Pfizer Medical Education Grant Program

A. Cover Page and Abstract

Title: Improving diagnosis and management of vulvovaginal atrophy, a health-system approach

Project Summary and Abstract

While vulvovaginal atrophy (VVA) is a known process that occurs among postmenopausal women in the absence of estrogen therapy, it is often not diagnosed. Additionally, once VVA is diagnosed, women with VVA are often not optimally managed. This is supported by our data in large population of postmenopausal women. To prepare for this application we identified 73,927 women aged 50-65 years of age who were enrolled within KPNW during the years 2011 and 2012, and nearly half of them (32,592, 44%) had a well woman visit during that time frame. Dispensing of estrogen containing products occurred for approximately 15% of these women during the previous year. Likewise, fewer than half had ever filled an estrogen prescription at any time during their KPNW enrollment. Finally, only one-third had filled a prescription for estrogen after the age of 50.

These patterns were also visible in referral patterns to our Urogynecology clinic. Referrals are made electronically and each referral contains specific instructions to treat atrophy prior to referral. Despite this recommendation, only 12 % of women referred for genitourinary disorders actually have received a prescription for local estrogen therapy. This lack of adherence may be due to lack of physician knowledge about the risks and benefits of local estrogen therapy, physician and patient attitudes towards localized estrogen therapy, and lack of readily available tools to use in the clinic setting to improve prescribing practices and patient assessment and education.

To address these issues, we will conduct a study examining gaps in provider education and patient care by randomizing our 16 family practice (FP), 12 internal medicine (IM) and 6 Obstetrics and Gynecology clinics (OB/GYN) clinics to either the intervention or control condition. We will randomize 9 clinics to receive the intervention and 8 clinics to control (because two of the clinics share many of the same staff, these two clinics will be randomized as one unit). We will provide an educational plan for clinicians and support staff in the intervention clinics on the pathophysiology of vulvovaginal atrophy (VVA), urogynecologic co-morbidities, assessment, and treatment. We will deliver these educational materials through in-office trainings and an on-line CME module. We will also develop clinical management support tools (called Smart Sets and Smart Text) in our electronic health record to help clinicians diagnose, treat, and educate their patients about VVA. We will assess the effect of our intervention through physician and patient survey assessments and through use of data contained within our electronic medical record. Our primary goals are as follows:

We will determine if, compared to control clinics, clinicians in the intervention clinics:
1) Diagnose VVA more often among postmenopausal women
2) Prescribe vaginal estrogen more often for genitourinary disorders among postmenopausal women
3) Are more likely to use the VVA SmartSet and SmartText to support patient care and education

As secondary outcomes we will evaluate provider knowledge and attitudes towards diagnosis and management of VVA, and determine whether patients in the intervention clinics indicate greater knowledge regarding VVA, receive better treatment, and experience quality of life after interacting with their provider.

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C. MAIN PROPOSAL

1. Overall Goal & Objectives:

We will randomize our primary care and gynecology clinics to intervention (9) and control (8) groups (with clinic randomization stratified by patient volume /number of providers and clinic type: internal medicine, family practice, OB/GYN). Dr. Vesco, Dr. Clark, and Ms. Beadle will craft an education plan for clinicians and support staff in the intervention clinics. Topics covered will include the pathophysiology of vulvovaginal atrophy (VVA), urogynecologic co-morbidities (urinary frequency, urgency, incontinence and recurrent UTI's), assessment, and treatment. We will give presentations at each site that will be supported with online and written materials. We have created a decision support tool (SmartSet, EpicCare EMR), which is a topic-specific grouping of clinical guidelines, diagnoses, preset orders, referrals, documentation templates and patient information, to facilitate efficient and accurate care of women with VVA. We have also created patient information resources in the format of "SmartText or dot phrases". These tools can be "turned on" in selected clinics and their use can be tracked as an outcome. We hypothesize that clinicians in the intervention clinics will be more likely to make the diagnosis of VVA, make treatment recommendations, and provide educational materials to their patients. We additionally hypothesize that woman attending the intervention clinics will be better informed about VVA and will have better condition-specific quality of life. Our primary goals are as follows:

Goal 1. Determine if providers in the intervention clinics diagnose VVA more often among postmenopausal women compared to control clinics

Goal 2. Determine if providers in the intervention clinics prescribe vaginal estrogen more often for genitourinary disorders among postmenopausal women compared to control clinics

Goal 3. Determine if providers in the intervention clinics are more likely to use the VVA SmartSet, SmartText, and dot phrases to support patient care and education compared to control clinics

As secondary outcomes we will evaluate provider knowledge and attitudes towards diagnosis and management of VVA, and determine whether patients in the intervention clinics indicate greater knowledge regarding VVA, receive better treatment, and experience quality of life after interacting with their provider.

