Controlled Trial of Tele-Support and Education for Women's Health Care in CBOCs

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Study Protocol and Statistical Analysis Plan

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Background

Women Veterans are a rapidly growing minority among VA patients. While entitled to receive care equivalent to their male counterparts, achievement of this goal is often complicated by a VA primary care workforce that has limited exposure to caring for women and, for patients in community-based outpatient clinics (CBOCs), significant distances to sources of women's health (WH) expertise. This proposal aims to test a provider education and interactive communication intervention for improving WH care in CBOCs.

It is particularly challenging to deliver comprehensive WH care (i.e. the full spectrum of primary, specialty, and mental health care, both gender-specific and gender-neutral) in CBOCs. CBOCs were developed to improve access to VA primary care (PC), reducing distances Veterans need to travel to receive basic services.[1] They were never set up to handle the complexity of services needed by the rapidly growing and younger population of new women Veteran users (e.g, reproductive health care, post traumatic stress disorder, sequelae of military sexual trauma).[2] Such care requires expertise and resources that are difficult to incorporate into small practices.[3,4] Concordantly, the majority of CBOCs currently do not have women's health specialty clinics and struggle to offer on-site PC services specific to women's needs.[5-8] Therefore, CBOC patients often must travel significant distances to VA Medical Centers (VAMCs) or use healthcare settings outside the VA to access WH expertise.[9] They also experience care fragmentation due to provider and site discontinuity. Further, with CBOC PC providers' (PCPs) small caseloads of women Veterans, and therefore limited ongoing exposure to a depth and breadth of WH issues, it is difficult for CBOC providers to maintain their WH knowledge and skills.[10] Recent data demonstrates that women Veterans give lower ratings for the WH skills of PCPs at small caseload CBOCs, compared with PCPs at large VA sites with WH centers.[8]

Although we know that improved provider knowledge and skills are essential for provider behavior change (and therefore, improved care), we also know that they generally are not sufficient.[26] However, mechanisms that build on provider knowledge and skills have been shown to be effective in promoting and supporting provider behavior change.[26] One such mechanism is interactive communication, defined as the "timely, two-way exchange of pertinent clinical information, directly between primary care and specialist physicians."[27] Interactive communication is common and effective in improving care in settings where it is supported. PCPs highly value direct interaction with specialists (rather than communication via chart notes).[28] When such interactions are done informally, they are referred to as "curbside consultations." A cross-sectional survey of PCPs found that 70% had participated in at least one curbside consultation in the previous week.[28] A meta-analysis showed that diabetes and mental health interventions that improve PCP-specialist interactive communication improve patient outcomes.[27]

In recognition of these issues, the VA launched efforts aimed to improve WH knowledge and skills of VA PCPs, with an emphasis on CBOCs. First, the VA established "Designated Women's Health Providers" (DWHPs) in CBOCS to consolidate the care of CBOC women Veterans to 1-2 providers, thereby increasing these providers' WH caseloads. Second, the VA instituted intensive one-time training opportunities—"WH mini-residencies"—for DWHPs.[11] However, substantial evidence demonstrates that one-time medical education is not sufficient, as knowledge attenuates over time.[12] Serial education re-enforcement over time is needed to produce and maintain long-term gains in knowledge or skills.[13] Furthermore, education alone is not sufficient to change provider behavior, and is not likely to improve care quality. Additional interventions, such as enhancements in communication between PCPs and specialists, are necessary to achieve quality gains.[14]

Research Aims

We propose to test an intervention for ***DWHP Support*** to improve CBOC delivery of comprehensive WH care. *DWHP Support* will be a combination of: 1) advanced WH serial patient-based education that exposes DWHPs, over time, to a depth and breadth of WH cases and issues; and 2) interactive communication between CBOC DWHPs and VAMC-based WH specialists for "just in time" support of DWHP WH care. It will be technology-supported and delivered non-face-to-face.

This proposal features Electronic Consults and DWHP-Specialist Clinical Tele-Videoconferencing (CTV), two potential mechanisms for improving and maintaining DWHP knowledge and skills and increasing communication between CBOC-based DWHPs and WH specialists. Technology-based care models have been proposed as being potentially efficient, cost-efficient (or even cost-reducing) mechanisms of overcoming specialty physician shortages in certain geographic regions (e.g., rural areas), providing continuing medical

education, and improving care quality.[29-31] Two such models, electronic-consults ("e-consults") and grouped PCP-Specialist Clinical Tele-Videoconferencing (CTV), are foci of this proposal.

Electronic consults ("e-consults) are asynchronous PC–specialist communication via an electronic medium (e.g., secure messaging, e-mail, or computerized note entry).[32] It formalizes and allows for long-distance "curbside consultations." E-consults allow PCPs to obtain access to the clinical expertise of a specialist without the patient having a separate appointment with the specialist, thereby eliminating patient travel and wait times. The PCP submits a consultation request for a defined clinical question pertaining to a patient. The specialist reviews the patient's chart, as needed, and provides an answer electronically, requests more information, or advises that the patient should receive an in-person consultation (so that the specialist can perform an enhanced examination or perform a diagnostic or therapeutic intervention).

Another complementary approach that has been used successfully to build PCP knowledge and skills and enhance provider communication is group PCP-specialist clinical tele-videoconferencing (CTV) sessions. These sessions provide participating PCPs with serial patient-based advanced education by exposing them, over time, to a depth and breadth of cases and issues within a defined clinical area. Prior to each session, PCPs submit data on patients about whom the PCPs are seeking diagnostic and/or therapeutic management advice from a multidisciplinary specialist team. The team reviews the submitted information prior to the session. During the scheduled session, a specialist team at a "hub" facility and PCPs at multiple "spoke" locations see and hear each other (via CTV) and engage in a real-time discussion about the management of the submitted patient cases. The specialist team, in addition to giving recommendations, discusses the evidence and/or rationale behind the recommendations, thereby increasing the session's educational value. The PCP who submitted the consult, as well as other PCPs participating in the session, interact with the specialist team, asking clarifying questions. The specialist team also provides a brief didactic relevant to the cases discussed. Such sessions have been shown, in one setting and condition, to improve PCP capacity to manage complex patients and positively affect patient care outcomes. Specifically, University of New Mexico implemented such a program for management of patients with hepatitis C, and, in a controlled trial, showed that PCPs who engaged in group CTV sessions with hepatologists improved patient access and achieved clinical outcomes comparable to those of the hepatologists.[38,39]

We hypothesize that *DWHP Support* will improve the quality and efficiency of WH care in CBOCs.

