of MHV enables communication and feedback between patients and HCPs. Veterans need to register online to use the system. After registering, it is required that they upgrade their status to an *authenticated account and opt in*. Only then Veterans can communicate with their HCPs via *secure messaging (SM)*. Not all Veterans who are registered are authenticated, which is a detailed process. MHV offers a promising tool for education, communication, and disease management of Veterans, at no additional cost to the VA.

At present, while many women Veterans are registering for MHV, most are not authenticated. Of the 1600 women Veterans ages of 45-60 at the Miami VAHS, 81.5% (n=1300) are registered in MHV, but only 22% (n= 285) are authenticated. In our survey of women Veterans, although >50% of the women reported use of MHV to check appointments and renew medications, only 20% use its SM feature. Among those who do not use SM, 80% would like to use it to communicate with their doctor or nurse about menopause symptom management, showing that it could be a promising tool that women Veterans would use.

Health Care Providers (HCP) may be challenged on discussing MAS with patients: Conversations regarding menopausal symptoms may be difficult for women to broach with their HCPs. Moreover, the HCPs may be challenged with how to address and/or initiate this complex dialogue. MAS are prevalent and women could benefit from these conversations with their HCP. HCPs are on the front line of managing women's midlife health and have the opportunity to offer appropriate dialogue on menopausal conditions, focus on overall well-being, QOL, and benefits and risks of appropriate (HT) for MAS. However HCPs may be limited by lack of knowledge, or appropriate tools to help them with the discussion.

Building on current work:
This project builds on our longstanding experience in the Miami VAHS with Telehealth, women's health issues, endocrinology, and MHV use in patients.
1. VHA T-21 Heart Failure Grant (Dr. Dang, PI): Dr. Dang has been funded by the VHA for using MHV for Heart Failure (HF) management. Her current project educates and monitors patients with HF, and has enrolled >100 patients in the Miami VAHS for this project. Patients get weekly educational material, and weekly questions to monitor their weight and HF symptoms via MHV.
2. MHV Clinic: Miami VAMC's MHV clinic will be the site we will use for educating women Veterans regarding MHV and SM use. Our staff is familiar with usability challenges in patients.
3. Pfizer Grant (Dr. Levis: PI): This project assesses values, perceptions, and barriers to HT and views about self-management using surveys and focus groups. We will use the results of the patient and provider focus groups to inform this current study (see needs assessment section).

ii. Target for the Intervention
The Miami VAHS consists of the Miami VA Medical Center (VAMC) and 6 Community–Based Outpatient Clinics. 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. MEANS

interventions will be targeted to (1) approximately 1600 women Veterans ages 45-60 who receive primary care at the Miami VAMC and Broward Clinic, and (2) the Health Care Providers (HCP) at these facilities. Women patients in this age group and their HCPs at the West Palm Beach and Orlando VA Healthcare Systems (VAHS) will serve as a comparison group.

C. 2. b. Intervention Design and Methods:

Theoretical framework: The intervention is theoretically based on the Shared Decision Making (SDM) model (Figure 1 and 2). *SDM is a collaborative process that allows patients and their HCPs to make health care decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.*[1] These are the subset of informed decision-making interventions that are carried out between one patient and her HCPs in clinical settings.[2, 3] This follows the principle "make no decision about me without me." SDM honors both the HCPs' expert knowledge and the patients' right to be fully informed of all care options and the potential harms and benefits. The process provides patients with the needed support to make the best individualized care decisions while allowing HCPs to feel confident in their prescribed care.
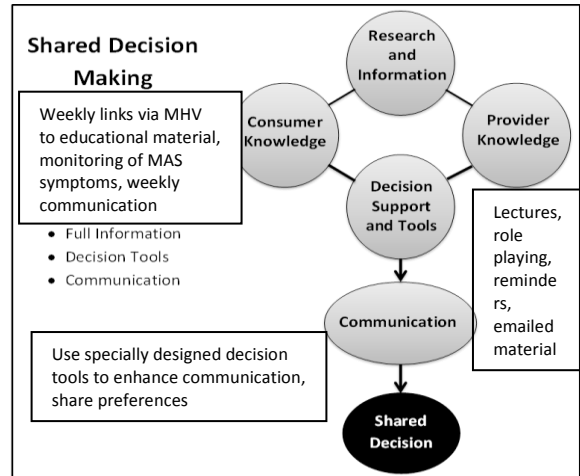

Figure 1 - Shared Decision Making Model as Framework for Interventions
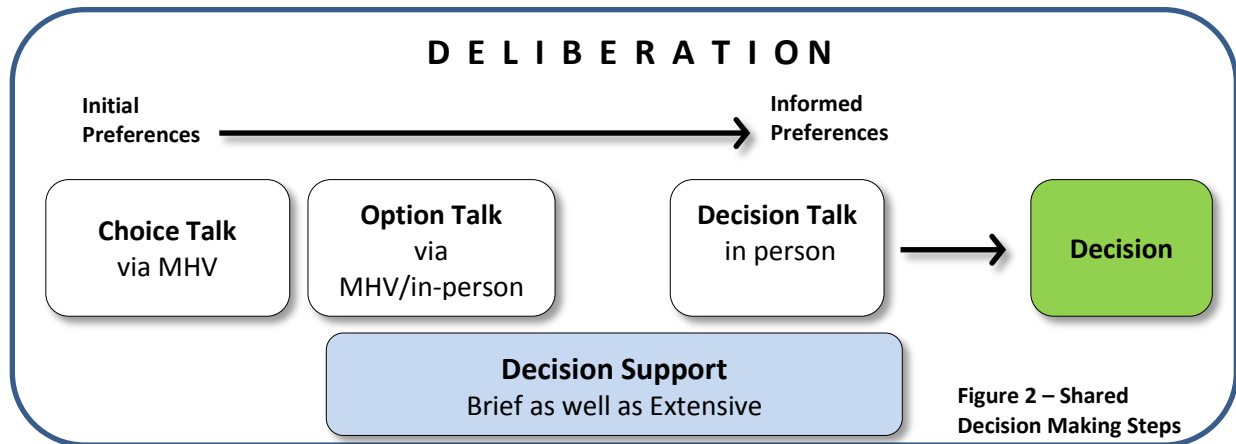

Figure 2 – Shared Decision Making Steps

The proposed SDM model will leverage the collaborative care principles and robust information technology already in place at VA. This theory will be applied to both patient and provider *MEANS* interventions, which will be delivered to both target groups via information technology, face-to-face, or in print, and give tools to enable effective dialogue about MAS between patients and the HCPs.

We will use the three key steps of shared decision making (SDM) for clinical practice, namely: *choice talk, option talk* and *decision talk* (Figure 2), *and design educational activities to support all 3 steps. Choice talk* refers to the step of making sure that patients know that reasonable options are available. *Option talk* refers to providing more detailed information

about options and is often best done outside the clinic visit encounter since patients want time to study new information and to consider their personal preferences. Patients want time to study new information, consider their personal preferences, discuss options with others, and deliberate outside the clinical encounter. _Decision talk_ refers to supporting the work of considering preferences and deciding what is best, and occurs during the clinical encounter.

This project will have 3 phases:

Phase 1: Preparation Phase (6 months) consisting of:

(a) *Submission to the Miami VAHS IRB and Education Committee.*

(b) *Develop MAS educational resources and decision support tools for patients and providers.*

(c) *Patient and provider focus groups to assess the educational resources and decision support tools and modification of the tools based on feedback.*

Phase 2: Intervention Phase (12 months) consisting of:

(d) *Enroll and authenticate women Veterans in MHV and teach them how to navigate MHV.*

(e) *Educate, monitor, and communicate with women Veterans via MHV regarding MAS.*

(f) *Strategies to Educate patients and health care providers (HCP) regarding MAS*

(g) *Shared Decision Making.*

Phase 3: Evaluation Phase (6 months) consisting of:

(h) *Evaluating the impact of MEANS interventions on outcomes.*

(i) *Data analysis and generation of reports.*

PHASE 1: PREPARATION PHASE

Phase 1 (a): *Preparation and Submission to the Miami VAHS IRB and Education Committee.*

Phase 1 (b): *Develop MAS educational resources and decision support tools for patients and providers:* Key to the success of the *MEANS* interventions will be developing and tailoring content that women will find appropriate, helpful and easy to understand regarding MAS and HT as part of patient-centered care; and in developing/adapting Decision Aids to provide information on MAS options, help people participate in decision making, and help providers discuss MAS and HT options with patients. The educational interventions and decision aids will be compiled from existing materials and current treatment algorithms and guidelines (North American Menopause Society, Australian Government National Health and Medical Research Council, etc.) to improve rates of screening for MAS, increase awareness of treatment options for MAS including appropriate HT, other drug therapies and lifestyle modalities to treat MAS, and improve SDM regarding MAS treatment. The educational materials, web resources, links, and information will be suitable for dissemination via MHV, at a 6th grade reading level, paying special heed to numeracy and literacy concepts in the design and adoption of the materials. Main tentative topics will be MAS, diet, lifestyle interventions, appropriate use of HT, and other approved

TABLE 1: MAIN TOPICS
1. About *MEANS*
2. Shared Decision Making
3. About Menopause
a. What is menopause
b. Stages of menopause
c. Symptoms of menopause
4. Menopause and sex
5. Menopause and other conditions
a. Heart Health
b. Osteoporosis
c. Thyroid
d. Mental Health and menopause
6. Menopause Treatments
a. Lifestyle changes
b. Hormone therapy
c. Natural treatments
d. Bio-identical hormones
e. Diet and exercise
7. What men/family should know (spouses or significant others)

therapies in postmenopausal women (Table 1).

