TITLE PAGE

Title: Raising Awareness Starting the Conversation

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1. ABSTRACT

Purpose-Our **primary goal** was to **change clinician behavior** to increase identification and appropriate management of symptomatic VVA for women ages 35-80 using Shared Decision Making (SDM) and facilitating practice change.
Scope- VVA affects 20%-45% of midlife and older women. Without treatment, women report reduced interest in and avoidance of sexual activity. Women also report a reluctance to discuss these symptoms with their healthcare provider and many healthcare providers are unaware of available evidence-based treatment options.
Methods- Two practice-based research networks, a patient engagement and communications company, a sexuality resource center and a medical education association developed educational materials to support a novel combination of evidence-based medical education methods to increase knowledge and application of that knowledge as it relate to the treatment of VVA. Spaced education, academic detailing and practice facilitation were combined to try to change clinician behavior.
Results-16 Family Medicine, General Internal Medicine, and Obstetrics and Gynecology clinics with 171 clinicians and staff participated in some or all aspects of this intervention. There was significant improvement in a variety of self-reported clinician behaviors. The percentage of clinicians who agreed/strongly agreed that they screened all of their post-menopausal patients for VVA increased from 41.9% to 74.2%. The percentage of clinicians who agreed/strongly agreed with always adding VVA to the electronic health record problem list increased from 51.6% to 74.2%. A large majority of patients like the SDM process and will recommend it to friends.
Key words- Vaginal atrophy, vulvovaginal atrophy, shared decision making, practice-based research, practice facilitation, physician education.

2. PURPOSE

Our **primary goal** was to **change clinician behavior** to increase identification and appropriate management of symptomatic VVA that results in improved quality of life for women ages 35-80 based on reduction in VVA symptoms. Secondary goals also included:

- Increase women's awareness of VVA symptoms and the association with menopause.
- Increase clinician and clinic staff knowledge about the effect of symptomatic VVA on postmenopausal women's quality of life.
- Develop an internet-based toolkit including awareness raising materials, a Shared-Decision Making decision aid to use in the treatment of VVA, and implementation methods that will be sustainable and widely disseminated.
- Increase diagnosis rates of symptomatic VVA in women age 35-80.
- Increase satisfaction with quality of live for women with symptomatic VVA.

3. SCOPE

A. Background

In 2013, two practice-based research networks, a patient engagement and communications company, a sexuality resource center and a medical education association joined forces to collaborate to raise awareness and to treat patients struggling with vulvovaginal atrophy. *Raising Awareness Starting the Conversation* began with recognition that symptoms of Vulvovaginal atrophy (VVA) affect 20%-45% of

midlife and older women. Lack of lubrication, pain with intercourse, burning, dysuria, dyspareunia, and vaginal discharge are commonly reported symptoms. Without treatment women report reduced interest in and avoidance of sexual activity. Women report a reluctance to discuss these symptoms with their healthcare provider and many healthcare providers are unaware of available evidence-based treatment options. Recent treatment advances can provide symptom relief. Shared decision making allows patients and providers to make the best health care decisions based on the clinical evidence available while taking into account the patient's values and preferences.

B. Context

Interstate Postgraduate Medical Association (IPMA), and two primary care practice-based research networks (PBRNs), Wisconsin Research and Education Network (WREN), and Duke Primary Care Research Consortium (PCRC) designed an initiative targeting increased awareness, improved diagnosis, Shared Decision Making (SDM) and improved Quality of Life (QOL) for the treatment of symptomatic vulvovaginal atrophy (VVA) in women ages 35-80. WREN and PCRC are practice based research networks (PBRNs). PBRNs are groups of primary care clinicians and practices working together to answer community-based health care questions and translate research findings into practice.

The partnering organizations combined expertise in education, systems change, clinical research, patient centered care and assessment to develop and execute our project. We developed an internet-based VVA SDM decision aid and educational interventions to teach SDM methods to clinicians to change clinician behavior that will result in an increase in appropriate management of symptomatic VVA. We evaluated methods to increase recognition and management of symptomatic VVA in family medicine and OB/GYN clinics by raising awareness of patients, clinicians, and office staff about the impact symptomatic VVA has on patient quality of life. We worked with clinics to incorporate use of the SDM decision aid into their workflows.

Raising Awareness was designed as a patient research project combined with clinician education. We engaged symptomatic patients in education, shared decision making, treatment options, and assessment of quality of life through our planned educational interventions. This included patient education materials and an internet-based shared decision making (SDM) decision aid.

In addition to IPMA, Duke PCRC and WREN, additional partners with smaller roles in the project were Emmi Solutions, Q Stream Spaced Education, and A Woman's Touch Sexuality Resource Center.

WREN – Wisconsin Research and Education Network

WREN was founded in 1987, and is one of the oldest and most respected practice-based research networks in the United States. WREN has 200 practicing clinicians located in 80 different clinic sites from 37 healthcare organizations. WREN physician, Paul Smith, MD, served as the lead clinical investigator for this project. Dr. Smith is a family medicine physician and served as WREN Director for over five years. Dr. Smith provided academic detailing and recruited WREN clinicians participating in this project. WREN staff conducted the practice facilitation, collected and analyzed the medical record data and conducted the patient clinical study.

Duke PCRC –Duke Primary Care Research Consortium

The PCRC is a network of primary care clinicians who work together to enroll patients in clinical research studies, including 33 practices in 7 counties of the Piedmont area of North Carolina (both urban and

rural). These practices are made up of the Duke Primary Care practices, the Ambulatory Care Service of the Durham VA Medical Center, and independent community practices with a total of 195 clinicians who care for an estimated 330,000 patients. Duke PCRC physician Rowena Dolor, MD, MHS served as the lead clinical investigator for Duke. Two additional physicians, Kristin Schmit, MD and Anne Ford, MD, served as co-clinical investigator and content expert for the project. Duke PCRC staff conducted the practice facilitation, collected and analyzed the medical record data, and conducted the patient clinical study.

IPMA – Interstate Postgraduate Medical Association
Since its foundation in 1916, Interstate Postgraduate Medical Association of North America has continuously maintained its original goal of clinician education that positively impacts patient care. As a not-for-profit 501(c)(3) educational association, IPMA's stated mission is to advance lifelong learning to improve patients' health and the value of healthcare. IPMA served as educational leader, CME accreditor, and project manager. Kate Nisbet, MBA served as project manager under the leadership of Mary Ales, Executive Director. IPMA holds accreditation with commendation from the Accreditation Council for Continuing Medical Education (ACCME).

Emmi Solutions, LLC ("Emmi") is the leading SaaS (Software-as-a-Service) provider of interactive patient engagement and empowerment programs. Emmi is a complete and integrated multi-modal patient engagement platform that leverages Web, mobile, email, video, IVR and print. Emmi developed our patient education, shared decision making module on vulvovaginal atrophy.

A Woman's Touch Sexuality Resource Center (AWT) is a business offering education, training, product development and a retail boutique based in Madison, Wisconsin. A Woman's Touch offers a unique combination of expertise in sexual health and pleasure and is owned by a sex educator and counselor, Ellen Barnard MSSW, and a physician, Myrtle Wilhite, MD, MS. Ms. Barnard served as a content expert for the patient and physician education materials and the shared decision making module.