2. Technical Approach
2.a. Current Assessment of need in Target Area

Although VVA is a known process that occurs among postmenopausal women in the absence of estrogen therapy, there is under diagnosis and management of symptomatic VVA among postmenopausal women. To prepare for this application we identified 73,927 women aged 50-65 years of age who were enrolled within KPNW during the years 2011 and 2012, and nearly half of them (32,592, 44%) had a well woman visit during that time frame.

Dispensing of estrogen containing products during 2011-2012 occurred for approximately 15% of this cohort (11,652). Less than half of the cohort (33,129, 45%) had ever filled an estrogen prescription at any time during their KPNW enrollment and only one-third had filled a

prescription for estrogen after the age of 50. There were 4,712 unique diagnoses among these women (4% of the cohort) of vulvar atrophy (624.1), atrophic vaginitis (627.3), or dyspareunia (625.0). A more detailed analysis is needed to explore these findings further, but these data suggest there is under diagnosis and treatment of vulvovaginal disorders within KPNW, especially given that research studies suggest that 20-45% of midlife and postmenopausal women may be affected by symptoms associated with vulvovaginal atrophy.

For the letter of intent, we selected the age group of 50-65 to represent women in perimenopause and early menopause and we conducted our power analysis for this group. For the full study, we will analyze diagnosis and treatment of VVA in all women > 50 years of age. Fewer data exist for older menopausal women.   Lower rates of vaginal symptoms were found in the Women's Health Initiative for women ages 50-79. With the progressive nature of VVA, one would expect higher rates in older women. But sexual activity declines with age, and this may result in less bother.

Referrals patterns to our Urogynecology clinic provide further evidence of barriers to estrogen therapy for genitourinary atrophy. Referrals are made electronically and each referral contains specific instructions to treat atrophy prior to referral. Despite this recommendation, only 12 % of women referred for genitourinary disorders actually have received a prescription for local estrogen therapy. We posit that this may be due to lack of physician knowledge about the risks and benefits of local estrogen therapy, physician and patient attitudes towards localized estrogen therapy, and lack of readily available tools to use in the clinic setting to improve prescribing practices and patient assessment and education. (See Appendicis)

Urinary incontinence increases in prevalence and severity with increasing age after menopause. A recent survey of women > age 65 who are members of our NW Kaiser health plan showed that 54% of 3757 women responded yes to the question, "Many people experience problems with the leakage of urine.[1] In the past 6 months, have you accidentally leaked urine?" Vaginal estrogen therapy (ET) has been shown to improve urinary stress incontinence, urgency, and urge incontinence. In one study of vaginal estrogen tablets, 1 in 5 women achieved continence. In contrast, systemic ET is associated with worsening of stress incontinence and worsening of any urinary incontinence symptoms. Few studies have compared vaginal ET to other treatments for urinary incontinence.[2] A comparison of the estradiol ring to oral oxybutynin showed similar effectiveness.[3] Undertreatment of VVA may lead to under treatment of urinary symptoms and result in more incontinence in our control group.

