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

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Structured Abstract

**Background**: Symptomatic vulvovaginal atrophy (VVA, now known as genitourinary syndrome of menopause, GSM) affects up to 50% of postmenopausal women. Data from our health care system suggested that GSM was underdiagnosed. We conducted a cluster randomized trial to test the efficacy of clinician education and electronic health record (EHR) patient care tools for improving GSM diagnosis and treatment.

**Methods**: We randomized primary care (PC) and gynecology (GYN) clinics to intervention or control. From September–November 2014, we provided training about GSM diagnosis, treatment, and EHR tool use to clinicians in the intervention clinics only. We used EHR data from 11/15/14–11/15/15 to assess clinician use of tools and proportion of well (annual) visits with GSM-related diagnoses and prescriptions among women aged 55 and older.

**Results**: Educational training was completed by 107 (58%) clinicians. EHR tools were used more often by clinicians in the intervention compared to control clinics (p<.001). The proportion of well visits that included a GSM diagnosis (9.8% vs 8.2%) or vaginal estrogen prescription (4.4% vs 3.5%) did not differ between study arms. There was a significant moderating effect of clinic type on the effectiveness of the intervention, such that the GSM diagnosis rate was greater in the intervention compared to the control GYN clinics with no difference between arms in the PC clinics (OR=1.54, p=.01).

**Conclusions**: EHR tools are more likely to be used if clinician education is included; however, the efficacy of tools and education alone for improving diagnosis and treatment of GSM in nongynecologic practices is limited.

**Key words**: Genitourinary syndrome of menopause (GSM), randomized clinical trial, electronic medical record tools, vulvovaginal atrophy (VVA), postmenopausal women, clinician education, pragmatic clinical trial
Purpose

In an effort to improve the genitourinary care of postmenopausal women in our health care system, we conducted a clinic-based, cluster randomized trial to test the effect of an intervention to increase detection and treatment of symptomatic vulvovaginal atrophy (VVA, now known as genitourinary syndrome of menopause, GSM). The intervention included in-person and online GSM-specific education for clinicians in intervention clinics and a suite of electronic health record-based tools to assist clinicians in diagnosing GSM and in providing evidence-based treatments and information about GSM to their patients. Our specific aims were to determine whether, compared to control clinics, clinicians in the intervention clinics:

1) Diagnose VVA (GSM) more often among postmenopausal women
2) Prescribe vaginal estrogen more often for genitourinary disorders among postmenopausal women
3) Are more likely to use GSM-focused electronic health record tools to support patient care and education

As secondary outcomes, we evaluated provider knowledge and attitudes toward diagnosis and management of VVA (GSM), and determined whether patients in the intervention clinics were more likely to discuss vulvovaginal, urinary, and sexual concerns with their providers and to receive information about GSM-related conditions.

Scope

Background

The postmenopausal loss of estrogen from the genitourinary tract has substantial implications for the genitourinary care of aging women. The term vulvovaginal atrophy (VVA) was used in the past to describe the effect of the loss of estrogen on the vulva and vagina. More recently, because the urethra and bladder are also affected, the North American Menopause Society (NAMS) recently developed and now promotes a new term: genitourinary syndrome of menopause (GSM).¹

VVA (GSM) can have a significant impact on postmenopausal women’s sexual function, urinary function, and quality of life. Two online surveys of U.S. women aged 55-65 years, “Women’s Voices in the Menopause” and “Vaginal Health: Insights, Views, & Attitudes (VIVA),” found that approximately half of postmenopausal women (43% and 48%, respectively) had experienced symptoms related to VVA (GSM), including dryness, discomfort, and pain during intercourse.²,³ Further, over half of these women reported the symptoms as moderate to severe. But one-third of the symptomatic women (33% and 37%, respectively) had not discussed their
symptoms with a health care provider. Their reasons included embarrassment, the feeling that it was inappropriate to discuss symptoms with others, and the belief that the symptoms were a natural part of aging. Some (20%) said they preferred that their provider initiate a conversation about symptoms with them.