C. Settings and Participants

This project took place in a total of sixteen clinical locations. Eight clinics were scattered around Wisconsin and eight clinics were located in and around Durham, North Carolina. Wisconsin sites represented 6 different health care organizations and North Carolina sites were all part of Duke Health. Ten clinics were family medicine, 5 were obstetrics and gynecology and one was general internal medicine. Nine primary care and 5 gynecology clinics completed participation in the study, two participating clinics had to drop-out during project implementation.

A total of 97 clinicians participated in the project out of a total 171 total clinicians and staff participating. 42 of the participating clinicians provided direct patient care. An additional 55 clinicians participated in some aspect of the education. A total of 41 clinicians and staff participated and received credit for all four individual educational activities offered as part of this program. 97 received credit for the Spaced Education module on Shared Decision Making, 90 received credit for the Spaced Education module on VVA, 107 received one credit for the Academic Detailing sessions and 59 completed all elements to receive the 20 Performance Improvement CME credits.

Three hundred forty six patients were referred into the study, 201 were enrolled, and 130 viewed entire decision aid. One hundred thirty patients completed the entire study, rating their symptom management post study.

D. Prevalence

Symptoms associated with VVA affect 20% to 45% of midlife and older women but only a minority seek help or are offered help by their healthcare providers.[i] [ii]Women often tolerate vasomotor symptoms (hot flashes, night sweats) that accompany loss of ovarian estrogen production as these often improve over time without estrogen treatment, but symptomatic VVA often worsens with time and can significantly impair the quality of life (QOL) of postmenopausal women and may be underdiagnosed. Clinicians can improve the sexual health and QOL of postmenopausal women through VVA patient education, symptom diagnosis, and appropriate treatment strategies. A number of surveys of postmenopausal women (VIVA, REVEAL, Healthy Women, CLOSER, REVIVE) have shown that VVA negatively affects sexual health and QOL. In an online survey conducted in 6 countries, an estimated 45% of postmenopausal women reported experiencing vaginal symptoms,[iii] but only 4% could identify these symptoms as VVA related to menopause. Seventy-six percent of women in Finland were satisfied with the available information about VVA; however, in the other 5 countries, including the United States and Canada, less than half (37%-42%) were satisfied. Among US women (n = 500), 63% associated vaginal symptoms with menopause, and only 41% of respondents believed that enough information about vaginal discomfort was available to them.[iv]

4. METHODS

This project involved 2 phases. 1) Development of educational materials; and 2) Educational program execution and implementation.

Materials Development

Patient education materials:

An advisory team of post-menopausal women, clinicians and clinic staff was established to give feedback about the materials developed. The core project team worked with Ellen Barnard MSSW, and Myrtle Wilhite, MD, from A Woman's Touch Sexuality Resource Center (AWT) to develop a poster, brochure and patient education handout for use at clinics to raise awareness and inform patients. These were developed to raise general patient awareness about VVA symptoms, to assist in starting the conversation and to encourage patients to ask questions when meeting with their doctor or provider. All materials were presented to the advisory panel during the development stage for feedback about the wording and understandability of questions and other educational content. All patient education materials are listed in **6. LIST OF PUBLICATIONS AND PRODUCTS** and provided as a separate attachment to the final report.

The same team also worked with staff from Emmi Solutions, LLC to develop a computer/internet decision aid for patients to view. The decision aid uses a combination of illustrations, text and voice over to present basic anatomy, signs and symptoms of VVA, current evidence for benefits and harms of treatment options and asks questions to help the viewer clarify values and attitudes related to the decisions that need to be made. The decision aid development process included: 1) Research through literature and guideline review; 2) Draft of content outline; 3) Draft script development with in depth

review by medical advisers; 4) Creation of a multimedia Alpha version including medical illustrations and computer generated voiceover that is viewed by medical advisers and patient advocates including patient focus groups; 5) Beta version created based on feedback with final review by patient and medical advisers; and 6) Final version created based on feedback and sent to outside independent testing organization to test technical functionality of program prior to release. The decision aid can be viewed at: https://www.my-emmi.com/SelfReg/VVA.

Clinician and staff education materials:

Spaced Education: Ms. Ales and Nesbit were primarily responsible for the development of the learning program. Drs. Paul Smith, Kristine Schmidt, Anne Ford and Myrtle Wilhite, and Ellen Barnard served as content experts during the development process. Knowledge on SDM methods, VVA diagnosis and treatment options were provided through the two on-line educational activities.

Spaced Education delivers brief, straightforward, and easily accessible education via the web or mobile device. We developed two educational modules. One module addressed education on the diagnosis and treatment of vulvovaginal atrophy. The second module was developed to educate on shared decision making. All participating clinic staff including physicians, clinicians and support staff were enrolled in both spaced education modules. One AMA PRA Category 1 Credit(s) was awarded to learners upon completion of each activity.

We also developed a ½ sheet card with key VVA diagnosis and treatment recommendations and a set of text phrases that could be inserted into appropriate areas of and electronic health record to facilitate documentation of VVA symptoms questions and answers, and patient instructions for treatment recommendations. All clinician education materials are listed in **6. LIST OF PUBLICATIONS AND PRODUCTS** as provided as a separate attachment to the final report.

Recruitment of participating sites

WREN and Duke PCRC site clinician leaders were contacted by email and telephone to assess interest in participation and a convenience sample of 8 sites from each PBRN were recruited. Site enrollment criteria were: 1) primary care, obstetrics and gynecology or gynecology only practices. 2) At least 3 willing participating clinicians (physician, Physician's Assistant or Advanced Practice Nurse). 3) Fully implemented electronic health record (EHR); and 4) Administrative support for participation and extraction of EHR diagnosis frequency data.

A. Education Program Implementation and Study Design

The intervention protocol was approved by the University of Wisconsin-Madison and Duke University Institutional Review Boards. We used a stepped-wedge design model for control and intervention groups. The stepped-wedge design is a randomized controlled trial research method where all practices start as control sites and practices are randomly assigned to sequentially receive the intervention until all practices become intervention sites. This was a selling point for our project as participating clinics would receive the educational intervention for both clinicians and patients.