Recurrent urinary tract infection (UTI) (defined as 3 UTIs in 1 year or 2 UTIs in 6 months) is estimated to affect 10-15% of postmenopausal women. Vaginal ET was found to prolong the time to next recurrence among postmenopausal women with recurrent urinary tract infection and to decrease the number of recurrences per year. The magnitude of the improvement is reported as proportion of women with infection at the end of the treatment period. An RR (relative risk) of 0.25 was reported for estriol cream and an RR of 0.64% for the estradiol ring in separate studies. Vaginal ET does not increase the risk of antibiotic resistance over time. Failure to treat VVA will likely result in more UTIs in the control group.[4]

2.b. Intervention Design and Methods:

There are approximately 424 clinicians (family practice, internal medicine, and obstetrician-gynecologists) practicing within 18 unique clinics across the KPNW region (FP 16 clinics, IM 12 clinics, OB 6 clinics). We will randomize 9 clinics to receive the intervention and 8 clinics to control (because two of the clinics share many of the same staff, these two clinics will be randomized as one unit). The intervention is designed to improve clinician and patient knowledge regarding VVA and reduce barriers to diagnosis and treatment of VVA. To determine if we have met our goals, we will compare outcomes for the intervention and control clinics. To further understand physician response to the intervention, the outcomes may be additionally stratified by provider characteristics—by specialty (Internal medicine, family practice, and gynecology); by clinician (physician and advanced practice nurses and physicians assistants);and by gender and age.

Intervention Group:

The intervention will include the following components:

1. Online CME Module

2. Decision Support Tool in Electronic Health Record (EHR)

3. Educational seminar for clinicians and their support staff

    a. Pathophysiology, Diagnosis and Treatment of VVA
    b. Use of decision support and electronic tools
    c. Resources for additional clinical education
    d. Resources for patient education

1) **Online CME Module.** Clinicians in the intervention group will be asked to complete a 1-hour online CME module about vulvovaginal atrophy. We will develop a Kaiser-specific module will be modeled after the NAMS module that can be found at http://www.mycme.com/symptomatic-vulvovaginal-atrophy-at-menopause-identification-and-intervention/activity/1333. Our module will be modified to reflect the Kaiser formulary which directs clinicians to use less expensive treatments first. In our system vaginal dilator therapy is more often initiated by OB/GYN physicians than physical therapy. We will include more detailed content about treating urogenital conditions of recurrent UTI and overactive bladder.

    Our module will be administered through KPNW's Knowledge Portal, a Kaiser system for administering and tracking education content. Through KPNW's knowledge portal, we will track timing and completion of the activity and pre- and post-test results. When the module is complete, clinicians will be sent a $10 gift card from a local merchant by email as an incentive.

2) **Decision Support Tool in EHR.** The outline for this tool (called a SmartSet) is shown in Figure 1. This tool provides consistent, accurate treatment options that are efficient and easily integrated into the clinician's workflow. The SmartSet begins with a link to a Practice Resource—a clinical guideline based on the recent NAMS Position Statement. This provides a succinct rationale and references for the resources listed within the

SmartSet. A checklist of diagnoses is available to allow quick, accurate and comprehensive coding of the diagnoses.   SmartOrders provide a checklist of available medications with pre-written dosages and sigs to ensure accuracy. For creams and tablets, the order is paired—an initial prescription for increased frequency in the first weeks, followed by a titration recommendation for refills for ongoing therapy. To enhance cost effective care, clinicians are encouraged to use lower cost treatments initially on formulary instead of the more expensive alternatives.   At the conclusion of each patient visit at Kaiser, patients receive an After Visit Summary (AVS) that summarizes the visit and allows for follow up instructions. SmartTexts have been created (see below) that provide patient information based on NAMS guidelines and describing local resources. These SmartTexts (see examples in Appendicis)may also be added to secure emails to patients. Kaiser conducts regular educational classes for members and 3 of those classes provide content relevant to VVA. With one click, patients are referred to the appropriate class. Information about the class will print on the patient's AVS and she will receive a telephone call from a receptionist to schedule her class.   These tools are widely used by Kaiser clinicians to maximize the limited time for clinician-patient interaction.

3) **Women's Midlife Transitions/Menopause Class.** This class is designed to give women information about managing menopause, discussing the most common symptoms in early and late menopause and how these symptoms can affect quality of life. Specific information is presented regarding how hormones change in menopause and the physiological effect that may cause symptoms. Both non-hormonal and hormonal options are reviewed to address symptoms like hot flashes, vaginal, sexual, mood and urinary changes. Other health risks associated with aging, identifying personal health risks and making lifestyle changes to prevent heart disease and osteoporosis are also reviewed. The 2.5 hour group format allows women to get information, ask questions, and share their own concerns and experiences.