Professional organizations such as the North American Menopause Society (NAMS), the American College of Obstetrics and Gynecology (ACOG), and the Endocrine Society promote the routine evaluation and treatment of VVA (GSM) symptoms in maintaining menopausal health. However, results of patient surveys suggest that providers infrequently ask about VVA (GSM) symptoms. In a survey of 2,791 postmenopausal women with VVA (GSM) symptoms who indicated they had a health care provider for gynecologic needs, 19% of women indicated that their provider asked them about sexual health during a routine gynecologic exam, and 13% said the health care provider initiated a conversation with them about VVA (GSM) symptoms specifically. To our knowledge, there are no published surveys of U.S. primary care providers, i.e., providers in internal medicine and family practice, and/or gynecologists to assess their knowledge, attitudes, and practices related to VVA (GSM). Further, we did not identify any randomized trials that demonstrated effective interventions for improving GSM care at the clinician, clinic, or health care system level.

Context/Settings

Kaiser Permanente Northwest (KPNW) is a large, nonprofit, prepaid, federally certified, Joint Commission-accredited, integrated health-care delivery system with more than 550,000 members in western Oregon and Washington state. Members include individuals and families covered by commercial group and individual self-pay health plans, Washington State Basic Health Plan (subsidized, Washington state only), Medicare Advantage, and Medicaid (Oregon and Washington state). Of these, approximately 17% of members are females aged 55 and older.

Within KPNW are Family Medicine and Internal Medicine clinics (Primary Care, PC) and Obstetrics & Gynecology (GYN) clinics. Clinicians in both PC and GYN clinics provide routine well-woman and problem-focused care. A review of KPNW data showed that 83% of coded well visits for women aged 55 and older were performed by a PC clinician. The PC and GYN clinics span the KPNW region, which covers a large distance ranging from Longview, in Southwestern Washington, to Salem, in Northwestern Oregon. Some clinics house both PC and GYN clinicians.
Participants

There were two populations of interest for this study: 1) KPNW primary care and gynecology health care providers, and 2) KPNW postmenopausal female patients. The characteristics of the study participants are described in detail in the Methods section.

Methods

Study Design

In an effort to improve the genitourinary care of postmenopausal women in our health care system, we conducted a clinic-based, cluster randomized trial to test the effect of an intervention to increase the detection and treatment of symptomatic VVA (GSM).

The intervention included VVA (GSM)-specific education, both in person and online, for clinicians in the intervention clinics, and a suite of electronic health record-based tools to assist clinicians in diagnosing VVA (GSM) and in providing evidence-based treatments and information about VVA (GSM) to their patients. Control clinicians received no training or notification about the tools.
Prior to development of the intervention materials, we conducted a survey of primary care and gynecological clinicians to determine their knowledge about the prevalence and progression of VVA (GSM), their practices regarding diagnosis and treatment of VVA (GSM), and their perceived barriers to diagnosis and treatment. We tested for differences between primary care and gynecological clinicians regarding their knowledge, practice, and barriers to VVA (GSM) diagnosis.

The primary outcomes of the trial were the proportion of well visits for women aged 55 and older that resulted in a VVA (GSM)-related diagnosis and/or prescriptions in the year following the intervention (11/15/14-11/15/15). We also compared the use of the GSM-specific electronic health record tools across intervention and control clinics.

Finally, we conducted a survey of female patients aged 55 or older who were seen for well care in the PC and GYN clinics. We asked them questions regarding medical and prescription history, and vulvovaginal, urinary, and sexual symptoms, and asked about their experience regarding communication with their clinician on these topics.

**Clinician Survey**

We collaborated with the Northwest Permanente Continuing Medical Education and Professional Development Department (NWP CME) to conduct a survey of PC and GYN clinicians practicing ambulatory medicine at KPNW. The target population was clinicians who performed “well care” (annual or routine) visits for adult women. In our health system, these visits are conducted by physicians, nurse practitioners, certified nurse midwives, and physician assistants in the departments of Internal Medicine, Family Medicine, and Obstetrics and Gynecology. We categorized all clinicians with ambulatory clinic practices within Internal and Family Medicine as Primary Care (PC) providers and all clinicians practicing within the Obstetrics and Gynecology Department as GYN providers. A query of the KPNW electronic health record (EHR) in 2013 showed that 83% of visits coded as “well care” for women aged 55 and older are conducted by PC clinicians, and 17% are conducted by GYN clinicians.

