Promoting Evidence-Based Diagnosis and Management of Postmenopausal Vulvovaginal

Symptoms in Primary Care Using an Electronic Patient Portal

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Implementation and Evaluation Proposal

1. Background and rationale

Vulvovaginal atrophy (VVA) symptoms are common in menopausal women, but are under-diagnosed and under-treated due to a combination of patient, provider, and system-level factors. Up to half of menopausal women develop symptoms such as dryness, soreness, itching, pain, or bleeding due to atrophy and inflammation of the vulvovaginal tissues.[1-3] Currently, most menopausal women with vulvovaginal symptoms do not seek treatment, either because they are embarrassed about having these symptoms, are anxious about undergoing evaluation for their symptoms, or do not realize that their symptoms may be caused by a treatable condition such as VVA.[2-4] At the same time, many primary care clinicians do not routinely assess for VVA symptoms in their menopausal patients, for reasons including lack of time during brief clinic visits, unfamiliarity with evidence-based diagnosis and treatment, growing pressure to address a wide array of health care priorities, or failure to appreciate the major impact that VVA symptoms can have on women's activities, feelings, and relationships.

There is a need for more effective and efficient point-of-care strategies to promote evidence-based diagnosis and treatment of VVA symptoms in the primary care setting. Rather than relying on patients to initiate discussion about their symptoms or requiring primary care clinicians to have expert knowledge about management of VVA, strategies for promoting evaluation and treatment of VVA symptoms should leverage existing practice support tools in ways that minimize burden to the patient, provider, and practice environment. Such strategies must be acceptable to female patients across a range of age and backgrounds as well as generalizable across large health care delivery organizations, in order to meet the needs of the large number of menopausal women suffering from VVA in the community. Furthermore, these strategies should be designed to accommodate the unique constraints of the primary care environment, which include short (<20 minute) patient visits, shrinking provider reimbursement, and a multitude of competing health care priorities.
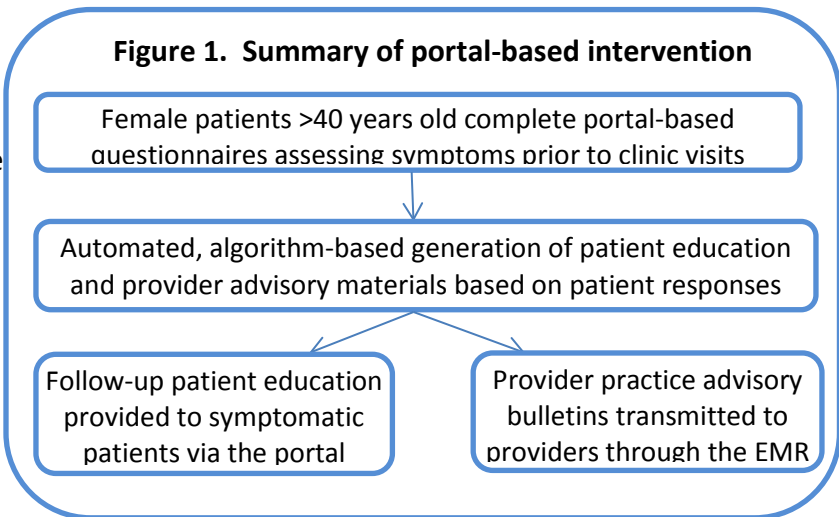
Electronic medical record and patient portal systems may provide a vehicle for overcoming barriers to discussion, evaluation and treatment of VVA symptoms in primary care. Over the past decade, outpatient practices have increasingly turned to electronic medical record (EMR) systems to enter, store, and organize patient information.[5,6] Some EMR systems include patient portals that allow patients to enter selected demographic and medical information, review their medical test results, and communicate electronically with their clinicians, thus allowing them to play a more active role in their own care. For assessment of sensitive genitourinary symptoms, these portals may also allow patients to self-screen for symptoms through an anonymous electronic interface rather than initiating discussion in person. As a result, a portal-based outreach intervention that systematically screens for vulvovaginal symptoms and creates tailored patient education and practice support messages to promote appropriate follow-up evaluation and treatment by providers has the potential to transform assessment and management of symptomatic VVA in primary care, provided that it can be smoothly integrated into the practice environment.

2. Project goals and objectives

1) To develop and refine an electronic patient portal-based intervention to promote more systematic recognition and evidence-based management of postmenopausal vulvovaginal symptoms in the primary care setting.