4) **Educational seminar for clinicians and their support staff.** The department chairs in OB/GYN and primary care have invited our team to present an educational talk at the monthly meeting at each clinic location. We will review key aspects in diagnosis and treatment of VVA and how to use the SmartSet and related resources in the EHR.   Time will be allowed to address barriers to VVA care.

Control Group:

The control group will not receive any specific education or training regarding vulvovaginal atrophy, use of Smart sets, or use of Smart text during the study period.   The Practice Resource will be available on the KPNW web-site, and the Smart Set and Smart Text, for patient information, will be available in the EHR. We believe that the use of these tools will be less frequent among control clinicians as they will not be advised regarding their presence or their use. Once the study period is over and we have assessed the success of our intervention in achieving our goals, we will provide education and training to the clinicians and staff in the control group.

Figure 1. Smart Set for Vulvovaginal Atrophy

Clinician resources (Links to:)
☐ Vulvovaginal Atrophy Practice Resource KPNW
☐ CME presentation on VVA, KPNW Knowledge Portal

Diagnoses
☐ Vaginal Atrophy, Atrophic Vaginitis (627.3)
☐ Vulvar Atrophy (624.1)
☐ Dyspareunia (625.0)
☐ Recurrent UTI (599.0)
☐ Female Stress Incontinence (625.6)
☐ Overactive Bladder (596.51) [urgency, frequency, nocturia, urge incontinence]

Referrals
☐ Referral OBGYN VVA [000000] (to be added to facilitate tracking)
☐ Referral Urogynecology [206825]

Prescriptions on Formulary
☐ Premarin Vaginal Cream-Initial and Titration [O196107]
☐ Estring-estradiol vaginal ring [200416]

Not on Formulary (When intolerant to Premarin and unable to use the vaginal ring)
☐ Vagifem 10 mcg Vaginal Tab [124133]
☐ Estrace Cream-estradiol 0.01% [346044]

Progress Note Template
☐ Vulvar and vaginal exam with SmartLists

Patient information for the After Visit Summary
☐ PI Vaginal Changes after Menopause that affect Vaginal Health (OP NW)
☐ PI Non-hormonal therapy for Vulvovaginal Atrophy (OP NW)
☐ PI Vaginal Estrogen AVS GYN (OP NW)

Refer to Class
☐ Women's Midlife Transitions
☐ Women's Sexuality Class
☐ Taking Control of Your Bladder

Anticipated challenges and solutions: Our primary challenge will be assuring all clinicians in the intervention clinics complete the Online Module and attend the educational program for VVA. We plan to provide email reminders until completion and small incentives to help them complete the education training. This will include providing CME for attendance at educational in-services and working with our continuing medical education department to assure clinicians and complete the on-line CME module. We will send each clinician a $10 gift card for a local merchant when they provide evidence of completion of the Online CME Module.

An additional challenge includes recruitment of patients for completion of surveys, which can be limited by patient willingness, comfort level, and time to complete follow up surveys. The mail/online format provides access to a large number of women which will offset the lower response rate that occurs with such surveys. The timing of conducting surveys presents limitations. Patients will have better recall of their visit immediately after it, but there will not have been sufficient time for the treatment to have an effect. CHR staff have decades of experience administering successful participant surveys and this experience will help us

successfully complete the proposed study (See Organizational Capacity).

Preventing dissemination of education from intervention to control groups. While some transfer is inevitable, we will notify EHR champions of the need to maintain separation of the groups. Information is currently available to all clinicians online and in scientific journals. Our intervention is to raise awareness and provide reliable navigation to the right information.

Increased awareness of VVA may result from media publication during the study, but this should affect the randomized groups equally.

2.c. Evaluation Design
2.c.1. Describe how you will determine if the practice gap identified in the needs assessment was addressed for the target group in terms of the metrics used for the needs assessment.

Evaluation:

Our primary outcome variable is the diagnosis of VVA and this will be measured by tracking:

1) Prevalence of diagnosis of VVA and related disorders (vulvar atrophy [624.1], vaginal atrophy, atrophic vaginitis [627.3], or dyspareunia [625.0]) among women aged 50 and older.