Our specific aims are:

> **Aim #1**: To evaluate the effect of *DWHP Support* on WH care quality and efficiency, using a stepped wedge design;
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> **Aim #2**: To explore the impact of *DWHP Support* in changing DWHP behavior and self-rated WH knowledge, skills, and self-efficacy;
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> **Aim #3:** To assess attitudes about *DWHP Support* and its use, specialist time for its implementation, and other features that could influence *DWHP Support's* effectiveness, sustainability and spread;
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> **Aim #4:** To develop tools to measure quality of WH care in VA.

This proposed research project was developed in partnership with VA Patient Care Services' Women's Health Services (WHS) and Specialty Care Services (SCS), VISN 22, and VA Greater Los Angeles Healthcare System. It will impact VA practice and policies in women Veterans' health care, access, and quality (HSR&D priority areas) as well as other specialty areas. Further, it will advance science in both WH care quality measurement and the delivery of health care through non-face-to-face interactions.

Research Design and Methods

Study Design and Overview: We propose to conduct a prospective, modified stepped wedge trial of *DWHP Support* for DWHPs in healthcare systems that participate in Gynecology SCAN-ECHO and have gynecology e-consults. To accommodate facility and VISN needs, we will work with our facility and women's health partners to stage the assignments for the stepped wedge rollout (i.e., it will not be randomized). We will introduce the intervention throughout one healthcare system at each step, with the intervention being directed to all DWHPs in that healthcare system.

We will use a mixed methods analytic approach to measure the intervention's effect, while also evaluating the

implementation processes and use of the intervention. Therefore, while testing *DWHP Support* effectiveness, this study will also advance our understanding of the context for its implementation, which can support its broad implementation in VA, as well as inform future trials. An advantage of our modified stepped wedge approach is that our intervention will occur in the "real world", i.e., not in a highly controlled experimental setting; this enhances the potential external validity of the intervention and thereby increases the possibility that the intervention could feasibly be spread to other VISNs, should it prove effective.

Setting and Participants: *DWHP Support* will be implemented in healthcare systems in VISN 22 and at other VA sites nationally. VISN 22 encompasses Southern California and the Las Vegas area. It has a racially and ethnically diverse women Veteran population, with 68% non-Hispanic White, 5% non-Hispanic Black, 21% Hispanic, and 6% other racial/ethnic groups.[45] The participants will be DWHPs in those settings.

DWHP Identification: We will identify DWHPs in two ways. First, we will contact the Women's Health Medical Director for each healthcare system, to obtain a current list of DWHPs. Second, in FY12, with funding from the WHS (the national WH strategic planning group), the *Women's Health Evaluation Initiative* (WHEI; PI: Frayne) is generating and validating a list of DWHPs by VA site. To identify our sample of DWHPs, at the start of this study, we will use these data sources to obtain the list of participating site DWHPs and their provider ID numbers. We will adhere to VA policy regarding secure data transfer to obtain this list.

Patient Identification: To identify patients who received care from participating site DWHPs, we will use the *Corporate Data Warehouse (CDW)* – national patient-level administrative data for VHA-provided health care encounters This was data previously contained in the *VHA Medical SAS (MedSAS) Outpatient Events (SE) and Visits (SF) datasets*.[47] We will obtain this data through VINCI, VA's platform for accessing CDW for research.

Intervention: *DWHP Support* will be comprised of two components. [1] Gynecology (Women's Health) E-consults: This is asynchronous PC consultation primarily via electronic communication; the telephone may also be used if needed. The DWHP will electronically message a gynecologist for expert guidance on WH issues that are within the scope of practice for the PC setting (i.e., medical and gynecologic in the Handbook 1330.01), but about which the DWHP needs additional guidance. The PC consultation component, adapted from the SCS's e-consult program, formalizes and allows for long-distance "curbside" consultations that are often used by PCPs in larger, multi-disciplinary settings. All e-consults will be answered within three business days. The gynecologists, who will have dedicated time protected, through clinical funds, to answer these consults, will review the patient's chart as needed, and provide an answer electronically. The DWHP is responsible for acting on the recommendations and/or submitting a request for an in-person consultation, if this is the recommendation or they are not comfortable implementing the care plan. The DWHP can also electronically ask the gynecologist clarifying or additional questions, if needed. If necessary, phone calls between the DWHP and gynecologist will be arranged. [2] SCAN-ECHO: In these monthly group interactive case consultation conferences, held via CTV, cases are submitted to the multidisciplinary team by DWHP participants, with defined clinical questions pertaining to a patient. Cases will be selected by the gynecologist based on their educational merit; those not selected will be answered electronically or by telephone (and thereby become e-consults). The gynecologist discusses the case with the patient's DWHP, with other DWHPs observing. For each session, the gynecologist also gives a 15-minute didactic related to the discussed case. Each tele-video conference thereby, in addition to providing expert consultation for the care of that patient, educates all the participating DWHPs on their care of patients with similar conditions. Participants receive continuing medical education (CME) credits for each SCAN-ECHO session.

Usual Care: Usual care in VA CBOCs includes availability of patient referral for in-person specialist consultation (typically at the parent VAMC); access to web-based tools such as *UpToDate*,[50] a clinical decision support system to which the VA subscribes; and access to monthly WH cyber-seminars.

Overview of Data Sources, Data Collection Time Points, and Key Measures: The data sources, data collection time points, and key measures to achieve our specific aims are discussed by specific aim, and

summarized in Table 1 below.