Phase 1 (c): *Patient and provider focus groups:* After we develop/adapt material, we will conduct focus groups with patients and providers to ensure that the decision aids are effective and provide information about MAS options at a suitable health literacy level, in sufficient detail, present probabilities of outcomes in an unbiased and understandable way, include methods for clarifying and expressing patients' values, support providers in discussing HT with patients, and include structured guidance for providers for helping deliberation and communication. 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.

PHASE 2: INTERVENTION PHASE:
Phase 2 (d): *Enroll and authenticate women Veterans and teach them how to navigate MHV:*
All 1600 women ages 45-60 who receive care at Miami VAHS will be invited by mailed flyers and clinic posters, and in-person to register and authenticate in MHV. We expect to enroll about 200 women for this study. Study coordinators will show them how to use the different functions in MHV. Study participants will also be instructed to use the SM feature of MHV to regularly communicate with study coordinators at least weekly.

Phase 2 (e*): Educate, monitor, and communicate with women Veterans via MHV and Secure Messaging (MHV-SM) regarding MAS: Choice talk and Option talk will occur predominantly via MHV-SM.* Women will be provided education and MAS related "choices" via the SM function in MHV by sending all enrolled women weekly MAS information as PDFs or as links. Additional information will be developed for patient education as questions arise about specific topics.

Additionally, women will be encouraged to assess for menopausal symptoms by responding to the monthly WHQ surveys sent to them via SM. We will monitor the improvement in rates of assessment of age-appropriate women for menopausal vasomotor symptoms and other menopausal conditions, and give a scalable ability to track such assessment via SM. Study coordinators will be able to monitor patients' responses. Study coordinators will be assigned to initially review the messages, resolve them if appropriate, and assign to HCP and other Patient Aligned Care Team members (PACT) - nurse, psychologist, and pharmacist, as needed. The Veteran may log on MHV and report MAS symptoms like hot flashes, etc. These weekly communication and tracking of MAS will encourage women to understand menopausal conditions better, and will provide a springboard for effective dialogue between women and their HCPs and other providers on the PACT team regarding these conditions, and subsequent SDM. Patients will be encouraged to use SM to start discussion with PACT team members prior to HCP visits. The benefits of using MHV as a vehicle for communication and education is believed to derive from its ability to address content and resources tailored to the needs of Veterans, and thus elicit trust by this group through its in-group affiliation.

Phase 2 (f): Strategies to Educate/Engage women patients and Healthcare Providers *(Table 2)*:

i. Weekly SM link (Patients): Weekly links to up-to date MAS summary informational materials, links to other relevant websites, videos, and diagrams, healthy lifestyle, and decision support tools. This material will be updated yearly.

ii. Menopause symptom assessment (Patients): Women will be encouraged to assess for menopausal symptoms monthly using WHQ surveys via MHV or weekly for other symptoms.

iii. Flyers (Patients): Flyers will encourage women to discuss MAS choices with providers, informing them of the *MEANS* study and how to enroll, and also give number of a pharmacist to discuss options via telephone if patients choose. These flyers will also be distributed in the waiting areas of the primary care clinics at the two target facilities, and mailed to all eligible women at 0, 4, and 7 months of the Intervention Phase.

iv. Play videos in clinic waiting areas (Patients): Video created by Dr. Levis to educate patients on HT will be updated and reproduced and played on TV monitors in the patient waiting areas, along with other educational/informational videos.

Table 2. Shared Decision Making Steps and Corresponding Intervention Strategies for Patients and Providers				
Shared Decision Making Steps	**Site**	**Intervention Strategies**	**Audience**	**Benefit**
Choice Talk	MVH/SM outside the clinic encounter	1. Weekly SM link pdfs, to up-to date MAS summary informational materials, HT, links to websites, videos, and diagrams, and decision support tools 2. Weekly menopause symptom assessment and monitoring via MHV and /or symptom diary 3. Flyers encouraging women to discuss MAS choices with providers, informing them of the *MEANS* study and number of a pharmacist to discuss options.	Patients Friends Families	Gives patients time to study new information, consider their personal preferences, discuss options with others
Option Talk	MHV/SM outside the encounter OR Face-to-face visit with HCP	1.Weekly SM link as above, decision aids 2. Flyers in clinic as above 3. Play videos in clinic waiting areas 4. Shared Medical Appointments for Menopause – provider, pharmacist, and nutritionist will see a group of patients for menopause and provide education, support and discuss options	Patients Families	Patients can deliberate outside the clinical encounter
Decision Talk	Face-to-face visit with HCP	1. Provider training with role play exercises and videos regarding SDM, and discussion of MAS options and HT 2. Menopause clinical reminder and links 3. Printed and on line decision support tools 4. Flyers in clinic asking patients to discuss MAS choices with providers and providing pharmacist number 5. Shared Medical Appointments 6. Video telehealth group visits for patients with expert endocrinologist 7. Expert to primary provider consult regarding HT	Patients Providers	Provider support the work of considering preferences and deciding what is best

v. Shared Medical Appointments (SMA) for Menopause (Patients and Providers): Shared medical appointments (SMAs) are used in the VA as a means to improve clinic efficiency and quality of care. Based on the chronic care model, SMAs are patient medical appointments in which a multi-disciplinary/ multi-expertise team of physician and non-physician providers sees a group of patients (4-20) in a 1.5 to 2 hour visit. SMAs are frequently utilized for conditions which require education and support of patients while they develop and implement self-management skills. The benefits of SMAs include dissemination of provider expertise and support among staff members and 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 in one appointment. 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. The *MEANS* Group Clinic will be a 90-minute SMAs staffed by a provider, pharmacist, and nutritionist to facilitate understanding for women with varied degrees of health literacy and numeracy, to provide education, support and discuss options utilizing educational materials, decision aids and clarification exercises that will focus on increasing awareness of MAS, MAS treatment options, and risks and benefits of HT.

vi. Provider training with role play exercises, videos, and one on one (Providers): We will develop role playing exercises and brief educational video for use with primary care staff to teach them SDM skills in discussing MAS options and the risks and benefits of HT. In addition, trained actors will be recruited to role paly with PCPs using pre-scripted exercises as they discuss MAS treatment options using SDM. Providers will also be taught regarding use of menopause clinical reminder and the various decision support aids and resources available to them. This will be done in their own clinics by a health educator. HCPs targeted by the program are PCPs, nurse practitioners, nurses, psychologists, and clinical pharmacists.

vii. Menopause clinical reminder and links (Providers): 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. 100% of all ambulatory and inpatient care is provided using CPRS, allowing providers to add new orders, review or add problems, write progress notes, or see results, and order medications. 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 providers 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 asking questions, ordering tests, and 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 clinical decision making, for improving care for Veterans. The Menopause Clinical Reminder is implemented at the Miami VAHS to facilitate the assessment of menopausal symptoms during clinic visits. It incorporates the Women's Health Questionnaire and updated links to medical society guidelines, point-of-care CMEs (short

paragraphs of information with questions linked to CME credits), and <u>handouts</u> for patients to be printed at the clinic site. *This will be amplified by adding decision support tools, and exercises.* A screen shot of the Menopause Clinical Reminder can be found in the Appendix. It was developed by Dr. Levis (PI) as part of a Pfizer grant.

viii. Printed and on line decision support tools (Patients and Providers): Decision Aids are

tools designed to provide information on options, help people participate in decision making, improve knowledge and realistic perception of outcomes, and help clarify and communicate personal values. They are not meant to advise people to choose one option over another or to replace physician consultation[4]. They also help options to be discussed in a standardized way. We will follow the proper suggested steps for Development of Decision aids (Table 3). *Decision aids* that specifically address issues that women have about HT, MAS treatment options, will be sent via MHV, printed versions mailed to all participants, and be available in all primary care clinics.

Table 3: Process for Development of Decision Aids
• Present information in a balanced manner
• Has a systematic development process
• Uses up-to-date evidence (cited)
• Disclosed conflict of interest
• Uses plain language
• Uses stories
• Follows guidelines for internet-based tools

ix. Video telehealth (Patients and Providers)

1. Group visits for patients with expert endocrinologist (Dr. Levis)

2. Expert Endocrinologist to provide consults for primary care providers who have questions regarding HT Telehealth Services. VHA uses Telemedicine Videoconferencing equipment throughout VHA to facilitate the delivery of 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 video telehealth visit with patients or providers at the Broward clinic. During a scheduled Video 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. The patient may or may not be present, as the primary provider deems best.