2) Use of the VVA smart set and smart text

3) Prescriptions for local estrogen therapy for VVA and related disorders (urinary incontinence, recurrent UTI, etc)

   a. Ordered by clinician

   b. Filled by patient

Our secondary measures will also include:

1) Effectiveness of Educational Intervention
2) Did clinicians complete the education? Did it change their knowledge? (assessment of intervention group after completion of training period, end of month 8)
   a. Completion of Online CME Module
      1. Results of pretest and post test

      2. Clinician evaluation of CME

   b. Attendance at educational seminar

      1. Clinician evaluation of CME

      2. Questions raised during seminar

3) Did the intervention change clinician behavior? (comparing intervention to control group after one year, after month 20)
   a. Number of diagnoses related to VVA (including urogenital symptoms)(see above)

   b. Number of prescriptions written for estrogen therapy

   c. Number of referrals to OB/GYN for VVA, referrals to Urogyn

   d. Number of AVS texts for VVA printed

e. Number of referrals to menopause classes

f. Number of women treated for VVA at time of referral to Urogyn

Assessment of Patient Outcomes

Using the KPNW electronic medical record, we will identify women in both the intervention and the control clinics who are seen for well woman exams. Six weeks after her visit, each woman will receive a mailing with a link to an online survey (details below). This mailing will encourage women to complete the survey online. If after the first 2 months of this process, we find survey yield is low, we will also provide the option of paper surveys that can be completed and mailed in a return envelope for women who are not comfortable with an online format.

We will take advantage of our research center's extensive experience developing online questionnaires to develop an online patient survey for this study. We will develop questions similar to the VIVA survey[6] to assess whether women receive education and treatment for VVA. These questions will include:

1) Whether patients perceive vulvovaginal atrophy and related symptoms as a concern, including urogenital symptoms

2) Whether this concern was addressed by their provider at their recent visit

3) Whether they are satisfied with the information and/or treatment received

4) What resources they used to get additional information or education about VVA.

We will use the Utian Quality of Life Scale (UQOL) to assess quality of life in our patient survey (See Appendecies)urinary.[5] The UQOL is self-completed questionnaire that contains 23 questions and provides results across four important domains—occupational, health, sexual, and emotional quality of life. The UQOL is a practical and validated instrument for measuring quality of life in a large cross-section of women. The UQOL has a long history of administration, over four decades, and is a useful measure of quality of life in the peri and postmenopausal periods. This survey is provided free of charge by the North American Menopause Society.

Sample Size and Power Analysis. From 2011-12, there were 32,592 wellness visit for women aged 50-65, with 4% having VVA or related diagnosis. Though there is variability in the number of women seen in each clinic, to facilitate the power analysis we used an average cluster size of 1,917 (32,592/17). We used PASS 2008 for comparing two proportions in a two-level cluster randomized trials to estimate the minimum detectable effect size (MDES) to achieve 80% power at a two-tailed alpha level of .05. Because we do not have any direct estimates of the intraclass correlation (ICC), we estimated the MDES for plausible values ranging from .005 to .05. Note that we did not power for a three-level design as power analysis is much more complicated and not well developed.

Using these estimates, we will be able to detect a difference in the proportion of women who are diagnosed as small as 2.2% to 8.4%, depending on the ICC. We found that of the women who are diagnosed (n=1304), 12% received a prescription for local estrogen therapy. Using these estimates, we will be able to detect a difference in the intervention group of 6.5% to 13.2%, depending on the ICC. Assuming that up to 2% of the control group women are assessed

using SmartSet, SmartText, and dot phrases, we will be able to detect a difference in the intervention group women of 1.7% to 7.0%.

Data management. We will audit data for quality, including missing data quantity and patterns. We will examine variable distributions to detect outliers and ensure variables meet the assumptions of planned analyses. The baseline characteristics will be presented as means and standard deviations for continuous variables and as percentages for categorical variables. Nominal variables will be dummy-coded for inclusion as predictors in multivariate analyses. Inferential tests will be carried out at a two-tailed alpha level of .05.

