

AHRQ FINAL REPORT TEMPLATE

Project Title: Evaluation of Shared Decision Making Between Patients and Providers to Improve Menopause Health Outcomes.

Principal Investigator: Laura M. Borgelt¹, PharmD, FCCP, BCPS, NCMP

Co-Investigators/Team Members: Robin Liston², MPH, Sandra Ruland³, DVM, MS; Miriam Dickinson³ PhD; Jennifer Carroll³, MD, MPH.

Organizations:

1. University of Colorado Anschutz Medical Campus, Departments of Clinical Pharmacy and Family Medicine, Aurora, Colorado;
2. American Academy of Family Physicians, National Research Network;
3. University of Colorado Anschutz Medical Campus, Department of Family Medicine, Aurora, Colorado

Inclusive Dates of Project: July 2013-December 2015

Funding Disclaimer: This study was supported by the American Academy of Family Physicians Foundation and is funded by Pfizer Independent Grants for Learning & Change.

ABSTRACT

Purpose: Shared decision making between patients and providers honors provider knowledge and emphasizes patients' values and preferences. We posited that utilizing tablet technology to engage shared decision making may lead to improved health outcomes and increased patient satisfaction.

Scope: The primary objectives were to evaluate the impact of shared decision making among providers and women regarding issues of menopause, medication use, breast cancer risk, lifestyle changes and improved information collection.

Methods: Women 45-65 years were recruited from August 2014 through August 2015 using a stepped wedge randomized design in primary care practices throughout the United States. Tablet technology incorporated surveys, menopause health assessment tools with scoring algorithms, and educational videos available at point-of-care for patients in the intervention group. All patients completed surveys including demographics, selected domains from the Ambulatory Care Experiences Survey (ACES), and changes (if any) in therapy for menopause. Providers participated in an educational webinar and completed a modified version of the ACES survey. Baseline and end-of-study electronic data queries were conducted to evaluate rates for diagnosis of menopause and/or postmenopause.

Results: Nine practices successfully implemented tablet technology into patient care. A total of 438 unique participants completed 408 full datasets for evaluation. Evaluation of shared decision making showed no significant differences between women in control and intervention groups regarding communication, personal treatment, trust, health promotion, or whole person orientation. Most patients in control and intervention groups were completely satisfied with the shared decision making process (143/154, 92.9% and 189/214, 88.3% respectively, $p=0.15$). During visits for women in control and intervention groups, lifestyle modification was discussed 84% and 88% of the time ($p=0.25$); menopause was discussed 75% and 79% of the time ($p=0.42$); and breast cancer risk was discussed 65% and 63% of the time, respectively ($p=0.71$). For women taking the menopause health assessment, 50% of women (127/252) indicated one severe or very severe symptom in somatic, psychological, and/or urogenital categories.

Key Words: menopause, shared decision making, postmenopause, perimenopause

Purpose:

The overall goal of this study was to promote shared decision making (SDM) through the use of tablet technology among health care providers and women age 45-65 years regarding peri-, menopause, post-menopause, hormone therapy (HT) use and breast cancer risk. The primary objectives were to evaluate the impact of using tablet technology to evaluate changes in documented diagnosis of menopause or postmenopause and evaluate patient and provider satisfaction with the SDM process. Secondary objectives were to determine the rate of prescription use to treat menopausal symptoms, determine the rate of HT discontinuation in women age 60-65 years; determine rate of patients age 45-59 years that discuss menopause or menopausal symptoms with their provider; and the rate of counseling regarding breast cancer risk prevention and lifestyle changes in women age 45-65 years.

Scope:

Approximately half of all women between 45 and 60 years experience at least one menopausal symptom or a combination of symptoms; thus, it is important to offer appropriate and individualized treatment options.¹ Hormone therapy (HT) has been proven to be the most effective treatment for vasomotor symptoms and is an acceptable option among many women up to 59 years of age; however, long-term use appears to impose greater risks than benefits.² Therefore it is equally important to ensure that women between the ages of 60-65 years discontinue using HT, unless deemed appropriate by her clinician using a shared decision approach. Additionally, breast cancer risk increases with age. Medications to reduce risk for primary breast cancer are recommended for women at higher risk; however, use of these medications remains low. Other treatments, including non-prescription therapies, may be more appropriate for individual situations. Women coming in and out of the menopause transition require individualized evaluation and management strategies.