Stepped-Wedge Controlled Trial Intervention Table

WI Clinics	NC Clinics	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Family Medicine	Family Medicine	Control	Intervention	Intervention	Intervention
Family Medicine	Internal Medicine	Control	Intervention	Intervention	Intervention
GYN	OB/GYN	Control	Intervention	Intervention	Intervention
Family Medicine	Family Medicine	Control	Control	Intervention	Intervention
Family Medicine	Family Medicine	Control	Control	Intervention	Intervention
GYN	OB/GYN	Control	Control	Intervention	Intervention
Family Medicine	Family Medicine	Control	Control	Control	Intervention
Family Medicine	OB/GYN	Control	Control	Control	Intervention

Patient Education: Posters were hung in hallways and clinic restrooms to raise awareness. Trifold brochures were placed in exam rooms and waiting rooms. Detailed patient education handouts were given to patients by clinicians at their discretion. Patients that viewed the VVA decision aid received education about present basic anatomy, signs and symptoms of VVA, current evidence for benefits and harms of treatment options

Clinician and Staff Education: Our educational intervention to clinicians and staff was provided through three components: knowledge, academic detailing and practice facilitation. Clinicians were required to participate in all phases and staff was encouraged to participate. Knowledge on VVA diagnosis and treatment options was provided through on-line spaced education learning. On-site academic detailing (clinician to clinician + staff lecture and discussion) followed the spaced-education as we moved groups from control to intervention. PBRN staff practice facilitators then coordinated the patient education implementation, worked with clinicians and clinic staff to modify existing workflows to raise patient awareness of VVA, efficiently diagnose and treat VVA, and conduct enrollment of patient subjects. PBRN practice facilitators also conducted chart reviews, obtained patient consent, and gathered baseline and post-intervention evaluation.

Our educational interventions were designed with two purposes: 1) Increase clinical knowledge and awareness by clinicians, their staff and postmenopausal women about the impact VVA has on quality of life, including impact on sexual functioning; 2) Provide training for clinicians and their staff on how to

engage patients in discussion of VVA impact on sexual health, general SDM principles, and use of the VVA SDM tool.

Spaced Education: Clinicians and clinic staff were enrolled in the spaced education program about 3 months prior to the first on-site meeting with project team members.

Academic Detailing: Academic detailing was presented through an on-site 60 minute conversation and presentation with one of the physician project leads. This was the first on-site meeting of site clinicians, staff and members of the project team. During the academic detailing sessions clinicians were provided: general details on the project including timeline, background information on the project, practice facilitation planning, how to enroll patients in the study, how to access the patient education shared decision making aid, review of the patient education materials: a poster, trifold and longer patient education document, and review of the clinician education materials. The goal of the academic detailing sessions was to create an agenda for change and a to-do list generated by the practice to serve as input to the practice facilitation sessions.

Performance Improvement with Practice Facilitation: Practice facilitation is a well-described effective method of assisting practices in changing the process of care. Project team members assisted practices in implementing their prioritized goals, changing practice workflow, and improving patient outcomes. Each site had at least six, on-site, one hour practice facilitation sessions. Working with the PBRN staff, the clinic teams chose areas to focus on to improve their diagnosis and treatment of VVA. The practice facilitation sessions were structured to provide a 20 credit *performance improvement project*. Participating clinicians were asked to attend meetings, review data, complete the spaced education modules and provide a reflection at the end in order to receive the 20 credits.

Educational gaps were identified and learning objectives developed for each of the four educational activities: the Shared Decision Making Spaced Education, the Understanding Vulvovaginal Atrophy Spaced Education, the Academic Detailing session and the Performance Improvement activity.

Educational Activity	**Educational Gaps**
Understanding Vulvovaginal Atrophy, Its Prevalence, and Impact on Postmenopausal Women (Spaced Education)	Knowledge of the prevalence of VVA and its impact on post-menopausal women. Knowledge of the symptoms of VVA in post-menopausal women. Ability to evaluate the evidence, risks and benefits of available VVA treatments.
Shared Decision Making and Its Role in Patient Care (Spaced Education)	Knowledge of the process of shared decision making and the role it plays in patient care. Ability to evaluate the evidence for shared decision making. Identification of the risks and benefits of using shared decision making in your practice.
Academic Detailing Session	Knowledge about the prevalence of VVA, as well as its symptoms and impact on post-menopausal women Application of the shared decision making process when talking about and treating VVA Understanding of the details of this clinical study
Performance Improvement	Application of practice facilitation to implement a quality improvement team project. Use of shared decision making in the diagnosis and treatment of VVA Recognition of the need to initiate the conversation and raise awareness of VVA

B. Data Sources/Collection

Clinician and Staff Data Sources

Clinician/staff pre evaluation: At the initial academic detailing session all attendees were asked to complete a pre-project survey. Any staff that missed the initial academic detailing session but wanted to participate in the project including the spaced education and the practice facilitation were asked to also complete the pre-evaluation.

Clinician/staff post evaluation: At the conclusion of the of the practice facilitation each participating clinician and staff member was asked to complete the post-evaluation. Those that had participated fully to receive the 20 credit performance improvement CME were asked to complete three reflection questions.

Educational activity evaluation reports: Each educational activity has its own activity evaluation report. The activity reports include summary information on the activities as well as summary learner results on the activity evaluations. Each activity required learners to complete a post activity evaluation. The two Spaced Education activities required completion in order for learners to print CME certificates. The clinician/staff pre-evaluation was completed and collected at the academic detailing session. The clinician/staff post-evaluation was completed and collected at the final practice facilitation session. The collective results were evaluated for each report. The evaluation reports are listed in **6. LIST OF PUBLICATIONS AND PRODUCTS** and provided as a separate attachment to the final report.

Diagnosis frequency: Diagnosis frequency was extracted from EHR data for each site. The patients eligible for the denominator for the calculation were identified using a standard definition of "active patient" having at least 2 office visits at the site with one of the participating clinicians in the 3 years prior to the academic detailing date. Using the denominator population, all patients were identified with either "Postmenopausal atrophic vaginitis" (ICD9 code 627.3 or ICD10 code N95.2) or "Vulvar atrophy" (ICD9 code 624.1 or ICD10 code N90) for the numerator.

Progress note documentation: Chart review was conducted for all eligible patients seen by participating clinicians during the year before their academic detailing meeting to 1 year after. Patients were eligible for chart review if they were 35 to 80 years old during that 2 year period of time, had a diagnosis of vaginal atrophy or vulvar atrophy that was newly diagnosed or had a change of therapy.

Patient Data Sources

Patient enrollment in VVA SDM process (Patient survey): Patients at participating sites were invited by clinic staff to enroll in an assessment of the SDM process. Patients were eligible to enroll if they: 1) were between ages 35 to 80; 2) Had a diagnosis of VVA; 3) Did not have a history of breast cancer. Data was collected by telephone survey at enrollment before viewing the VVA decision aid and 2 months after viewing the decision aid and completing follow-up communication with the clinician in person, by email or phone.

Patients Emmi Solutions VVA Decision Aid. Patient decision aid use data was generated by a report of computer tracked progress through each section of the decision aid identified by patient specific code.

Chart review was conducted as noted above to extract patient symptom, evaluation, current VVA treatments and recommended VVA treatments or changes in treatment. An electronic health record data pull was conducted at each study clinic for women ages 35-80 with no history of breast or gynecologic cancers and a diagnosis code of 627.3 (vaginal atrophy). The visit associated with the diagnosis code 627.3 was eligible for review if a new diagnosis of VVA was made at that visit or if there was a change in treatment for VVA. The date of that visit was documented as the "index visit" and was also used to determine if the patient was pre or post intervention. The same patients were not used for both pre and post-intervention chart review. If a visit date on the patient list did not reveal a new diagnosis of VVA or a change in treatment, the following terms were searched in the EHR: atrophy/atrophic, vaginal/vaginitis, estrogen, and dryness. If another visit date was indicated a new diagnosis of VVA or change in treatment, the date was confirmed to be within the project pre/post-intervention time period and was reviewed.

