Main Proposal

Overall Goal & Objectives

Given that approximately half of all women between the ages of 45 and 60 years of age experience at least one menopausal symptom or combination of symptoms, it is important to tailor and offer appropriate and *individualized* treatment options. Hormone therapy (HT) has been proven to be the most effective treatment for menopausal symptoms and is an acceptable option in many women up to 59 years of age. However, long-term use appears to impose greater risks than benefits. Therefore it is equally important to ensure that women between the ages of 60-65 years stop using HT unless deemed appropriate using a shared decision approach. Furthermore, breast cancer risk increases with age. Medications to reduce risk for primary breast cancer are recommended for women at increased risk; however, use is low. Issues at both sides of this age spectrum (under and over 60 years) are important and require different management strategies.

Improved shared decision making opportunities for patients should help ensure higher quality medical decisions and focus health care on patients' personal values and preferences. Most current electronic health records (EHRs) mirror paper-based charts and are rudimentary for supporting shared decision making to meet the needs of newly menopausal and late postmenopausal women. We propose to incorporate tablet computer technology into clinical practices that will be integrated into the EHR and allow for shared decision making at the point of care.

This study will evaluate a patient-centered, shared decision intervention in 12 primary care practices that are members of the American Academy of Family Physicians (AAFP) National Research Network (NRN). The AAFP NRN was established in 1999 to conduct, support, promote, and advocate for primary care research in practice-based settings. The AAFP NRN has grown to include approximately 2,000 clinician members across three member types: individual clinician members, affiliated regional network members, and electronic data system members.

The **primary goals** for this project are to evaluate the impact of improved information collection and shared decision making among health care providers and women age 45-65 years regarding issues of menopause, postmenopause, hormone therapy, and breast cancer risk using a collaborative framework among researchers, clinicians and patients. The specific aims, hypotheses, and methods are listed in Table 1.

Table 1. Specific Aims, Hypotheses, and Methods

PRIMARY OUTCOMES	HYPOTHESIS	METHOD FOR ASSESSMENT
1. Evaluate changes in documented diagnosis of menopause or postmenopause state	Documented diagnosis of menopause or postmenopause state will increase after physician education intervention and health risk tools discussed with patient. (Baseline: 16%; Post-intervention: 36%)	Pre- and post-intervention assessment via query of EHR for diagnosis of menopause or postmenopause in women age 45-65 years.
2. Evaluate patient and provider satisfaction with	Women and physicians will be very or completely satisfied with the shared decision making process to aid in health	Women will complete exit questions and a brief patient experiences survey

the shared decision making process	care decisions. (Baseline: 40%; Post-intervention: 70%)	following the provider visit. Providers will complete a brief survey at 7 months (baseline), 13 months, and 18 months.
SECONDARY OUTCOMES	HYPOTHESIS	METHOD FOR ASSESSMENT
3. Evaluate implementation success of validated health risk appraisal tools for menopause	Validated health risk assessment tools embedded in tablet technology will be integrated into a majority of EHRs for physician viewing at the point of care. (Baseline: 0%; Post-intervention: 80%)	Determine number (%) of practices that are able to view health risk appraisal tools at the point of care (after patient completes them) in EHR.
4. Determine the rate of all prescription use to treat menopausal symptoms over a specific time period	Documented prescription use for HT and non-hormonal therapies (such as SSRI, SNRI, or gabapentin) for menopausal symptoms will increase for women age 45-59 years. (Baseline: 28%; Post-intervention: 34%)	Pre- and post-intervention assessment via query of EHR for prescriptions of HT or non-hormonal therapy in women age 45-59 years. Women will also be asked about therapy changes after visit with provider.
5. Determine the rate of HT discontinuation in women age 60-65 years	Documented prescription use for hormone therapy for menopausal symptoms will decrease for women age 60-65 years. (Baseline: 8.6%; Post-intervention: 4%)	Pre- and post-intervention assessment via query of EHR for prescriptions of HT in women age 60-65 years. Women will also be asked about therapy changes after visit with provider.
6. Determine rate of patients age 45-59 years that discuss menopause or menopausal symptoms with provider	Discussions about menopause or menopausal symptoms will increase for women age 45-59 years after taking the MRS. (Baseline: 38%; Post-intervention: 50%)	Women will be asked about discussions with their provider about menopause or menopausal symptoms after the visit.
7. Determine rate of counseling regarding breast cancer risk prevention in women 45-65 years	Counseling regarding breast cancer risk will increase for women age 45-65 years after taking breast cancer risk assessment. (Baseline: 20%; Post-intervention: 50%)	Women will be asked about discussions with provider about breast cancer risk after the visit.
8. Determine the	Counseling about lifestyle modification	Women will be asked about