Table 1: Data sources, data collection time points, and key measures by research specific aim

Data sources	Data collection time point(s)	Key Measures
Aim 1: Effect of *DWHP Support* on care quality and efficiency		
Electronic medical records	Baseline & throughout implementation*	Quality of Care: Proportion of care that is guideline-adherent; Efficiency of Care: Proportion of in-person specialist visits that are preventable
Aim 2: Impact in changing provider behavior, self-rated WH knowledge, skills, and self-efficacy		
E-consult referring provider brief survey	After each e-consult	Change in patient management for patient who is the subject of the SCAN/e-consult; change in provider knowledge
DWHP self-assessment tool	Baseline and during implementation	DWHP self-rated WH knowledge, skills, and self-efficacy
Aim 3: Attitudes about *DWHP Support*, its use, specialist time for implementation, other features		
Semi-structured interviews with DWHPs	Baseline and during implementation	Familiarity with SCAN-ECHO programs. Attitudes and beliefs regarding intervention; motivation and opportunity for its use. Familiarity with *DWHP Support* (reach and adoption) and other SCAN-ECHO programs; Influence of acceptability, usability, barriers and facilitators on use; Motivation and opportunity for sustained use
Aim 4: Develop tools to measure quality of WH care in VA		
Clinical practice guidelines	To commence at start of study	Not applicable [chart abstraction templates will be produced]

*Electronic records from the baseline time periods will be assessed retrospectively

Specific Aim #1: *To evaluate the effect of DWHP Support on WH care quality and efficiency using a stepped wedge design with sites participating in DWHP Support.*

We hypothesize that *DWHP Support* will improve the quality and efficiency of WH care in CBOCs. We expect that these effects may be influenced by baseline characteristics of the DWHPs (e.g., time in practice), patient conditions and characteristics, and practice characteristics, as well as DWHPs' use of the intervention. For this aim, our analytic sample will be limited to sites participating in DWHP Support outside of GLA, given that DWHP support was piloted in GLA and therefore does not have a recent "control" period (i.e., GLA was contaminated by the pilot). We will, however, use GLA data to pilot our electronic medical record (EMR) data abstraction procedures. We will also collect GLA e-consult data because this data were not contaminated by the piloting of SCAN-ECHO at GLA.

Dependent Variables: The main outcome measures will be quality of care defined by adherence to practice guidelines. We will assess quality of care and efficiency of care using the VA electronic medical records (EMR) of all female patients seen by DWHPs during the data collection period. With the modified stepped wedge design, each participating site healthcare system is contributing data to both intervention and control periods, thereby addressing comparability concerns. We expect to identify multiple episodes of care per DWHP over the combined data collection periods, where we define an episode of care as the care initiated by the DWHP for a WH condition, irrespective of whether it occurs over one or multiple encounters, and is face-to-face or not.[54]

Electronic medical record (EMR) data abstraction: To assemble the relevant data from the EMR using the VHA Health Information Access (HIA) program's Data Use Agreement protocols, we will use the *Corporate Data Warehouse (CDW)*, accessed through VINCI and discussed above and, as needed, the *Compensation and*

Pension Record Interchange (CAPRI), which provides direct access to *VistA medical records (Computerized Patient Record System, CPRS)* from multiple VistA systems with a single access/verify code[51-53] Through the VINCI system, we will obtain from CDW lists of all patients seen within participating site healthcare systems within our data collection periods. We will maintain these lists in VINCI workspace. From these lists, we will identify patients seen by DWHPs so that we can describe characteristics of their patient populations. We will then identify the subset of DWHP female patients with the study tracer conditions for quality assessment. To do this, we will use ICD9 codes, CPT codes, and, for some conditions, consult requests, medications prescribed, and/or laboratory tests ordered, in combination with the previously described DWHP list. For these patients, we will collect patient demographics, provider(s) associated with each encounter, clinic stop codes (which identifies the clinic type), and all EMR notes, orders, consult requests, and test results (e.g., laboratory, pathology, radiology) for our data collection periods. This data will be downloaded to the VA GLA Research Server.

EMR de-identification for blinded review: Nurse abstractors and implicit reviewers will be blinded to whether the episodes of care that they are reviewing are from the intervention or control periods. During an initial training period, all records will be reviewed by supervising research staff. After this initial training period, for the duration of the data collection period, records will be randomly spot-checked to verify adherence to the protocol.

Quality of Care – Guideline-adherent care classification procedure: We will conduct medical record abstraction to identify a sample of episodes of care for tracer clinical conditions. We will categorize care as guideline-adherent versus not guideline-adherent. The tracer conditions will be evaluation/management of: abnormal uterine bleeding;[55-58] menopause management, and urinary incontinence.[69] To determine if the care is or is not guideline-adherent, we will develop quality measurement tools. The methods we will use to develop these tools are described below in Specific Aim #4.

Trained chart abstractors will review each chart to complete the chart abstraction templates with the information requested. They will not be making a direct determination of care quality or efficiency, but rather obtaining the information for a computerized algorithm that will do this. A WH specialist will be available to them to answer questions that may arise. We will develop a database (using REDcap software) so that data may be entered directly into REDcap via a study computer. Senior research staff who are clinicians will randomly spot-check chart abstraction data, throughout the data collection period, to verify adherence to study protocols.

Independent Variables: *DWHP characteristics* may influence the quality and efficiency of the care that they provide, as well as their response to the intervention. We will extract DWHP characteristics from the *Personnel and Accounting Integrated Data System (PAID)* Master File, which contains the human resources data for all VA employees, including provider gender, age, education and licensure (MD, NP, PA), and medical specialty.[71]

We will obtain *characteristics of patients* seen by the DWHP in the study period from VA administrative data. This data will include: female caseload (# of uniques) and workload (# of encounters), female percent of total caseload and workload. We will derive percent of female workload by age category (<45, 45-64, 65+, corresponding to reproductive age group, age for emergence of chronic conditions, and older).

Aim #1 Statistical Analysis: We will calculate descriptive statistics of the proportion of CBOC women's primary care that is guideline-adherent. We will examine each of these descriptive statistics by clinical condition, and conduct z-tests for differences in proportions between conditions. We will also evaluate a series of logistic regressions to test for association of the composite measure of quality with each of the various independent variables in order to build a predictive model. Because of the hierarchical nature of the data (episode of care within patient within DWHP), a generalized linear model (GLM) approach using a logit link will be used to estimate and test the significance of the regression coefficients.

For the analysis of the intervention effect over time, we will conduct a modified stepped-wedge analysis. This analysis takes into account the hierarchical nature of the data, with episodes of care occurring over time, and being nested within DWHPs. In the stepped wedge analysis, calendar time is divided into steps, corresponding to the time periods when providers are initially exposed to the intervention.