It has been demonstrated that only 28% of menopausal women receive some type of treatment for their menopausal symptoms, despite a majority (69%) saying that these symptoms negatively impact their quality of life. Almost two-thirds of them stated they had not talked to their provider about HT or other treatment options for their symptoms, and 48% of them stated they were not familiar with HT. Additionally, many women (45%) felt that information about managing and treating symptoms of menopause was confusing.¹ Furthermore, an initial query of aggregate data was conducted from November 1, 2010, to October 31, 2012 from the DARTNet practice performance and patient outcomes database, representing 160 practices including approximately 1.5 million patients. 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 HT or alternative treatments such as selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), or gabapentin. For the 4,653 women (21.4%) with a menopause diagnosis who received therapy, 2,026 (43.5%) received HT, 2,449 (52.6%) received a SSRI, 375 (8.1%) received a SNRI, 542 (11.7%) received gabapentin and 499 (10.8%) received both HT and one or more alternative therapies.

For women 60 years and older with a diagnosis of menopause, 8.6% (1,352/15,633) had a prescription for HT. These alarming data make it critical for providers and patients to participate in and effectively communicate shared health decisions regarding menopausal symptoms and treatment. These data indicated many women are eligible for treatment and would like to discuss treatment options.

Enhanced shared decision making (SDM) opportunities between patients and their providers can help improve the quality of medical decisions and focus all aspects of health care on patients' values and preferences, thereby increasing the satisfaction with the healthcare experience for patients and providers. Good SDM requires clinicians to have access to patient information, recent evidence, and be able to share it in a way that supports thoughtful deliberation.³ Using patient decision aids during the provider visit has been an effective technique to facilitate SDM.⁴ Tablet technology serves as a conduit for patients to provide valuable information about their condition(s) and symptom(s) to enhance clinical decisions, but has not been evaluated in menopausal women. Using tablet technology to engage patients and providers in innovative practice-based research that incorporates SDM may lead to improved health outcomes and increased satisfaction with the healthcare experience for menopausal women.

Most current electronic health records (EHRs) mirror paper-based charts and are rudimentary for supporting SDM or enhancing the patient-provider visit to meet the needs of newly menopausal and late postmenopausal women. We incorporated tablet computer technology into clinical practices allowing for SDM at the point of care.

Methods:

Using a stepped wedge randomized design, nine primary care practices throughout the United States, located in varied geographic areas (e.g., rural, suburban, urban) were enrolled, with 1 to 4 participating providers per site. Sites were recruited through the American Academy of Family Physicians (AAFP) National Research Network using email and an electronic news magazine. Peri-, menopausal and post-menopausal women aged 45-65 seen at a routine appointment between August 2014 and August 2015 were recruited to participate. This study was approved by the AAFP Institutional Review Board.

This study design involved sequential roll-out of the intervention to practices over a number of time periods. By the end of the study, all practices had patients that received the intervention, although the order in which practices received the intervention was determined at random and the time they spent in the intervention phase varied. The total enrollment period for practices was 12 months from baseline (Table 1). The goal was to enroll approximately four-five patients per month per practice (40-60 patients total per practice) for a total of 480 patients.

Table 1. Proposed Stepped Wedge Randomization Design

Practice	Time in Study					
	T0 (mo 1-2)	T1 (mo 3-4)	T2 (mo 5-6)	T3 (mo 7-8)	T4 (mo 9-12)	N (approximate number of enrollees)
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

*0 represents the control group and 1 represents the intervention group.

All eligible women received a tablet computer at the beginning of their clinic visit and carried the table with them throughout the appointment; all data were collected on the tablet. Tablet technology was used to facilitate surveys, health assessment tools with scoring algorithms and educational videos for participants. Patients in the control group completed a demographic survey at the beginning of the clinic visit and an exit survey which included questions about their visit and selected domains of the Ambulatory Care Experiences Survey.⁵ Demographic surveys collected information about age, race/ethnicity, past medical history including breast cancer, menopausal status, medications or alternative treatments for menopause, and duration of relationship with provider. As a proxy for SDM, exit surveys collected data from selected domains of the Ambulatory Care Experiences Survey (ACES) including data about patient-provider communication, interpersonal treatment, patient trust, whole-person orientation, and health promotion. Exit surveys were also used to collect data regarding the level of satisfaction with the SDM process; discussion of menopausal symptoms, breast cancer risk, and lifestyle modifications; and medication changes for menopause.