rate of counseling regarding lifestyle changes (e.g., diet, exercise, alcohol) in women age 45-65 years	will increase for women age 45-65 years after taking the MRS and breast cancer risk assessment. (Baseline: 25%; Post-intervention: 40%)	discussions with provider about lifestyle modifications after the visit.

Technical Approach

Current Assessment of Need in Target Area

In a recent survey by The Endocrine Society and its Hormone Health Network, it was found that half of women between the ages of 45 and 60 years were experiencing symptoms of menopause. Only 28% of those women were receiving some type of treatment for their menopausal symptoms, despite a majority (69%) saying that these symptoms negatively impacted their quality of life. Almost two-thirds of them stated they had not talked to their provider about hormone therapy or other treatment options for their symptoms, and 48% of them stated they were not familiar with hormone therapy. Additionally, many women (45%) felt that information about managing and treating symptoms of menopause was confusing.[1]

Given this very interesting information, we performed an initial review of aggregate data from the DARTNet practice performance database, a collection of databases that reside in multiple member practices and are linked through a secure Web-based system so they can be searched and queried as one large database while maintaining privacy and confidentiality of patient data. This database represents 160 practices including approximately 1.5 million patients from November 1, 2010, to October 31, 2012. We analyzed the most recent appointment for each woman age 45-60 years within that time frame. We found that only 15.92% or 14,797 of 92,958 women had a documented diagnosis of menopause. Similar to the survey data, 10,144 (68.6%) of those women with a diagnosis of menopause have never received hormone therapy or alternative treatments (SSRI, SNRI, or gabapentin). For the 4,653 women (21.4%) with a menopause diagnosis who received therapy, the treatment frequencies are provided in Table 2.

Table 2. Selected treatments for women age 45-60 years with a diagnosis of menopause (n=4653)

Treatment	Number (%)
HRT	2,026 (43.5%)
SSRI	2,449 (52.6%)
SNRI	375 (8.1%)
Gabapentin	542 (11.7%)
Any (1 or more) alternative therapy	3,126 (67.2%)
Both HRT and one or more alternative therapies	499 (10.8%)

We recognize that non-hormonal treatments may be used for other diagnoses, but these data highlight the potential use of these treatments in this population. We were unable to track specific symptom complaints through this database, but we can estimate based on this

information and previously published data (including the survey), that many more women are eligible for treatment and would like to discuss treatment options.

An important consideration regarding these data is that a diagnosis of menopause may be given only when women complain of significant symptoms or desire treatment enough to warrant it. However, all women experience menopause (at an average age of 51 years) and should have a documented diagnosis. We would have expected our initial review of aggregate data to indicate a much higher diagnosis rate than 16%. When combining this information with reported high frequency of symptoms and the lack of any clear therapy in almost 75% of women, there appears to be a critical need to further assess the documentation of menopause and adequacy of treatment.

When discussed, menopausal symptoms and genitourinary concerns typically are assessed during an annual exam when performing a review of systems and symptoms. These approaches are not standardized and not tied to any impact on quality of life (QoL) or to any educational interventions or treatment options in many cases. As the healthcare system moves forward with the patient-centered medical home, the concept of measurement based care is essential. Measurement based care is enhanced precision and consistency in disease assessment, tracking, and treatment to achieve optimal outcomes.[2] The key elements of measurement based care are:

- assessments that are specific, targeted to a specific issue, tailored to the individual, psychometrically and conceptually sound, brief, and inexpensive; and
- action plans that are specific, evidence-based (when possible), flexible (by providing an array of options) and evaluable.