Analysis of Aim 1. For the primary outcomes, we will use three-level hierarchical linear models (HLMs)[7-9] to determine whether there are differences between the control and intervention groups. Because the primary outcomes are binary, we will use a generalized form of the HLM with a log link and the binomial distribution. For all models, the first level of the model will represent the person level variability, and will include the following covariates: age and race and ethnicity. The second level of the model represents provider level variability and the third level represents clinic level variability. The third level will include arm as the predictor variable. A significant, positive coefficient for arm on the person level intercept would provide support for the effectiveness of that outcome (e.g., higher rate of VVA or related diagnosis, prescription for local estrogen therapy, and use of SmartSet, SmartText, and dot phrases).

2.c.2 Change expected from this intervention

Many of our proposed measures are directly or indirectly measuring physician behavior. These include diagnosis of VVA as documented by a use of the Smart Set or Smart text, placement of a diagnosis code in the medical record, and referral of patients for additional services.

We believe we will achieve the goals proposed for this work in showing that the intervention clinics will be twice as will be twice as likely as control group to use Smart Set for visits conducted among postmenopausal women and to diagnose VVA among postmenopausal patients. Using these SmartSets will better inform these providers' practice, and this will result in a two-fold increase in the proportion of women referred to urogynecologists who are prescribed estrogen prior to referral (from 12 to 24%).

2.c.3 Assessment of audience engagement.

We will use various measures to determine audience engagement with this research. First, we will assess rates of attendance at our in-office educational sessions. Second, we will measure the response rates to our patient surveys among our target population. Third, we will use data on completion of online modules to determine what proportion of eligible providers complete this training. We will assess this through a modified REAIM approach.

Reach: Will assess the number of staff reached by the education (would include types of staff and proportion attending/completing CME)

Effectiveness: Determine if there is a difference between intervention and control groups in our primary outcomes/goals

Adoption: Assess the level of willingness among clinicians to adopt the new tools and the use rates of these tools once adopted.

Implementation: Describe the process of implementing the intervention, including the on-line CME module, number and length of office-based CME training sessions, and physician and patient assessments.
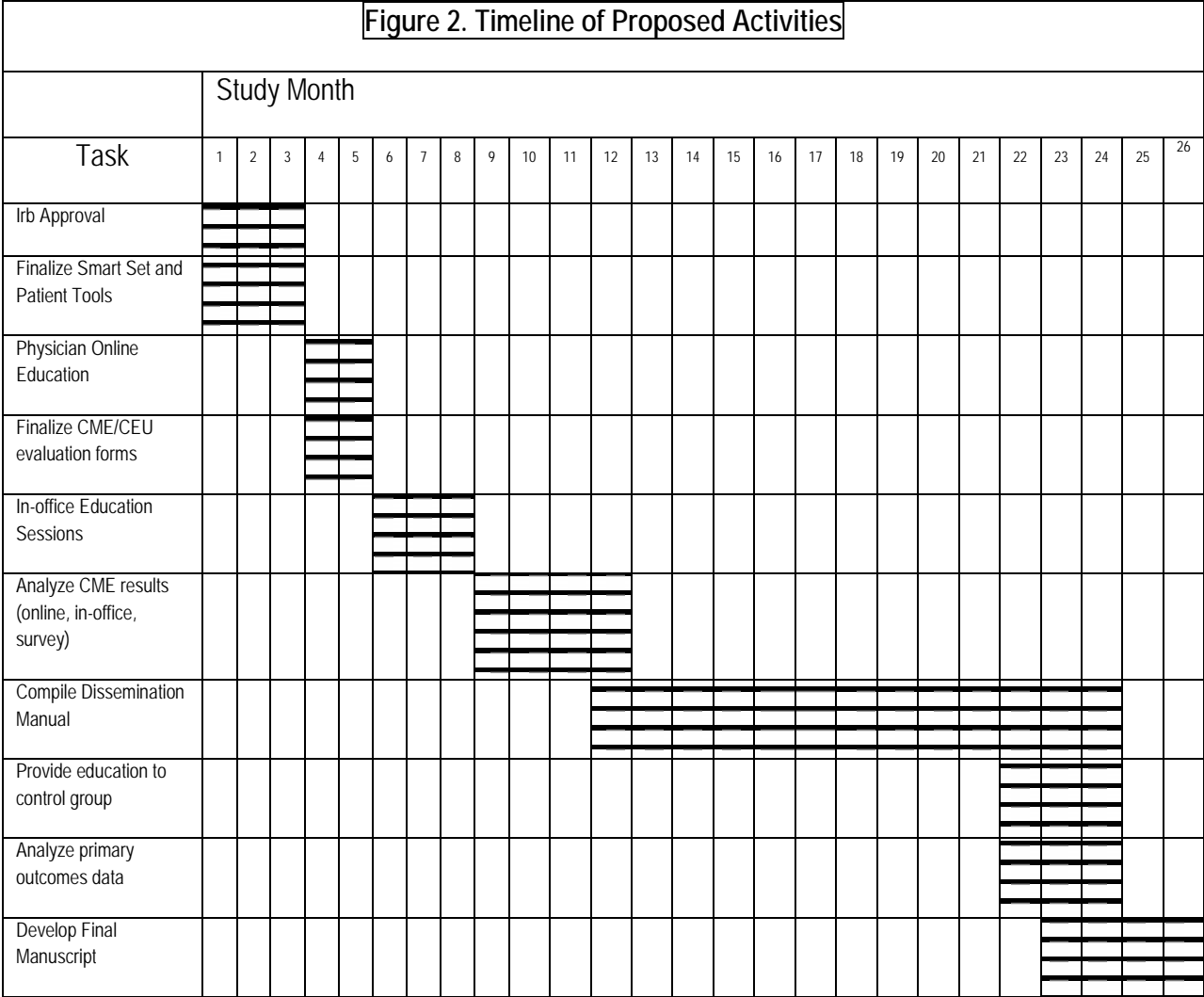
2.c.4. Dissemination Plan

