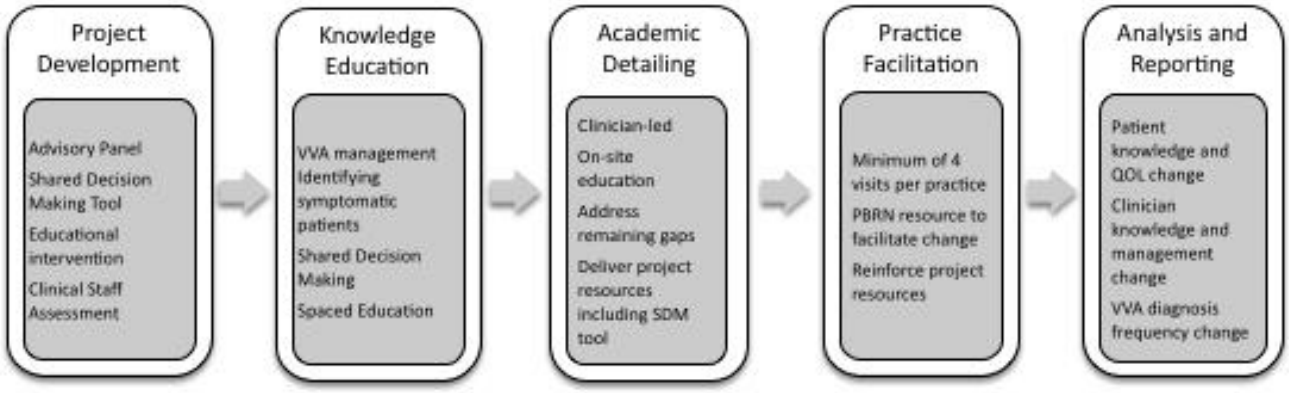
Raising Awareness – Starting the Conversation

Cover Page

Proposal

Interstate Postgraduate Medical Association (IPMA), and two primary care practice-based research networks (PBRNs), Wisconsin Research and Education Network (WREN), and Duke Primary Care Research Consortium (PCRC) have designed an initiative targeting increased awareness, improved diagnosis, Shared Decision Making (SDM) and improved Quality of Life (QOL) for the treatment of symptomatic vulvovaginal atrophy (VVA) in women ages 50-80. Each organization brings its expertise in education, systems change, clinical research, patient centered care and assessment. Collectively we reach nearly 400 physicians in 113 practices throughout Wisconsin and North Carolina. We will work with an experienced team of SDM decision aid developers at EMMI Solutions to create our SDM decision aid. We will also work with experienced sex educators and therapists at A Woman's Touch Sexuality Resource Center (AWT) as advisors for development of our patient and clinician education methods and content.

Our project, *Raising Awareness – Starting the Conversation*, will develop an internet-based VVA SDM decision aid and educational interventions to teach SDM methods to clinicians to **change clinician behavior that will result in an increase in appropriate management of symptomatic VVA**. We will evaluate methods to increase recognition and management of symptomatic VVA in family medicine and OB/GYN clinics by raising awareness of patients, clinicians and office staff about the impact symptomatic VVA has on patient quality of life. We will work with clinics to incorporate use of the SDM decision aid into their workflows. As you read through the following proposal, the figure below and the supporting definitions set the stage for the project design, education, interventions and analysis.



Definitions:

Academic Detailing: An on-site 60-90 minute conversation between a respected academic primary care physician who is knowledgeable about the subject matter and the clinicians and staff who wish to improve the quality of care for women with VVA symptoms.

Clinicians: For this project, "clinicians" include any healthcare professional that has prescribing privileges including physicians, advanced practice nurses, and Physician Assistants.

Practice Based Research Networks: PBRNs are groups of primary care clinicians and practices working together to answer community-based health care questions and translate research findings into practice. PBRNs engage clinicians in quality improvement activities in an evidence-based culture in primary care practice to improve the health of all Americans.

Practice Facilitation: Practice facilitation is a well-described effective method of assisting practices in changing the process of care. [1]External facilitators assist practices in implementing their prioritized goals, changing practice workflow, and improving patient outcomes.
Shared Decision Making (SDM): Dialog between the clinician and patient through all phases of the decision-making process resulting in a treatment choice that incorporates the clinical evidence as well as the personal values and preferences of the patient.
Spaced Education: Delivers brief, straightforward, and easily accessible education via the web or mobile device. Instant feedback allows learners to self-assess or validate their current knowledge or practice.
Stepped-Wedge Design: The stepped-wedge design is a randomized controlled trial research method where all practices start as control sites and practices are randomly assigned to sequentially receive the intervention until all practices become intervention sites.