Sample Size and Power Calculations: The power calculations are predicated on the goal of evaluating the performance of DWHPs through the episodes of care they see. There are two levels of clustering: DWHPs within healthcare systems and episodes of care within DWHPs. We are making the assumption that there is little or no correlation between the DWHPs. As a result, we performed the calculations via the single level of clustering within DWHPs, with the episode of care as the unit of analysis. We will assume two values for the intra-cluster correlation coefficient (ICC): 0.03 and 0.05. The latter is relatively large compared to results that have been reported in the literature.[72] The calculations assume a two-tailed 5% significance level and power of 80% to detect a difference between the study arms (with the study arm referring to intervention versus control, and including all data collection in each of those study periods, respectively). The statistical test involved is a simple z-test for the comparison of two proportions, but the actual analysis will be more sophisticated using covariates and adjusting for the actual number of episodes seen by a given DWHP. Thus, it can be assumed that the sample size calculations presented here are conservative.

With a baseline estimate from our preliminary data that 67% of episodes of care are fully proficient, then with 25 episodes of care per DWHP, we could detect small to medium effects of the intervention (see Table 2). If the baseline proficiency was 80%, then we could detect a medium size intervention effect, whereas if the baseline proficiency was 50%, we could detect a very small effect. If we increased the number of eligible episodes of care from which to measure proficiency to 50 per DWHP, then with a baseline proficiency of 67%, we could detect a small intervention effect. The number of available DWHPs (approximately 20 per study arm) and episodes of care provides us with >80% power.

Table 2: Number of DWHPs needed to detect the effects in each scenario with 80% power

% of episodes of care with fully proficient care quality and efficiency		25 episodes per DWHPper study arm*		50 episodes per DWHPper study arm*	
Control	Intervention (effect size)	ICC=0.03	ICC=0.05	ICC=0.03	ICC=0.05
80%	90% (medium)	14	18	10	14
67%	83% (medium)	8	10	6	8
67%	77% (small)	22	28	16	22
50%	63% (very small)	16	20	12	16

*study arm refers to intervention versus control, and includes all data collection

Aim #2:

We hypothesize that *DWHP Support* will increase DWHPs' practice expertise, and thereby modify their practice behavior, resulting in improved quality and efficiency (the focus of Aim 1). To test this hypothesis, we will collect process outcomes for the components of the intervention and their effects on patient care with a SCAN/e-consult referring provider survey (here after referred to as e-consult survey).

Provider Behavior: *e-consult referring DWHP brief surveys*: We will obtain the names of participating providers who initiate gynecology e-consults by obtaining from CDW, through VINCI, a list of all participating site gynecology e-consults. After each e-consult has been completed, we will email a request for the providers who initiated the consult to complete a brief survey about the encounter, including if and how it impacted their management plan. More specifically, we will ask: to what extent the consult altered the diagnostic, patient counseling, and/or treatment plans for this patient; the provider's confidence in their ability to implement the recommended diagnostic, patient counseling and/or treatment plans; how much, if at all, the provider learned something from the consult; and how, if at all, the consult affected the provider's plans to refer the patient for an in-person consultation. For the referring provider surveys, we will use the question about effect on the provider's plans to refer the patient to separately estimate number of avoidable consults averted by the availability of e-consults. An open-ended question, asking for additional comments, will also be included. The e-consult referring provider survey will be administered online (using Inquisite software) and responses will be confidential.

Self-rated WH knowledge, skills, and self-efficacy: *DWHP self-assessment tool*: Prior to the start of *DWHP Support, or early in its implementation,* and again after at least 12 months of use by study providers, we will administer a self-assessment tool to all DWHPs to assess their self-rated WH knowledge, skills, and self-efficacy in delivery of WH care. The self-efficacy assessment is modeled after the WVHSHG mini-residency self-evaluation tool, which examined 15 clinical content areas using a 5-point Likert scale. The 12-month self-efficacy assessment will be expanded to add items for clinical content areas covered during the SCAN sessions. We will also assess perceived change in self-efficacy in WH delivery, and perceptions about influences on this change. We will generate summary descriptive statistics for each of the data fields assessed.

Aim #3: *To assess attitudes about DWHP Support and its use, specialist time for its implementation, and other features that could influence DWHP Support's effectiveness, sustainability and spread*.

Because we are interested in affecting CBOC DWHP behavior—as well as knowledge, skills, and self-efficacy—it is necessary to develop an understanding of the context in which the changes are to occur and the resource needs that could impact maintenance of *DWHP Support*. Accordingly, our evaluation includes baseline assessment of DWHP providers, a process evaluation of the intervention, and a post-intervention assessment. We do so guided by the RE-AIM framework – a comprehensive framework designed to evaluate the impact of multilevel interventions in real-world settings.[74] RE-AIM has as a central tenet that the ultimate impact of an intervention is due to a combination of its reach, effectiveness, adoption, implementation, and maintenance. Aim 3 examines reach, adoption, and implementation of *DWHP Support*. *Reach* refers to the participation rate among those approached, which we will document. Barriers to participation (e.g., scheduling) may impact reach, and will be assessed. *Adoption* concerns the percentage and representativeness of settings that will conduct a given program. Adoption is impacted by several organizational factors, e.g., level of resources and expertise required, and how similar the proposed intervention is to current practices. We will measure potential variables influencing adoption of practice standards. Hypothesized effects of *DWHP Support* include reduced need for in-person specialty consultation, and fewer in-person visits associated with specialty consultations; therefore, we will calculate the number of SCAN/e-consults needed to avert one in-person specialist visit. *Implementation* refers to intervention integrity, or the quality and consistency of delivery. We will conduct a process evaluation to provide a context for the effectiveness findings, and to define resources and other factors that influence implementation.

Semi-structured interviews will be conducted with all DWHPs to assess their attitudes and beliefs regarding the proposed intervention (platforms and content), and motivation and opportunity for its use. Use of other care delivery and educational supports and participant characteristics will be assessed during the interview. We will also assess prior exposure to SCAN-ECHO clinics and electronic consultations for other clinical areas. All interviews will be digitally recorded and professionally transcribed. For respondents who are interviewed after the start of the intervention, we will ask about exposure to SCAN and e-consults for other clinical areas. With an eye toward potential maintenance of the intervention, participants will be asked to provide recommendations for sustainability and spread.