Our deliverables will include a manuscript that will describe our intervention and the results of the three primary goals listed above and a dissemination packet which will include the details of the educational program we develop (including the in-service/group presentation outline and PowerPoint slides and supplemental handouts) and screen shots of SmartSets and SmartTexts with detailed descriptions of their contents so these clinical tools could be recreated in other electronic medical record systems or could be adapted to non-electronic practice environments. We anticipate dissemination of our intervention through publication of our work in a scientific journal and presentations at meetings such as the HMO Research Network, the North American Menopause Society, and the American Urogynecologic Society Annual Meetings.

2. *Work plan and Delivery Schedule*

The study timeline is displayed in Figure 2. Upon receipt of funding, Dr. Vesco will work with our project manager, Ms. Bachman, to submit study materials to the IRB and receive IRB approval to conduct the study. This will occur during months 1-3. During this same time Dr. Vesco will work with the study team to finalize the Smart Sets, Smart Texts, and other materials that will be used throughout this study. During months 3 and 4 our project manager will contact the intervention clinics to schedule educational sessions that the study team will conduct in the clinics. This team will include Dr. Vesco, Dr. Clark, and Ms. Beadle, along with Ms. Bachman (Project Manager). During this same time period we will work with KPNW and the physicians group to finalize their approval of the CME and CEU approval for all office trainings. We will conduct these educational sessions during months 6, 7, and 8. During months 4 and 5, we will conduct our online education module with physicians in the intervention group. Drs. Vesco, Clark, and Beadle will work with the study's research analyst to develop the online content for the online eduction models for physicians.

We will devote months 9-12 of the study to analyzing the results to the CME portion of study including proportion completing on-line training. We will also assess the proportion of providers attending an office training session and our response rates to patient surveys regarding attitudes and barriers. We will use these results over the following year to develop a detailed dissemination manual that will allow us to spread this intervention beyond our health system. We will conduct patient accrual for outcome assessment during months 9-20.

During months 20 and 21, Ms. Bachman will contact the control clinics to schedule educational sessions. We will provide education to clinicians in control groups during months 22-24, at which time we will also being analyzing data for our primary outcomes. Based on this analysis, we will develop a final manuscript and will submit the first manuscript for publication in a peer-reviewed journal before the end of month 27. We will attend scientific meetings and present the results of this study during years 2 and 3.