Goals and Objectives

Our **primary goal** is to **change clinician behavior** to increase appropriate management of symptomatic VVA that results in improved QOL of women ages 50-80. Secondary goals include:

- Increase women's awareness of VVA symptoms and the association with menopause.
- Increase clinician and clinic staff knowledge about the effect of symptomatic VVA on postmenopausal women's quality of life.
- Develop an internet-based toolkit including awareness raising materials, an SDM decision aid to use in the treatment of VVA, and implementation methods that will be sustainable and widely disseminated.
- Increase diagnosis rates of symptomatic VVA in women age 50-80.
- Increase satisfaction with QOL for women with symptomatic VVA.

Technical Approach

IPMA and our PBRN partners will recruit clinics to participate in this randomized controlled trial using a *stepped-wedge design* of an educational intervention for family medicine and OB/GYN clinicians. Chart reviews will be completed to provide a baseline measurement prior to the educational interventions and post-intervention for comparison. Our intent is to **change clinician and clinical staff behavior** that will result in an increase in appropriate management of symptomatic VVA through sustainable change in the clinic setting. There are several treatment options and potentially strong feelings toward some options. Once significant symptoms are identified, the clinicians will need methods and skills to have a conversation about potential benefits and harms of treatment options to maximize the effectiveness of and patient satisfaction with the treatment chosen. In the book Manual of Management, Counseling for the Perimenopausal and Menopausal Patient: A Clinician's Guide the author stresses the importance of open dialog[2]. This Manual also states that women and their doctors "need to break the barriers, openly communicate and honestly address all issues which may include physical, emotional and sexual issues." We believe that SDM with a patient decision aid is the

best available method to facilitate open communication of these sensitive issues between patients and their clinicians[3] .

Our program provides an innovative and multi-phased approach to raising awareness, educating women and educating health care providers on VVA while working to improve diagnosis and treatment. Our project will be implemented in primary care and OB/GYN sites in the WREN and PCRC PBRNs. Based on the experience of the PBRNs and their clinicians, our study will provide a model and tools for information dissemination, practice process change and evaluation that will be disseminated to other PBRNs, interested clinicians and healthcare organizations. We will engage symptomatic patients in education, SDM, treatment, and assessment of quality of life through our planned educational interventions and approach. We will:

- Develop patient education materials
- Develop an internet-based shared decision making (SDM) decision aid
- Create a clinician and clinical staff educational intervention
- Use existing electronic health records (EHRs) and websites to enhance our interventions

Patient Education Materials - Upon project award we will immediately begin development of print, electronic and web-based VVA patient education materials. Print materials will have two components. The first set will include materials developed to raise general patient awareness about VVA symptoms. These materials will be provided in patient waiting rooms to assist in starting the conversation and encouraging patients to ask questions when meeting with their doctor. More detailed print materials will be developed that provide more explicit information on VVA symptoms, treatment, and impact on sexual health and quality of life. The more detailed materials will be available in the exam rooms and generated off of patient education materials files in the EHR or paper files for sites that might not have electronic patient education materials available. All of these materials will be developed by our project team and will include the expertise of our gynecology physician advisor, Dr. Anne Ford and our consultants from A Woman's Touch Sexuality Resource Center (AWT). We have provided sample educational materials from AWT to demonstrate the quality and content of their work. These materials will be completed and ready for dissemination prior to patient enrollment in the study. Materials will be shared with NAMS and all interested groups as we post, publish and distribute our study findings and outcomes.

Shared Decision Making (SDM) Aid – We will also immediately begin development of an internet-based SDM decision aid for use by the clinicians and their patients. This tool will be promoted in the patient education materials and include specific content related to increasing knowledge about impact of VVA on women's sexual health, quality of life, diagnosis and treatment options. After a conversation about VVA symptoms, patients will be given a paper "prescription" by the clinician with access information and instructions to complete the SDM decision aid. The clinician will also recommend enrollment in the research component of this project and setting up a follow up appointment for the SDM discussion. Informed consent and baseline data will be obtained from participating patients. The SDM aid will be jointly

developed by project staff, our clinician consultants, real patients and EMMI Solutions, an internet tool developer focused on actively engaging patients in their care. The decision aid development process includes: 1) Research through literature and guideline review; 2) Drafting a content outline; 3) Draft script development with in depth review by medical advisors; 4) Creation of a multimedia Alpha version including medical illustrations and computer generated voiceover that is viewed by medical advisors and patient advocates including patient focus groups; 5) Beta version is created based on feedback with final review by patient and medical advisors; and 6) Final version is created based on feedback and sent to outside independent testing organization to test technical functionality of program prior to release to be used in this project. See addendum for more details about the SDM development process.

Clinician and Patient Education –Our educational intervention will have 2 purposes: 1) Increase clinical knowledge and awareness by clinicians, their office staff and postmenopausal women about VVA impact on quality of life including impact on sexual functioning. The education for clinicians will include how to diagnose VVA including symptom assessment, vaginal pH testing and Vaginal Maturity Index testing, and appropriate billing for these tests. 2) We will also include training for clinicians and their staff on how to engage patients in discussion of VVA impact on sexual health, general SDM principles, and use of the VVA SDM tool.