In addition to the surveys completed by women in the control group, those in the intervention group completed a health assessment survey prior to seeing their provider and had the opportunity to watch videos about how to incorporate SDM if menopausal symptoms were present.⁶

The Menopause Rating Scale (MRS) and Breast Cancer Risk Assessment Tool scores [i.e., National Cancer Institute and the National Surgical Adjuvant Breast and Bowel Project (NCI/NSABP) interactive tool] were combined into one Menopause Health Assessment Report (Appendix A) which was printed, saved to a secured server for uploading into the EHR and available on the tablet at point-of-care. The Menopause Health Assessment Report was performed in the waiting room or patient exam room prior to the provider visit. The health risk appraisal tools were age-specific such that women age 45-59 received the MRS and breast cancer risk assessment; women age 60-65 received the MRS and breast cancer risk assessment and were asked more specifically about their current use of HT (if applicable). Women with a history of breast cancer were not provided the breast cancer risk assessment. Women and providers

saw the Menopause Health Assessment Report as soon as it was completed. The results of the MRS were displayed as “positive” or present with severe to very severe symptoms when there was any score of 3 or 4 (on a 0-4 scale) on any of the three items – psychological, somatic and/or urogenital. For women with a positive score on any of the three items, educational video vignettes (~6 minutes in length) relevant to their specific symptoms were available to provide women guidance on how to enhance discussions about menopause and SDM with their provider.⁶ For women that had all scores <3, they were encouraged to discuss results with their provider and continue healthy lifestyle behaviors. The breast cancer risk assessment displayed 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. Women with a 5-year risk of invasive breast cancer $\geq 1.7\%$ were encouraged to discuss results with her provider and those with a 5-year risk of invasive breast cancer $< 1.7\%$ were encouraged to ask their clinician about screening if/when appropriate and healthy lifestyle (e.g., exercise, alcohol in moderation, maintain healthy weight). Each risk assessment had a brief explanation to help the patient and provider understand what the data meant.

At the start of the study, providers took a pre-test to assess baseline knowledge of menopause. Approximately one month prior to initiation of the intervention group at their practice, providers completed a webinar with a live question and answer session that included: terminology used to describe menopause and its treatment options; physiological changes that occur in perimenopause and through menopause; assessment tools for menopausal symptoms and breast cancer risk; clinical trials and position statements that have provided evidence to influence clinical practice; therapeutic options to manage the symptoms of menopause; and communication strategies to discuss symptoms with patients and design appropriate pharmacotherapy regimens. A post-test knowledge assessment occurred after the webinar. Continuing medical education credit was provided for the presentation and participation in the study. Providers also completed a modified version of the ACES survey at baseline, 6 months and the end of the study.

Baseline and end of study EHR data queries were used at each participating practice to evaluate changes in rates for diagnosis of menopause and/or postmenopausal status. Baseline rates for diagnosis of menopause and/or postmenopausal disorders (ICD-9 codes 627.1-627.9) and use of medications for menopause for women age 45-65 years via EHR data audit were performed for women seen at the most recent visit with an enrolled provider from January 1, 2011, to December 31, 2012. HT consisted of any estrogen or estrogen + progestogen regimen appropriate for menopausal symptoms. A similar EHR data query was performed at the conclusion of the study for women seen at the most recent visit with an enrolled provider from August 15, 2014 to August 15, 2015.

Prior to randomization into the stepped wedge design, four relatively homogeneous strata were created using baseline practice characteristics (e.g., practice size, percent Medicaid, EHR type). Within each stratum of four, practices would 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.

We anticipated the following changes with the intervention proposed 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 aged 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%)

A sample size of 480 patients was estimated to provide >99% power to detect anticipated differences in primary outcomes (diagnosis, satisfaction with shared decision making). Power was calculated to be greater than 80% for the secondary outcomes of lifestyle modification and discussion of breast cancer risk.

Initially, descriptive statistics (mean, SD, proportions) were computed for baseline patient and practice characteristics. In addition, chi-squares and t-tests were used to determine whether there were 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 determined whether these outcome variables were normally distributed prior to analysis. In the event that normality assumptions were not met, we used 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 was the unit of analysis, clustered within practices. General (generalized) linear mixed model approaches (GLMMs) were 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 outcomes, adjusted for covariates. Random effects were 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 were performed using SAS version 9.3. (SAS Institute Inc., Cary, NC).