The survey was submitted to NWP CME, where it was programmed using Survey Monkey (www.surveymonkey.com). In August 2014, the CME department sent an email request to complete the survey and the survey link to all PC and GYN clinicians (n=360) who had a valid email address. The survey was introduced to clinicians as a request to guide development of educational materials and support tools for the diagnosis and treatment of symptomatic
vulvovaginal atrophy. All data were collected electronically. There was a 4-week timeframe for completion, which included two email reminders to complete the survey.

**Intervention**

We chose to perform a clinic-based, rather than clinician-based, randomized trial because it was not feasible to provide a face-to-face intervention to clinicians one-on-one (there are over 400 PC and GYN clinicians in our region). Further, we know that clinicians practicing in the same clinic often share information regarding disease-specific treatments and patient care tools, and it would be difficult to prevent spread of knowledge and patient care practices between clinicians in the same clinic.

Because PC and GYN clinicians differ in their training and scope of practice, we wanted to ensure balanced randomization of the PC and GYN clinics. We examined the well-care visit volume of women aged 55 and older for each PC and GYN clinic and determined which clinics housed both PC and GYN clinicians. We used stratified randomization based on well-visit volume (high vs low) and medical specialty clinic (PC, GYN, or both PC and GYN) to ensure balance across the intervention (n=11) and control (n=11) groups and to prevent patient cross over and sharing of information between intervention and control clinics.

Once the clinics were randomized, we approached the lead physician at each clinic to obtain permission to attend either their monthly clinician education meeting or their monthly clinic staff meeting (which includes support staff as well as clinicians). Our preference was to attend the meetings that included support staff (nurses and medical assistants) to facilitate dissemination of information to patients.

Our educational package for intervention clinicians included the following: 1) a suite of electronic health record-based patient care tools specific to the diagnosis and treatment of GSM, 2) face-to-face educational presentations in the intervention clinics, and 3) an online educational video.

**Electronic Health Record Patient Care Tools**

We developed electronic health record-based tools for providers to use during patient encounters to facilitate GSM diagnosis, treatment, and advice. The tools included a SmartSet (Appendix 1), a SmartRx (Appendix 2), and SmartText (Appendix 3). (SmartSet, SmartRx, and SmartText are registered trademarks of Epic Systems Corporation.) A SmartSet is a topic-specific grouping of clinical guidelines, diagnoses, orders, referrals, and documentation templates, as well as links to place pre-written information (SmartText) in the patient’s "Aftervisit
Summary. A SmartRx contains diagnosis-specific medications with the correct dosing for quick ordering at the point of care. SmartText is written information that is intended to be provided to patients and is typically diagnosis specific. SmartText can be linked to a SmartSet or used by itself. The advantage of the SmartSet is that includes all diagnosis, treatment, and patient information text in one location. The advantage of the SmartRx is it can be used to quickly facilitate medication ordering at the point of care. We found during development of these tools that some clinicians prefer SmartSets and some prefer a SmartRx. The use of all of these tools can be tracked electronically.

In-Clinic Presentations

We conducted 20-minute in-clinic educational presentations (Appendix 4) with time for questions at each intervention clinic. For participating, clinicians received 0.5 hours AMA Category 1 Continuing Medical Education credit. We used the same PowerPoint slides and the same handouts at each clinic location. Presentations included information about the prevalence and diagnosis of symptomatic VVA (GSM), a review of evidence-based treatment strategies, a hands-on demonstration of various prescription and nonprescription treatment options, and handouts displaying the EHR tools.