Consideration of the patient's personal experiences and goals are primary objectives for person-centered care. Patient assessments in measurement based care require reliable instruments that can continuously and systematically improve quality of care. To accomplish this in menopausal women, we need to improve how we measure menopausal symptoms and create some level of standardization of assessment so that we can create an active learning and shared decision making environment for different approaches to care. Questions concerning menopause, sexual health, and genitourinary symptoms are commonly asked on the intake forms for annual exams; however, they are not standardized nor tied to an educational intervention or treatment plan.

When taking different approaches to care, some women will prefer non-pharmacologic treatment (e.g., dressing in layers, using cold packs or fans, drinking ice water) while others will choose pharmacologic treatment. Hormone therapy has been shown to be the most effective therapy for menopausal vasomotor symptoms and their potential consequences including poor sleep quality, irritability, trouble concentrating, and decreased quality of life.[3] However, HT has significant cardiovascular and breast cancer risks, especially if used for a long duration or in patients older than 60 years. The potential benefits and risks of hormone therapy need to be carefully considered in every patient who expresses an interest in medical therapy. We need to introduce new ways of explaining these benefits and risks to patients to help them better understand whether HT or alternative therapies, which are not as effective as HT, would be feasible options for treatment of their symptoms. We also need to create methods for a complementary assessment of breast cancer risk to help make clinical decisions about appropriateness of HT.

Finally, there are clearly a number of older women on HT that need to be re-assessed including careful evaluation of their breast cancer risk. In our preliminary analysis looking at aggregate data from the DARTNet practice performance database, we found that 2.2% (1,475/66,807) of all women 65 years and older had a prescription for HT. For women 60 years and older with a diagnosis of menopause, 8.6% (1,352/15,633) had a prescription for HT. Therefore it is equally important to ensure that women over the age of 60 years are no longer using HT unless deemed appropriate using a shared decision approach.

The methods and evaluation we are proposing with our system will meet all these needs in an approach that is simple to deploy and has been used in multiple primary care locations for other health issues. If successful, the surveys and risk calculators we will use are open source documents that can be embedded in personal health records or other data collection systems for easy and no or low cost dissemination.

The target audiences for this intervention are primary care clinicians and staff caring for women 45-65 years of age. These target audiences, including the women in the study, will also be the primary beneficiaries of the project outcomes.

Intervention Design and Methods

This study will evaluate a patient-centered, shared decision intervention in 12 primary care EHR-enabled practices recruited from the AAFP NRN, including its affiliated networks if necessary. This number of practices is based on feasibility within the given budget and past experience of recruitment for other studies. The AAFP NRN has a track record of successful collaboration, and it has successfully recruited diverse practices for over 40 studies in the past eight years. Recruitment will begin with email communication to each of the AAFP NRN's member practices including the 450+ physician members, the 100+ residency members and the 300+ electronic network member practices. The initial email will provide an overview of the study and requirements for participation, and will ask interested practices to contact our office. For studies with similar requirements, this email usually generates 30 to 40 or more responses. At the same time, the AAFP will run a brief article about the study in its electronic news magazine, *AAFP News Now*, which reaches up to 35,000 active AAFP members. Combined, these two approaches almost always generate enough interest to fill studies. Yet if necessary, additional recruitment strategies will include contacting AAFP NRN affiliate networks (22 networks with over 2,000 practices) to engage interested practices, and directly calling members who have been involved in previous quality improvement projects.