Figure 2. Timeline of Proposed Activities

Task	\ Study Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Irb Approval		X	X	X																							
Finalize Smart Set and Patient Tools		X	X	X																							
Physician Online Education					X	X																					
Finalize CME/CEU evaluation forms					X	X																					
In-office Education Sessions							X	X	X																		
Analyze CME results (online, in-office, survey)										X	X	X	X														
Compile Dissemination Manual													X	X	X	X	X	X	X	X	X	X	X	X	X		
Provide education to control group																							X	X	X		
Analyze primary outcomes data																							X	X	X		
Develop Final Manuscript																								X	X	X	X

D. ORGANIZATIONAL DETIAL

D.1. Leadership and Organizational Capability:

This pragmatic clinical trial takes full advantage of the highly sophisticated and refined EMR that has been operational at KPNW since 1996. Our research team and KPNW informatics support staff have extensive experience with designing electronic tools "that make the right thing easy to do." The overall system design allows analysis of large complex data systems at low cost. Dr. Vesco has completed several studies that have taken advantage of KPNW's electronic data resources. Dr. Clark actively works on development of EMR tools for patient care. Further, Ms. Beadle has successfully conducted menopause education for many women in KPNW and serves as a clinician leader/educator within KPNW. Our team will work to provide this broad education program that will target clinicians and support staff to help increase awareness and diagnosis of VVA and related symptoms, to provide tools to help clinicians make treatment recommendations, and facilitate patient use of available resources.

The Center for Health Research–Northwest (CHR-NW) is an academic-model organization that conducts independent research in a wide variety of areas including health services, public health, tobacco cessation, obesity and weight loss, mental health, maternal health, cost-effectiveness, cancer screening, and many others. A significant portion of our research is conducted in the setting of a real-world health plan, Kaiser Permanente Northwest. Through CHR's relationships with Northwest Permanente physicians and access to the comprehensive EMR linked to individual members' health records (including pharmacy data, tumor registries, and end-user databases unavailable to many other health organizations with large EMR systems), we have a unique capacity for innovative, large-scale research. KPNW serves approximately 480,000 members and includes one of the largest dental plans in the United States, with about 200,000 members.

In addition to conducting studies with our own databases and EMRs, CHR-NW researchers participate in a variety of formal and informal research networks. We collaborate locally with scientists and physicians at Oregon Health & Science University and Portland State University, regionally with other Kaiser Permanente health plans and research divisions, and nationally in networks such as HMORN, DeCIDE, CHARN, CRN, PBRN, and many others. These networks allow us to share data across multiple health systems and engage in multi-site research projects that give us access millions of individual health records.

Access to Data-Rich Electronic Medical Records. CHR researchers have access to the electronic medical records (EMRs) stored in KP HealthConnect, the world's largest privately deployed EMR system. All aspects of a member's health care—including vital statistics, hospital stays, ER visits, pharmacy dispenses, mental health care, imaging, and lab test results—are captured in KP HealthConnect and associated with the member's unique health record number. Health plan members agree to allow their records to be used for research when they join the plan. The link between our research databases and KP HealthConnect enables our researchers to conduct both retrospective and prospective studies. To facilitate study recruitment, researchers can scan the EMR for specific diagnoses that are necessary inclusion criteria.

Access to Clinical Expertise. Our researchers have access to 1,300 board-certified or board-eligible physicians and surgeons from the full range of practice areas. These clinicians may serve as clinical investigators who lead their own studies at CHR, or they may serve as consultants and partners who lend their expertise to help our investigators shape and deliver the interventions they test.

Rapid Translation of Research into Practice. CHR research projects benefit from the full support of KPNW health-plan leaders. If an intervention is shown to be successful, the health plan can implement new ideas with minimal delay. Conducting studies within a health plan also allows our researchers to refine study interventions to meet the needs and time constraints of both patients and providers.

Recruitment. The Center for Health Research has extensive experience recruiting large populations for diverse lifestyle interventions. Staff members are adept at collaborating effectively with community, research, and medical professionals to recruit eligible study participants. In 2011, for example, staff successfully recruited more than 1,600 participants for the Promoting Adherence to Improve Effectiveness of Cardiovascular Disease Therapies (PATIENT) study within a three-month period. CHR recruiters also achieved a more than 95% retention rate for 6-month follow up interviews for the Pregnancy and Influenza Project (PIP). Additionally, CHR recruitment staff maintained a retention rate of 86% for the Study of Adolescence and Depression (STAND) study, working with a teenage population.

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