Phase 2 (g*): Shared Decision Making: Decision talk will occur in the clinical encounter with the HCPs.* The goal of the *MEANS* program will be to generate effective conversations regarding the diagnosis and management of MAS between women and HCPs. We will use <u>role playing exercises</u> with pre-scripted scenarios using all the steps of choice, option, and decision talk (See Table 4, detailed examples in Appendix), to help all PACT providers get comfortable with discussing HT options and SDM with patients individually, and in Shared Medical Appointments. HCPs and patients will have decision support tools to assist with SDM, which will be mailed in print, via MHV, and used in print during face-to-face visits. These tools will summarize information already presented to patients via MHV, in formats that are easy to understand, thus making the conversation more efficient and effective. These tools will also be made available as

Table 4. Summary Steps of the Shared Decision Making Model (Detailed in Appendix)
Choice talk
• Step back
• Offer choice
• Justify choice - preferences matter
• Check reaction
• Defer closure
Option talk
• Check knowledge
• List options
• Describe options – explore preferences
• Harms and benefits
• Provide patient decision support Summarize
Decision talk
• Focus on preferences
• Elicit preferences
• Move to a decision
• Offer review

links to the "menopause clinical reminder" already in use in the Miami VAHS (screenshot of the reminder in Appendix). The SDM steps and corresponding sites and strategies for patients and providers are listed in Table 1, and described in *Phase 2 (f). MEANS* Strategies will be implemented via MHV, individual and group patient visits, and via telephone consultations.

C.2.c. Evaluation Design (Phase 3: EVALUATION PHASE)
i. Assessment Metrics and expected change

This is a pre-post study design with a control group that will target the Miami VAHS HCP and their female patients age 45 to 60. HCP 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 ≥1 primary care visit at the Miami, West Palm Beach and Orlando VAHS' to determine the number and proportion of those who used MHV and SM; 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. Retrospective data gathered from all women 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 *MEANS* intervention period. Data will be retrieved at the end of the 12-month intervention.

Primary Outcomes

Aim 1: Increase enrollment and authentication in MHV. We will measure enrollment and authentication of women Veterans in MHV, and in *MEANS*, as a proportion of all eligible women before and after the program in Miami. We hypothesize that the proportion of eligible women patients in the Miami VAHS who are enrolled and authenticated in MHV will increase by 20% after the *MEANS* intervention.

Aim 2: Develop a library of MAS material, links and information suitable for dissemination weekly via MHV as educational and SDM tools to enable women Veterans age 45-60 to discuss with HCP regarding MAS. These resources will be deliverables that will make this a scalable project. We propose to develop 24 PDFs for 6 months and at least 5 SDM tools.

Aim 3: Determine the feasibility of using MHV/SM to educate and track women Veterans regarding MAS using the WHQ. We will monitor the proportion of women who document access the information on MHV, and proportion that monitor MAS at the beginning of the intervention, and after 3 months of being in the study. Among women in the Miami VAHS who enroll in *MEANS* project, we will track (a) the number of times they use the weekly information sent via MHV; (b) the proportion of times they respond to the weekly WHQ sent via MHV, at the beginning of the *MEANS* intervention, and at 3 months.

Aim 4: Evaluate the impact of *MEANS* interventions among health care providers (HCP) and eligible women Veterans age 45 to 60 years at the Miami VAHS who receive the *MEANS* intervention on the womens' self-reported knowledge on MAS and MAS treatment options (a) before and after the intervention, and (b) compared to a control group of HCP and eligible women patients between 45-60 years who do not receive the *MEANS* intervention at the West Palm Beach and Orlando VAHS, before and after the intervention at the Miami VAHS.

We hypothesize that knowledge scores of enrolled patients before and after will increase by 20% after the *MEANS* intervention. This Aim will be used to calculate sample size.

<u>Secondary Aims</u>

<u>Aim 5:</u> Evaluate the impact of MHV on rates of "shared decision making" (SDM): Measure the proportion of women seen in the clinics who feel that they had an effective dialogue with their HCP regarding MAS and treatment as a proportion of all women enrolled in the *MEANS* before and at end of project; (i) chart review for documentation of patient counseling related to MAS and rates of MAS counseling using SM, if there is discrepancy, the chart will be reviewed by two of the co-investigators to help explain what had transpired in the meeting with the HCP; ii) survey of patients post-primary HCP visits to measure whether women feel the MHV intervention led to more focused discussions of their MAS and if they feel they have a better understanding of their menopausal symptoms and the treatment options available following the dialogue with the HCP or receiving materials on menopause; and iii) satisfaction with MAS related care.

<u>Aim 6:</u> Establish and compare the effect of the *MEANS* intervention on rates of diagnosis and appropriate management of MAS: i) identification and management of MAS as assessed by the proportion of eligible women who have ICD9 codes for MAS, HT, and SSRIs; and ii) proportion of eligible patients with menopausal ICD9 codes 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 with menopause symptom ICD9 codes enrolled in the *MEANS* in the Miami VAHS who receive HT will increase by 10% after the *MEANS* intervention.

<u>Aim 7:</u> Qualitative Evaluation of *MEANS*: To obtain detailed information about MHV participants' perspectives regarding their experience with the MHV, we will conduct a qualitative evaluation based on in-depth semi structured interviews with approximately with 3 focus groups of 6 to 10 participants (total 20-30) who are of R or R/A (registered and authenticated) status to obtain their impressions and feedback regarding the use of MHV. Prior to the start of data collection, an interview guide will be developed in collaboration with a qualitative methodology expert to provide adequate structure and consistency to the interviews. Interviewers will also ask follow-up questions for clarification and pursue themes as they emerge during the interviews on perceived quality of care, ease of using the online web site and convenience and quality of life improvements due to using MHV. Dialogues and prompts will be used to elicit responses and to ensure unbiased content inference. We hope to understand the reasons why patients felt that the materials were effective or not. Participants will be asked to provide their impressions regarding a variety of dimensions associated with *MEANS* including impact on SDM, appropriateness and usefulness of tools used to prompt SDM with providers, satisfaction with *MEANS*, convenience, perceived benefits, as well as barriers and facilitators to accessing and using MHV and *MEANS* resources such as decision aids.

<u>Aim 8:</u> Physician satisfaction and recommendations assessed by survey at the end of the trial. We will also conduct a summative evaluation of the usefulness of using *MEANS* from a provider perspective. All providers who see women in primary care will be invited to participate in focus groups using semi-structured interviews. Participants will be asked to provide their impressions regarding a variety of dimensions associated with *MEANS*, including impact on SDM, the appropriateness and usefulness of tools used to prompt SDM with patients,

satisfaction with *MEANS*, convenience, and perceived benefits, as well as the helpfulness and appropriateness of the manner in which *MEANS* can be used to improve clinical care. Barriers and facilitators to accessing and using *MEANS* resources will also be explored.

Data Sources: (1) <u>VHA Corporate Data Warehouse</u> (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. 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. CDW's SharePoint site provides an up-to-date list of available domains with some structural documentation in the Metadata Reports section. VistA is the primary source of CDW data. No filtering of records, editing of content or business rules have been applied to these data. 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. ICD9 and HT data will be collected by conducting queries in the CDW. Report templates will be created by the Data Manager and tested during the preparation phase. (2) The <u>Almanac</u> 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. Dr. Rodriguez will create the monthly Almanac reports. (3) MHV Reports for numbers of enrolled and authenticated Veterans, and numbers using SM by MHV Coordinator Joseph Thames. (4) CPRS - notes will be used to collect data on shared decision making or SDM.

- <u>Comparison group</u>. Women in the target age group and their HCPs at West Palm Beach and Orlando VAHS will not receive the intervention and will serve as the comparison group.

Table 5. Data collection and data sources	
Independent Variables/Covariates	**Data Source**
Socio-demographics :Age, Gender, race, ethnicity, income, marital status, education	CDW
Clinical: height, weight, BMI, tobacco and alcohol, comorbidities, medications	CDW
Health Literacy	Brief Health Literacy Screening tool
Enrollment in MHV, Registration (R) status	MyHealtheVet reports
Number of days in R status in the study period	MyHealtheVet reports
Authentication status (R/A)	MyHealtheVet reports
Number of days in R/A status in the study period	MyHealtheVet reports
Use of secure messaging (patient hit days)	MyHealtheVet reports
Menopause ICD9 codes; Use of Hormone Therapy and low dose SSRIs	DSS, Almanac, CDW, DSS NDE
Self-reported MAS knowledge	Patient questionnaire
Patient satisfaction with *MEANS* and patient QoL	Surveys, focus groups
Provider satisfaction	Surveys, focus groups
Shared Decision Making	CPRS, patient/provider surveys
Healthcare Utilization: frequency of primary care and specialty visits	CPRS

   ii. Data Analyses: The following data will be extracted from the CPRS: 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). Our analyses will first look at descriptive calculations of number of eligible patients in the

Miami VAHS enrolled in MHV before and after the intervention, and at the West Palm Beach and Orlando VAHS. We will determine if there is a significant increase in the proportion both overall and by race/ethnicity and age categories. We will assess the number of women who are enrolled in the MEANS project who send information via MHV. We will track a) the proportion of total women who send information; b) the number of times they send information weekly; and c) the proportion of times they respond to the WHQ. 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 with yes/no for sending information will be used to adjust for demographic (age, race, ethnicity) and clinical factors (body mass index, medications, prior fractures, comorbidities, etc.). Linear regressions will be used for the number of times patients send information weekly, with the same adjustment variables. Finally, we will use generalized linear regression models with a logit link and the binomial family for determining whether there are significant differences in proportions of times patients respond to the WHQ and proportion of weeks where information is sent by patients; again adjusting for demographic and clinical factors.