Baseline Estimates

Prior to the start of the intervention, we will estimate baseline rates for diagnosis of menopause and/or postmenopausal disorders (ICD-9 codes 627.1-627.9) and use of hormone therapy for women age 45-65 years via EHR data audit. Women seen at the most recent visit with a provider from January 1, 2011, to December 31, 2012, will be evaluated. Hormone therapy will consist of any estrogen or estrogen + progestogen regimen appropriate for menopausal symptoms. This data will provide a baseline assessment to further define the gap that may exist between diagnosis and appropriate treatment. Ideally, data would be collected to include specific symptom complaints, but that level of detail would be too difficult to extract through an EHR audit. For the EHR enabled practices in one of the DARTNet affiliated

networks, eNQUIRENet, we routinely perform data pulls of this type as evidenced by the data above. For other practices, approximately 75% of AAFP members now use EHRs and many can create these types of reports.

Educational CME Webinar/Academic Intervention

Providers in all 12 practices will receive an online educational presentation about menopause. This will be delivered to each group of practices 1 month prior to the initiation of their designated intervention phase (see stepped-wedge description, below). This 1-hour education session presented by the PI, Dr. Laura Borgelt, will include definitions (and diagnosis) of menopause, available treatment options including non-pharmacologic, hormonal and non-hormonal therapies, results of key trials including the Women's Health Initiative (and sub-analyses) and the Kronos Early Estrogen Prevention Study, appropriate candidates for use of HT and non-hormonal therapy, appropriate duration of therapy, and communicating with patients about menopausal symptoms. She will also provide an overview of the health risk appraisal tools used in this study (i.e., Menopause Rating Scale and breast cancer risk assessment). This will be provided using a Webinar presentation format that will allow providers to ask questions in a live virtual environment, a well-accepted method of education by the collaborating practices which has been successfully used for other studies. Continuing medical education credit will be obtained for this presentation. We will assess the providers' knowledge using pre- and post-assessment questions. Dr. Borgelt will also be available for ad hoc consultations with the study clinicians during the initial intervention period for their practice.

Stepped Wedge Trial Design

After the educational webinar, practices will be randomized to an intervention implementation time using a stepped wedge study design. Stepped wedge randomized trial designs involve sequential roll-out of an intervention to participants over a number of time periods. By the end of the study, all participants will have received the intervention, although the order in which participants receive the intervention is determined at random.

Prior to randomization, four relatively homogeneous strata will be created using baseline practice characteristics (e.g., practice size, percent Medicaid, EMR type). Within each stratum of four, practices will be randomly assigned to intervention initiation times (three practices per initiation time) using a random number generator and sorting (low to high) to establish the order of treatment initiation. This will help balance the number of patients receiving the intervention across time points. Additionally, although we do not expect to see temporal or seasonal effects this design will allow us to examine these possibilities. Intervention initiation times will occur every two months with enrollment extending four months beyond the last initiation time (to month 18) to ensure adequate enrollment of patients in the intervention condition (if enrollment goals have not been met already). Thus, the total enrollment period for practices will be 12 months from baseline. In the table below, 0 represents usual care (control group) and 1 represents the intervention condition. The goal is to enroll eight patients per time block per practice (40 patients total per practice) for a total of 480 patients.

Table 3. Stepped Wedge Design

Practice	Time					
	T0 (mo 7-8)	T1 (mo 9-10)	T2 (mo 11-12)	T3 (mo 13-14)	T4 (mo 15-18)	N
1, 2, 3	0	1	1	1	1	120
4, 5, 6	0	0	1	1	1	120
7, 8, 9	0	0	0	1	1	120
10, 11, 12	0	0	0	0	1	120

For the control group (T0 and all designated with "0" in stepped wedge design), women age 45-65 years presenting to the practices for a chronic care visit or annual exam will be given the opportunity to participate in the study. Those who are interested will be handed a tablet device, which they will keep through the entire visit. Prior to seeing the provider, each woman will be consented through the tablet device. (We are currently using the tablet devices to handle the informed consent process in other studies.) After providing her consent, the women will then be asked to provide some basic demographic information (age, race, past medical history, menopausal status, history of breast cancer) and verify current drug therapy for menopause. In practices where it is possible, a full medication list will be verified through tablet and EHR integration. It is estimated that it will take approximately 5-10 minutes to complete input of the information, which can accomplished in the waiting room and/or examination room. After the provider visit, women will answer a few exit questions and perform a patient experiences survey (see exit information below) on the tablet.