C. Measures

Patient surveys included questions about symptoms based on the Menopause-Specific Quality of Life Questionnaire (MenQOL)[v] using the same format and same exact wording for "hot flashed or flushes", "difficulty sleeping", "frequent urination", "Involuntary urination when laughing or coughing", "Change in your sexual desire", "Vaginal dryness during intercourse", and "Avoiding intimacy". Using the same method, other symptoms were assessed based on the list from the North American Menopause Society Menopause Health Questionnaire.[vi] Additionally, we used a single question screen to assess health literacy level.[vii]

There are no standardized instruments for the factors assess in the clinician and staff surveys. These surveys were developed based on previous survey questions and methods used by the project team in the past and tested internally for understandability and usability.

Data was analyzed using repeated measures cross-sectional comparisons which account for the clustered effects. Identification by time comparisons for diagnosis frequencies was used to determine effect variation over time. Descriptive statistics were used to create summed scores for the VVA management, diagnosis frequency, knowledge about VVA and MenQOL measures. Paired t tests were used to analyze the continuous measures; pre–intervention and post–intervention results will be compared.

D. Strengths

This project was conducted in the Midwest and eastern regions of the country at 16 sites with Family Medicine, General Internal Medicine and Gynecology clinics within multiple health care systems. Two different research networks completed a similar process in clinician and staff education and patient study enrollment. All patient education and clinician and staff education and interventions were identical. Resources were shared throughout the entire 2.5 year project. Project team meetings were held at regular intervals throughout the entire time frame.

We received positive feedback on our patient and clinician education materials. Many participating clinicians commented that the Shared Decision Making educational activity is far more difficult and complex than they expected. We were approached by other departments including oncology to revise and share our patient education materials for women experiencing VVA as a result of cancer treatment.

While we do not know how many clinicians in oncology are actively using our materials, we do know that they have been distributed and we have received additional positive comments. Clinicians have commented that they appreciate the Emmi Decision Aid and having a program to direct patients to watch and consider. Women who completed the clinical study provided positive feedback in their completion surveys.

E. Limitations

A number of limitations and barriers occurred through the course of the project.

Limitations include:

1) We forgot to obtain age data for the participating staff and clinicians. We did not discover this until very recently and will endeavor to obtain this data for our manuscripts for publication.

2) The patient survey population is primarily non-Hispanic white, affluent with adequate health literacy. It is not clear if a SDM process would work as well or have the same benefits for other populations.

3) We have no comparison group for the patient survey, so it is unknown is a SDM process resulted in better patient outcomes than usual care.

4) The patient chart review population is primarily non-Hispanic white, with commercial or Medicare insurance. It is not clear if a SDM process would have similar results for other populations.

5) We have not completed all of the analysis yet.

Barriers include:

1) Project Planning Barriers:

- Delay in IRB approval in 2014.
- Clinic recruitment was difficult and took longer than anticipated. The VVA topic was not an area of high interest in gaining clinic participation, although there was more interest in learning about shared decision making, especially in the gynecology clinics.

2) Intervention Barriers:

- Enrolling the Spaced Education modules was difficult. The Spaced Education was started too far in advance of the beginning of the academic detailing and practice facilitation. There were several barriers to the spaced education enrollment: staff enrolled that weren't knowledgeable about the project, staff enrolled did not routinely check email and missed invitations or couldn't keep up with the education.
- All of our participating sites had difficulty identifying eligible patients for the survey project including high volume gynecology clinics. Many patients were already adequately treated at the gynecology sites and many of the family medicine sites had relatively younger populations with insufficient numbers of post-menopausal patients.
- Patient use of the Emmi decision aid has been lower than anticipated/desired for patients that were not interested in study but given a referral to watch the Emmi too.

- The Emmi tool was developed to allow to viewers to answer questions, take notes and print a summary report. This design meant that it couldn't be watched on a smart phone, tablet or iPad. While this was not initially considered a barrier, in review, we now feel it was a limiting factor in patients viewing the tool.
- Fewer non-study or patient recruitment clinicians participated in the educational activities than we had hoped to engage.

3) Data gathering Barriers:

The data gathering from the medical records was very time consuming and difficult. The Wisconsin clinics are not on the same electronic health record so each data pull (both pre and post) was a very manual process.

5. RESULTS

A. Principal Findings

Our primary outcome was to change clinician behavior. We accomplished this goal based on clinicians' self-reported increased frequency of always screening for VVA symptoms and adding VVA diagnoses to the EHR problem list. Unfortunately, we have not completed analysis of chart review data to assess changes in behavior for evaluation and treatment recommendations documented in the medical record.

A secondary goal was to improve the quality of life for patients with VVA. There was significant improvement for virtually all VVA symptoms with decreased pain with intercourse having the most dramatic improvement of 2.2 points on a 0-6 point scale.

Patients were overwhelming positive about the SDM process. Positive responses included: 1) 76% of the patients that went through the SDM process liked the VVA decision aid; 2) 94% agreed that their treatment decision was consistent with their personal values; 3) 87% were satisfied with the decision they made; and 4) 85% will recommend the SDM process to their friends.

Based on overwhelmingly positive responses by patients completing the SDM process, clinicians delivered many key elements of SDM. Patients agreed with the following statements: 1) My clinician wanted to know exactly how I wanted to be involved in making the decision. (74%); 2) My clinician told me that there are different options for treating my vulvovaginal atrophy. (92%); 3) My clinician helped me understand all the information. (88%); 4) My clinician and I selected a treatment option together. (67%); and 5) I had as much input as I wanted in the choice of treatment for my problem. (93%).

B. Outcomes

Clinic Outcomes

16 clinics participated; eight in Wisconsin and eight in North Carolina. Five of the clinics were Obstetrics and Gynecology or Gynecology only, 10 were Family Medicine and one was a General Internal Medicine clinic. Two Family Medicine clinics dropped out of the study shortly after starting due to clinicians leaving unexpectedly with substantially increased workload of remaining clinicians and staff.

The following table reflects clinic staff participation in the educational offerings. A total of 146 individual clinicians and staff participated in at least one of the educational activities: spaced education, academic

detailing, or performance improvement. Additional staff members might have been included at the clinic level but did not receive any form of educational credit from IPMA. 43 of the participating clinicians provided direct patient care.

Specialty	Number of sites	Clinicians enrolling survey patients	Clinicians not enrolling	Staff
Wisconsin Clinics				
Family Medicine	10	12 MD/DO 5 PA 7 NP	5 MD 2 PA 1 NP	7 RN 19 MA/LPN 5 Other
Ob/Gyn or Gyn only	5	13 MD/DO 3 NP	4 MD 3 NP	7 RN 7 MA/LPN 24 other
Internal Medicine	1	3 MD	1 NP	1 RN 3 MA/LPN 1 Other

Clinician Education Summary

41 clinicians participated and received credit for all four individual educational activities offered as part of this program. 97 clinicians and staff received credit for the Spaced Education module on Shared Decision Making, 90 clinicians and staff received credit for the Spaced Education module on VVA, 107 received one credit for the Academic Detailing sessions and 59 completed all elements to receive the 20 performance improvement CME credits.