Our educational intervention will be provided through three components: knowledge, academic detailing and practice facilitation. Knowledge on VVA diagnosis and treatment options will be provided through on-line spaced education learning. Spaced-ed requires that the learner have the correct answer before being allowed to move-on to the next issue and question. Learners keep getting questions and answering them until they have completed all of the programming. All participating clinicians will be enrolled in this continuing educational program. On-site academic detailing (doctor to doctors + staff lecture and discussion) will follow the spaced-education as we move groups from control to intervention. SDM decision aid and project patient education materials will be reviewed. The goal of the academic detailing sessions is to create an agenda for change and a to-do list generated by the practice that serves as input to practice facilitation. PBRN staff practice facilitators will then coordinate the patient education implementation, work with clinicians and clinic staff to modify existing workflows to raise patient awareness of VVA, efficiently diagnosis and treat VAA, and conduct enrollment of patient subjects. PBRN practice facilitators will also conduct chart review, obtain consent, baseline and post-intervention evaluation.

To enhance the development of our patient and clinician/clinical staff educational content and methods, we will create an Advisory Panel (AP) with clinicians, clinic staff and patients to give feedback during the development of processes and materials.

Use of EHR for Decision Support -- WREN and PCRC experience has been that different healthcare organizations have different capabilities and processes for making rapid software changes for decision support. Organizational wide priorities often override a request to use Information Services staff resources for software changes for a few sites. However, in spite of these limitations, we will work with clinics to: 1) Identify and execute methods using the EHR to

alert clinicians and clinic staff of potential patient subjects for this intervention; 2) House patient education materials in the EHR or have links to the documents housed on our project webpages so they are available for printing and providing to patients; 3) Create EHR progress note text phrases with prompts with VVA symptoms, evaluation methods and treatment options that can be inserted into progress notes as decision aids at the point of care; and 4) Create EHR patient instruction text phrases that can be inserted into the After Visit Summaries that are given to patients and are required for EHR Meaningful Use Certification.

Internet-based Study Materials Access -- WREN will add a webpage to its current website that contains the project patient education materials, link to the VVA SDM tool and links to other VVA tools and information such as the NAMS website, Mayo Clinic and Harvard Medical School vaginal atrophy webpages.

Current Assessment of Need in Target Area

The current life expectancy for American women at birth is 80.5 years and continues to increase.[4] If the average age of menopause is 50, [5] and life expectancy is increasing, many women may expect to live almost 40% of their lives after menopause. Menopause is a midlife event and needs to be treated as such within a clinical setting. Symptoms associated with VVA affect 20% to 45% of midlife and older women but only a small number of women seek help or are offered help by their healthcare providers. Women can live with vasomotor symptoms (hot flashes, night sweats) that accompany loss of ovarian estrogen production and can improve over time without estrogen treatment, but symptoms associated with VVA can be progressive and less likely to resolve without estrogen treatment.

A recent survey of 110 primary care clinicians within the WREN and PCRCPBRN systems identified two knowledge gaps: 1) On a scale of 1-5, clinicians' averaged 3.5 for knowledge of current evidence for benefits and harms of hormonal therapy for VVA. Only 5 clinicians felt very knowledgeable about current HRT evidence; 2) On the same scale, clinicians' averaged 3.11 for knowledge about SDM techniques while 65% (72 clinicians) had only some, little or no knowledge of SDM. Using EHR billing data, PCRC found that only 1.1% (301/27,048) of female patients age 50-80, seen in primary care, had a diagnosis of VVA. Similarly, the University of Wisconsin Dept. of Family Medicine (where WREN is based) found that 3.9% (779/19,848) of female patients age 50-80 seen in primary care had a diagnosis of VVA. A 2010 study published in Mayo Clinic Proceedings women self-reported VVA symptoms in a range of of 4% in premenopausal women to 47% in postmenopausal groups.[6] The data suggests that clinicians have significant knowledge gaps and VVA is underdiagnosed and undertreated at our institutions.

Primary Audience – The primary audience for the educational intervention are the participating WREN and PCRC clinicians and their clinical staff. The beneficiaries of the program are women ages 50 – 80 seen in these clinic sites.