Online Clinician Educational Video

The online educational video, a voiceover PowerPoint presentation (Appendix 5), was developed by the investigators and detailed the physiology and epidemiology of VVA (GSM), provided diagnosis and treatment information, and reviewed the electronic health record patient care tools. The KPNW Continuing Medical Education (CME) department facilitated the recording, posting and tracking of completion of the video. All clinicians in the intervention clinics were sent an email notifying them of the goal to improve the vulvovaginal health of our members and the link to the video. We were able to track completion of the video. We were not permitted to provide any incentive to clinicians to watch the video other than free CME credit (1.0 hour AMA Category 1 CME credit). Approximately 3 months after completing the in-person presentation, we sent reminders about watching the video to all intervention clinic clinicians who had not completed the video or attended an in-person presentation.

Patient Survey

The patient survey contained questions drawn from existing measures related to menopausal and genitourinary health issues as well as new items we designed to obtain information from patients regarding their health care experience. As part of survey development
and to get feedback from patients, we conducted three focus-group sessions of 8-12 women aged 50 and older and menopausal (defined as not having a menstrual period for 12 months). Only women who could read and speak English participated in the focus groups. Data from these groups were used to improve the survey instrument and make it accessible to women with a wide variety of socioeconomic and educational backgrounds. Focus group feedback provided crucial feedback to the development of the final survey.

Focus groups were coordinated by a facilitator. At the beginning of the session we reviewed the informed consent/authorization form and answered questions, then participants who consented to participate signed the form. The focus group facilitator introduced the study and the draft survey was distributed to participants, who were given as much time as needed to complete it. We used this opportunity to get an initial assessment of the length of the survey. When participants completed the survey, the facilitator used an interview guide to lead them in a discussion of the key issues such as the language used in the survey to describe the anatomy of the genitourinary region and potential genitourinary symptoms related to estrogen loss. We asked participants to give us feedback with questions or concerns regarding the survey. The focus groups met for approximately 90 minutes. Each participant attended only one focus group. The focus groups used a written version of the survey. Given that we intended to deliver the final survey electronically, we programmed the final survey into REDCap™ and had several volunteers among women in our target age range take the web-based version survey to provide feedback regarding its electronic usability prior to sending it to patients.

Our target population for the patient survey was female KPNW health plan members aged 55 years or older with a well-woman visit in PC or GYN between March and October 2015. We identified potentially eligible women using data from the KPNW electronic health record system. Each eligible woman with an email address on file in the EHR was sent an email invitation to take the online survey within one week of her well visit. The email invitation contained basic elements of informed consent and provided a link that took the respondent to a web page with a full informed consent letter. Interested respondents clicked a button on the web page noting their desire to participate and then answered questions to confirm eligibility and verify their identity. Women who did not respond to the survey invitation within a week were automatically sent the invitation a second time. The online consent, eligibility, and survey data collection were conducted using REDCap™. For completing the survey, participants received a $5 gift card delivered electronically.
Measures

Clinician Survey

The clinician survey (Appendix 6) had three content areas: 1) clinician knowledge of VVA (GSM), 2) practice behavior and confidence with regard to diagnosis and treatment of VVA (GSM), and 3) perceived barriers to diagnosis and treatment of VVA (GSM). Because GSM terminology was not in active use when we developed the survey, we used the terminology “vulvovaginal atrophy” and “VVA” rather than GSM.

Knowledge about VVA (GSM) prevalence, diagnosis, and treatment was assessed via eight multiple-choice questions. These questions were adapted from a complementary 2014 CME course called “Postmenopausal Vulvovaginal Atrophy: Breaking Down the Barriers to Identification and Treatment,” which was produced by Haymarket Medical Education and sponsored by NAMS. We reported the knowledge score as the proportion of correct responses.

The practice behavior section contained three questions regarding how likely the clinician was to assess for VVA (GSM) symptoms at a routine (well) visit; how confident they were in advising patients about VVA (GSM) symptoms; and how confident they were in counseling about the risks and benefits of local estrogen therapy. The responses contained a 5-point scale ranging from highly unlikely to highly likely and from very low to very high.

We also asked clinicians “Which of the following are barriers to identification and treatment of VVA (GSM) among patients in your practice?” A 12-item list was provided and clinicians were asked to “Check all that apply.”