For all women who are enrolled, we will be collecting information self-reported knowledge on MAS and MAS treatment options. This will be collected via survey both before and after the intervention, and will be compared to a comparison group of women patients between 45-60 years who did not receive the MEANS intervention at the West Palm Beach and Orlando VAHS. A linear regression analyses, controlling for pre- versus post intervention, VA site, age, and hormonal therapy (if known) will be done to determine if there are differences between groups in terms of self-reported knowledge. For all analyses, patients will be stratified based on adherence to technology use. Use of MHV-SM more than 50% of the time will be considered adherent to technology. Before *the implementation of any statistical tests, we will use descriptive statistics* to assess the distributional properties of the different variables and their interrelationships and to determine missing data and detect outliers. For analyses including variables with skewed distributions (e.g. BMI) we will use either nonparametric techniques or appropriate transformations such as logarithmic or square root transformations. Whenever appropriate, missing data will be imputed case wise using mean-based or regression-based imputation procedures. All statistical analyses will be performed on an intent-to-treat basis using SAS/STAT® Software (SAS Institute, Inc., Cary, NC 27513-2414). All statistical tests will be two-sided tests and conducted at an alpha level of 0.05, except for baseline comparisons that will use an alpha level of 0.10.

Sample size calculations indicate that a sample size of 50 in each group will provide 90% power to detect a 20% difference in the knowledge score of women before and after the intervention assuming a significance level of 0.05 (Primary Aim 4). We plan to enroll 200 women in the intervention in Miami. We expect that about 25% of the women in the intervention group will be adherent to technology >50% of the time, therefore 50 women in the intervention group will complete the intervention as expected. This is based on literature from Saver et al. who randomized women aged 45-75 to use web-based decision support for post-menopausal health decisions called CHESS-MAB or usual care.[5] Post-intervention knowledge scores for the intervention group were significantly greater (difference in change = 1.3 points; 95% CI = -0.1, 2.6), as was the difference in change from baseline (p = 0.05). Greater improvement was seen in the decisional satisfaction of the intervention group than in the usual care group (difference

in change = 2.2 points; 95% CI = 0.2, 4.2). Another similar study (Trudeau et al) designed to evaluate knowledge gain and program satisfaction showed that knowledge before and after the intervention improved from 5.6 to 6.6 correct responses ($t34 = 3.64$, $p = 0.001$).[6] A Wilcoxon signed-rank test also had a significant result ($Z = 3.23$; $p = 0.001$). Based on these studies showing increase in knowledge after patients used a web-based intervention for menopause information, we expect that this study will have enough power to detect a difference in the knowledge of patients before and after the *MEANS* intervention. We hypothesize that knowledge scores of enrolled patients will increase by 20% after the *MEANS* intervention.

Our analyses will first look at descriptive calculations of number of eligible patients in the Miami VAHS before and after the intervention. We will determine if there is a significant increase in the proportion both overall and by race/ethnicity and age categories. We will assess the number of women who are enrolled in the *MEANS* project who send information via MHV. We will track a) the proportion of total women who send information; b) the number of times they send information weekly; and c) the proportion of times they respond to the WHQ.

For all women who are enrolled, we will be collecting information self-reported knowledge on MAS and MAS treatment options. This will be collected via survey both before and after the intervention, and will be compared to a control group of women patients between 45-60 years who did not receive the *MEANS* intervention at the West Palm Beach and Orlando VAHS. A linear regression analyses, controlling for pre- versus post intervention, VA site, age, and hormonal therapy (if known) will be done to determine if there are differences between groups in terms of self-reported knowledge.

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 *MEANS* are listed below.

Reach: From the pool exposed to recruitment (survey), how many responded? From the pool of eligible providers, how many utilized the SM? From the pool of patients having a visit with a SM, 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 using SM. Characterize providers who are not users of the Reminder (larger patient panel, sicker patients, more male patients on panel), and patients who do not participate in MHV.

Implementation: We will track usage of MHV, SM and SDM 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: This project will design and implement a learning and change-based program that enables effective dialogue between the HCP and the midlife woman regarding diagnosis and management of MAS and HT by:
- weekly encouragement of tracking MAS in age-appropriate women
- ability to track such symptoms and subsequent shared decision-making
- increasing women's knowledge of MAS by weekly dissemination of resources
- improving HCPs knowledge of MAS and SDM, and encouraging in-person and computer-mediated discussions about MAS & HT

- reminders to patients and HCPs to encourage effective dialogue regarding MAS
- developing decision aids to provide information and help people participate in SDM

This project will implement a patient-centered approach that uses MHV to deliver reliable and individualized education to women regarding MAS. It will provide: 1) A replicable model for effective and efficient delivery of patient education and self-management training to women Veterans with MAS that respects patient privacy and confidentiality; 2) Protocols for HCPs for MAS management and communicating via MHV; 3) Protocols for HCPs to use for SDM regarding MAS. Long term, program may be disseminated via mobile phones or tablet devices.

The VHA has been fully committed to training providers to become proficient in women's health. We will build the concept of SDM, and specifically MAS-related SDM ideas and practices, into standardized training curricula for professional education, practice, and care. These training curricula will be available for dissemination, as will be the patient decision aids. VHA promotes best practices and disseminates and implements successful pilot programs at other sites. These will be disseminated via several possible venues: a) National Women's Health Mini-Residency program b) 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. c) Cyber Seminar Spotlight on Women's Health: VA Health Services R&D's education series offered to VHA facilities nationwide. d) VA sponsored national VA Women's Health research conference. e) VA Women's Health Practice-Based Research Network Consortium's (PBRN): whose mission is to train and educate, foster research-clinical partnerships, and disseminate best practices by dissemination and implementation of successful pilot programs at other sites to enhance the delivery of health care for women Veterans. Dr. Levis is member. f) The VA Reproductive Health Working Group consists of VA providers and scientists interested in Veteran women's health. 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.

C.3. Detailed Workplan and Deliverables Schedule:

The work plan and schedule of deliverables is listed in Table 6, after the Budget Justification. The first 6 months will be PREPARATION Phase 1, to prepare all *MEANS* interventions. After submission and approval of the project by the Miami VAMC IRB, we will design the decision tools, and get feedback on them via focus groups with patients and providers. The data obtained from these activities will assist in modifying the decision tools, and *MEANS* intervention. Baseline data from CDW for Miami, Orlando, and Tampa regarding menopause ICD9 codes and estrogen prescriptions will be obtained just before starting the intervention. As described above, the *MEANS* interventions includes secure messages, print, face-to-face, and IT activities. The *MEANS* INTERVENTION Phase 2 will be 12 months. It will begin with training of the providers during the weekly staff meeting and in clinics with videos, one on one, trained actors, and role playing. Flyers will be mailed to patients and placed in the clinic waiting areas, where TV monitors will show the videos on Menopause. After the conclusion of the INTERVENTION PHASE, another survey will be mailed to patients and final data from CDW and CPRS will be retrieved. The last 6 months will EVALUATION Phase 3, dedicated to analyzing data and preparation of manuscripts and reports. See Appendix for Detailed Timeline and steps.

D. Organizational Detail

   1. Leadership and Organizational Capability:

The Veterans Health Administration (VHA) is currently preparing for the largest number of women ending their military service. The number of women Veterans using the VHA services has doubled in the past decade. In order to ensure they receive the high-quality health care and services they deserve, the VHA is requiring a rapid increase of services and support for women Veterans programs, including the placement of full time Women Veterans Program manager at every facility and implementation of comprehensive primary care for Women's health. There were 552,662 unique women Veterans enrolled in VHA Fiscal Year 2011, of which 235,297 were between the ages of 45 and 64 years. The majority of these women receive their care in Primary Care/Medicine clinics or Comprehensive Women's Health clinics. The VHA has been very supportive in improving gender-based care for women and eliminating disparities in disease outcomes. There is also an emphasis on providing gender-specific primary care, including management of menopause-related concerns. Technology at VHA provides a unique opportunity for novel interventions and measurement of outcomes. CPRS (Computerized Medical Record System) is the electronic health record used throughout VHA.