Participation in Education Activities

	VVA Spaced Ed n=97	SDM Spaced Ed n=90	Academic Detailing n=107	PI CME n=59	All Activities n=41
MD/DO	30	27	33	11	11
NP	12	12	12	7	5
PA	7	6	8	5	5
RN	12	12	15	10	10
Other	36	33	39	26	10

1) Clinician and staff surveys:

Clinician and staff evaluation data was gathered on 121 clinicians/staff. 67 clinicians and staff completed the pre and post evaluation and of those 67, 31 were clinicians. As changing clinician behavior was the focus of our project, we concentrated on analyzing the pre- post- intervention clinician survey results. There were a total of 31 clinicians (9 APNP, 5 PA, 2 DO, and 15 MD) who completed both a pre and post survey as part of project evaluation during the initial academic detailing session and at the last practice facilitation session.28 were female and 3 were male. Thirteen out of 14 of the study clinics had one or more clinicians complete both surveys. The following clinic specialties were represented: 20 Family Medicine, 2 Internal Medicine and 9 OB/GYN. Of the 31 clinicians who completed both surveys, 54.8%

(17) had previously attended a planning or discussion meeting for a Quality Improvement project and only 38.7% (12) had actively participated in a project that included practice facilitation.

Other descriptors of the study clinicians: The majority of clinicians were somewhat familiar with SDM before the educational program, although anecdotally, many comments were made during the practice facilitation about how hard and time consuming it was to apply all the SDM concepts and methods in actual practice. After completing practice facilitation, the majority of clinicians plan on continuing to use SDM methods for developing treatment plans and wanted to use the educational methods again in the future. See tables below.

Descriptors of study clinicians (pre-practice facilitation sessions) (study clinicians who completed both pre and post surveys (N=31))

Statement	**N (%)**			
	Strongly disagree/Disagree	*Neutral*	*Agree/Strongly agree*	*Refused/ Missing*
1. I fully understood how to do shared decision making before I went through the educational program	17 (54.8)	5 (16.1)	9 (29)	0 (0)
2. I had used shared decision making with patients before I went through the educational program	8 (25.8)	3 (9.7)	20 (64.5)	0 (0)
3. I have used paper or computer shared decision making decision aids with patients in the past	18 (58.1)	1 (3.2)	12 (38.7)	0 (0)
4. I have used a VVA shared decision making decision aid with patients in the past	27 (87.1)	2 (6.5)	2 (6.5)	0 (0)
5. I will use email/internet spaced education for future educational programs	2 (6.5)	4 (12.9)	24 (77.4)	1 (3.2)
6. I will recommend using email/internet spaced education to my colleagues	2 (6.5)	6 (19.4)	23 (74.2)	0 (0)
7. Academic detailing presentation was effective	1 (3.2)	1 (3.2)	28 (90.3)	1 (3.2)
8. Academic detailing presentation was appropriate for my practice	1 (3.2)	1 (3.2)	28 (90.3)	1 (3.2)
9. Academic detailing information was fair, balanced and free of commercial bias	1 (3.2)	3 (9.7)	26 (83.9)	1 (3.2)

Descriptors of study clinicians (post-practice facilitation sessions) (study clinicians who completed both pre and post surveys (N=31))

Statement	**N (%)**		
	Strongly disagree/Disagree	*Neutral*	*Agree/Strongly agree*
1. I intend to use the VVA internet Decision Aid in the future	3 (9.7)	3 (9.7)	25 (80.7)
2. I intend to use shared decision making with patients with symptomatic VVA in the future	1 (3.2)	0 (0)	30 (96.8)
3. I will use the VVA patient education documents from this project in the future	2 (6.5)	0 (0)	29 (93.6)
4. Practice facilitation helped us change our workflows	4 (12.9)	8 (25.8)	19 (61.3)
5. I intend to use shared decision making while treating patients with other diagnoses in the future	0 (0)	5 (16.1)	26 (83.9)
6. Participation in this program was worth my time	2 (6.5)	4 (12.9)	25 (80.7)
7. I want to participate in similar educational programs in the future	3 (9.7)	9 (29)	19 (61.3)

Clinicians were ask how much they agreed or disagreed ((scale: 0 for “strongly disagree” to 4 for “strongly agree”) with statements about screening for VVA and putting VVA diagnosis on the problem list before and after the educational intervention. There was significant improvement in self-reported behaviors. See Table below. The percentage of clinicians who agreed/strongly agreed with screening for VVA increased from 41.9% to 74.2% pre and post survey. The percentage of clinicians who

agreed/strongly agreed with adding VVA to the problem list increased from 51.6% to 74.2% pre and post survey.

VVA: clinician screening and adding to the problem list (scale: 0 for "strongly disagree" to 4 for "strongly agree")

	Pre				Post				
Statement	**Mean**	**N**	**Range**	**SD**	**Mean**	**N**	**Range**	**SD**	**p-value**
1) I screen all my post-menopausal patients for VVA	2.2	31	0-4	1.3	2.8	31	1-4	0.9	.002
2) I always add vaginal atrophy to the problem list after making initial treatment recommendations	2.4	31	0-4	1.3	3.0	31	1-4	0.9	.002

α=.05; Paired T-test was used

Commitment to Change

We also asked questions about intention to change and actual self-reported change. Not surprisingly, not quite as much change was reported compared to intention to change. A majority of clinicians reported moderate or a lot of change for screening for VVA symptoms, frequency of screening for VVA symptoms, use of SDM and documentation in the electronic health record. See tables below.

Commitment to change (pre-intervention) (study clinicians who completed both pre and post surveys (N=31))

Statement	**N (%)**			
	No commitment/Low level of commitment	*Neutral*	*Commitment to change/High level of commitment*	*I already do this*
1. Screen all menopause patients for VVA symptoms	0 (0)	3 (9.7)	26 (83.9)	2 (6.5)
2. Put vaginal atrophy diagnosis on problem list	0 (0)	1 (3.2)	27 (87.1)	3 (9.7)
3. Use VVA shared decision patient internet tool*	1 (3.3)	3 (10)	26 (86.7)	0 (0)
4. Use project VVA patient education documents	1 (3.2)	2 (6.5)	28 (90.3)	0 (0)
5. Use shared decision tools in treating patients with other diagnoses	0 (0)	5 (16.1)	25 (80.7)	1 (3.2)

*only 30/31 clinicians answered this statement

Change in practice (post-intervention) (study clinicians who completed both pre and post surveys (N=31))

Statement	**N (%)**			
	No change/A little change	*Some change*	*Moderate change/A lot of change*	*I was already doing this*
1. How we screen for VVA symptoms	7 (22.6)	2 (6.5)	20 (64.5)	2 (6.5)
2. How often I screen for VVA symptoms	6 (19.4)	3 (9.7)	19 (61.3)	3 (9.7)
3. Adding vaginal atrophy to the problem list	9 (29)	4 (12.9)	16 (51.6)	2 (6.5)
4. How we document about VVA in the EHR	8 (25.8)	6 (19.4)	15 (48.4)	2 (6.5)
5. Using shared decision making for VVA in my practice	3 (9.7)	8 (25.8)	18 (58.1)	2 (6.5)
6. Using the VVA patient Decision Aid	5 (16.1)	5 (16.1)	21 (67.7)	0 (0)
7. Use of shared decision tools in treating other diagnoses*	9 (30)	9 (30)	11 (36.7)	1 (3.3)

*only 30/31 clinicians answered this statement

Practice-facilitation evaluation

Clinicians and staff were asked questions about practice facilitation at the final meeting in the post-intervention survey. Post- intervention survey results showed a large majority of participants agreed that PF was effective. See tables below.