2) To examine the impact of this intervention on rates of patient-provider discussion about postmenopausal vulvovaginal symptoms, evaluation and treatment for symptoms, and improvement in symptom-specific outcomes at an urban academic medical center.

3. Overview of intervention

To promote more effective evaluation and management of symptomatic VVA, we propose to leverage an electronic patient portal (MyChart) that is integrated into a large ambulatory care electronic medical record system (Epic). Specifically, we will create and refine a portal-based screening instrument to systematically identify menopausal female patients with vulvovaginal symptoms, and link this portal-based assessment to provision of targeted, patient-oriented education as well as provider-directed recommendations for evaluation and treatment through the EMR (Figure 1). Female patients over 40 years of age who are scheduled for annual or follow-up visits in the UCSF General Medicine Practices and are enrolled in the MyChart portal will be asked to answer a brief series of questions about their menstrual history, vulvovaginal symptoms, and other contributory factors through the portal, approximately one week prior to their visits. Those who are symptomatic will receive automatic, targeted patient-education information directly through the MyChart portal. At the same time, their primary care providers will receive a concise summary of their portal-based evaluations along with recommendations for follow-up evaluation and treatment, in the form of electronic practice advisory messages that can be directly linked with the clinical encounter and incorporated into the EMR. After creating, pre-testing, and refining this intervention, we will implement it in the practice and collect data on key outcomes.

Figure 1. Summary of portal-based intervention

Female patients >40 years old complete portal-based questionnaires assessing symptoms prior to clinic visits

Automated, algorithm-based generation of patient education and provider advisory materials based on patient responses

Follow-up patient education provided to symptomatic patients via the portal

Provider practice advisory bulletins transmitted to providers through the EMR

If appropriately integrated into clinical practice, this portal-based intervention has the potential to overcome multiple barriers to diagnosis and treatment of VVA symptoms in primary care. First, the intervention is designed to systematically identify menopausal female patients with vulvovaginal symptoms, thus obviating the need for women to bring up this problem independently. Provision of important patient education information about VVA will occur prior to the clinic visit, without using up valuable time in the clinical encounter. Providers will automatically receive targeted practice-support information and treatment recommendations

through the EMR, without having to master diagnostic or treatment algorithms in advance of the visit. The provider advisory bulletins will also include tools to facilitate documentation, coding, and billing for VVA within the EMR, thus supporting provider reimbursement. In summary, this intervention will not only use the portal as an innovative health screening tool, but also create tailored health messages and provide practice support information in order to enhance quality of care for VVA in ways that benefit the patient, provider, and practice.

4. **Practice environment and context**

The UCSF General Medicine Practices: Project activities will be based at two adult general internal medicine practices with over 80 full- and part-time providers, who collectively follow approximately 23,500 adult patients making over 40,000 visits annually. Currently, providers include 21 faculty physicians, 30 primary care internal medicine residents, 28 categorical internal medicine residents, and 5 nurse practitioners. These providers are organized into eight practice "teams" to allow providers to share coverage responsibilities and streamline workflows for collaborating with team medical assistants and other support staff. Patients seen at the practices are racially and ethnically diverse: 49% White, 24% Asian, 15% Latino, 11% African-American, and 1% American Indian. The payer mix is also diverse: 32% Medicare, 34% managed care, 15% Medicaid, 13% contracts, 4% non-capitated insurance, and 2% self-pay.

Overview of Epic and MyChart: In April of 2011, the practices transitioned to use of Epic, an ambulatory EMR system that integrates chart review, order management, and documentation, and is used at all of the University of California medical centers, as well as other academic and community-based medical centers across the country (including Duke University Health Systems, Boston's Partners Healthcare, Dartmouth-Hitchcock Medical Center, and the Kaiser Permanente Medical Care program). The Epic EMR system (rebranded as APEX for the UCSF Medical Center) includes an electronic patient portal, MyChart, that allows patients to communicate securely with their healthcare providers, track current and past prescriptions, and view selected medical data in the EMR. Patient enrolled in MyChart receive e-mail notifications whenever new message, prescriptions, or test information become available; using a secure log-on and password, they can then access the portal to view this information and respond as needed (see Appendix B for sample screenshots of the MyChart interface).