   2. Staff Capacity:

Stuti Dang, MD, MPH, PI, is an Associate Professor of Clinical Medicine at the Univ. of Miami. At the Miami VAMC, she is a GRECC researcher and staff physician, and since 2002, she had been Clinical Director of T-Care and the Telephone-Linked Care for Dementia. Dr. Dang is a member of the National VA Care Coordination Home Telehealth Outcomes Workgroup and VA National Telehealth Dementia Disease Management Protocol Work Group. She has extensive experience with technology-based intervention programs, and has been funded by the State of Florida, NIH, and VA for using MHV for heart failure management projects and for using mobile technologies, web, and home telehealth for CHF, diabetes, and stroke management. She will use her experience with the MHV CHF project to set up the Menopause and Associated Symptoms MHV Clinic. This will be a site for educating patients regarding MHV use. This project is a natural extension of Dr. Dang's long standing experience with Telehealth, chronic disease management, and MHV use for patient monitoring and education. She is also interested in women's health issues. She has a grant from the VA Office of Health Equity, with Dr. Levis to develop a patient-centered model for assessing cardiovascular risk in young (40-65 y/o) post-menopausal women, Veterans. She also wrote an opinion piece titled "If You Take It, It Works …" *Journal of Women's Health.* **Dang S**, Levis S, & Lagari VS. March 2014, 23(3): 278. doi:10.1089/jwh.2013.4699. Dr. Dang will oversee the project.

Silvina Levis, MD, Co-Investigator, is Professor of Medicine at the Univ. of Miami and interim Associate Clinical Director in GRECC, Miami VAMC. As an endocrinologist, Dr. Levis has extensive experience in the management of menopausal women. She was PI of a 5-year, NIH-funded clinical trial demonstrating the lack of effectiveness of phytoestrogens in preventing menopausal symptoms (Levis S. et al. 2011 Soy isoflavones in the prevention of menopausal bone loss and menopausal symptoms: A randomized, double-blind trial. Archives of Internal Medicine 171:1363–1369). She was also awarded a Pfizer grant "Technology and collaborative care improve the use of hormone therapy (HT) in Postmenopausal Women Veterans". Drs. Dang and Levis have worked together and shared funding in the past. Both have been jointly funded to use telehealth for women's health and dementia consultation to remote VA clinical

sites, and for developing a patient-centered model for assessing cardiovascular risk in young (40-65 y/o) post-menopausal women Veterans (VA Office of Health Equity, FY 2014). Dr. Levis will help with all educational content for this project, and provide consultation.

Remberto Rodriguez, MD, Collaborator is Director of Primary Care at the Miami VAHS. He establishes clinical priorities and has oversight responsibilities for all Primary Care Providers for the achievement of quality measures that apply to men and women's health. Dr. Rodriguez has experience with patient education initiatives using computer-based avatars as training tools. In this project, he will have a role in the development of the *MEANS* information and education interventions and implementation, for both patients and providers. As Director of Primary Care, he has access to the Almanac for all providers and will be provide the monthly Almanac reports with data from each provider and the overall group. He will also conduct chart review.

Panagiota Caralis, MD, JD, Collaborator, is Medical Director of the Women's Program at the Miami VAHS, and is tasked with providing quality care for women Veterans and serves as the clinical leader for women's health in the facility, working in close collaboration with Primary Care leadership. She develops and supervises clinical education programs for women's health providers and has authored video-based training modules for providers on domestic violence. Dr. Caralis will have a primary role in implementing and supervising the proposed interventions for both the female patients and providers and will conduct chart review.

Jason Dahn PhD, Collaborator, is a licensed clinical psychologist at the Miami VAHS. He also serves as team leader in Veterans Health Education, which provides training to primary care staff in patient-provider communication, shared decision making, and patient-centered practices, and use of clinical reminders including the importance of standardized administration. His duties also include training staff in motivational interviewing skills, demonstrating use of these skills such as eliciting patients' health concerns, expressing concern, affirming steps toward change, and providing explicit advice on treatment recommendations. His research interests, clinical duties, and committee involvement are closely aligned and provide a strong foundation to assist Dr. Dang and facilitate the proposed research.

Project Manager (TBA) 100% effort. A project coordinator will be hired with a 100% effort to the coordinate and manage all activities outlined in the proposal. The person taking this position will have experience in the clinical setting and in project management. He/she will work close with the PI and other investigators in the building and tailoring of the *MEANS* interventions, modification of videos, scheduling of mailings, patient education, provider education via role play, shared medical appointments, and ensure that MHV secure messages are ready and delivered weekly, and that updates are done on time. The person filling this position will be responsible for writing a manual of operations, registering and authenticating patients in MHV at the Miami VAMC, setting up MHV training for them, and recruiting patients for the focus groups, and for scheduling and setting up focus groups, surveys, patient group sessions, and videoTelehealth consultations. In addition, he/she will be responsible for supervising the study coordinator and data manager.

Study Coordinator (TBA) 50% effort for the Broward Clinic with similar responsibilities.

William A. Lapcevic, Data Manager 10%, Mr. Lapcevic will be responsible for developing, overseeing the data management system and abstracting data from VA administrative databases to conduct the multivariate modeling necessary. He will also assist in analyzing the program evaluation and producing statistical reports on the same using SAS programs. Other

responsibilities include preparation of data to submit to Univ. of Miami Collaboration and Biostatistics Consulting Core and general assistance to the Project Manager.

Margaret M. Byrne, Statistician. Dr. Byrne is an experienced Health Economist; she will serve as the point person for all statistical methodology and analysis. She also has training and extensive experience in econometric analysis techniques. Economists' approach to statistical methodology and analysis differs in some respects from that of biostatisticians, for example being more concerned about data meeting the assumptions underlying the statistics methods that are used. Therefore, she will also be able to share econometric methodology that is currently not commonly used in a health care setting.

Luis Colon, CPRS manager. Mr. Colon is Health Informatics Specialist in the Department of Clinical Informatics at the Miami VAMC. With input from the investigators, he will be responsible for amplifying the Menopause Clinical Reminder in CPRS, updated and adding decision support tools to the reminder as easy-to-use screens that will include checkboxes and drop-down menus. As providers make their selections, the information is automatically included in the electronic health record clinic note in text form. He will also add updated links in the Reminder to medical society guidelines, patient handouts and point- of-care CMEs. Mr. Colon will design the reports that will be utilized during the study to retrieve frequency of use and data entered in the Menopause Clinical Reminder.

Health Educator (TBA), 25% effort. The person fulfilling this job will be experienced in health education tailored to the intended Veteran population; he/she will have knowledge of menopause and related women's issues. He/she will collaborate in the development of the *MEANS* health education program, role playing sessions and focus groups. His/her responsibilities will include evaluating the effectiveness of programs and educational materials, assisting in the training of staff who will implement the *MEANS* program, provided feedback for the further advocating of improved health resources and policies to promote women's health.

Jorge Ruiz MD, Consultant. Dr. Ruiz is Associate Professor of Clinical Medicine at the Univ. of Miami. His career is dedicated to the application of e-learning and educational technologies to health care professional education. He is Director, Miami GRECC Laboratory of E-learning and Multimedia Research, an interdisciplinary research group that investigates the use of desktop virtual reality technologies to improve patient education and self-management. Dr. Ruiz will serve as a consultant and offer his expertise and experience in healthcare provider education.

Julie Volkman PhD, Consultant, is faculty at the VA eHealth QUERI and Center for Health Quality, Outcomes, and Economic Research (CHQOER) at the Bedford VAMC, and an Assistant Professor at the Univ. of Massachusetts Medical School. Her research on health communication focuses on the dissemination of public health information, and social and communication interactions contributing to health behavior change. Her work includes information-seeking and Internet use, along with health message design considerations for populations of interest. She has examined how to communicate women's health issues and prevention (e.g., breast cancer, osteoporosis and folic acid intake recommendations), and how these messages can contribute to behavioral intentions and behavior change. Dr. Volkman is trained in mixed-method data collection including focus groups, interviews, survey design and factorial designs, and has conducted qualitative and quantitative analyses (e.g., thematic analyses, quantitative coding, and structural equation modeling). Her experience in mixed-methods and translating health information for lay audiences will be used for the proposed study.