Tablet Technology

Tablet computers are fully functional touch-screen computers that are particularly well suited for use by patients and have been used in other AAFP NRN practice-based studies. Each practice will be provided two tablet computers that will be offered to women coming to the clinic for a chronic care visit or annual exam. These tablet computers will be encrypted such that when a name or Medical Record Number (MRN) is added, the practice can link the patient information provided to their EHR while it generates a study ID number for the research team, and the tablet information is provided anonymously to the research data server. The tablet will be programmed to have a "control group" application that will launch appropriate forms and surveys for patients in the control group and an "intervention group" application that will launch the appropriate forms, health risk appraisals, videos, and surveys for patients when the practices begin the intervention (see below). Research personnel at the practices will ensure the appropriate application is launched for their enrolled patients. We successfully have used tablet computers for similar projects on ADHD and health literacy and have been able to easily integrate tablet information with many different EHR systems by exporting health risk appraisals and their results into different formats (e.g., PDF, Excel, flat file).

Patient Enrollment

When the intervention occurs for the practices, women age 45-65 years coming to the clinic for a chronic care visit or annual exam will be offered the opportunity to join this study. Those who are interested will be handed a tablet device, which they will keep through the entire visit. Prior to seeing the provider, each woman will be consented through the tablet device, then asked to provide some basic demographic information (age, race, past medical history, menopausal status, history of breast cancer), verify current drug therapy for menopause (or full med list verified through tablet and EHR integration), and take two validated health risk appraisals: the Menopause Rating Scale (MRS) and the NCI/NSABP Breast Cancer Risk Assessment Tool (available at http://www.cancer.gov/bcrisktool/). It is estimated that it will take approximately 15-20 minutes to complete the form and surveys, which can be accomplished in the waiting and/or examination room. The results of these health risk appraisals will be provided to the patient and provider (results inserted immediately into the EHR) so that they can be discussed during the visit.

Validated Health Risk Appraisal

Women in the intervention group will take the health risk appraisals for menopausal symptoms (i.e., MRS) and breast cancer risk (i.e., NCI/NSABP tool). This will be performed in the waiting room or patient exam room prior to a chronic care or health maintenance/annual visit. The health risk appraisal tools will be age-specific such that women age 45-59 will receive the MRS and breast cancer risk assessment; women age 60-65 will also receive the MRS and breast cancer risk assessment and they will be asked more specifically about their current use of HT. Women with a history of breast cancer will not be provided the breast cancer risk assessment.

We selected the MRS because it is a validated, brief (11 questions) questionnaire that is designed to measure in a standardized way the following: health-related quality of life (QoL) or severity of complaints in aging women, changes over time and across different cultures (it is available in 25 languages), and changes before/after treatment of with hormone replacement therapy. Each of the 11 symptoms are scored from 0 (no symptom) or up to 4 (severe symptom), depending on the severity of the complaints perceived by the woman completing the scale. The total score of the MRS ranges between 0 (asymptomatic) and 44 (highest degree of complaints). The minimal/maximal scores vary between the three dimensions depending on the number of complaints allocated to the respective dimension of symptoms: psychological, somatic, and urogenital. All three dimensions are extremely important for menopausal women and can help providers and patients target specific symptoms with appropriate treatments.

We selected the NCI/NSABP breast cancer risk assessment tool because it is a nationally recognized interactive tool designed to estimate a woman's 5-year and lifetime risk of developing invasive breast cancer. It is based on the well-known Gail Model and also includes women of various racial/ethnic backgrounds, such as White, African American, and Asian and Pacific Islander. This tool puts the breast cancer risk into perspective by comparing individual risk with a woman of the same age and race/ethnicity in the United States. This information can help physicians and patients determine what therapy may be most appropriate for menopausal symptoms or breast cancer risk reduction when needed.