Qualitative Data Analysis: All digital recordings of semi-structured interviews will be sent to Keystrokes, a VA-approved medical transcription company, via a secure website for verbatim transcription. Transcripts will be reviewed and edited for accuracy by study staff. Analysis of the qualitative data will be conducted using ATLAS.ti, a qualitative data analysis software program that allows for fluid "interaction" of data across types and sources. Initially, a top-level codebook will be developed for the baseline interviews based on the interview guide.[75] Using a constant comparison analytic approach, this codebook will be elaborated upon based on emergent themes, and it will be adjusted as each round of interviews is reviewed. Interviews will be compared across DWHPs, and over time.

In the pre-intervention transcripts (i.e., baseline assessment), we will identify commonly shared knowledge, attitudes, and beliefs related to the intervention's potential for effectiveness as well as motivation and opportunity to use the intervention. We will synthesize this information to create baseline summaries. In post-intervention interview data, we will assess adoption, focusing on factors facilitating and impeding implementation of the intervention, and strengths and weaknesses of the intervention as implemented. In conjunction with logs that will be maintained during the intervention, we will assess the extent to which the

intervention was utilized by whom (i.e., "reach"), and we will identify which components and/or content was most salient for participants. We will examine whether (and why) this differs among DWHPs.

Aim #4: *To develop tools to measure quality of WH care in VA*.

To complete the work in Aim 1, we will need to develop tools to measure the quality of WH care in VA. VA monitors two gender-specific quality indicators as part of its annual External Peer Review Program performance monitoring – timely receipt of breast and cervical cancer screening. Though relatively easy to measure, there is little variation in these quality indicators across VA sites.[76] Therefore, we have selected alternate gynecology tracer conditions for our quality assessment. Explicit evidence-based quality guidelines exist for each of the selected tracer conditions (abnormal uterine bleeding;[55-58] counseling in patients prescribed teratogenic medications, contraception counseling and management;[60,61] preconception counseling;[66-68] menopause management, and urinary incontinence.[69]). The goal of Aim 4 is to operationalize these guidelines into quality measurement tools. The process for achieving this aim consists of four steps – translating guidelines, defining CPRS data sources and elements, developing EMR abstraction forms, and creating computer programs based on specifications.[77] Serial testing and revising will be done within each step.

Translating Guidelines: We will first construct, modify, or augment the algorithm for each guideline. Next, we will translate each guideline into a series of binary "if/then" statements.[78] We will also define terms as needed for clarifying these if/then statements. Two investigators will independently draft these "if/then" statements for each guideline and then reconcile their statements, discussing differences, to form for each guideline one draft series of if/then statements. To validate these if/then statements, these drafts and the guidelines and algorithms associated with them will then be given to members of our quality measurement tool validation, who will comment on our interpretation of the guidelines (to create the algorithm and specify terms) and our if/then statements, and then back-translate them to reconstruct quality guidelines.[79] If there are discrepancies between the versions reconstructed by our panel members, and the actual guidelines, we will investigate the source of these discrepancies and modify/clarify our if/then statements as needed. We will do this serially until we have a final set of validated if/then statements and associated definitions.

Defining CPRS data sources and elements: We will next define the data sources and elements for each if/then statement.[77] For each source, we will define the elements to abstract. To reduce the complexity of the quality assessment process, we will choose a subset of if/then statements for selected aspects of care with data sources that are more easily assessable in the electronic medical record (rather than attempt to collect data sources for the universe of if/then statements). Once we define all the data sources and elements for each if/then statement within a series, we will test them by reviewing the EMRs of a sample of approximately 10-20 patients with the conditions to verify our data sources and elements, revising as needed. In order to identify a sample of 10-20 patients with each selected condition, the VINCI data manager will pull the electronic medical records of VA Greater Los Angeles women patients from FY09 to FY13 (approximately 40,000 records), as described above. These records will be stored on the VINCI server. Using ICD-9 and CPT codes, while working on the VINCI server platform, we will identify the 10-20 patients with the conditions and download these electronic medical records to the VA GLA Research Server to develop the chart abstraction forms.

Developing chart abstraction forms: We will then develop chart abstraction forms for each guideline.[80] We will develop a series of questions that query for these data elements, specifying data sources. We will develop rules for each question. For example, again referring to figure 4, we will develop a rule for what needs to be in the chart to indicate that the provider "referred the patient to a surgeon" (e.g., submitted a consult request to General Surgery). The form, and its data elements, and abstraction process instructions will be developed iteratively with two nurse abstractors, we will test our form, rules and guidelines. With this test, we will ask the nurse abstractors to first review the form and guidelines, letting us know where it needs to be revised for

clarity. After we make this initial revision, we will ask the nurse abstractor to use the form to abstract data from the EMRs of 10-20 patients (identified via the same process as the initial 10-20 patients, using ICD9 and CPT codes while working on the VINCI server platform), asking questions when needed and noting difficulties. We will revise the form based on this feedback and then re-test serially until all problems are resolved. We will also develop training materials for our nurse abstractors.

Creating computer programs to operationalize specifications: Finally, we will create a program, using STATA 11, to operationalize the specifications and algorithms. As needed by our if/then statements, this will include variable construction, such as converting linear variables (e.g. age) to bivariates/categorical (e.g., >30 years of age or $\leq$30). Then we will develop programs to operationalize the algorithms formed with the if/then statements to make a final determination of whether or not the care was guideline adherent (as a yes/no determination). For each episode of care, all relevant if/then statements must reflect the guideline-adherent action in order for that episode of care to be classified as guideline-adherent. For cases in which the program determines the care to not be adherent, the program will also specify where in the algorithm the care failed to be guideline adherent. We will test and validate this program for a sample of 25 cases in each condition, by having an investigator who is blinded to the computer determination, review the information entered into the abstraction form and determine if the care was adherent, and if not, identify where it was non-adherent. We will compare these manual determinations to those of the computer, correcting any errors in the programming that may be revealed by the discordances. The investigator will also have both the EMR chart extract and the completed chart abstraction form, to determine if all of the pertinent information is in the form to allow him/her to make an accurate decision.

Implicit review forms: Guided by the RAND DRG project's implicit review form, we will develop a structured implicit review form that elicits judgments from reviewers for defined items for each non-tracer condition episode of care. An example of an item is "rate the quality of care for this episode of care on a 5-point scale." Baseline encounter data will be available at the start of the project for use in developing this form. This form will also request information about the factors that influenced the quality rating, and this will be coded for all implicit review forms.