Intervention Design and Methods:

We will enroll 16 clinics from the two PBRNs: 12 primary care and 4 OB/GYN will be recruited by PBRN staff based on the following criteria: 1) Three or more family medicine or OB/GYN clinicians willing to participate in the project; 2) Fully implemented EHR; 3) Clinic information services staff with capability to extract diagnosis, procedure and visit data from the EHR database; 4) Sufficient female patients ages 50-80 to fulfill recruitment requirements. We will use the stepped-wedge design model for control and intervention groups. We will randomly pick 6 practices (4 primary care and 2 OB/GYN) for educational interventions in Quarters 3+4 and 4 primary care practices in Quarter 5 for the step-wedge design. EHR data will be extracted to assess baseline and post-intervention VVA diagnosis frequencies and identify appropriate patients for chart review. Chart review will be conducted for patients with VVA diagnosis, 30 before intervention and 30 after intervention for each clinician. Chart review will assess changes in clinician evaluation methods, including vaginal pH and Vaginal Maturity Index testing, and treatment recommendations including estrogen and selective estrogen receptor modulator therapy. Two symptomatic VVA subjects per month per clinician will be enrolled at intervention sites and pre- and post-intervention surveys will be administered to assess the women's VVA knowledge and Quality of Life.

Stepped-Wedge Controlled Trial Intervention Table

WREN clinic	Duke clinic	Quarter 2	Quarter 3	Quarter 4	Quarter 5
1 FP	1 FP	Control	Intervention	Intervention	Intervention
2 FP	2 FP	Control	Intervention	Intervention	Intervention
3 GYN	3 OB/GYN	Control	Intervention	Intervention	Intervention
4 FP	4 FP	Control	Control	Intervention	Intervention
5 FP	5 FP	Control	Control	Intervention	Intervention
6 GYN	6 OB/GYN	Control	Control	Intervention	Intervention
7 FP	7 FP	Control	Control	Control	Intervention
8 FP	8 FP	Control	Control	Control	Intervention

Evaluation Design

Data Analysis and Project Evaluation

As mentioned above, we identified two practice gaps: 1) Clinicians have significant knowledge gaps about current evidence for benefits and harms of hormonal therapy for VVA; 2) VVA is underdiagnosed, especially in primary care practices. Our hypotheses are: Increased clinician knowledge of SDM and current evidence for benefits and harms of treatments for VVA will result in: 1) Increased clinician knowledge about appropriate management of symptomatic VVA; 2) Change in clinician behavior to increase appropriate management of symptomatic VVA; 3) Increase diagnosis rates of symptomatic VVA in women age 50-80. 3) Improved Quality of Life (QOL) for women with symptomatic VVA as measured by the Menopause-Specific Quality of Life Questionnaire (MenQOL).

Increased physician VVA management knowledge: We will evaluate our educational intervention by assessing clinician knowledge of SDM and VVA management with a survey before and after the educational intervention. We are unable to find any validated measures of SDM knowledge nor knowledge of VVA management. As a result, we will develop a short survey about these topics and then conduct cognitive testing with representative clinicians. We will ask the respondent to read each item out loud and tell us what it means to them, what they think about as they answer it and why they picked the answer they did. Any unclear questions will be modified and retested. It is not within the scope of this project formally validate these survey questions by analyzing predictive validity and construct validity which will require larger samples and comparison groups to test predicted differences between groups.

Increased Clinic Staff knowledge of VVA: Clinical staff will be included in the academic detailing educational interventions as they will be instrumental in the process and practice change, identification of eligible patients required by this project, and long term sustainability. We will conduct a pre- and post-academic detailing survey of clinical staff to measure change in knowledge including questions related to the association between menopause and VVA symptoms.

Change in physician VVA management behavior: We will use EHR billing data and extract a list of patients diagnosed with VVA for each participating clinician pre and post-intervention. We will randomly select 30 from each time period (60 total per clinician) and conduct chart reviews to extract management data. We choose this number of subjects for chart review as it is generally accepted to be sufficient to identify meaningful change for quality improvement projects. Data extracted will include patient demographics and VVA management variables including vaginal pH and Vaginal Maturity Index testing, and treatment recommendations including estrogen and selective estrogen receptor modulator therapy.

Diagnosis rates of symptomatic VVA: We will use EHR billing data and assess frequency of VVA diagnosis for women age 50-80 for one year pre-intervention and each quarter post intervention. Analysis will assess overall change in diagnosis frequency and post-intervention diagnosis frequency change over time.

Quality of Life and Patient Knowledge of VVA: We will enroll 2 patient subjects per month per clinician with symptomatic VVA at each site starting after completion of the educational intervention. With the stepped-wedge design, this will give us a total of 300 patients when we complete enrollment at all sites in Quarter 6. We choose this number based on our experience with a balance between feasibility of recruiting in a primary care practice and sufficient recruiting requirements to keep clinicians engaged during the duration of the project. We will assess quality of life with the MenQOL at enrollment and by telephone interview 2 months after patient/clinician visit for SDM VVA discussion and recommendations. We will also test pre and post-SDM patient knowledge about VVA symptoms, and treatment options.