The most recent version of Epic (Epic 2012) allows for creation of structured patient-oriented questionnaires within the MyChart portal interface as well as automatic download and integration of questionnaire data into the EMR (see Appendix B for screenshots). This new functionality of MyChart offers the potential for systematic collection of patient-reported symptom and clinical history data for quality improvement and research purposes. The Epic 2012 platform also allows for generation of "Best Practice Advisory" messages directed at providers, which automatically appear when providers open up the record for a given patient's clinical encounter. Practice advisory messages can be used to alert providers when patients meet criteria that make them eligible for quality improvement initiatives, and can be programmed to provide practice support information to facilitate discussion, evaluation, and documentation of health issues in the EMR. *In summary, the current MyChart/EPIC platform allows for creation of electronic patient questionnaires, automated intergration of questionnaire data into the EMR, and triggering of provider advisory messages to facilitate*

evaluation and treatment of issues identified questionnaires, in ways that can promote greater recognition and improve management of under-recognized health problems.
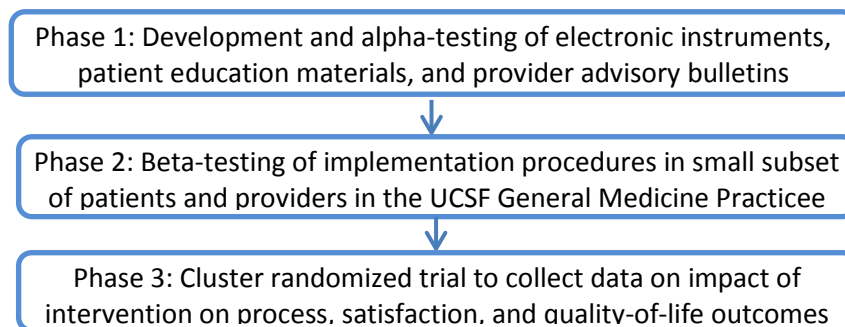
5. Assessment of local gaps in practice

To assess whether gaps in assessment of VVA symptoms identified on the national level also exist within our local practice environment, we surveyed a random sample of 20 primary care providers in the UCSF General Medicine Practice (approximately a quarter of the total provider pool) about their approaches to assessing vulvovaginal symptoms in female patients over 40 years of age. Of the 20 respondents, 8 were faculty, 2 were fellows, and 10 were residents (including 2 interns and 8 PGY2/PGY3 residents); 25% spent at least half of their time providing primary care, with the other 75% spent the majority of their time on other inpatient, research, or teaching activities. Only 10% of respondents indicated that they assessed menopausal status in at least 80% of their annual visits with female patients over 40 years of age, and over half of respondents indicated that they assessed menopausal status in less than 40% of such visits. No respondents indicated that they actively questioned their female patients over 40 years of age about vulvovaginal symptoms in at least 80% of visits, and 80% of respondents indicated that they assess vulvovaginal symptoms in under 40% of these visits.

When providers were asked about the reasons why they did not screen for vulvovaginal symptoms, the most commonly cited reasons were: 1) lack of time during clinic visits (90% of respondents), 2) not feeling adequately prepared to evaluate symptoms (30% of respondents), 3) a perception that vulvovaginal symptoms were not as important a problem as other medical issues (15% of respondents), and 4) concern that patients might not be comfortable discussing these symptoms (10% of respondents). *These findings provide preliminary evidence that primary care providers at the UCSF General Medical Practice, like their counterparts nationally, do not routinely assess for menopause-related vulvovaginal symptoms, even during annual visits that are meant to facilitate comprehensive assessment of patients' health problems.* Furthermore, providers at this practice also suffer from inadequate time to assess vulvovaginal symptoms and lack of preparation to evaluate these symptoms, even though these symptoms are widely prevalent in menopausal female patients presenting to primary care.

6. Implementation and evaluation strategy

Figure 2. Overview of implementation and evaluation of the intervention

Phase 1: Development and alpha-testing of electronic instruments, patient education materials, and provider advisory bulletins

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Phase 2: Beta-testing of implementation procedures in small subset of patients and providers in the UCSF General Medicine Practicee

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Phase 3: Cluster randomized trial to collect data on impact of intervention on process, satisfaction, and quality-of-life outcomes

6.A. Phase 1: Development and alpha-testing of instruments and materials

6.A.1. Overview of phase 1

During phase 1, we will create the portal-based patient screening instruments and follow-up patient education materials and refine them through one-on-one pre-testing (alpha-testing) in at least 10 symptomatic postmenopausal women. We will also develop the EMR-based provider advisory bulletins designed to facilitate appropriate evaluation and treatment of vuvlvoaginal symptoms, and refine them through pre-testing in 10 primary care clinicians. This process will result in development of a preliminary portal-based intervention that is simple, brief, user-friendly, and designed to facilitate evidence-based evaluation of vulvovaginal symptoms within the constraints of the primary care environment.