REFERENCES

1) Chapko MK, Borowsky SJ, Fortney JC, Hedeen AN, Hoegle M, Maciejewski ML, VanDeusen Lukas C. Evaluation of the Department of Veterans Affairs community-based outpatient clinics. *Med Care*. 2002 Jul;40(7):555-60.

2) Haskell SG, Gordon KS, Mattocks K, et al. Gender differences in rates of depression, PTSD, pain, obesity, and military sexual trauma among Connecticut War Veterans of Iraq and Afghanistan. J Women's Health (Larchmt). 2010 Feb;19(2):267-71.

3) **Cordasco KM, Zephyrin LC**, Keesler CS, Mallard M, Canelo I, **Rubenstein LV, Yano EM.** 2011 VHA Emergency Services For Women (ESW) Survey, Final Report. 2012, in press

4) **Washington DL, Yano EM, Goldzweig C,** Simon B. VA emergency health care for women: condition – critical or stable? *Women's Health Issues*. 2006 May-Jun;16(3):133-8.

5) **Yano EM, Washington DL, Goldzweig C**, Caffrey C, Turner C. The organization and delivery of women's health care in Department of Veterans Affairs Medical Centers. Women's Health Issues. 2003 Mar-Apr;13(2):55-61.

6) **Bean-Mayberry BA, Yano EM,** Caffrey CD, **Altman L, Washington DL**. Organizational characteristics associated with the availability of women's health clinics for primary care in the Veterans Health Administration. Mil Med. 2007 Aug;172(8):824-8.

7) U.S. Government Accountability Office (GAO). *VA Health Care: VA has taken steps to make services available to women Veterans, but needs to revise key policies and improve oversight processes*. GAO-10-287, Washington, DC, March 2010. Available at www.gao.gov.

8) **Washington DL**, **Bean-Mayberry B**, Mitchell MN, Riopelle D, **Yano EM**. Tailoring VA Primary Care to Women Veterans: Association with patient-rated quality and satisfaction. *Women's Health Issues*. 2011;21(4S):S112-9.

9) **Washington DL, Yano EM**. *Women Veterans' Ambulatory Care Use Project, Phase II: Final Report*. Los Angeles, CA: VA HSR&D (IAE-06-083), 2010. Available at: http://www.hsrd.research.va.gov/research/abstracts.cfm?Project_ID=2141696839

10) Landon BE, Wilson IB, Wenger NS, Cohn SE, Fichtenbaum CJ, Bozzette SA, Shapiro MF, Cleary PD. Specialty Training and Specialization Among Physicians Who Treat HIV/AIDS in the United States. JGIM 2002 Jan; 17(1):12-22

11) VA Women Veterans Strategic Health Care Group and Patient Care Services. VHA Training Providers in Health Care for Women Veterans. http://www.simlearn.va.gov/feature/feature11_09.asp, Accessed December 4th, 2011.

12) Grimshaw J, Shirran L, Thomas R, et al. Changing Provider Behavior: An Overview of Systematic Reviews of Interventions. *Medical Care. 2001;* Vol. 39, No. 8, Supplement II pp. II2-II45.

13) Mansouri M, Lockyer J. A meta-analysis of continuing medical education effectiveness. *Journal of Continuing Education in the Health Professions*. 2007 Winter; 27(1): 6-15.

14) Davis DA; Thomson, MA; Oxman AD; Haynes RB. Changing Physician Performance: A Systematic Review of the Effect of Continuing Medical Education Strategies. *JAMA*. 1995;274:700-705.

15) Frayne SM, Phibbs C, Friedman SA, et al. Sourcebook: Women Veterans in the Veterans Health Administration. Volume 1. Sociodemographic Characteristics and Utilization of VHA Care. Washington DC: Department of Veterans Affairs; 2010.

16) **Yano EM, Washington DL**, **Bean-Mayberry B**. *Impact of Practice Structure on Quality of Care for Women Veterans (Phase 2): Final Report*. Los Angeles, CA: VA HSR&D (IAE-07-170), 2009.

17) **Washington DL**, **Bean-Mayberry B**, Riopelle D, **Yano EM**. Access to care for Women Veterans: Delayed healthcare and unmet need. J Gen Intern Med. 2011 Nov; 26 (Suppl 2): S655-61.

18) Department of Veterans Affairs. *Veterans Health Administration Policy for Planning and Activating Community Based Outpatient Clinics*. VHA Directive 97-036. July 1997:16.

19) **Washington DL, Yano EM**, Simon B, Sun S. To use or not to use: what influences why women Veterans choose VA health care. *J Gen Intern Med*. 2006;21:S11-18.

20) **Washington DL**, Kleimann S, Michelini AN, Kleimann KM, Canning M. Women Veterans' perceptions and decision-making about Veterans Affairs Health Care. *Mil Med*. 2007;172(8):812-7.

21) Saultz JW and Lochner J. Interpersonal Continuity of Care and Care Outcomes: A Critical Review. *Annals of Family Medicine.* 2005 Mar; 3(2):159-166