Evaluation Component	Measurement Tool	Frequency of Measure	Total N of subjects
Change in clinician VVA management	EHR extraction + chart review	Pre- and post-intervention	30 pts. X 48 clinicians=1440 Pre-intervention = 1440 Post-intervention = 1440
Frequency of diagnosis of VVA	EHR extraction	Retrospective	Total eligible patients=7200* Cntrl=1575, Intrvntion=5625
Women's knowledge of VVA and QOL	Knowledge questions MenQOL	Enrollment, post SDM discussion and 2 mo. post intervention.	N=300
Clinicians + staff understanding of VVA, vaginal health, and treatment options	Pre & Post questionnaire	Pre- and post-academic detailing	N=36 primary care clinicians N=12 OB/GYN clinicians N=144 office staff N=192 total

*assumptions: 150 total potentially eligible patients/clinician, 3 clinicians/site seen once during study time period. This will be higher for OB/GYN clinicians.

Fidelity of Intervention: There are two main components to the fidelity assessment: 1) Determining how well the program was implemented; and 2) Documenting adjustments made to the initial program plan as the program is implemented to adapt to changing or unanticipated circumstances and enhance its effectiveness. Data for this assessment will come from administrative records, which will document 1) Clinicians participation in the spaced-education activities; 2) Timing of academic detailing visit; 3) Number and timing of practice facilitation visits; 4) Participants in sessions conducted; and 4) Project personnel involved.

Analysis: The **primary outcome will be to increase clinician knowledge about appropriate management of symptomatic VVA** based on chart reviews of patients having a diagnosis of VVA. Data will be analyzed using repeated measures cross-sectional comparisons which account for the clustered effects. Identification by time comparisons for diagnosis frequencies will determine effect variation over time. Descriptive statistics will be used to create summed scores for the VVA management, diagnosis frequency, knowledge about VVA and MenQOL measures. The reliability for all scales will be calculated using Bland Altman analysis. Paired t tests and repeated-measures analysis of variance (ANOVA) for continuous measures and McNemar tests for categorical variables will be used to analyze the measures; pre–intervention and post–intervention results will be compared.

Expected Change and Engagement of Target Audience

We anticipate change in clinician behavior in 75% of clinicians that results in an increase in appropriate management of symptomatic VVA for women ages 50-80. Based on WREN and Duke experience with multiple similar projects, we anticipate several challenges that will need to be addressed to fully engage our clinicians in this project. We first need to ensure that the enrolled sites have clinician buy-in. Primary care clinicians treat all ages of patients with many and varied health concerns. We believe our project will particularly appeal to mid and late-career clinicians that tend to have an older patient population as well as those who do not feel

they have adequate knowledge about menopause and VVA. The clinician education, patient education materials, and web-based SDM aid are all selling factors to the participating clinic and demonstrate our desire to provide them with educational knowledge and tools as a benefit of their participation. Many of the possible clinic participation sites are residency training sites. This study could easily serve as a third year residency research project and will be communicated as such to the PBRNs.

Project Outcomes Sustainability and Dissemination -We will ensure sustainability of this project by making a **tool-kit** available for broad dissemination. This tool-kit will include the educational intervention, methods to implement the intervention, patient education materials and SDM aid. The tool-kit will be distributed and posted in several locations including: WREN and PCRC websites and newsletters; National Resource Center for Academic Detailing; and the Agency for Healthcare and Research and Quality National PBRN Resource Center. We expect the participating practices to continue to apply the SDM methods to other aspects of care they provide. We will also disseminate our findings and materials through presentations, shared educational materials and published articles. The findings will be shared with the participating practices and throughout WREN and PCRC and will be distributed to other PBRNs nationally via the AHRQ supported PBRN listserve. We will **present** the results of our educational interventions, analyzed data and outcomes at a state and national level. Each PBRN physician lead and project manager will take responsibility for their own PBRN presentation. Paul Smith, Principal Investigator, will present at the national meetings. Planned meeting presentations include: The Wisconsin and North Carolina PBRN meetings; The National PBRN Conference; and the American Academy Family Physicians Scientific Assembly. We will also disseminate the full outcomes report and tool-kit in the continuing medical education profession including the Journal of Continuing Education in the Health Professions and CME Congress.