All women and providers will receive a report of their health risk appraisal results. The results of the MRS will be displayed as positive when there is any score of 3 or 4 (on the 0-4

scale) on one of the items. For women that have all scores <3, they will be encouraged to continue health lifestyle behaviors. The breast cancer risk assessment will display the 5-year risk and lifetime risk of the individual woman and the average woman of the same age and race/ethnicity in the form of a percentage risk. Each risk assessment has a brief explanation to help the patient and provider understand what the data mean.

Shared Decision Making Materials

After the woman completes the health risk appraisals, the tablet will present a video based on the specific appraisal results. These video vignettes, approximately 5-7 minutes in length, will briefly describe the results of their health risk appraisals and potential treatment options for menopausal symptoms. Clear information about the benefits and risks of HT as well as non-hormonal treatments will be provided. Specifically, video content based on health risk appraisal scores will include:

<u>RESULTS FROM MRS:</u>

"Positive" psychological subscale (a score of 3 or 4 in any one category): empathy about menopausal symptoms, discussion with provider about symptoms, potentially target treatments involving SSRI or SNRI

"Positive" somatic subscale (a score of 3 or 4 in any one category): empathy about menopausal symptoms, discussion with provider about symptoms, potentially target treatment involving HT, explain benefits and risks of HT

"Positive" urogenital subscale (a score of 3 or 4 in any one category): empathy about menopausal symptoms, discussion with provider about symptoms, potentially target treatment involving local or systemic HT, explain benefits and risks of HT

For women that score "positive" on more than one subscale, they will be offered the videos relevant to their health risk appraisal findings.

"Negative" score (a score 0-2 in all categories): promote continued health and wellness, healthy diet and exercise, alcohol in moderation, tobacco cessation, use of calcium and vitamin D

<u>RESULTS FROM BREAST CANCER RISK ASSESSMENT:</u>

"Positive" breast cancer risk assessment (as evidenced by a 5-year risk of invasive breast cancer ≥1.7% based on BCPT and STAR trials[6,7]): discuss results with provider

"Negative" breast cancer risk assessment (as evidenced by a 5-year risk of invasive breast cancer <1.7%): encourage routine self-breast exam and ask physician to show her how to do a self-breast exam if she doesn't know, ask physician about screening if/when appropriate, healthy lifestyle (exercise, alcohol in moderation, maintain healthy weight)

The patient-specific videos should help further engage patients in the shared decision process by increasing patients' knowledge and their involvement in the decision making process. At the end of each video, patients will be encouraged once again to speak with their provider about the results and the information they learned in the video(s). Patients will be able to replay the video during the visit in the event that she has specific parts she would like to discuss with her provider.

Exit Process and Patient Experiences Survey

After the provider visit, women will answer a few exit questions and perform a patient experiences survey. It is estimated that this will take 5-10 minutes. Patients will be asked questions about what was discussed during the patient visit (e.g., menopausal symptoms, breast cancer risk, lifestyle modifications); what medication changes were made, if any, related to menopausal symptoms or breast cancer risk; whether or not they enjoyed using the tablet, health risk appraisal tools, and videos; and if they are leaving more or less confused about menopause symptoms and treatment. A brief patient survey, the Ambulatory Care Experiences Survey (ACES), will be provided to assess the shared decision making process. This survey produces 11 summary measures of patients' experiences across 2 domains: quality of physician-patient interactions (communication, integration of care, knowledge of the patient, and health promotion) and organizational features of care (organizational access, visit-based continuity, clinical team, and office staff). It was developed in 2002 and has been prominent in numerous large-scale initiatives nationwide. The ACES is a copyrighted document, made freely available to those who wish to use it in research or practice.