Practice facilitation - clinicians (post-practice facilitation sessions) (study clinicians who completed post surveys (N=32))

Statement	N (%)			
	Strongly disagree/ Disagree	*Neutral*	*Agree/Strongly agree*	*Refused/ Missing*
1. Practice facilitation sessions addressed protocol and process changes needed to integrate the VVA SDM process and clinical study into our regular workflow	1 (3.1)	4 (12.5)	26 (81.3)	1 (3.1)
2. Practice facilitation sessions provided ongoing support and shared learning at our clinic	1 (3.1)	4 (12.5)	26 (81.3)	1 (3.1)
3. Practice facilitation sessions provided tools and recommendations for the long-term sustainability of VVA shared decision making beyond the clinical study	2 (6.3)	5 (15.6)	24 (75)	1 (3.1)

Practice facilitation - staff (post-practice facilitation sessions) (study staff who completed post surveys (N=42))

Statement	N (%)			
	Strongly disagree/Disagree	*Neutral*	*Agree/Strongly agree*	*Refused/ Missing*
1. Practice facilitation sessions addressed protocol and process changes needed to integrate the VVA SDM process and clinical study into our regular workflow	0 (0)	7 (16.7)	34 (81)	1 (2.4)
2. Practice facilitation sessions provided ongoing support and shared learning at our clinic	0 (0)	7 (16.7)	34 (81)	1 (2.4)
3. Practice facilitation sessions provided tools and recommendations for the long-term sustainability of VVA shared decision making beyond the clinical study	0 (0)	9 (21.4)	32 (76.2)	1 (2.4)

Diagnosis frequency demographics for all study clinics:

Diagnosis frequency data for all of the study clinicians' patients with a diagnosis code of 627.3 (vaginal atrophy) or 624.1 (vulvar atrophy) during a specific timeframes based on the stepped-wedge design was collected for each study clinic, but has not yet been analyzed. Demographic data will show the total number of patients included in the numerator along with the average age, standard deviation and range.

Patient Participant and Chart Review Outcomes

There are four sets of outcomes for the patients in the study.

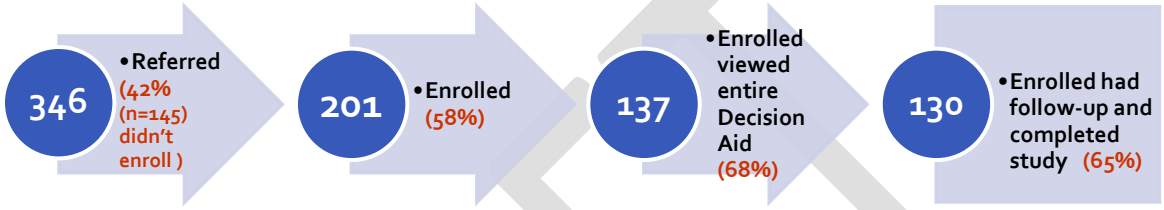
- Patient survey participants self-report through the pre and post evaluation documents for symptoms and study participation

- Patient completion rate of Emmi Solutions Shared Decision Making patient engagement tool
- Medical record review pre and post for diagnosis and symptoms

Patient Survey Summary

One hundred thirty patients completed the entire study, including pre and post-SDM process surveys.

- Patients who completed entire study: 130/201 enrolled (65%)
- Mean Age 58
- Age Range: 42 – 76



Of those referred, but were not enrolled: 23 were not eligible; 51 declined participation; and 71 were unable to be reached.

Patient Survey Participant Demographics

This population is mostly non-Hispanic white, well educated, mostly affluent with adequate health literacy.

Patient demographics (of those enrolled in the study who completed both pre and post surveys)		
Characteristics	**N (%)**	**Mean (SD)**
Female	**130** (100)	
Age (years)		57.9 (7.4) Range: 42-76
Race		
White or Caucasian	120 (92.3)	
Black or African American	7 (5.4)	
American Indian or Alaskan Native	2 (1.5)	
Asian	1 (0.8)	
Native Hawaiian or Pacific Islander	0 (0)	
Other	3 (2.3)	
Ethnicity		
Hispanic or Latino	4 (3.1)	
Non-Hispanic or Latino	126 (96.9)	
Highest education completed		
Less than 12 years	1 (0.8)	
High school	24 (18.5)	
Up to 4 years of college	71 (54.6)	
Any post-graduate work	34 (26.2)	
Total household income before taxes		
Prefer not to answer	17 (13.1)	
Less than $10,000-$29,999	14 (10.8)	
$30,000-$49,999	20 (15.4)	

$50,000-$99,999	36 (27.7)
$100,000 or above	43 (33.1)
Living situation	
Alone	26 (20)
With 1 or more other people	104 (80)
Heard of the terms “vaginal atrophy” or “vulvovaginal atrophy”	
Yes	54 (41.5)
No	76 (58.5)
Heard of the term “shared decision making”	
Yes	64 (49.2)
No	66 (50.8)
Has used a paper or internet shared decision aid with a health care provider to reach a decision on treatment for a specific health condition	
Yes	17 (13.1)
No	113 (86.9)
Confidence in filling out forms by self (health literacy measure)	
Not at all/A little bit/Somewhat	4 (3.1)
Quite a bit	27 (20.8)
Extremely	99 (76.2)

Patient Survey Self-Reported VVA Symptoms

Patient survey participants were asked if they had specific VVA related symptoms in the past month and if they had the symptom, how much they were bothered by the symptom on a scale of 0 (not bothered at all) to 6 (extremely bothered).

There was significant improvement for virtually all VVA symptoms with decreased pain with intercourse having the most dramatic improvement of 2.2 points on the 0-6 point scale.

Pre-post treatment data has been collected for those patients who completed both pre and post surveys, but has not yet been analyzed. Patients were asked about which treatment options they have heard of to help alleviate VVA symptoms. They were then asked if they have ever used any options to help their own symptoms and whether or not they were currently using any at the time of the survey.