6.A.2. Content development

The preliminary electronic patient screening instrument, patient educational materials, and provider advisory bulletins will be developed by investigators Alison Huang, MD, Tami Rowen, MD, and Miriam Kuppermann, PhD.   Content will be adapted from existing printed and on-line and materials that have been developed and tested in other research or patient care settings but have not previously been administered through an EMR system (Table 1). The project team will prepare materials for administration through the portal and EMR, paying special attention to: 1) the feasibility of conveying information in an electronic format, 2) the appropriateness of instruments and materials for administration in the primary care setting, and 3) the diversity of the UCSF General Medicine Practice population.

Table 1. Expected sources of content for portal- and EMR-based education materials
Patient education materials
• NAMS "Sexual Health and Menopause" on-line patient education module • Mayo Clinic "Vaginal Atrophy" on-line patient information module • Harvard Medical School "Vaginal Atrophy" on-line patient education center module
Provider advisory bulletins
• Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society[7] • Althof, S. E., R. C. Rosen, et al. (2013). "Standard operating procedures for taking a sexual history." J Sex Med **10**(1): 26-35[8] • Management of vulvovaginal atrophy-related sexual dysfunction in postmenopausal women: an up-to-date review" Menopause 19(1):109-117.[9]

For this project, all patient-directed instruments and materials will be developed in English; however, language will be adapted to be appropriate for patients with a sixth-grade reading level. At a minimum, content of the electronic patient assessment instrument, follow-up patient education materials, and provider advisory bulletins will include:

Table 2. Proposed minimum content of portal- and EMR-based materials	
Portal-based screening instrument	Assessment of menopausal status, years since last menses, presence and severity of vulvovaginal symptoms (none, mild, moderate, severe- according to FDA guidances[10]), impact of symptoms on sexual activity and other activities of daily living, current/past use of systemic and topical estrogen therapies, current/past use of other treatments

Follow-up patient educational materials	Patient-oriented summary of possible causes of vulvovaginal symptoms (including but not limited to VVA), discussion of possible exacerbating factors, "What to Expect During Your Clinic Visit", review of possible treatments for symptoms, web-based links to detailed patient resources
Follow-up provider advisory bulletins	Summary of portal-based patient evaluation, review of possible etiologies of symptoms (including VVA), recommendations for evaluation (e.g., pelvic exam), guide to interpretation of findings on pelvic exam (with web-based links to detailed pictorial guide), review of treatments and prescribing info, Epic-based "smartphrases" to facilitate documentation and billing

6.A.3. Programming of instruments and materials onto a MyChart/EPIC platform

The project team will work with analysts in the MyChart IT section of the UCSF Medical Center to program the above instruments and materials into the MyChart and EPIC platforms (see letter of support from Brian Cosgrove, supervisor of the MyChart IT support section). Given the already sizable workload of the MyChart IT analyst team, funds have been requested to support the time and effort of an external programmer/consultant to work specifically on this project, under the supervision of the main MyChart analyst team. After creation of the preliminary instrument and materials, the project team will revise instruments and materials to address limitations detected during alpha- and beta-testing.

6.A.4. Pre-testing (alpha testing) procedures for patient-directed materials

The project team will recruit at least 10 postmenopausal women with ongoing vulvovaginal symptoms and invite them to review and provide feedback on the preliminary electronic patient assessment instrument and educational materials. Women will be recruited from the general San Francisco Bay Area community using fliers posted in clinics, local business, and community centers. At pre-testing sessions, women will complete the preliminary instrument on the computer, after which they will be asked to comment on the clarity, appropriateness, and format of the question instructions, stems, and response options. Scripted and unscripted probes will be used to assess women's understanding of questions, clarify cognitive processes involved in answering questions, and determine if any questions are viewed as offensive. Pre-testing interviews will also be used to gather feedback on follow-up educational materials. After each 2 to 3 sessions, instruments and materials may be revised based on participant feedback, and revised versions prepared for administration in additional women. Given that the goal is to produce instruments and materials in English, only English-speaking women will be interviewed; however, subjects will be recruited from diverse racial/ethnic backgrounds (Black, Latina, Asian) and ages (e.g., < 50, 50 to 64, ≥ 65 years old). Each participant will receive $20 in gift cards for her contribution.