22) Mainous AG and Gill JM. The Importance of Continuity of Care in the Likelihood of Future Hospitalization: Is Site of Care Equivalent to a Primary Clinician? *Am J Public Health* 1998; 88:1539-1541
23) Haggerty JL, Reid RK, Freeman GK, Starfield BH, Adair CE, McKendry R. Continuity of care: a multidisciplinary review. *BMJ* 2003; 327(7425):1219-1221
24) VA Women Veterans Strategic Health Care Group and Patient Care Services. VHA Training Providers in Health Care for Women Veterans. http://www.simlearn.va.gov/feature/feature11_09.asp, Accessed December 4th, 2011.
25) Baier L, **Yee EFT**, **Veet L**, Bonnema R, **Hayes P**. Re-educating VA Primary Care Providers: A program to improve care for women Veterans of childbearing age. VA HSR&D Women's Health Conference. July 2010.
26) **Rubenstein LV,** Mittman BS, **Yano EM,** Mulrow CD. From Understanding Health Care Provider Behavior to Improving Health Care: The QUERI Framework for Quality Improvement. Medical Care 2000 Jun; 38(6):129-141
27) Foy R, Ovretveit J, Shekelle PG, Pronovost PJ, Taylor SL, Dy S, Hempel S, McDonald KM, **Rubenstein LV,** Wachter RM. The role of theory in research to develop and evaluate the implementation of patient safety practices. BMJ Qual Saf. 2011 May;20(5):453-9. Epub 2011 Feb 11.
28) Berendsen AJ, Benneker WH, Schuling J, Rijkers-Koorn N, Slaets JP, Meyboom-de Jong B. Collaboration with general practitioners: preferences of medical specialists--a qualitative study. BMC Health Serv Res. 2006 Dec 4;6:155.
29) Smith Anthony C, Bensink M, Armfield N, Stillman J, Caffery L. Telemedicine and rural health care applications. *Journal of Postgraduate Medicine*. 2005; 51(4):286-293.
30) Charles BL. Telemedicine can lower costs and improve access. *Healthcare Finanacial Management*. 2000 Apr;54(4):66-9
31) Speedie SM, Ferguson AS, Sanders J, Doarn CR. Telehealth: the promise of new care delivery models. *Telemed J E Health*. 2008 Nov; 14(9): 964-7.
32) Horner K, Wagner E, Tufano J. Electronic consultations between primary and specialty care clinicians: early insights. Commonwealth Fund Issue Brief, pub. 1554, vol. 23. 2011 October. Available at: http://www.commonwealthfund.org/Publications/Issue-Briefs/2011/Oct/Electronic-Consultations.aspx.
33) Rushakoff RJ, Woeber KA. Evaluation of a "formal" endocrinology curbside consultation service: advice by means of internet, fax, and telephone. *Endocr Pract*. 2003 Mar-Apr;9(2):124-7.
34) Wegner SE, Humble CG, Feaganes J, Stiles AD. Estimated savings from paid telephone consultations between subspecialists and primary care physicians. *Pediatrics* 2008;122:e1136-40.
35) Kim-Hwang JE, Chen AH, Bell DS, Guzman D, Yee HF, Kushel MB. Evaluating electronic referrals for specialty care at a public hospital. *J Gen Intern Med*. 2010;25(10):1123-8.
36) Harno K, Paavola T, Carlson C, Viikinkoski P. Patient referral by telemedicine: effectiveness and cost analysis of an Intranet system. *Journal Of Telemedicine And Telecare* 2000;6(6):320-329.
37) Jaatinen P, Aarnio P, Remes J, Hannukainen J, Köymäri-Seilonen T. Teleconsultation as a replacement for referral to an outpatient clinic. *Journal Of Telemedicine And Telecare*. 2002;8(2):102-106.
38) Arora S, Thornton K, Murata G, et.al. Outcomes of treatment for Hepatitis C virus infection by primary care providers. *N Engl J Med* 2011;364:2199-2207.
39) Arora S, Kalishman S, Dion D, et.al. Partnering urban academic medical centers and rural primary care clinicians to provide complex chronic disease care. *Health Affairs* 2011;30(6):1176-84.
40) Department of Veterans Affairs (2010, February 4). *Budget request for FY2011 and FY2012, Statement of The Honorable Eric K. Shinseki, House Committee on Veterans Affairs*. Available at: http://democrats.veterans.house.gov/hearings/Testimony.aspx?TID=72714&Newsid=507&Name=The%20Honorable%20Eric%20K.%20Shinseki.
41) Agency for Healthcare Research and Quality. FEDERAL PATIENT CENTERED MEDICAL HOME (PCMH) COLLABORATIVE. Available at: http: www.pcmh.ahrq.gov Accessed Dec 5th, 2011.
42) Perednia DA and Allen A. Telemedicine Technology and Clinical Applications. JAMA 1995;273(6):483-488.
43) Department of Veterans Affairs. *Report of the Under Secretary for Health Workgroup: Provision of Primary Care to Women Veterans*. Office of Public Health and Environmental Hazards, Women Veterans Health Strategic Health Care Group. Washington, DC, November 2008.
44) Zephyrin L, FY10 VHA Gynecology Physician Productivity and Staffing report, Women Veterans Health Strategic Health Care Group. Washington, DC, May 2011.