DEPARTMENT OF VETERANS AFFAIRS
VA Sunshine Healthcare Network
VISN 8
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St. Petersburg, FL 33716
Office: (727) 727-575-8069 Fax: (727) 575-8114

September 2, 2014

Stuti Dang, MD, MPH
Researcher, Geriatric Research Education & Clinical Center
Miami Veterans Affairs Healthcare System/SFVAFRE
University of Miami Miller School of Medicine, Miami, FL 33125

Re: Enabling effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause utilizing the electronic health record, Pfizer (IGL&C)

I am in full support of the proposed research project "MEANS" (MyHealtheVet to Enable And Negotiate for Shared decision making) regarding Menopausal and Associated Symptoms in Postmenopausal Women Veterans. The goal of this project is to employ MyHealtheVet in women Veterans ages 45-60, as an educational and shared decision making platform to enhance communications between patients and their providers, in regards to Menopause and associated symptoms. Dr. Stuti Dang, MD, MPH, who is an experienced geriatrician, will serve as the project director. She has vast experience utilizing MHV and other technologies. Drs. Silvina Levis, MD, Remberto Rodriguez, MD, and Panagiota Caralis, MD, JD, will be actively working together with Dr. Dang.
The proposed project is well-aligned with the Pfizer's IGL&C initiative to accelerate the adoption of evidence-based innovations through the support of independent educational activities.
As the VISN Program Manager for Geriatrics, I believe that this program will allow the VA to serve its aging women Veteran population more uniquely. This is really important for the Veteran Affairs Healthcare System, as we have an increasing number of women patients.
Based on the expertise of the project team and the importance and relevance of the study to the VA population, I offer my highest endorsement for the proposal and will work towards mechanisms to endorse the sustainment of the project, and its possible implementation at other sites in VISN 8. This project is consistent with the VA's vision to develop and implement innovative healthcare practices for the 21st century.

Sincerely,

Dr. Samer Nasr, MD
VA Sunshine Healthcare Network
VISN 8 Product Line Manager
Palliative, Geriatric & Extended Care

September 9, 2014

Stuti Dang, MD, MPH
Associate Professor of Clinical Medicine and
Investigator, Geriatric Research Education & Clinical Center
Miami Veterans Affairs Healthcare System/SFVAFRE
University of Miami Miller School of Medicine, Miami, FL 33125

Re: Enabling effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause utilizing the electronic health record, Pfizer (IGL&C)

As the Director of the of the Miami Geriatric Research, Education, and Clinical Center (GRECC), I am pleased to offer my enthusiastic support to the proposal, "**M**yHealtheVet to **E**nable **A**nd **N**egotiate for **S**hared decision making" (MEANS) to address menopausal and associated symptoms in postmenopausal Veterans, that your Miami Veterans Affairs Healthcare System (VAHS) team is submitting in response to the Pfizer IGL&C RFA.

I have a solid appreciation for the challenges faced by women with menopause, and many of the barriers to effective treatment. I am confident on your skills as Principal Investigator for the proposed research project, building upon your prior work on telehealth and other technologies in previous research projects.

The goal of this innovative project is to employ MyHealtheVet in women Veterans ages 45-60, as an educational and shared decision making platform to enhance communications between patients and their providers.

Your team is really outstanding. It includes Dr. Silvina Levis, a Professor of Medicine at the University of Miami and Associate Clinical Director (i) in our GRECC who is an endocrinologist with extensive experience in the management of menopausal women and has been awarded a Pfizer grant in the past to develop and use a menopause clinical reminder. In addition, two key leaders in the Miami VAHS support your efforts: Dr. Remberto Rodriguez, Director of Primary Care at the Miami VA, who has oversight responsibilities for all Primary Care Providers for the achievement of quality measures and Dr. Pat Caralis, Medical Director of the Women's Program at the Miami VAHS, who she serves as the clinical leader for women's health in the facility.

I am confident that under your leadership the MEANS project will provide the framework for administrators and clinicians to discuss the impact of this project on the VA's Women's Health Initiatives. I fully endorse and support this project, which is consistent with the VA's vision to develop and implement innovative healthcare practices.

Sincerely,

Hermes Florez, MD, PhD, MPH
GRECC Director, Miami VA Healthcare System
Professor of Medicine & Public Health Sciences
University of Miami Miller School of Medicine

In Reply Refer To:

September 9, 2014

Stuti Dang, MD, MPH
Researcher, Geriatric Research Education & Clinical Center
Miami Veterans Affairs Healthcare System/SFVAFRE
University of Miami Miller School of Medicine, Miami, FL 33125

Re: Enabling effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause utilizing the electronic health record, Pfizer (IGL&C)

I fully endorse and support the proposed research project "MEANS" (MyHealtheVet to Enable And Negotiate for Shared decision making) regarding Menopausal and Associated Symptoms in Postmenopausal Women Veterans. The goal of this project is to employ MyHealtheVet (MHV) in women Veterans ages 45-60, as an educational and monitoring platform to enhance communications between patients and their providers, in regards to Menopause and associated symptoms. As an experienced geriatrician with vast experience utilizing telehealth and other technologies, I am confident in your ability to serve as our site's project director. Drs. Silvina Levis, MD, Panagiota Caralis, MD, JD, as well as I will be actively working together on this project.

Dr. Levis is a Professor of Medicine at the Univ. of Miami and interim Associate Clinical Director in GRECC, Miami VA. As an endocrinologist, she has extensive experience in the management of menopausal women and has been awarded a Pfizer grant in the past. Dr. Caralis is Medical Director of the Women's Program at the Miami VA; she works closely with the Associate Chief of Staff for Medical Services to provide quality care for women Veterans and serves as the clinical leader for women's health in the facility.

As the Primary Care Director for the Miami VA, I will help ensure that our leadership will promote the MEANS project with the Patient Aligned Care Teams providers by working with you to provide opportunities to meet with administrators and clinicians to discuss the impact of the project on the VA's Women's Health Initiatives. I believe that this program will allow the VA to serve its aging women Veteran population more uniquely. This is really important for the Veteran Affairs Healthcare System, as we have an increasing number of women patients.

I look forward to working with you on this project that has the potential to make an immediate impact on improving the lives of our women Veterans. I endorse and support the proposal and will work alongside the team for the sustainment of the project.

Sincerely,

Remberto Rodriguez, MD
Primary Care Director
Miami Veterans Healthcare System

In Reply Refer To:

September 5, 2014

Stuti Dang, MD, MPH
Researcher, Geriatric Research Education & Clinical Center (GRECC)
Miami Veterans Affairs Healthcare System/SFVAFRE
University of Miami Miller School of Medicine, Miami, FL 33125

Re: Enabling effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause utilizing the electronic health record, Pfizer (IGL&C)

Dear Stuti,

I enthusiastically support your proposed research project "MEANS" (MyHealth*e*Vet to Enable And Negotiate for Shared decision making) regarding Menopausal and Associated Symptoms in Postmenopausal Women Veterans. The goal of this project is to employ MyHealth*e*Vet in women Veterans as an educational and shared decision making platform to enhance communications between patients and their providers and improve menopause management. The project is well-aligned with the Pfizer's IGL&C initiative to accelerate the adoption of evidence-based innovations.

As an endocrinologist in the GRECC with extensive experience in the management of menopausal women and a Pfizer grant award recipient to develop menopause clinical reminders at the Miami VA, I believe that this innovative program is a natural extension of the previous grant. It takes our work to the next level, allowing us to leverage the VHA's unique and innovative technologies that assist us in providing healthcare. I have worked with you, and Drs. Rodriguez and Caralis on several previous projects and your study will be a continuation of our collaboration.

I believe that this proposed grant will allow the VA to serve its aging women Veterans more uniquely and help provide quality care. As you know, we have an increasing number of women Veterans joining the VA. As a champion for women's health issues and based on the importance and relevance of this study to the VA's women patients, I am happy to work alongside you for the sustainment of the project.

Sincerely,

Dr. Silvina Levis, MD
Interim Associate Clinical Director, GRECC
Miami Veterans Healthcare System

In Reply Refer To:

September 8, 2014

Stuti Dang, MD, MPH
Researcher, Geriatric Research Education & Clinical Center
Miami Veterans Affairs Healthcare System/SFVAFRE
University of Miami Miller School of Medicine, Miami, FL 33125

Re: Enabling effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause utilizing the electronic health record, Pfizer (IGL&C)

This letter is in support of Dr. Stuti Dang, MD, MPH, as the Miami VA Healthcare System (VAHS) site Principal Investigator in the proposed project "MEANS" (MyHealtheVet to Enable And Negotiate for Shared decision making) regarding Menopausal and Associated Symptoms in Postmenopausal Women Veterans. The goal of this project is to employ MyHealtheVet in women Veterans ages 45-60, as an educational and shared decision making platform to enhance communications between patients and their providers, in regards to Menopause and associated symptoms. I am happy to participate in this project alongside Dr. Dang, Dr. Silvina Levis, MD, and Dr. Remberto Rodriguez, MD, at the MVAHS. Dr. Dang, an experienced researcher and geriatrician, will serve as the principal investigator. She has a lot of experience with implementation and research in Telehealth.

As the Medical Director of Women's Program at the Miami VA I am working closely with Dr. Dang and I believe that this program will allow the VA to serve its growing women Veterans population. I will work to ensure the success of this project by remaining intimately involved in all phases of this project.

I look forward to working with Dr. Dang and her investigative team on this worthwhile project that has the potential to make an immediate impact on improving the lives of our women Veterans. I offer my support of the proposal and will work alongside the team for the sustainment of the project.