VVA and related symptoms									
	Pre				**Post**				
Problem	**Mean**	**N**	**Range**	**SD**	**Mean**	**N**	**Range**	**SD**	**p-value**
Hot flushes or flashes	1.9	130	0-6	2.0	1.4	130	0-6	1.8	<.001
Difficulty sleeping	2.8	130	0-6	2.0	2.0	130	0-6	1.9	<.001
Frequent urination	2.1	130	0-6	2.2	1.3	130	0-6	1.7	<.001
Involuntary urination when laughing or coughing	1.9	130	0-6	2.0	1.2	130	0-6	1.7	<.001
Frequent urinary tract infections	0.6	130	0-6	1.5	0.2	130	0-6	1.0	.02
Change in your sexual desire	2.0	130	0-6	2.3	1.2	130	0-6	2.0	<.001
Vaginal dryness during intercourse	3.6	130	0-6	2.4	1.9	130	0-6	2.1	<.001
Avoiding intimacy	2.2	130	0-6	2.3	1.4	130	0-6	2.1	<.001

Pain with intercourse	2.9	130	0-6	2.6	1.3	130	0-6	1.9	<.001
Vulvar itching or burning	1.7	130	0-6	2.1	0.9	130	0-6	1.5	<.001
Composite score	21.7	130	0-60	13.0	12.8	130	0-60	10.6	<.001

α=.05; Paired T-test was used

Patient Survey Self-Reported Views on Decision Process

Patient survey participants were asked to rate how much they agreed or disagreed with each statement at the time of the survey: strongly disagree, disagree, neither disagree or agree, agree, strongly agree or no opinion.

Patients were overwhelming positive about the SDM process. Positive responses included: 1) 76% of the patients that went through the SDM process liked the VVA decision aid; 2) 94% agreed that their treatment decision was consistent with their personal values; 3) 87% were satisfied with the decision they made; and 4) 85% will recommend the SDM process to their friends.

Based on overwhelmingly positive responses by patients completing the SDM process, clinicians delivered many key elements of SDM. Patients agreed with the following statements: 1) My clinician wanted to know exactly how I wanted to be involved in making the decision. (74%); 2) My clinician told me that there are different options for treating my vulvovaginal atrophy. (92%); 3) My clinician helped me understand all the information. (88%); 4) My clinician and I selected a treatment option together. (67%); and 5) I had as much input as I wanted in the choice of treatment for my problem. (93%).

Decision process on treating vulvovaginal atrophy (N=130))

Statement	**N (%)**		
	Strongly disagree/Disagree	*Neither disagree or agree/No opinion*	*Agree/Strongly agree*
1) My clinician made clear that a decision needs to be made.	31 (23.8)	45 (34.6)	54 (41.5)
2) My clinician wanted to know exactly how I wanted to be involved in making the decision.	9 (6.9)	23 (17.7)	98 (75.4)
3) My clinician told me that there are different options for treating my vulvovaginal atrophy.	1 (0.8)	10 (7.7)	119 (91.5)
4) My clinician helped me understand all the information.	1 (0.8)	15 (11.5)	114 (87.7)
5) My clinician asked me which treatment option I prefer.	11 (8.5)	10 (7.7)	109 (83.8)
6) My clinician and I thoroughly weighed the different treatment options.	12 (9.2)	22 (16.9)	96 (73.8)
7) My clinician and I selected a treatment option together.	16 (12.3)	27 (20.8)	87 (66.9)
8) My clinician and I reached an agreement on how to proceed.	6 (4.6)	16 (12.3)	108 (83.1)
9) I was adequately informed about the different treatment options for my problem.	4 (3.1)	13 (10)	113 (86.9)
10) The decision I made was the best decision possible for me personally.	2 (1.5)	15 (11.5)	113 (86.9)

11) My decision was consistent with my personal values.	0 (0)	8 (6.2)	122 (93.8)
12) I expect to continue to carry out the decision I made.	3 (2.3)	15 (11.5)	112 (86.2)
13) I had as much input as I wanted in the choice of treatment for my problem.	1 (0.8)	8 (6.2)	121 (93.1)
14) I am satisfied with the decision that was made about treatment for my problem.	2 (1.5)	15 (11.5)	113 (86.9)
15) I was annoyed that I had to see my clinician again after I went through the internet VVA program.	103 (79.2)	18 (13.8)	9 (6.9)
16) I will recommend using the internet VVA program to my friends.	7 (5.4)	24 (18.5)	99 (76.2)
17) I will recommend this shared decision making process to my friends.	5 (3.8)	14 (10.8)	110 (84.6)

Pre-post treatment data has been collected for those patients who completed both pre and post surveys, but has not yet been analyzed. Patients were asked about which treatment options they have heard of to help alleviate VVA symptoms. They were then asked if they have ever used any options to help their own symptoms and whether or not they were currently using any at the time of the survey.

Viewing and Completion Rates of Patient Shared Decision Making Aid

Clinicians were asked to provide access to the Emmi Solutions Shared Decision Making aid to all patients that referred to the study, even those that were not interested in study participation. A total of 240 views were made of the Shared Decision Making tool. Of those views, 167 completed the entire program and 130 of the completions came from patients enrolled in the patient survey study. The following chart depicts completion rates and clinic assignment.

Type of Referral	100% Completion n=167	50 - <100% Completion n=44	10 – <50% Completion n=29
Family Medicine/Internal Medicine Clinic	81 49%	6 14%	10 34%
Ob/Gyn Clinic	75 45%	31 70%	14 48%
Patient referred to decision aid but not interested in study	4 2%	3 7%	1 3%
Unable to determine affiliation	7 4%	4 9%	4 14%

Patient Chart Review *Summary*

Chart reviews were conducted for 755 patients from all of the study clinics (370 pre-intervention and 385 post-intervention). The mean age was 60.3 and the majority of patients were non-Hispanic white, with commercial or Medicare insurance. See chart below.

Patient demographics (of those included in chart reviews from every study clinic)		
Characteristics	**N (%)**	**Mean (SD)**
Female	**755** (100)	
Age (years)		60.3 (8.5) Range: 36-79
Race		
White or Caucasian	675 (89.4)	
Black or African American	49 (6.5)	
American Indian or Alaskan Native	2 (0.3)	
Asian	13 (1.7)	
Native Hawaiian or Pacific Islander	0 (0)	
Other/Declined/Unknown	16 (2.1)	
Ethnicity		
Hispanic or Latino	14 (1.9)	
Non-Hispanic or Latino	725 (96)	
Declined/Unknown	16 (2.1)	
Insurance Status		
Commercial	459 (60.8)	
Medicare	272 (36)	
Medicaid	11 (1.5)	
No insurance	12 (1.6)	

VVA Documented Symptoms

321/370 (86.8%) reported any symptoms at index visit pre-intervention and 321/385 (83.4%) at index visit post-intervention. The mean number of symptom categories per patient was essentially the same pre and post-intervention at 1.7. The number of patients reporting a variety of symptoms is reported in the table below.

Overall pre-post chart review data was collected for current treatments and recommendations of patients, but has not yet been analyzed. Future data analysis will also provide a more comprehensive statistical analysis as well as results for OB/GYN vs primary care clinics a part of the study and data on follow-up 1 and 2 visits for each patient included in chart review.