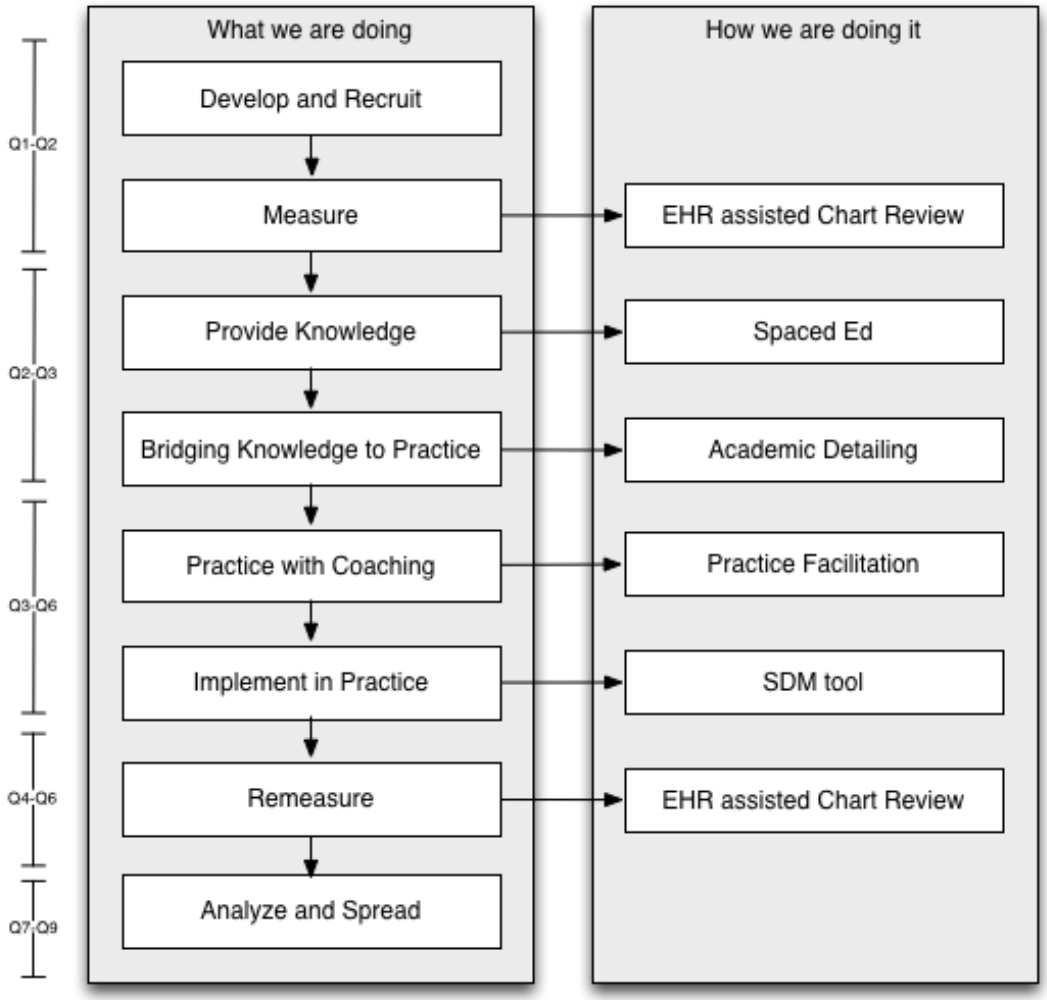
Detailed Workplan and Deliverables Schedule:
Our Workplan and Deliverables schedule follows a two year time project timeline, February 1, 2014 – January 31, 2016.

Project Management: Dr. Paul Smith will be responsible for all aspects of this project with shared responsibilities across all four partners. IPMA's project manager will: 1) Coordinate overall project management between the three PBRNs; 2) Manage budget and subcontracts; 3) Host regular meetings to ensure we meet our deliverable schedule; 4) Assist PBRN project managers in site training and materials preparation; 5) Oversee the spaced-education activities; 6) Certify educational content for CME and CEU credit; and 7) Have primary responsibility for outcomes reporting. WREN's project manager will provide oversight of most intervention tasks working with PCRC project managers to: 1) Oversee IRB approval; 2) Practice site and clinician recruitment; 3) Protocol training; 4) Patient subject identification; 5) Enrollment, scheduling of academic detailing and practice facilitation visits; 6) Oversight of practice facilitation staff; 6) Data collection procedures; and 6) Regulatory compliance.

Data Management: Dr. Smith and WREN staff will oversee the database development and management, data collection, analysis and reporting. Study data will be collected and managed

using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at the University of Wisconsin-Madison, School of Medicine and Public Health. REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) An intuitive interface for validated data entry; 2) Audit trails for tracking data manipulation and export procedures; and 3) Automated export procedures for data downloads to common statistical packages. REDCap enables high-quality data collection and robust quality assurance processes by employing features such as field level validation including range and format checks and branching/skip logic. REDCap provides an integrated database while simultaneously allowing remote site staff access to only their participants' data. This enables real-time data quality checks, safety monitoring, and enables accrual to be monitored closely. PBRNs are accustomed to using REDCap for data management and integration. We will utilize REDCap's robust security system to customize security schemes for individual case report forms, data export functions, and reporting. Data will be collected at each individual PBRN with data entry directly into REDCap through the secure Web-based interface.

The following diagram provides a summary presentation of our planned work over the course of the two year project.