For all interested patients, practices will provide a DVD or booklet copy of the Informed Medical Decisions Foundation Shared Decision-Making® program called "Managing Menopause: Choosing Treatments for Menopause Symptoms." This is a decision aid for patients (and their families) to provide unbiased, evidence-based information about available treatment options and possible outcomes so patients are better equipped to make an informed decision that aligns with their values and preferences. These aids are designed to complement the provider interaction. This particular program for managing menopause is designed for women age 40-60 years who are currently going through menopause or will be going through it in the near future. It is available as a DVD and a booklet. It provides an overview of menopause, common symptoms, and managing symptoms. Hormone therapy, non-hormonal therapies, lifestyle modifications, and complementary and alternative therapies are discussed. The program includes real patient interviews and how and why treatment decisions were made.

Physician Feedback

The impact of this project will also be evaluated through physician feedback. We will solicit feedback from physicians through surveys at baseline (7-8 months), 13 months, and 18 months about the effectiveness of integrating technology, impact on the efficiency of the visit, and shared decision making into the patient care visit. These surveys will evaluate the same domains found in the ACES survey. Additionally, we will inquire about the feasibility of incorporating this type of approach for other women's health issues.

Evaluation Design

We expect that implementation of an educational program for physicians, followed by the implementation of a shared decision model in primary care practices, will maximize the awareness of menopause and menopausal symptoms and improve treatment strategies. This collaborative approach will allow for individualized treatment plans taking into account the best available scientific evidence and patient values and preferences.

Based on the specific aims, we will be able to address the practice gaps identified in our needs assessment. We will be using information from the tablets and the EHRs to determine rates of diagnosis, treatment, and health risk assessments and survey results.

The number of women included in the study is targeted based on anticipated improvement in assessment and diagnosis of menopause and shared decision making. We anticipate enrolling 8 women per time block (4 patients per month) per practice. Therefore the target is a total of 480 patients.

We anticipate the following changes with the intervention for women 45-65 years:

- 20% or higher change in rate of documented diagnosis of menopause or postmenopause (baseline: 16%; after education/intervention: 36%)
- 70% of women and providers will be very or completely satisfied with the shared decision making process (baseline: 40%; after education/intervention: 70%)
- 80% rate of successful implementation of tablet information into EHR (baseline: 0%; after implementation: 80%)
- 20% or higher increased rate of hormone therapy or non-hormonal therapies for menopause symptoms (baseline: 28%; after education/intervention: 34%)
- 50% discontinuation rate of HT for women over 60 years (baseline: 8.6%; after education/intervention: 4%)
- 50% of women age 45-59 years will discuss menopause or menopausal symptoms with physician (baseline: 38%; after education/intervention: 50%)
- 50% of women will discuss breast cancer risk with provider during visit (baseline: 20%; after education/intervention: 50%)
- 40% of women will discuss lifestyle modification with provider during visit (baseline: 25%; after education/intervention: 40%)

We will be able to determine if the target audience was fully engaged in the intervention by evaluating the interaction with the tablet throughout the entire visit. Time spent viewing the information on the tablets (including viewing of videos) is available through the tablet software. As part of our evaluation, we will report the percentage of women that did not complete, partially completed, or totally completed the intervention.

Power and Sample Size

This sample size will provide >99% power to detect anticipated differences in primary outcomes (diagnosis, satisfaction with shared decision making).[4] Power is greater than 80% for the secondary outcomes of lifestyle modification and discussion of breast cancer risk.

Analysis

Initially, descriptive statistics (mean, SD, proportions) will be computed for baseline patient and practice characteristics. In addition, chi-squares and t-tests will be used to determine whether there are differences between patients receiving the intervention and controls on sociodemographic and clinical characteristics. Primary and secondary outcomes are described above. For outcome variables that are continuous (or ordinal) we will explore whether these outcome variables are normally distributed prior to analysis. In the event that normality assumptions are not met, we will use transformations to normalize distributions,

ordinal or Poisson regression where appropriate, or techniques using the appropriate link function (e.g., logit link for dichotomized measures). The patient will be the unit of analysis, clustered within practices. General (generalized) linear mixed model approaches (GLMMs) will be used to obtain adjusted estimates of outcomes, e.g., differences in estimated means or odds ratios of intervention to control patients for each of the above clinical outcomes, adjusted for covariates.[5] Random effects will be included for practice with fixed effects for time (1, …, T-1) and an indicator variable for treatment mode for each cluster at each time point. All statistical analyses will be performed using SAS version 9.3. (SAS Institute Inc., Cary, NC).