Reported VVA symptoms at index visit (for all patients included in chart reviews from all study clinics)

	Pre (N=370;		**Post (N=385;**	
VVA symptom	**N**	**%**	**N**	**%**
Dryness/Decreased lubrication	135	36.5	157	40.8
Urinary tract symptoms	109	29.5	116	30.1
Vaginal insertion pain/Tightness	125	33.8	130	33.8
Pain/Pressure/Burning/Irritation	80	21.6	74	19.2
Discharge/Odor	44	11.9	38	9.9
Itching	29	7.8	27	7
Bleeding	24	6.5	29	7.5
Other	17	4.6	22	5.7
No documented symptom	49	13.2	64	16.6

Columns do not sum to 100% because some patients reported more than one symptom

VVA Documented Evaluation

Examination and testing documentation is reported in the table below. Analysis for pre-post changes is in process.

Type of evaluation at index visit* (for all patients included in chart reviews from all study clinics)				
	Pre (N=370)		**Post (N=385)**	
Type of Evaluation	**N**	**%**	**N**	**%**
Physical exam	275	74.3	316	82.1
Pelvic exam	309	83.5	285	74
Wet prep/vaginal smear	43	11.6	31	8.1
Vaginal pH	0	0	1	0.3
Vaginal Maturation Index	0	0	0	0
Other	20	5.4	22	5.7
None	16	4.3	16	4.2

*More than one type of evaluation may have occurred at an index visit

Current Treatments and Recommendations

Overall pre-post chart review data was collected for current treatments and recommendations of patients, but has not yet been analyzed. Future data analysis will also provide a more comprehensive statistical analysis as well as results for OB/GYN vs primary care clinics a part of the study and data on follow-up 1 and 2 visits for each patient included in chart review.

C. Discussion

This project tested a new combination of established evidence-based medical education interventions to change clinician behavior as it relates to using Shared Decision Making in the process of developing a treatment plan for patients with symptomatic Vulvovaginal Atrophy. It appears that we accomplished this goal based on self-reported change in behavior and patient survey reports of clinician behavior. The majority of clinicians and patients liked the SDM process and most of the clinicians plan on continuing to use their new skills. Our analysis is incomplete and ongoing at this time. Whether our intervention changed the frequency of diagnosis of VVA or clinician documented behaviors based on chart review is unknown at this time.

Although limited due to a lack of a control group, the patient-centered outcome of VVA associated symptoms significantly improved for all symptoms assessed.

Clinicians were generally supportive of the concepts of SDM, learned the key elements of SDM and performed the key elements of SDM for this project. However, there were many antidotal reports of concerns about the time required to do all the SDM elements, the 30 minute time required for patients to view the decision aid and patient reluctance to return for a visit to finish the discussion after viewing the decision aid. It is interesting to note that when asked if they were annoyed by the need to return for a follow up visit with the clinician after viewing the VVA computer Decision Aid, very few patients were annoyed. It appears that the clinician's concerns about patient reluctance to attend a return visit are unfounded. Unfortunately, the current health care environment, including time pressure on clinicians to see patients quickly, cost of co-payments for patient return visits and reimbursement rates for intellectual work compared to procedures, all work against broadly applying SDM methods during treatment decisions.

Some elements of our intervention were very time consuming to develop, especially the spaced-education knowledge assessment and transfer questions, and the computer Decision Aid. However once created for a particular topic, the spaced education questions and Decision Aid only require periodic updates based on new evidence which will be much less time consuming. Practice facilitation is also moderately time consuming for project staff and clinicians and their office staff. Although the literature is strong for the effectiveness of practice facilitation, it is not clear how many meetings are necessary to accomplish the desired changes. Based on our experience, the number of meetings seems to vary from site to site based on a variety of factors. More research about use of practice facilitation for clinician and staff behavior change is needed.

Completion of analysis of chart review data will reveal if documentation of symptoms, evaluation, current treatments and recommendations changed before and after the intervention.

D. Conclusions

General

Our methods of education and facilitating practice change were successful in a variety of practice sites in multiple health systems located in 2 states, in 2 regions of the country, suggesting our results can be generalized and reproduced elsewhere. These methods are also reproducible for a wide variety of healthcare topics and issues.

Patient Participants

Although not the focus of this project, patient participants overwhelmingly liked the SDM process in general and specifically liked the computer decision aid and printed educational handout. The overwhelming majority of patients will recommend the SDM process and the VVA computer Decision Aid to friends. Aggregated results of patient reported symptoms significantly improved for all symptoms accessed, often with dramatic improvement.

Clinician Participants

This multimodal educational strategy and Practice Facilitation supports change in physician behavior. The majority of clinicians would like to use these educational methods in the future. Based on patients' survey responses, clinicians used Shared Decision Making concepts and methods during their discussion with patients about treatment options. The majority of clinicians plan on using SDM methods for VVA and other medical condition in the future.

E. Significance

We believe that this project was the first to combine three evidence-based effective methods of clinician medical education into a program that successfully changed clinician behavior and positively impacted patient care. Spaced education provided knowledge assessment and knowledge transfer; academic detailing provided peer-to-peer reinforcement of the knowledge and motivation to apply the new knowledge in practice; and finally, practice facilitation provided the venue and assistance for clinicians and office staff to change work flows and processes and apply the new knowledge in their unique practice environment. This combination of adult educational methods can be applied to almost any medical topic or condition.

F. Implications

These methods of education and practice change are reproducible in other healthcare environments. The spaced education content can be used immediately and continue to be used until the content needs to be modified based on new evidence. Academic detailing is already fairly commonly used with minimal training. Practice facilitation is a set of skills that require a moderate amount of training and practice to be effective, but training programs exist such as the Agency for Healthcare and Research and Quality Practice Facilitation Handbook (http://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/index.html) . In addition, once the concepts and methods of Shared Decision Making have been learned and applied in one clinical situation, this patient-centered method of developing treatment plans can be applied to any appropriate clinical situation going forward without additional training.

6. LIST OF PUBLICATIONS AND PRODUCTS

Project Documents

Patient Education:

- Att 1: Emmi Shared Decision Making Aid Flyer
- Att 2: Clinic Hallway/Bathroom VVA Poster
- Att 3: Patient VVA Trifold
- Att 4: VVA patient information packet
- Att 5: VVA in women with breast cancer information packet

Clinician Education:

- Att 6: Treatment of VVA provider card

Evaluation Components:

- Att 7: VVA patient enrollment evaluation document
- Att 8: VVA patient follow-up evaluation document
- Att 9: Clinician and staff pre evaluation document
- Att 10: Clinician and staff post evaluation document

Clinician Education Evaluation Reports

- Att 11: Spaced Education - Understanding Vulvovaginal Atrophy, Its Prevalence, and Impact on Postmenopausal Women
- Att 12: Spaced Education - Shared Decision Making and Its Role in Patient Care
- Att 13: Academic Detailing Activity Evaluation Report
- Att 14: Performance Improvement Activity Evaluation Report

Summary Project Documents

- Att 15: Poster Presentation

List of Presentations:

- ✓ North American Primary Care Research Group, July 2016, Bethesda, Maryland

List of Poster Presentations:

- ✓ World Congress on Continuing Professional Development, March 2016, San Diego, California
- ✓ North American Menopause Society Annual Meeting, October 2016, Orlando, Florida
- ✓ Health Literacy and Annual Research Conference, October 2016, Boston, Massachusetts
- ✓ IPMA Primary Care Update, October2016, San Antonio, Texas

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