Detailed Workplan and Deliverables Chart

Deliverable	Timeframe to Completion	Partner Responsibility
Planning and Development		
Notification of Award	December 2013	Pfizer
Official Start Date	February 1, 2014	Pfizer
Establish Advisory Panel (AP)	Feb - Mar 2014	IPMA, WREN, Duke, AWT
Develop educational intervention and materials for spaced-ed and academic detailing	March - May, 2014	IPMA, WREN, Duke, AWT, Advisory Panel
UW IRB Approval	Feb - May 2014	WREN
Develop patient education materials	Feb - May 2014	All partners with AWT and Advisory Panel
Duke IRB Approval	April - June 2014	DUKE
Recruit Clinics and Clinicians	Feb - June 2014	WREN and Duke
Project webpage development	Feb -June 2014	IPMA, WREN, Duke, AWT, Advisory Panel (WREN lead)
Database development	April - June 2014	WREN
Develop SDM Tool	Feb - July 2014	Emmi, MD+ Patient consultants
Baseline clinician and clinic staff knowledge surveys	July 2014- Feb 2015	WREN and Duke
Finalize Educational Intervention	July 2014	IPMA, WREN, Duke, AWT, AP
Intervention		
Start spaced-ed for 1st round clinicians	June 2014	IPMA
1st Round of Interventions in 6 clinic sites (Total 4 primary care + 2 OB/GYN intervention, 10 control)	August – Oct 2014	WREN and Duke
Start patient subject enrollment at intervention sites	August 2014	WREN and Duke
Start patient subject telephone follow-up	October 2014	WREN and Duke
Start spaced-ed for 2nd round clinicians	Sept 2014	IPMA
2nd Round of Interventions in 6 clinic sites (Total: 8 primary care + 4 GYN, 4 control)	Nov 2014 - Jan 2015	WREN and Duke
Start patient subject enrollment at intervention sites	Nov 2014	WREN and Duke
Start patient subject telephone follow-up	January 2015	WREN and Duke

Start spaced-ed for 3rd round clinicians	December 2014	IPMA
3rd Round of Interventions in 4 primary care clinics (Total 12 primary care + 4 OB/GYN all intervention	Feb – April 2015	WREN and Duke
Start patient subject enrollment at intervention sites	February 2015	WREN and Duke
Start patient subject telephone follow-up	April 2015	WREN and Duke
Data Collection and Analysis		
Clinician knowledge change assessment	May – July 2015	IPMA
Educational data results manuscript development	September 2015	IPMA, WREN, Duke
Complete patient subject follow-up telephone surveys	May – July, 2015	WREN and Duke
Chart reviews and analysis of pre- and post-intervention patients	Aug - Oct 2015	WREN and DUKE
Analysis of clinical data	Oct - Dec 2015	WREN
Outcomes reporting	January 2016	IPMA
Dissemination and Sustainability		
Results and materials distributed via national PBRN listserv	September 2015	WREN, PCRC
Regional and National PBRN Meetings- prelim results	September 2015	WREN, PCRC
National PBRN meeting	June 2016	WREN
AAFP Scientific Assembly	Fall 2015	WREN
Materials on Health System and NAMS Website	December 2015	WREN, PCRC
Clinician behavior change manuscript development	Fall 2015	All partners
Publications (JCEHP)	2016	IPMA

Organizational Detail

Leadership and Organizational Capacity

WREN – Wisconsin Research and Education Network

The mission of the Wisconsin Research and Education Network (WREN) is to improve health outcomes for the people of Wisconsin through education, and through promoting and conducting primary care research in partnership with primary care clinicians and the communities they serve. WREN was founded in 1987, and is one of the oldest and most respected practice-based research networks in the United States. WREN is comprised of approximately 300 members, 200 of whom are practicing clinicians. Members come from 80 different clinic sites representing 37 healthcare organizations. WREN clinicians practice in a variety of settings, ranging from small independent practices to large integrated health systems. WREN members conduct high-quality translational research projects in "real-world" family practices across Wisconsin. Since 2007, WREN has participated in 29 funded projects, 13 funded by AHRQ, four funded by the NIH, and 12 non-federally funded projects. Since its inception in 1987, WREN projects have resulted in 90 publications

WREN maintains a core of full-support practices, contracted to participate in WREN projects on a regular basis. Each full support practice receives financial support each year to offset the costs of implementing WREN projects as well as administrative support from a WREN Regional Research Coordinator assigned to the practice. In addition to Full Support clinics, WREN has done projects with clinics all across the state. WREN is part of two AHRQ funded (P 30) Research Centers in Practice-Based Research and Learning consortiums. These consortia of PBRNs form an infrastructure to accelerate the generation of new knowledge and a community of learning for primary care practices to improve quality, patient safety, and effectiveness of care. The two networks are: The Coordinated Coalition of Networks (CoCoNet2): Oklahoma, New York, Los Angeles, Wisconsin and the coordinating center Westat; and The Meta-Network Learning and Research Center (Meta-LARC): Oregon, Iowa, Colorado, Quebec and Wisconsin.