Results:

Nine of 12 family medicine practices completed the study and were included for analysis. Eleven of the 12 practices successfully completed all study enrollment requirements and two of the 11 practices were excluded early in the study due to inability to incorporate tablet technology into workflow and inadequate patient enrollment. The nine included practices successfully implementing tablet technology into patient care workflow and had 14 participating providers. Practices were located in various states including Massachusetts, Pennsylvania, Georgia, Ohio, Virginia, Iowa, Connecticut, and California. Of the nine practices, eight were primary care practices in rural (2), suburban (5), and urban (1) areas and one was an urban residency training practice.

A total of 438 unique participants completed 408 full datasets for evaluation. Patients were given the option to not answer survey questions which accounts for some differences in patient responses. Patient demographics are shown in Table 2.

Table 2. Patient Demographics

Description	Total N=408	Control n=177 (43.4%)	Intervention n=231 (56.6%)	p-value	Overall p- value
Age					
45-49 years	84 (20.6%)	33 (18.6%)	51 (22.1%)	0.4	0.7
50-54 years	116 (28.4%)	53 (30.0%)	63 (27.3%)	0.55	
55-59 years	114 (27.9%)	53 (29.9%)	61 (26.4%)	0.43	
60-65years	94 (23.0%)	38 (21.5%)	56 (24.2%)	0.51	
Race					
AI/AK	1 (0.2%)	0 (0.0%)	1 (0.4%)		0.03
Asian	5 (1.2%)	3 (1.7%)	2 (0.9%)		
Black/AA	65(15.9%)	35 (19.8%)	30 (12.9%)	0.06	
Unknown	7 (1.7%)	5 (2.8%)	2 (0.8%)		
White	332 (81.0%)	134 (75.7%)	198 (85.0%)	0.01	
Ethnicity					
Hispanic	24 (5.9%)	12 (6.8%)	12 (5.2%)	0.5	
Non-Hispanic	384 (94.1%)	165 (93.2%)	219 (94.8%)		
Menopausal status					
Perimenopausal	60 (14.7%)	27 (15.3%)	33 (14.3%)		0.97
Menopausal	98 (24.1%)	44 (25.0%)	54 (23.4%)		
Postmenopausal	123 (30.2%)	50 (28.4%)	73 (31.6%)	0.73	
Surgical Menopause	50 (12.3%)	22 (12.5%)	28 (12.1%)		
Unknown	76 (18.7%)	33 (18.8%)	43 (18.6%)		
History of breast cancer					
Yes	23 (5.7%)	10 (5.6%)	13 (5.6%)	0.97	
No	384 (94.3%)	167 (94.4%)	218 (94.4%)		
Concurrent conditions					
Anxiety	112 (27.5%)	37 (11.2%)	75 (32.0%)	0.02	

Back Pain	93 (22.8%)	40 (21.4%)	58 (23.8%)	0.56	
Depression	104 (25.5%)	39 (22.0%)	65 (28.1%)	0.57	
High Cholesterol	132 (32.4%)	61 (33.3%)	24 (31.6%)	<0.0001	
Hypertension	149 (36.5%)	75 (41.2%)	76 (32.9%)	0.05	
Obesity	94 (23.0%)	37 (20.3%)	59 (25.1%)	0.27	
Allergic Rhinitis	58 (14.2%)	24 (13.6%)	34 (14.7%)	0.7	
Asthma	50 (12.3%)	21 (11.9%)	29 (12.6%)	0.6	
Diabetes	48 (11.8%)	22 (13.6%)	14 (10.4%)	0.03	
Hypothyroidism	54 (13.1%)	15 (8.5%)	39 (16.5%)	0.01	
None	69 (16.9%)	30 (16.4%)	40 (17.3%)	0.92	
Reflux Esophagitis	71 (17.4%)	37 (20.3%)	35 (15.2%)	0.13	
Medications for menopause					
Black cohosh	8 (1.9%)	3 (1.6%)	5 (2.1%)		
Combined estrogen and progesterone (in one dosage form)	8 (1.9%)	4 (2.2%)	4 (1.6%)		
Compounded bioidentical hormone therapy	6 (1.4%)	0 (0.0%)	6 (2.5%)		
Estrogen	25 (5.8%)	9 (4.9%)	16 (6.6%)		
Gabapentin	7 (1.6%)	4 (2.2%)	3 (1.2%)	0.03	
None	297 (69.4%)	143 (77.7%)	154 (63.1%)		
Other	18 (4.2%)	7 (3.8%)	11 (4.5%)		
Progesterone	16 (3.7%)	5 (2.7%)	11 (4.5%)		
SNRI (e.g., venlafaxine)	11 (2.6%)	2 (1.1%)	9 (3.7%)		
SSRI (e.g., sertraline, fluoxetine, paroxetine)	32 (7.5%)	7 (3.8%)	25 (10.3%)		