A dataset of survey responses was provided by the NWP CME department to our team for analysis. To ascertain potential non-response bias, we compared responders to non-responders by age, gender, department of practice, and clinician type (physician vs non-physician health care provider). We examined descriptive statistics for all survey items to check for unrealistic or outlying values and assess missing data. To determine whether there were differences between PC and GYN providers on the three Likert scale-based practice questions, we performed multiple regression. For binary outcomes, which included the individual knowledge and barrier questions, we used multiple logistic regression. In all regression models, the independent variable was an indicator for provider department (GYN=1, PC=0), and covariates were age, sex and clinician type. We reported the unstandardized regression coefficients for the multiple regression analyses and odds ratios for the logistic regression analyses, along with 95% confidence intervals for these analyses.
EHR Data-Only Study

From the electronic medical record, we identified all well visits occurring in PC or GYN clinics from 11/15/14 through 11/15/15 using level of service codes (G0101, G0402, G0438, G0439, 99386, 99387, 99396, 99397), GSM diagnoses occurring at the visits using vulvovaginal and urinary ICD-9 and ICD-10 codes (Table 1), and prescriptions for vaginal estrogen or topical lidocaine products occurring at the time of the visit. We also evaluated clinician use of the SmartSet, SmartRx, and SmartText during the observation period.

| Table 1. International Classification of Disease Codes to Identify GSM Diagnoses |
|---------------------------------|--------|--------|
| Diagnosis                        | ICD 9  | ICD 10 |
| Vulvovaginal diagnoses          |        |        |
| Stricture or Atresia of Vagina   | 623.2  | N89.5  |
| Atrophy of Vagina               | 624.1  | N90.5  |
| Other specified noninflammatory disorder of the vulva or perineum | 624.8  | N90.89 |
| Unspecified noninflammatory disorder of the vulva and perineum | 624.9  | N90.9  |
| Dyspareunia                     | 625.0  | N94.1  |
| Other specified symptom associated with female genital organs | 625.8  | N94.89 |
| Unspecified symptoms associated with female genital organs | 625.9  |        |
| Postmenopausal atrophic vaginitis | 627.3  | N95.2  |
| Urinary diagnoses               |        |        |
| Overactive bladder              | 596.51 | N32.81 |
| Urinary tract infection         | 599.0  | N39.0  |
| Urge incontinence               | 788.31 | N39.41 |
| Urge frequency                  | 788.41 | R35.0  |
| Urgency of urination            | 788.63 | R39.15 |
| Nocturia                        | 788.43 | R35.1  |

Patient Survey

The patient survey (Appendices 7 and 8) consisted of several sections, including demographics; medical and prescription history related to VVA (GSM); vulvovaginal, urinary, and sexual symptoms; and the patient’s health care visit experience. For each symptom domain (vulvovaginal, urinary, and sexual) we asked whether the patient and clinician had discussed the topic, and if so, who started the conversation and whether the patient was satisfied with the conversation. If women had not discussed the topic, we asked if they wished they had
discussed it, and if so, we asked why the topic wasn't discussed. Finally, we asked what treatments and referrals their clinician recommended.

At the time of survey development in 2014, there was no symptom-specific quality of life instrument for vulvovaginal atrophy/genitourinary syndrome of menopause. We created our survey questionnaire by adapting relevant sections of other validated questionnaires.

**Results**

**Principal Findings**

**Clinician Survey**

Of the 360 clinicians who were sent an email request, 119 completed the survey (33% response rate). Female clinicians were more likely to respond than male clinicians, but there was no difference in survey response with respect to age, specialty, or type of clinician. Overall, 66% of knowledge questions were answered correctly. Questions about VVA (GSM) prevalence and treatment of VVA (GSM) in women with a history of breast cancer received the lowest proportion of correct responses (35% and 22%, respectively). The proportions answered correctly for individual questions varied by department. There were more correct answers from GYN clinicians (77% correct, ranging from 50-100%) than PC clinicians (63% correct, ranging from 25-87.5%). A greater proportion of GYN clinicians correctly answered two questions about VVA (GSM) treatment and estrogen therapy for VVA (GSM).