6.A.5. Pre-testing (alpha testing) procedures for provider-directed materials

The project team will also revise the EMR-based provider advisory bulletins through one-on-one pre-testing sessions with at least 10 primary care providers, recruited from satellite primary care practices at the UCSF Medical Center (e.g., the UCSF Primary Care Practice at Laurel Village, which also uses the EPIC system). Providers will be asked to provide feedback on the clarity and appropriateness of the information in the patient advisory

bulletins, including the summary of participants' responses to the portal-based screening questions, follow-up instructions for pelvic exams and/or further testing, and recommendations for treatment, where appropriate. After each 2 to 3 provider pre-testing sessions, the content and design of the provider advisory bulletins may be revised based on feedback, and revised versions prepared for review by additional providers. Each provider will receive $20 in gift cards as reimbursement for his or her contribution to the project.

6.B. Phase 2: Beta-testing of implementation in the practice setting:

6.B.1. Overview of phase 2

During phase 2, we will briefly field-test (beta-test) implementation procedures for the intervention in a small subset of female patients scheduled for visits at the UCSF General Medicine Practices, in order to assess barriers to larger-scale roll-out during phase 3. The focus of beta-testing will be testing and refining workflows for transmitting and tracking the portal- and EMR-based patient assessment instruments, follow-up patient educational materials, and provider advisory bulletins. Additionally, the project team with beta-test procedures for collecting data on outcomes, including administration of web-based patient questionnaires and abstraction of data from the medical record after clinic visits. Based on the results of this beta-testing, the project team may modify procedures for implementing and evaluating the intervention, including the timing of screening messages, the number or content of reminder messages, and the content and format of screening instruments and follow-up materials, as well as procedures for collecting outcomes data.

6.B.2 Beta-testing procedures

With the support of the leadership of the UCSF General Medicine Practice (see attached letters of support), female patients over 40 years of age who are enrolled in MyChart and scheduled to see a "sentinel" set of primary care providers in the practice (no more than 5 providers) will be sent messages through MyChart, inviting them to complete the portal-based screening instrument approximately one week before their visits. A dedicated clinical coordinator (Traci Plaut, B.S.) will track rates of patient responses to portal-based questionnaires and ensure that follow-up patient education materials are sent to patients through the portal in accordance with the pre-established algorithm. As described previously, patients reporting vulvovaginal symptoms will receive targeted follow-up

Figure 3. Overview of workflows for implementation and assessment
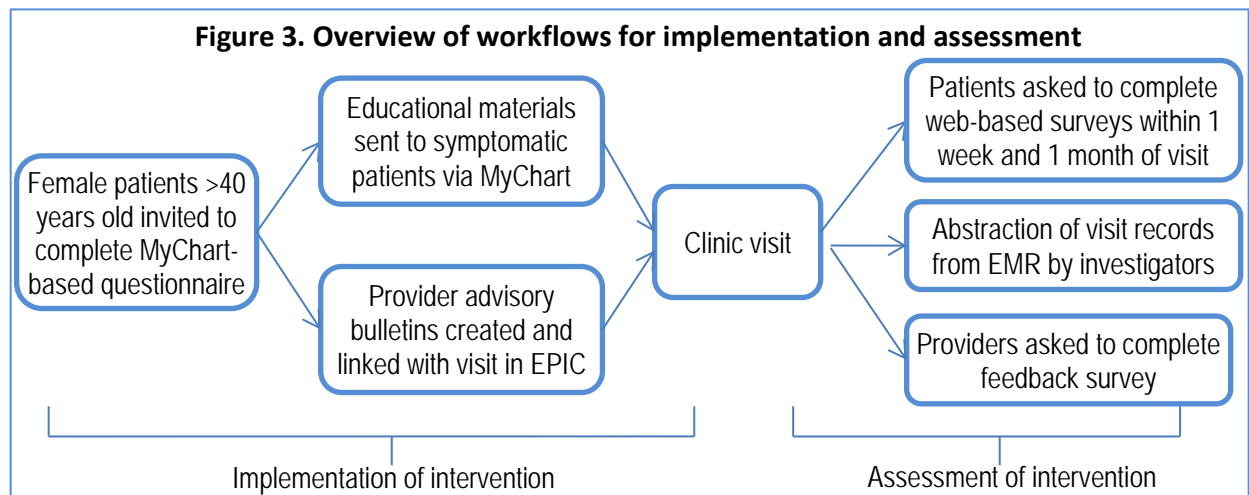
educational information through the portal, while their providers will receive practice advisory messages through the EMR that will be directly linked to patients' visits. Patients reporting vulvovaginal symptoms will be asked to complete on-line surveys one week and one month after their visit, to provide information about the impact of intervention. The project team will also abstract records of visits to collect additional data on diagnoses, evaluation, and treatment initiated during the visit. Finally, providers will provide feedback on the intervention, including effects on practice efficiency and provider satisfaction.