Patient Outcomes

Patient experience from the modified ACES survey was used as a proxy to evaluate various aspects of the shared decision making process. There were no significant differences found between women in the control and intervention groups regarding communication, interpersonal treatment, patient trust, whole person orientation or health promotion. All patients rated providers 90% or higher in all components. For patients responding to questions about satisfaction with the shared decision making process, most patients in the control and intervention groups were completely satisfied (143/154, 92.9% and 189/214 88.3% respectively, $p=0.15$). Furthermore, discussions about menopause, breast cancer risk, and lifestyle occurred for a majority of patients in both groups and were not statistically significantly different (Table 3).

Table 3. Discussions among patients and providers.

Discussion Topic	Control	Intervention	P-value
Lifestyle modification	151/179 (84.4%)	225/255 (88.2%)	0.25
Menopause (age 45-59 years)	79/106 (74.5%)	112/142 (78.9%)	0.42
Breast cancer risk	109/167 (65.3%)	146/230 (63.5%)	0.71

For women in the intervention group, the MRS survey was presented prior to the other surveys so information would be readily available at the point of care during the provider visit. For this reason, 252 women completed the MRS survey and 127/252 (50.4%) indicated at least one severe to very severe symptom in one of three categories: somatic, psychological, and/or urogenital. Specifically, 87/252 (34.5%) had at least one somatic severe to very severe symptom, 65/252 (25.8%) had at least one severe to very severe psychological symptom, and 69/252 (27.4%) had at least one severe to very severe urogenital symptom. Specifics of each symptom category can be found in Table 4. The most prevalent symptoms with >40% of women experiencing moderate, severe, or very severe symptoms include muscular pain, sleep issues, depression, exhaustion, and sexual symptoms.

Table 4. Individual symptoms for women taking the menopause rating scale.

Symptom	Frequency (%) n=252
Somatic symptoms	
Hot flushes, sweating	
None	75 (29.6%)
Mild	96 (37.9%)
Moderate	53 (21.0%)
Severe	22 (8.7%)
Very severe	7 (2.8%)
Joint and muscular discomfort	
None	57 (22.8%)
Mild	87 (34.8%)
Moderate	64 (25.6%)
Severe	37 (14.8%)
Very severe	5 (2.0%)
Sleep problems	
None	58 (22.9%)
Mild	63 (24.9%)
Moderate	83 (32.8%)
Severe	39 (15.4%)
Very severe	10 (4.0%)
Heart discomfort	
None	148 (58.5%)
Mild	71 (28.1%)
Moderate	29 (11.5%)
Severe	4 (1.6%)
Very severe	1 (0.4%)
Psychological symptoms	
Anxiety	
None	83 (32.9%)
Mild	83 (32.9%)
Moderate	62 (24.6%)
Severe	19 (7.5%)
Very severe	5 (2.0%)