Duke PCRC –Duke Primary Care Research Consortium

The PCRC is a network of primary care clinicians who work together to enroll patients in clinical research studies, including 33 practices in 7 counties of the Piedmont area of North Carolina (both urban and rural). These practices are made up of the Duke Primary Care practices, the Ambulatory Care Service of the Durham VA Medical Center, and independent community practices with a total of 195 clinicians who care for an estimated 330,000 patients. The goals of the PCRC are to (a) perform clinical studies that will improve health care delivery and patient outcomes, (b) provide educational opportunities for clinicians to maintain their clinical skills and develop new research skills, (c) offer clinicians support through a central administrative office and trained study coordinators enabling them to participate in primary care research, and (d) generate research to support the practice of evidence-based medicine.

Since its inception in 1997, the PCRC has enrolled more than 6000 subjects from more than 60 trials. Over 100 clinicians have assisted with recruitment and follow-up at their practice sites. The Duke PCRC has extensive experience in conducting short- and long-term clinical trials in

hypertension and ischemic heart disease; some trials included long-term follow-up of 4 years (Julius 2004, O'Connor 2003). Some example projects include (a) a randomized study of SSRI antidepressants in primary care (Kroenke 2001), (b) a randomized study of intranasal steroids compared to placebo nasal spray for recurrent sinusitis (Dolor 2001), (c) validation of the Duke Anticoagulation Satisfaction Survey within community-based primary care practices (Samsa 2004), and (d) a study comparing influenza vaccine schedules in 6 to 23 month old children (Englund 2005).To date, 32 manuscripts and 35 abstract presentations have resulted from work performed by the Duke PCRC. In 2002, the PCRC became one of 36 Primary Care Practice-based Research Networks funded by the AHRQ to create an infrastructure and conduct a pilot project to implement evidence-based strategies for practice improvement. In 2004 the PCRC collaborated with the AHRQ PBRN Resource Center and 5 other PBRN networks on the National Children's Study pilot within the pediatric, obstetric and family practices in the network.

IPMA – Interstate Postgraduate Medical Association

Since its foundation in 1916, Interstate Postgraduate Medical Association of North America has continuously maintained its original goal of clinician education that positively impacts patient care. As a not-for-profit 501(c)(3) educational association, IPMA's stated mission is the dissemination of medical knowledge and the improvement of clinicians' ability to prevent, detect and treat disease. A diverse array of educational activities and initiatives apply evidence-based adult learning strategies to transform practice, ultimately improving patient health.

Each educational initiative is carefully designed to effectively change clinician practice, impact clinician performance, and ultimately improve patient and community health. IPMA's diverse educational offerings include comprehensive needs assessments that identify learner gaps and educational needs; an annual Primary Care Update conference that delivers practical, clinically focused education; and cutting-edge performance improvement initiatives that incorporate self-directed learning to advance clinical practice. IPMA has developed educational tools and curriculum for clinicians in perimenopause, menopause, and management of VMS symptoms. Central to these resources has been applying patient focused decision making grounded in evidence-based data. IPMA is proud to hold accreditation with commendation from the Accreditation Council for Continuing Medical Education (ACCME).

Emmi Solutions, LLC ("Emmi") is the leading SaaS (Software-as-a-Service) provider of interactive patient engagement and empowerment programs designed to ***improve clinical and financial outcomes*** for healthcare providers and payers. A true patient engagement industry pioneer, Emmi is tackling some of the most complex business issues facing healthcare providers and payers today in an effort to reduce costs, increase revenue, and improve clinical outcomes and quality. Emmi is a complete and integrated multi-modal patient engagement platform that leverages Web, mobile, email, video, IVR and print. Emmi can engage patients in any setting and on almost any third-party device (desktop, smartphone, tablet, mobile phone, etc.), allowing it to target, prescribe and deliver efficacious, high value-add solutions at discrete points of care – when and where they are needed most and are most likely to yield the greatest overall benefit to patients. Accordingly, Emmi goes beyond simply engaging patients and is focused on delivering and measuring efficacious programs at a granular individual patient level.

A Woman's Touch Sexuality Resource Center (AWT) is a business offering education, training, product development and a retail boutique based in Madison, Wisconsin. A Woman's Touch offers a unique combination of expertise in sexual health and pleasure and is owned by a sex educator and counselor, Ellen Barnard MSSW, and a physician, Myrtle Wilhite, MD, MS. Each has worked with health care providers and consumers to provide education and training to address the most common sexual issues due to changes in physical health and ability, cancer treatment, and aging. Over the past 16 years, they have specialized in developing integrated approaches to help post-menopausal women and cancer survivors find solutions to allow them to enjoy satisfying intimacy and sexual function. Ms. Barnard and Dr. Wilhite train and consult with health care providers and therapists to teach them how to offer the most effective solutions to the most common sexual concerns presented to them. Their cross-disciplinary approach increases providers' comfort and capacity to address patients' sexual health needs.

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