Sincerely,

Panagiota Caralis, MD, JD
Medical Director of Women's Program
Miami Veterans Healthcare System

September 10, 2014   In Reply Refer To:

Stuti Dang, MD, MPH
Researcher, Geriatric Research Education & Clinical Center
Miami Veterans Affairs Healthcare System/SFVAFRE
University of Miami Miller School of Medicine, Miami, FL 33125

Re: Enabling effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause utilizing the electronic health record, Pfizer (IGL&C)

This letter of support is for your proposed research project "MEANS" (MyHealtheVet to Enable And Negotiate for Shared decision making) regarding Menopausal and Associated Symptoms in Postmenopausal Women Veterans. The goal of this project is to employ MyHealtheVet in women Veterans ages 45-60, as an educational and Shared Decision Making platform to enhance communications between patients and their providers, in regards to Menopause and associated symptoms. I would be glad to collaborate with you alongside Drs. Silvina Levis, MD, Remberto Rodriguez, MD, and Panagiota Caralis, MD, JD, at the Miami VA. You are an experienced geriatrician, have successfully employed MHV and other technologies in previous research projects and will operate as the director of this project.

As a licensed clinical psychologist and Staff Psychologist at the Miami VA, I have substantial clinical and research experience in the areas of adjustment/coping with medical illness (e.g., prostate cancer) and health behaviors. My duties and responsibilities include providing motivational interviewing training and health coaching to primary care staff members throughout our healthcare system, as well as coordinating and supervising trainees who are providing integrated mental health services within primary care. Additionally, I serve with a team under Veterans Health Education which provides training to primary care staff in patient-provider communication, shared decision-making and patient-centered practices. I serve on the GRECC Advisory Committee, Patient Aligned Care Team Steering Committee, and as co-chair of the Health Promotion and Disease Prevention Committee.

I am enthusiastic that this project has the potential to make an immediate impact on improving the lives of our women Veterans. I offer my support for this proposal and will do anything necessary to ensure this project is a success.

Sincerely,

Jason Dahn, PhD
Licensed Clinical Psychologist
Health Behavior Coordinator
Mental Health and Behavioral Sciences

Miami VA
Healthcare System
★★★★★

September 8, 2014

In Reply Refer To:

Stuti Dang, MD, MPH
Researcher, Geriatric Research Education & Clinical Center
Miami Veterans Affairs Healthcare System/SFVAFRE
University of Miami Miller School of Medicine
Miami, FL 33125

Re: Enabling effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause utilizing the electronic health record, Pfizer (IGL&C)

This letter is in support of Stuti Dang, MD, MPH, as the Miami VA Healthcare System (VAHS) site Principal Investigator in the proposed project "MEANS" (MyHealtheVet to Enable And Negotiate for Shared decision making) regarding Menopausal and Associated Symptoms in Postmenopausal Women Veterans. The goal of this project is to employ MyHealtheVet in women Veterans ages 45-60, as an educational and shared decision making platform to enhance communications between patients and their providers, in regards to Menopause and associated symptoms. I am excited about this project that Drs. Dang, Levis, Caralis, and Rodriguez are proposing at the MVAHS. Dr. Dang is an experienced clinician and researcher, and has vast experience utilizing telehealth and other technologies.

I look forward to supporting Dr. Dang and her team on this worthwhile project that has the potential to make an immediate impact on improving the lives of our women Veterans. As the Chief of Medicine at the Miami VA, I offer the support of the Medical services to help in this project implementation. I understand the potential impact of the proposed project on the Miami VA Healthcare System, and I offer my highest endorsement of this proposal.

Sincerely,

Thomas M. Hooton, MD
Associate Chief of Staff, Miami VA Healthcare System
Professor of Clinical Medicine, University of Miami School of Medicine

September 9, 2014

Stuti Dang, MD, MPH
Researcher, Geriatric Research Education & Clinical Center
Miami Veterans Affairs Healthcare System/SFVAFRE
University of Miami Miller School of Medicine, Miami, FL 33125

Re: Enabling effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause utilizing the electronic health record, Pfizer (IGL&C)

This letter of support is for Dr. Stuti Dang, MD, MPH, as the Miami VA Principal Investigator for the proposed research project "MEANS" (MyHealtheVet to Enable And Negotiate for Shared decision making) regarding Menopausal and Associated Symptoms in Postmenopausal Women Veterans. The goal of this project is to employ MyHealth*e*Vet in women Veterans ages 45-60, as an educational and shared decision making platform to enhance communications between patients and their providers, in regards to Menopause and associated symptoms. I would be glad to contribute in any way I can to this project alongside Drs. Dang, Silvina Levis, MD, Remberto Rodriguez, MD, and Panagiota Caralis, MD, JD, at the Miami VA. Dr. Dang, who is an experienced geriatrician, will operate as the director of this project. She has successfully employed MHV and other technologies in previous research projects.

As the MyHealth*e*Vet Program Coordinator for the Miami VA Healthcare System, I will support this project with the use of MyHealth*e*Vet by implementing the secure messaging platform between investigators and Veterans. I will set up a secure platform for the Veterans in Dr. Dang's program to communicate with the nurse coordinator, as done for other past projects with the GRECC. I will also help by getting all needed data from MHV data files.

I am enthusiastic that this project has the potential to make an immediate impact on improving the lives of our women Veterans. I offer my support for this proposal and will do anything necessary to ensure this project is a success.

Sincerely,

Joseph C. Thames, MBA
MyHealtheVet Coordinator
Miami Veterans Healthcare System

Appendix Table of Contents

1. References
2. Abbreviations
3. Tables with Steps for the Shared Decision Making Options
4. Screenshots of MyHealtheVet Heart Failure and Menopause Clinical Reminder
5. Provider Laminated Card (Educational Materials)

References

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3. Sheridan, S.L., R.P. Harris, and S.H. Woolf, *Shared decision making about screening and chemoprevention. a suggested approach from the U.S. Preventive Services Task Force.* Am J Prev Med, 2004. **26**(1): p. 56-66.
4. O'Connor, A.M., F. Legare, and D. Stacey, *Risk communication in practice: the contribution of decision aids.* BMJ, 2003. **327**(7417): p. 736-40.
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Abbreviations

CBOC	Community-Based Outpatient Clinic
CDW	Corporate Data Warehouse
CHESS-MAB	Comprehensive Health Enhancement Support System - Menopause and Beyond
CHF	Congestive Heart Failure
CHQOER	Center for Health Quality, Outcomes, and Economic Research
CME	Continuing Medical Education
CPRS	Computerized Medical Records System
DS	Decision Support
DSS NDE	Decision support system - National Data Extract
ED	Emergency Department
EHR	Electronic Health Record
GRECC	Geriatric Research, Education, and Clinical Center
HCP	Healthcare Provider
HF	Heart Failure
HT	Hormone Therapy
ICD9	International Classification of Diseases 9th revision
MAS	Menopausal and Associated Symptoms
MEANS	**M**yHealtheVet to **E**nable **A**nd **N**egotiate for **S**hared decision making
Med SAS	Medical SAS data sets
MHV	MyHealtheVet
MI	Motivational Interviewing
NIH	National Institutes of Health
PACT	Patient Alligned Care Team
PBRN	Practice-Based Research Network Consortium
PCMH	Patient Centered Medical Home
PHR	Personal Health Record
QOL	Quality of Life
RE-AIM	Reach, Efficacy, Adoption, Implementation, Maintenance
SCAN-ECHO	Specialty Care Access Network-Extension for Community Healthcare Outcomes
SDM	Shared Decision Making
SimLEARN	Simulation Learning, Education and Research Network
SM	Secure Messaging
SMA	Shared Medical Appointment
SSRI	Selective Serotonin Reuptake Inhibitor
TLC	Telephone Linked Care
VA	Veterans Affairs
VAHS	Veterans Affairs Healthcare System
VAMC	Veterans Affairs Medical Center

Abbreviations

VANTS	Veterans Affairs Nationwide Teleconferencing System
VHA	Veterans Healthcare Administration
VIReC	VA Information Resource Center
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture
VMS	Vasomotor Symptoms
VSSC	VHA Support Service Center
VVA	Vulvo-Vaginal Atrophy
WHQ	Women's Health Questionnaire

Shared Decision Making Detailed Steps

Shared Decision Making: Choice Talk Steps (via MHV)

Choice talk is about making patients aware that reasonable options exist. This step does not necessarily have to be done face-to-face — an email, letter or a telephone call can also be effective: e.g. asking a patient whose tests come back showing a herniated intervertebral disc to use a decision support website.

'Choice talk' is a *planning* step. Components of the choice talk include:

a) Step back. Summarize and say: "Now that we have identified the problem, it's time to think what to do next"

b) Offer choice. Beware that patients often misconstrue the presentation of choice and think that the clinician is either incompetent or uninformed, or both. Reduce this risk by saying: "There is good information about how these treatments differ that I'd like to discuss with you."

c) Justify choice. Emphasize: 1) the importance of respecting individual preferences ("Your opinion counts in deciding whether the benefits are more important to you than the harms.") and, 2) the role of uncertainty.