45) **Washington DL**, **Yano EM, Bean-Mayberry B,** Mitchell M, Sun S, Canning M, Yosef J, Riopelle D. Assessment of the health care needs and barriers to VA use experienced by Women Veterans. Unpublished data.
46) Primary Care Management Module User Manual. Available at: http://www4.va.gov/vdl/documents/Clinical/Pri_Care_Mgmnt_Module_(PCMM)/pcmmug.pdf.
47) VA Information Resource Center (VIReC), VHA Medical SAS Datasets – Documentation. Available at: http://www.virec.research.va.gov/DataSourcesName/Medical-SAS-Datasets/SASdocumentation.htm.
48) Kirchner J, Edlund CN, Henderson K, Daily L, Parker LE, Fortney JC. Using a multi-level approach to implement a primary care mental health (PCMH) program. *Families, Systems, & Health*. 2010;28(2):161-74.
49) **Hamilton-Brown A,** Cohen AN, Chinman MJ, Kessler C, Young AS. EQUIP: implementing chronic care principles and applying formative evaluation methods to improve care for schizophrenia: QUERI Series. Implement Sci. 2008 Feb 15;3:9.
50) UpToDate, available at http://www.uptodate.com/index
51) Department of Veterans Affairs, Health Information Access – HIA. Available at: http://vaww4.va.gov/hia/.
52) Department of Veterans Affairs, Compensation Pension Records Interchange (CAPRI). Available at: http://www.va.gov/vdl/application.asp?appid=133 . – links to user manual and release notes
53) Department of Veterans Affairs, Office of Enterprise Development, VistA Compensation and Pension Record Interchange (CAPRI) GUI User Manual, June 2011. Available at; http://www.va.gov/vdl/documents/Financial_Admin/CAPRI/dvba_27_p000_um.pdf.
54) McGlynn EA, Kerr EA, Adams J, Keesey J, Asch SM. Quality of health care for women – a demonstration of the Quality Assessment Tools System. *Med Care* 2003;41:616-25.
55) ACOG Committee on Gynecology. Practice Bulletin 14. Management of Anovulatory Bleeding. ACOG Compendium of Selected Publications 2009. Also published in Obstet Gynecol 2000; 95(3). Reaffirmed in 2009.
56) Kaiser Permanente Southern California. Acute uterine bleeding unrelated to pregnancy. Pasadena (CA): Kaiser Permanente Southern California; 2006 Aug. Guideline Summary NGC-5180 available at: National Guideline Clearinghouse, http://www.guideline.gov.
57) Amann M, Anguino H, Bauman RA, Cheung ML, Harris S, Kennedy J, et.al. Chronic abnormal uterine bleeding in nongravid women. Pasadena (CA): Kaiser Permanente Southern California;2006 Dec. Guideline Summary NGC-5687 available at: National Guideline Clearinghouse, http://www.guideline.gov.
58) Amann M, Anguino H, Bauman RA, Cheung ML, Harris S, Kennedy J, et.al. Postmenopausal uterine bleeding. Pasadena (CA): Kaiser Permanente Southern California; 2006 Dec. Guideline Summary NGC-5688 available at: National Guideline Clearinghouse, http://www.guideline.gov.
59) Institute for Clinical Systems Improvement. Health Care Guideline: Diagnosis of Breast Disease. 2010 Jan. 13th Edition. Available at: http://www.icsi.org/improvement_resources.
60) ACOG Committee on Gynecology. Practice Bulletin 73. Use of Hormonal Contraception in Women with Coexisting Medical Conditions. ACOG Compendium of Selected Publications 2009. Also published in Obstet Gynecol 2006; 107:1453-72. Reaffirmed in 2008.
61) Centers for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition. MMWR. 2010 Jun 18;59(RR-4):1-85.
62) Nelson HD, Haney EM, Dana T, Bougatsos C, Chou R. Screening for Osteoporosis: An Update for the U.S. Preventive Services Task Force. Ann Intern Med. 2010;153:99-111.
63) Lewiecki EM, Watts NB. New Guidelines for the Prevention and Treatment of Osteoporosis. Southern Medical Journal. 2009;102:175-9.
64) Hamdy RC, Baim S, Broy SB, Lewiecki EM, Morgan SL, Tanner SB, Williamson HF. Algorithm for the Management of Osteoporosis. Southern Medical Journal. 2010;103:1009-15.
65) North American Menopause Society. Management of osteoporosis in postmenopausal women: 2010 position statement of The North American Menopause Society. Menopause 2010 Jan-Feb;17(1):25-54. Guideline Summary NGC-7590 available at: National Guideline Clearinghouse, http://www.guideline.gov.
66) ACOG Committee on Gynecologic Practice. Committee Opinion 313. The importance of preconception care in the continuum of Women's Health Care. ACOG Compendium of Selected Publications 2009. Also published in Obstet Gynecol 2005; 106:665-6. Reaffirmed in 2009.
67) Lu MC. Recommendations for Preconception Care. Am Fam Physician 2007;76:397-400.

68) Centers for Disease Control and Prevention. Recommendations to Improve Preconception Health and Health Care – United States. MMWR. 2006 Apr 21;55(RR-6):1-23.
69) ACOG Committee on Gynecology. Practice Bulletin 63. Urinary Incontinence in Women. ACOG Compendium of Selected Publications 2009. Also published in Obstet Gynecol 2005; 105:1533-45. Reaffirmed in 2011.
70) Fleiss, J. L., Levin, B. and Paik, M. C. (2004) The Measurement of Interrater Agreement, in Statistical Methods for Rates and Proportions, Third Edition, John Wiley & Sons, Inc., Hoboken, NJ, USA.
71) Shane AC, Phibbs CS. *Guidebook for Research Use of PAID Data*. Guidebook. Menlo Park, CA. VA Palo Alto, Health Economics Resource Center; 2010.
72) Campbell MK, Steen IN, Grimshaw JM, et.al. Design and statistical issues in implementation research. In Thorsen T, Makela M (eds). Changing Professional Practice. Copenhagen: DSI: Danish Institute for Health Services Research and Development, 1999.
73) Cook TD, Campbell DT. Quasi-Experimentation: Design & Analysis Issues for Field Settings. Houghton Mifflin Co., Boston, 1979.
74) Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM Framework. *Am J Public Health.* 1999;89:1322-1327.
75) Glaser BG, Strauss AL. *The discovery of grounded theory: Strategies for Qualitative Research*. New York NY: Aldine Publishing; 1967.
76) **Goldzweig CL**, Parkerton PH, **Washington DL**, Lanto AB, **Yano EM**. Primary care practice and facility quality orientation: influence on breast and cervical cancer screening rates. Am J Manag Care. 2004 Apr;10(4):265-72
77) Pronovost PJ, Miller MR, Dorman T, Berenholtz SM, Rubin H. Developing and implementing measures of quality of care in the intensive care unit. Curr Opin Crit Care 2001, 7:297–303
78) Shekelle PG, MacLean CH, Morton SC, Wenger NS. Acove quality indicators. Ann Intern Med 2001 Oct 16;135(8 Pt 2):653-67.
79) Greenfield S, Cretin S, Worthman L. Comparison of criteria maps to a criteria list in quality of care assessment for patients with chest pain: the relation of each to outcome. Med Care 1981: 19:255-272
80) **Rubenstein LC,** Kosecoff J, Kahn KL, et al. Medical Record Abstraction Form and Guidelines for Assessing Quality of Care for Hospitalized Patients with Cerebrovascular Accident. Santa Monica, Calif: RAND Corp; 1988. N2802-HCFA.
81) Knowles M. Adult Learning. In RL Craig (Ed.), The ASTD Training and Development Handbook. New York: McGraw-Hill Publishers, 1996, pp 253-264.
82) Coppus SFPJ, Emparanza JI, Hadley J, et al. A clinically integrated curriculum in evidence-based medicine for just-in-time learning through on-the-job training: The EU-EBM project. *BMC Med Educ*. 2007;7:46.
83) Duffy TM, Jonassen DH. Preface to Constructivism and the Technology of Instruction: A Conversation. Hillsdale, NJ: Laurence Erlbaum & Associates, 1992.
84) Kirkpatrick DL, Kirkpatrick JD. Evaluating Training Programs: The Four Levels. 3rd ed. San Francisco; Berrett-Koehler Publishers, 2006.
85) **Washington DL**, Caffrey C, **Goldzweig C**, Simon B, **Yano EM**. Availability of comprehensive women's health care through Department of Veterans Affairs Medical Centers. *Women's Health Issues.* 2003;13(2):50-54.