Dissemination

The main goal of dissemination is spreading new knowledge to other settings—educating physicians, practice staff and patients—so they understand the need to make changes in their care. If this intervention does lead to better patient care, it can easily be implemented in any medical practice with an EHR. We will begin dissemination by submitting a paper describing our findings to an appropriate peer-reviewed journal, such as *Menopause*. We will then work to educate practicing clinicians and family medicine institutions through one or more of the AAFP's many physician-oriented publications, including *American Family Physician* and *Family Practice Management*. We will disseminate our results to practicing physicians through CME opportunities provided by the AAFP, including the annual Scientific Assembly and the Conference on Practice Improvement which is held by AAFP's sister organization, the Society for Teachers of Family Medicine (STFM). In addition, we will disseminate our results to primary care researchers through the North America Primary Care Research Group (NAPCRG) annual meeting.

Strengths/Weaknesses

Participating practices must have an EHR and be willing to integrate tablet technology into their workflow. This may create selection bias toward practices that are moving proactively toward innovative activities. Given that approximately 75% of AAFP members now use an EHR and virtually all members not planning retirement in the near future are installing EHRs, this particular requirement will not affect eventual dissemination. If this projects proves to be successful, the solution to this will be to create ways for practices to implement easy and convenient ways of providing health risk appraisals to patients and providing information to both providers and patients about the shared decision making process. This could be through tablet based solutions, templates in EHRs, or surveys administered through Patient Health Records. The critical first step is to demonstrate the value of the processes.

Selection bias may also occur since patients will opt in or opt out by engaging with (or not) the tablet devices. Patients unfamiliar with tablet technology may not be willing to participate. Our experience to date with the tablet technology we will be using, specifically designed for low literacy and low technology savvy groups, has been that patients of all adult ages have not had problems navigating the tablet system. Additionally, we will include surveys and educational materials in both English and Spanish.

Detailed Workplan and Deliverables Schedule

This two-year project will begin with a formal assembly of the project team. In month 1, team members will engage in a kick-off meeting during which we will review the timeline for

the project, deliverables, and roles and responsibilities. The PI and project manager will establish a schedule for regular meetings. The project manager and PI will prepare and submit the Institutional Review Board (IRB) application. In month 1, the research assistant and project manager will purchase the tablet computers, and through month 4 they will work with the tablet programmer to input into the tablets the control group and intervention group applications including appropriate data collection instruments, health risk appraisals, the shared decision making materials, and surveys. During this time they will also prepare for EHR integration. At approximately the same time as the tablet programming, the PI will work with the team to finalize the content of the academic detailing educational webinar.

We will recruit and randomize practices once IRB approval is received (expected by month 3). The research team and managers will schedule the academic detailing webinars at a time that works for the practices. Production of the video vignettes will begin in month 4; when completed (month 6) they will be loaded onto the tablets for the intervention. During this time, practices will conduct their EHR data pull in order to report baseline rates of diagnosis and treatment for menopause. The research group will then mail tablets to the participating practices. Before each practice begins enrolling patients into their designated intervention phase, they will engage in the educational webinar. As practices enroll patients, the research team will be available to trouble-shoot any issues. Practices will continue their stepped implementation of the intervention, as shown in Table 3, through month 18. Physician feedback will be gathered through a survey to providers at 7 months, 13 months, and 18 months. As the intervention wraps up, data analysis will begin in month 19. The PI and team will create reports, draft manuscripts for submission to peer-reviewed journals, and prepare submissions for national meetings through month 24.

Direct Costs (excludes personnel costs and institutional overhead/indirect costs). Personnel Costs span the entire period and cannot easily be linked to milestones/ deliverables.

References

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