Personalizing preferences: Explaining that different issues matter more to some people than to others should be easily grasped. Say: "Treatments have different consequences … some will matter more to you than to other people…"

Uncertainty: Patients are often unaware about the extent of uncertainty in medicine: that evidence may be lacking and that individual outcomes are unpredictable at the individual level. Say: "Treatments are not always effective, and the chances of experiencing side effects vary…" "The decision to try hormones or wait and see if things improve on their own is a personal one...Scientific studies show hormones have both benefits and harms. We use the lowest effective dose for the shortest time it is needed, but there are no strong studies showing how much the harm is lowered."

d) Check reaction. Choice of options may be disconcerting: some patients may express concern. Suggested phrases: "Shall we go on" or 'Shall I tell you about the options?"

e) Defer closure. Some patients react by asking clinicians to "tell me what to do …" We suggest that *deferring closure* if this occurs, reassuring that you are willing to support the process. Say: "I'm happy to share my views and help you get to a good decision. But before I do so, may I describe the options in more detail so that you understand what is at stake?"

Shared Decision Making Detailed Steps

Shared Decision Making: Option Talk Steps (via MHV or Face-to-Face Visit with Health Care Provider)

a) **Check knowledge**. Even well-informed patients may only be partially aware of options and the associated harms and benefits, or misinformed. Check by asking: "What have you heard or read about the treatment of MAS?"

b) **List options.** Make a clear *list* of the options, as this provides good structure. Use a focused tool with the list, and say: "Let me list the treatment options for Menopause and associated symptoms before we get into more detail." If appropriate, include the option of 'doing nothing."

c) **Describe options**. Generate dialog and explore preferences. Describe the options in practical terms. Say that there are different medical treatments: "Both options are similar and involve taking medication on a regular basis." Point out when there are clear differences (medical vs. non-medical), where postponement is possible, or where decisions are reversible. Say: "These options will have different implications for you compared to other people, so I want to describe …"

   - Benefits and Harms. Being clear about the pros and cons of different options is at the heart of shared decision making. Learn the about effective risk communication, about framing effects, and the importance of providing risk data in absolute as well as relative terms. Try giving information in 'chunks' (chunking and checking).

   1. Benefits: Hormones are very effective in relieving hot flushes that disturb your sleep... [If 1000 people like you took it, about 800 would be helped and 200 would not be helped; you usually know within days whether you will be helped].

   2. Harms: There is an increased risk of a serious outcome. [If 1000 women like you took the hormones used in the scientific studies for a year, about 999 women would not be harmed from taking it, but one woman would be harmed... it may be either a heart attack, or a blood clot in the lungs, or a stroke, or if you had been taking hormones for more than four years, a breast cancer. With lower doses, other routes, and other preparations, the chance of a serious outcome may be lower than 1 in 1000 but we don't know for sure. One outcome I have not mentioned, but you may hear about, is the extra risk of Alzheimer's; this has been found in women over 65 years].

d) **Provide patient decision support.** These tools make options visible and may save time. Some are sufficiently concise to use in clinical encounters. Examples of these short tools are Issues Cards, Decision Boards, and Option Grids (http://www.optiongrid.co.uk/). SDM may need more than one encounter. More extensive patient decision support tools may play a crucial role. Say: "These tools have been designed to help you understand options in more detail. Use them and come back so that I can answer your questions."

Shared Decision Making Detailed Steps

Shared Decision Making: Decision Talk (During Face-to-Face Visit with HCP, who will be trained on this through role play)

a) **Bring up the question regarding MAS and check if they are having MAS.**

b) **Clarify patient values/Focus on preferences.** Guide the patient to form preferences. Suggested phrases: "What, from your point of view, matters most to you?" "What is more important to you: relieving your symptoms or the worry about the increased chance of harm?"

c) **Elicit a preference.** Be ready with a back-up plan by offering more time or being willing to guide the patient, if they indicate that this is their wish.

d) **Screen for decisional difficulties.** "Are you ready to decide?" or "Do you want more time?"

e) **Moving to a decision.** Try checking for the need to either *defer* a decision or *make* a decision. Suggested phrases: "Do you have more questions?" "Are there more things we should discuss?"

f) **Offer review**. Reminding the patient, where feasible, that decisions may be reviewed is a good way to arrive at closure.

Secure Messaging

- **This message was sent to a Distribution Group. You cannot reply to this message. If needed, create a new message to the sender.**

New Message

Inbox   (1)
Appointment   (0/0)
Medication   (0/0)
Test (0/0)
General   (1/1)

Escalated   [0]
Drafts   [0]
Sent
Completed
Deleted   [0]
Reminder
Reassign

My Folders   edit

add new folder

Print Message   **Close**

◀ Previous Message | Next Message ▶

Sent: 04/22/2014 12:25 PM
From: MIA Grecc MHV Heart
To: ███████████
Message ID#: 250582959
Subject: [General ▾]   MyHealtheHeart Week #8

📎 8. Heart Failure - Evaluating Your Heart.pdf (117.46 KB)

Dear Veteran,

Welcome to week #8 of the MyHealtheHeart Patient Education Project! If you haven't already, please send us the answers to last week's questions in a separate Secure Message with the title "Week #7".

Attached to this message is the educational information on heart failure. To open the document simply click on the file named "8. Heart Failure - Evaluating Your Heart.pdf" attached to this message.

Please answer the following questions by using the following steps:

-Highlight the text from question 1 through question 7 in the body of this message by pressing and holding the left mouse button before the 1 then dragging down to the end of question 7.

-Copy the text by pressing and holding down the Control button (Ctrl) and at the same time pressing the letter C once.

-Click on the reply button at the top of your message.

-Paste the text you just copied by pressing and holding down the Control button (Ctrl) and at the same time pressing the letter V once.

-Type your weight in pounds next to question number 1 and type Yes or No next to each question thereafter:

1.   How much do you weigh today?_____lbs.

2.   Have you changed your medications in the last week? (Y/N)

3.   Do you have any new or any more swelling than usual in your feet or ankles compared to yesterday? (Y/N)

4.   Do you have any more shortness of breath compared to yesterday? (Y/N)

5.   Did you wake up in the middle of the night coughing or to catch your breath? (Y/N)

6.   Did you need to increase the number of pillows you slept on compared to yesterday because of trouble breathing? (Y/N)

7.   Compared to 1 week ago, does walking a block make you more short of breath now? (Y/N)

Once you have finished answering all of the questions, click on the send button to send us your message. If you have any questions or concerns, please feel free to send us a message through the Secure Messaging system or call us at (305)575-7407.

*If you cannot view PDF files, you can download Acrobat Reader for free from Adobe Systems, Inc. at http://get.adobe.com/reader/
In order to use PDF files, you must have Acrobat installed on your computer

☑ Menopause Screen

Menopause Status

☑ Premature [   ]

☑ Postmenopausal

☑ Induced [   ]

☑ Hormone therapy

Menstrual Periods

◯ Hysterectomy

◯ Regular

◉ Irregular

  ◯ Menorrhagia associated with menopause

  ◯ Amenorrhea less than 12 months

  ◯ Amenorrhea 12 months or greater

Menopause Symptoms

☑ Hot flashes

  [▾] per [▾]

  How bothersome? * [   ]

  ☐ Not at all ☐ A little ☐ Quite a bit ☐ Extremely

☑ Night sweats

  [▾] per [▾]

  How bothersome? * [   ]

  ☐ Not at all ☐ A little ☐ Quite a bit ☐ Extremely

☑ Trouble sleeping [   ]

☑ Sexual issues * [   ]

  ☐ Loss of interest in sex ☐ Painful intercourse ☐ Other:

☑ Vaginal symptoms

☑ Incontinence [   ]

☑ Other:

Clear	Clinical Maint	Visit Info	< Back	Next >	Finish	Cancel

WH Global Reminder:
  Menopause Screen

Health Factors: **MENOPAUSE SCREEN DONE**

* Indicates a Required Field

Steps for Shared Decision Making

1. **Invite the patient to participate:** Inviting patients to participate lets them know that they have options and that their goals and concerns are a key part of the decision making process.

2. **Present options:** Patients need to know the available options.

3. **Provide information on benefits and risks:** Provide balanced information based on the best available scientific evidence. Check back with patients to be sure they understand.

4. **Assist patients in evaluating options based on their goals and concerns:** To understand patients' preferences, ask them what is important to them and what they are concerned about.

5. **Facilitate deliberation and decision making:** Let patients know they have time to think things over, and ask them what else they need to know or do before they feel comfortable making a decision.

6. **Assist patients to follow through on the decision:** Lay out the next steps for patients, check for understanding, and discuss any possible challenges with carrying out the decision.

Adapted from the Informed Medical Decisions Foundation.