PC clinicians reported being less likely to assess for VVA (GSM) symptoms during a routine visit compared to GYN clinicians after controlling for covariates (adjusted mean difference=1.0, 95% CI [0.60,1.5]). In addition, PC clinicians were less confident than GYN clinicians in counseling about VVA (GSM) symptoms (adjusted mean difference=0.66, 95% CI [0.33, 0.99]) and in advising patients about the risks and benefits of vaginal estrogen (adjusted mean difference=0.76, 95% CI [0.42,1.10]). When we dichotomized the scale (highly likely/likely vs highly unlikely/unlikely/maybe or very high/high vs very low/low/medium), compared to PC clinicians, more GYN clinicians reported being highly likely or likely to assess for VVA (GSM) symptoms during a routine visit (72% vs 28%), and highly or very highly confident in counseling about VVA (GSM) symptoms (72% vs 33%) and in advising on risks/benefits of vaginal estrogen (76% vs 30%) (Figure 2).

Lack of time was the most commonly selected barrier to VVA (GSM) diagnosis and treatment (71% of responders), followed by lack of educational materials for patients (selected by 44%). The two least commonly reported barriers were provider discomfort with discussing
sexual concerns (2%) and urinary concerns (2%) with their patients. More than 1 in 3 clinicians identified the designation of systemic estrogen as a high-risk medication for the elderly as a barrier to treatment of VVA (GSM).

Figure 2. Clinician practice related to vulvovaginal atrophy (VVA)

GYN clinicians identified five barriers more often than PC clinicians: estrogen as a high-risk medication in the elderly, the FDA black box warning for a vaginal estrogen prescriptions, patient dissatisfaction with options for vaginal estrogen, cost of vaginal estrogen, and lack of educational materials for patients; however, the only significant difference between GYN and PC clinicians was in the selection of the cost of vaginal estrogen therapy as a barrier (GYN 48%, PC 18%, adjusted OR=4.8, 95% CI [1.8, 12.9]).

Reach of Educational Training

Overall, we reached 107 (58%) of the intervention clinic health care providers through the on-line and in-person presentations. We found that 92 (49%) of the intervention clinic providers attended a clinic-based presentation, 39 (21%) viewed the online, voiceover PowerPoint presentation, and 22 (12%) participated in both types of presentations.

EHR Data-Only Study

There were 407 clinicians (206 intervention, 201 control) and 15,062 well visits (7,749 intervention; 7,313 control) during the study period. The average patient age (66.4 ± 8.4 years) and BMI (29.0 ± 7.0 kg/m²) in the intervention clinics did not from the age (66.5 ± 8.3 years) and BMI (28.7 ± 6.7 kg/m²) in the control clinics. Eighty percent of the clinicians were primary care providers and 85.8% of the well visits occurred in primary care clinics. The intervention
clinicians were significantly more likely to use the SmartSet and the SmartText for patient care; however, there was a moderating effect of department on the use of the SmartRx (Table 2).

<table>
<thead>
<tr>
<th>Tool*</th>
<th>Intervention (206 clinicians)</th>
<th>Control (201 clinicians)</th>
<th>Intervention vs Control</th>
<th>PC vs GYN interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GYN N=44</td>
<td>PC N=162</td>
<td>Overall N=206</td>
<td>GYN N=36</td>
</tr>
<tr>
<td>SmartSet</td>
<td>31.7%</td>
<td>20.8%</td>
<td>23.1%</td>
<td>5.5%</td>
</tr>
<tr>
<td>SmartText</td>
<td>52.3%</td>
<td>33.3%</td>
<td>37.3%</td>
<td>44.4%</td>
</tr>
<tr>
<td>SmartRx</td>
<td>4.5%</td>
<td>17.3%</td>
<td>14.6%</td>
<td>16.7%</td>
</tr>
</tbody>
</table>

GYN = gynecology, PC = primary care
*SmartSet, SmartText, and SmartRx are registered trademarks of Epic Systems Corporation.