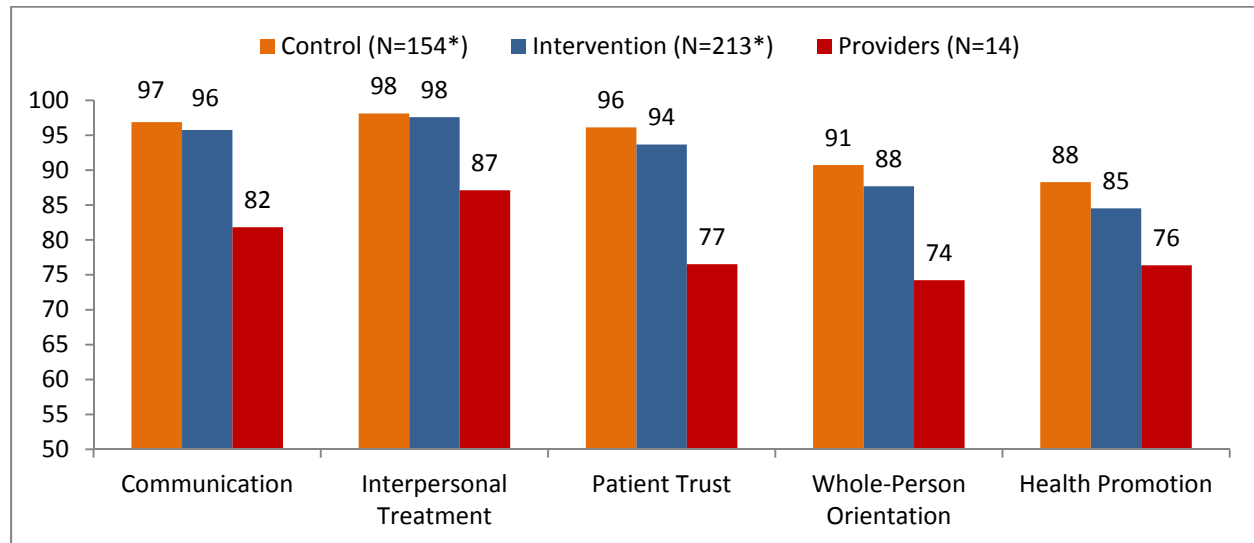
Depressive mood	
None	74 (29.3%)
Mild	69 (27.3%)
Moderate	80 (31.6%)
Severe	26 (10.3%)
Very severe	4 (1.6%)
Irritability	
None	65 (25.8%)
Mild	93 (36.9%)
Moderate	66 (26.2%)
Severe	24 (9.5%)
Very severe	4 (1.6%)
Physical and mental exhaustion	
None	47 (18.7%)
Mild	89 (35.3%)
Moderate	75 (29.8%)
Severe	33 (13.1%)
Very severe	8 (3.2%)
Urogenital symptoms	
Dryness of vagina	
None	103 (41.0%)
Mild	58 (23.1%)
Moderate	51 (20.3%)
Severe	26 (10.4%)
Very severe	13 (5.2%)
Bladder problems	
None	95 (37.9%)
Mild	79 (31.5%)
Moderate	50 (19.9%)
Severe	20 (8.0%)
Very severe	7 (2.8%)
Sexual problems	
None	82 (32.7%)
Mild	56 (22.3%)
Moderate	66 (26.3%)
Severe	32 (12.8%)
Very severe	15 (6.0%)

Many women were receiving treatment for various menopausal symptoms at the time of study enrollment (see Table 2). Medication changes for menopause symptoms were reported by 11/177 (6.2%) of women in the control group and 27/231 (11.7%) of women in the intervention group which indicated a trend toward significance ($p=0.06$) when the MRS data was available at the point of care on the tablet. Other medication changes such as calcium and vitamin D, and allergy medication were noted, but not considered in the analysis regarding medications for menopause. Given that all medication changes were either substitutions (e.g., discontinue oral contraceptive and initiate HT) or additions, no discontinuation of HT occurred for women age 60-65 years.

Provider Outcomes

Providers typically scored themselves lower on the ACES compared with patients as shown in Figure 1.

Figure 1. ACES survey results from participants and providers



*Control/Intervention population numbers are an average of respondents across the 5 domains. Note: No statistical difference was detected between intervention and control groups.

Based on the EHR data extraction for all women age 45-65 years in each provider's patient panel, the total number of women age 45-65 years with a diagnosis of menopause was 42.8 per clinician at baseline and 70.5 per clinician at completion of the study. The number of medications prescribed for menopause (e.g., HT, SSRI) was 29.6 per provider at baseline and 42.8 per provider at completion of the study.

Providers (n=14) completed a pre- and post-test assessment of an educational webinar designed to impact clinical practice. There was an insufficient sample size to detect a difference, but trend indicates improved knowledge (mean correct: pre=66%, post=74%, p-value = 0.07) on this assessment of 14 multiple choice questions.