The proportion of visits that included a vulvovaginal or urinary diagnosis did not differ significantly between the intervention and control groups, nor did the proportion of visits that included a GSM-related diagnosis (Table 3). However, there was a significant moderating effect of clinic type on the effectiveness of the intervention, such that the GSM diagnosis rate was greater in the intervention compared to the control GYN clinics, but there was no difference in diagnosis rate between arms in the PC clinics (OR=1.54, p=.01).

There was no significant difference between the intervention and control groups in the proportion of visits in which vaginal estrogen was prescribed for a GSM diagnosis (4.4% vs 3.5%, respectively) or in which topical lidocaine was prescribed for a vulvovaginal diagnosis (0.2% vs 0.1%). There was also no modifying effect of clinic type on these outcomes.

<table>
<thead>
<tr>
<th>Diagnoses</th>
<th>Intervention</th>
<th>Control</th>
<th>Intervention Vs Control</th>
<th>PC vs GYN Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GYN n=1313</td>
<td>PC n=5645</td>
<td>Overall n=6958</td>
<td>GYN n=847</td>
</tr>
<tr>
<td>Vulvovaginal</td>
<td>25.7%</td>
<td>3.5%</td>
<td>7.7%</td>
<td>20.1%</td>
</tr>
<tr>
<td>Urinary</td>
<td>4.4%</td>
<td>2.1%</td>
<td>2.6%</td>
<td>4.0%</td>
</tr>
<tr>
<td>GSM</td>
<td>28.0%</td>
<td>5.5%</td>
<td>9.8%</td>
<td>23.3%</td>
</tr>
</tbody>
</table>

GYN = gynecology, PC = primary care, GSM = genitourinary syndrome of menopause, includes vulvovaginal and urinary diagnoses.
Patient Survey

Of the 7,625 eligible women, 78% (5,915) had a working email address; the final survey response rate was 26% (1,546/5,915). Thirteen respondents who had been seen by study clinicians were dropped from the analysis, resulting in a total analytic sample of 1,533. The majority of respondents were seen by primary care providers (83%; PC=1,273 vs. GYN=260).

Approximately 22% of women reported that they discussed vulvovaginal symptoms with their clinician, but this varied significantly by clinician type (PC=15%, GYN=54%, p<.001). Most women reported that they started the conversation (51%). Most women (83%) were satisfied or very satisfied with the conversation: women seen in GYN were more likely to be “very satisfied” (56%), while women seen in PC were more likely to be “satisfied” (67%; p<.001).

Urinary symptoms were discussed during the visit by 21% of women, and this varied significantly by clinician type (PC=20%, GYN=27%, p=.01). Respondents reported that they and their clinician started the conversation at about the same rate (patient 43%, clinician 40%). Most women (77%) were satisfied or very satisfied with the conversation; women seen in GYN were more likely to be “very satisfied” (58%) than women seen in PC (38%, p=.0581).

Approximately 14% of women reported that they discussed sexual health symptoms with their clinician, but this varied significantly by clinician type (PC=9%, GYN=38%, p<.001). Overall, the respondents reported that they started the conversation (42%) about the same percentage of the time as the clinician did (39%). However, this varied significantly by clinician type, with the GYN clinicians starting the conversation 51% of the time and PC clinicians initiating the conversation 28% of the time (p=.006). Most women (80%) were satisfied or very satisfied with the conversation: women seen in GYN were more likely to be “very satisfied” (61%), while women seen in PC were more likely to be “satisfied” (42%; p=.002).

Only 8% of women who did not discuss vulvovaginal symptoms wished that they had, with a similar percentage (7%) wishing they had discussed sexual symptoms. A higher percentage (14%) of women who did not discuss urinary symptoms wished that they had. For all symptom types, the two most commonly reported reasons were: “I forgot or chose not to bring them up” (vulvovaginal 48%, urinary 62%, sexual 45%) and “My provider didn't bring them up” (vulvovaginal 42%, urinary 35%, sexual 49%).

There were no main effect differences between the intervention and control groups. However, initial analyses of the interactions suggest that the intervention may have had a significant effect on the experience of women who saw a GYN clinician.
Discussion

Our goal was to determine whether we could increase the frequency of diagnosis and treatment of symptomatic VVA (GSM) by providing an educational intervention and electronic health record-based patient care support tools for primary care and gynecology clinicians. We found that clinicians are more likely to use electronic patient care tools if they have been informed of their presence or indication for use. This is important for health systems to realize as EHRs have made it easy to create electronic support tools; however, without appropriate clinician education and leadership driving the use of these tools, they may never be used. Despite greater use of patient care tools among providers in both the PC and GYN intervention clinics, increased VVA (GSM) detection was observed only in the GYN intervention clinics compared to controls.

In terms of how best to educate clinicians about new guidelines for patient care, we found that we reached a much larger number of clinicians through our in-person clinic visits than with the online presentation that they could complete on their own time. If we had been able to attend the clinics more than once or meet with each clinician one-on-one, we could have attained a greater reach. Whether this would have led to a different outcome is unclear. Furthermore, during the educational training and study periods, there were no other organizational initiatives or incentives to drive clinician interest in the topic of GSM or to drive motivation to increase detection of GSM.

When we asked clinicians in our pre-intervention survey what barriers they perceived in relationship to diagnosis and management of symptomatic VVA (GSM), time was listed as the most common constraint. While symptomatic VVA (GSM) may affect the quality of life of postmenopausal women, how concerns about it rank in relationship to other medical issues is hard to determine. For a healthy postmenopausal woman with no other medical issues, symptomatic VVA (GSM) may have a greater impact on quality of life than for a woman with multiple medical illnesses requiring more active medical attention. We did not have the ability within our EHR to determine whether women with a greater burden of medical illness were less likely to receive a VVA (GSM) diagnosis.

We found that, compared to PC providers, GYN care providers have greater knowledge about VVA (GSM), are more likely to screen women for VVA (GSM) symptoms at a routine visit, and are more confident in their ability to counsel women about VVA (GSM) treatment options. While this is not surprising given the women’s health focus of a gynecologist’s training, it is concerning given the millions of postmenopausal women who may only see a primary care
provider after the cessation of pap testing. Because of the structure of Medicare reimbursement for the Annual Wellness Visit, women over the age of 65 are directed to primary care providers for a more comprehensive Annual Wellness Visit every 2 years. Gynecologists may only bill Medicare for cervical cancer screening, pelvic exams, and problem focused visits.

One consideration is to improve the residency training experience of primary care and gynecology residents related to the menopausal and postmenopausal genitourinary issues of women. Two U.S. surveys, one of primary care providers and one of obstetrics and gynecology residents, suggest educational training and knowledge related to menopausal medicine may be lacking and that treatment issues are complicated. The North American Menopause Society and American Congress of Obstetrics & Gynecology have joined efforts to create an academic curriculum for Ob/Gyn residents that will address education and tools needed to management menopausal health. Additional work may be needed across both Primary Care and Ob/Gyn training programs to assure residents have adequate opportunities to care for postmenopausal women under the guidance of clinical proctors with experience in menopausal and urinary health.

Conclusions

Knowledge about VVA (GSM) and confidence in its diagnosis and treatment vary among primary care and gynecology clinicians. Clinician-perceived barriers to GSM diagnosis and treatment included lack of time and lack of educational materials for patients. PC and GYN clinicians will use electronic patient care tools when aware of the rationale and their presence. However, the efficacy of tools and education alone for improving diagnosis and treatment of GSM in nongynecologic practices is limited. Future research is needed to determine how to further improve GSM diagnosis and treatment.

Significance and Implications

GSM affects a large proportion of women. It is critical to ensure that gynecologists and primary care clinicians are adequately prepared through residency training to screen for, diagnose, and treat symptomatic VVA (GSM), and, when in clinical practice, have the time and resources required to diagnose and treat VVA (GSM). To increase the frequency of conversations about GSM between patients and providers, it may also be worthwhile to consider direct outreach to postmenopausal women to increase awareness that VVA (GSM) symptoms are not just a part of aging that they have to live with and that effective treatment options are available.
Bibliography of Presentations


Appendices

Appendix 1: SmartSet
Appendix 2: Smart Rx
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Appendix 7: Patient Survey
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Bibliography