Discussion:

The methods and evaluation used with this integration of tablet technology and EHR met the needs of menopausal women in an approach that was simple to deploy and has been used in multiple primary care locations for other health issues. The surveys and risk calculators used are documents that can be embedded in personal health records or other data collection systems for easy and no or low cost dissemination. It is important for patient care, monitoring, and follow-up that these assessment tools used with tablet technology were able to become part of EHR.

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 develop some level of standardization of assessment so that we can create an active learning and SDM 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 or tied to an educational intervention or treatment plan. Tablet technology is one tool that can be used to facilitate this person-centered care and this study indicates that it is a preferred tool in the clinical practice setting.

The MRS was selected 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 with HT. 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.

The NCI/NSABP breast cancer risk assessment tool was chosen 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, Hispanic, Asian-American and American Indian or Alaskan Native. 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 providers and patients determine what therapy may be most appropriate for menopausal symptoms or breast cancer risk reduction when needed. Methods for a complementary and efficient assessment of breast cancer risk to help make clinical decisions about appropriateness of HT need to be created. Tools are readily available on the internet, but are often not accessed during a provider visit. Having this breast cancer risk tool embedded into the tablet technology helped women and providers to quickly see results of breast cancer risk so treatment decisions could be made.

Although the number of women diagnosed with menopause or postmenopause improved with the intervention, this still represents a minority (approximately 16% at baseline and 17% at study completion) of women aged 45-65 years. This may be because most providers did not include a diagnosis unless women had been prescribed a medication related to menopause. We would argue that having this diagnosis readily

apparent in the EHR helps to ensure re-assessment of menopausal symptoms and appropriate medication use on a routine basis.

The potential benefits and risks of HT need to be carefully considered in every patient who expresses an interest in medical therapy. New ways of explaining these benefits and risks to patients need to be introduced 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. In this study, videos featuring accurate scenarios and questions for menopausal women were included. The limited number of views of the videos received made it difficult to discern if videos played a major role in SDM, but warrant further consideration and research. Most women indicated they enjoyed using the tablet, but it did not change their understanding of menopause symptoms and treatment.

Patients reported high satisfaction with provider-patient interactions across several domains; clinician perceptions were lower. Most providers discussed lifestyle modification and issues related to menopause; fewer discussed breast cancer risk.

There are several limitations to the study and surveys used. Participating practices were required to have an EHR and be willing to integrate tablet technology into their workflow. This may create selection bias toward practices that are already moving proactively toward innovative activities. Given that approximately 75% of AAFP members use an EHR and virtually all members are not planning retirement in the near future are installing EHRs, we believe this particular requirement did not affect recruitment or eventual dissemination. Selection bias may also occur since patients will opt in or opt out by engaging with (or not) the tablet device. Patients unfamiliar with tablet technology may not be willing to participate. Our experience to date with the tablet technology we used, 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. Educational status of patients participating in the study was not collected. Additionally, the mere presence of the tablet (in either group) could have impacted provider behavior.

Practice-based research represents the “final step” in translational research as it is implemented in the usual clinical environment. Creating a link between research and providers allows for high-quality patient-oriented evidence that can be readily implemented in clinical practice to improve the quality of patient care. However, the use of practice-based research sacrifices high control of patient behavior and internal validity. This research is dependent upon practices implementing the research tool(s) and collecting the appropriate data with the right patients at the right time. While we had several tools to aid practices in implementing tablet technology into their workflow, levels of patient recruitment and participation varied. For this study, not all enrolled patients were able to complete all aspects of the study. Reasons for withdrawing early from the study included not enough time to finish within the visit, no longer interested in participating and believing all data were completed.

Conclusions:

Tablet technology can be successfully integrated at the point of care to provide effective shared decision making for providers and women age 45-65 years. This study was able to demonstrate that tablet technology can provide valuable, individualized and specific information regarding issues related to menopause at the point of care. Providers were also more likely to document menopause as a diagnosis which may serve as a valuable reminder for routine follow-up. Providers discussed lifestyle, menopause, and breast cancer risk most of the time with their patients. This is important given that half of these women had severe or very severe menopause symptoms. In this cohort of women, the most prevalent symptoms were not hot flashes, but >40% of women experienced moderate, severe, or very severe symptoms of muscular pain, sleep issues, depression, exhaustion, and sexual symptoms. This provides valuable information about how providers and patients can further engage in shared decision making to determine the most appropriate methods of treatment.

List of Publications and Products:

1. Medscape Medical News. Menopause symptoms untreated for many women. Available at: <http://www.medscape.com/viewarticle/763380>. Accessed February 26, 2016.
2. North American Menopause Society. The 2012 hormone therapy position statement of the North American Menopause Society. *Menopause*. 2012;19(3):257-271.
3. Agoritsas T, Heen AF, Brandt L, et al. Decision aids that really promote shared decision making: the pace quickens. *BMJ*. 2015;350:g7624.
4. Stacey D, Légaré F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews* 2014, Issue 1. Art. No.: CD001431. DOI: 10.1002/14651858.CD001431.pub4.
5. Safran DG, Karp M, Coltin K, et al. Measuring Patients' Experiences with Individual Primary Care Physicians. *J Gen Intern Med*. 2006;21:13-21.
6. The University of Colorado Anschutz Medical Campus and American Academy of Family Physicians (AAFP) National Research Network. Moments in Menopause. Available at: <https://www.youtube.com/user/momentsinmenopause> Accessed February 26, 2016.

Appendix A. Example of Menopause Health Assessment Report.

Menopause Health Assessment Summary			
<p>This page summarizes your menopause health assessment responses and provides information about any identified risks. Click HERE to get instructions about how to PRINT this summary.</p> <p>If you answered that you are experiencing "severe" or "very severe" symptoms of menopause, we invite you to watch the video (link provided) to learn more about these symptoms, how to best manage them, and discussing these issues with your provider. Feel free to share any of your questions or concerns with your provider.</p> <p>Make sure you keep your tablet throughout your visit so you can complete the study. Click here to complete the patient demographics survey.</p>			
Menopause Health Assessment		Completed:	9/28/2015
Practice:	Patient Name:	DOB:	ID:
zzHRT test provider intervention	Test, Woman	9/9/1960	Menopause-675
Menopause Rating Scale: *Only categories with a severe or very severe rating will offer a video.			
Hot flashes/body	Hot flashes, sweating	Very Severe	hotflashes-video
Psychological	Depressive mood Irritability	Severe Severe	psychological-video
Breast Cancer Risk Assessment:			
5 year risk: This woman (age 45) = 0.90% Average woman (age 45) = 1.00% Lifetime risk This woman (to age 90): 10.6% Average woman (to age 90): 11.9%		Your estimated risk for developing invasive breast cancer over the next 5 years is <1.7% (low risk). You should know how your breasts normally look and feel and report any breast changes promptly to your health care provider. It is recommended by national guidelines that you have a mammogram every year. Please ask your provider about the best screening options for you. To minimize your risk of breast cancer, we encourage you to maintain a healthy lifestyle including eating a well-balanced diet, exercising 30 minutes daily most days of the week, refraining from smoking, limiting alcohol intake to 1 drink per day, and maintaining a healthy weight.	
Responses:			
#	Question	Answer	
1	Hot flashes, sweating (episodes of sweating)	very severe	
2	Heart discomfort (unusual awareness of heartbeat, heart skipping, heart racing, tightness)	moderate	
3	Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early)	moderate	
4	Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings)	severe	
5	Irritability (feeling nervous, inner tension, feeling aggressive)	severe	
6	Anxiety (inner restlessness, feeling panicky)	moderate	
7	Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness)	mild	
8	Sexual problems (change in sexual desire, in sexual activity and satisfaction)	mild	
9	Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence)	mild	
10	Dryness of vagina (sensation of dryness or burning in the vagina, difficulty with sexual intercourse)	mild	
11	Joint and muscular discomfort (pain in the joints, rheumatoid complaints)	none	
12	Do you have a medical history of any breast cancer or of ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS)?	No	
13	What is your age?	45	
14	What was your age at the time of your first menstrual period?	12 to 13	
15	What was your age at the time of your first live birth of a child?	No births	
16	How many of your first-degree relatives - mother, sisters, daughters - have had breast cancer?	0	
17	Have you ever had a breast biopsy?	No	
18	How many breast biopsies (positive or negative) have you had?	N/A	
19	Have you had at least one breast biopsy with atypical hyperplasia?	N/A	
20	What is your race/ethnicity?	White	
21	What is your sub race/ethnicity?	N/A	