<u>6.B.3. Data management and analyses for phase 2</u>

Patients' responses to initial MyChart-based screening questionnaires will be stored in Epic as part of the official medical record, whereas data derived from post-visit web-based surveys will be stored in a separate, encrypted database that is distinct from the EMR, but will include participant ID numbers allowing linkage with data stored the EMR. No formal statistical analyses will be performed for phase 2; however, to assess the feasibility and appropriateness of workflows, the team will track parameters such as:

- % of female patients invited who complete MyChart questionnaires before their visit
- average number of days for female patients to complete MyChart questionnaires
- % of patients completing MyChart questionnaires who report vulvoaginal symptoms
- % of symptomatic patients who complete post-visit web-based outcome surveys
- % of symptomatic patients who report discussion of their symptoms at clinic visits
- % of symptomatic patients whose providers document symptom evaluation in EMR

6.C. Phase 3: Cluster randomized trial for outcomes assessment:

<u>6.C.1. Overview of phase 3</u>

During phase 3, we will conduct a small cluster randomized trial to collect data on the impact of the portal-based intervention on rates of patient-provider discussion, evaluation, treatment, and referral for vulvovaginal symptoms. Female patients who meet menopausal and symptom criteria will be randomly assigned (at the level of the provider) to receive either: 1) the full intervention that includes targeted patient education and provider practice support for vulvovaginal symptoms, or 2) a control intervention involving screening for a variety of health-related symptoms (including but not limited to vulvovaginal symptoms), without targeted education or follow-up for symptomatic VVA. To assess outcomes, patients will be asked to complete follow-up web-based surveys after their clinic visit, and investigators will perform chart reviews of encounters documented in EPIC as well as billing code data available through UCSF's EMR-based cohort selection tool. Finally, providers will be surveyed about their satisfaction with the intervention, including its effects on practice efficiency, provider satisfaction, and the provider-patient relationship. Each patient and provider contributing to this phase of the project, including those in the control group, will receive $20 in gift cards in recognition for their time and effort.

<u>6.C.2. Randomization strategy</u>

We considered practice teams, providers, and patients as potential units of randomization. Randomization of practice teams would not be optimal; with only 8 teams, this would

effectively result in a quasi-experiment. Randomizing patients would risk contamination because individual providers would see patients assigned to both intervention and control groups. Instead, randomization will occur at the level of the provider, stratified by practice team and provider type (faculty/nurse practitioner versus resident/fellow). After collection of baseline data, but prior to randomization, we will create two matched sets of primary care providers based upon their personal and practice characteristics (e.g., gender, percent time in practice, appointment/training level, panel size, % women in panel). Following this, one matched set will be randomized to the intervention, the other to control. This procedure will help to ensure equivalent intervention and control groups. Although there is potential for contamination if primary care providers assigned to opposing intervention groups discuss the project with each other in a way that influences their clinical practice, the effect of any contamination would be to bias experimental group differences toward zero (i.e., the direction of bias is known). We will address this possibility by increasing sample size and allowing detection of smaller intervention effects.

6.C.3. Outcomes measurements

Primary process outcome—rates of patient-provider discussion of vulvovaginal symptoms
Patient-reported discussion of symptoms: Patients will be asked to complete web-based surveys within one week of their visits, in which they will indicate whether a discussion of vulvovaginal symptoms took place and, if so, whether it was initiated by patient or provider
Provider-documented discussion of symptoms: Investigators will review medical records abstracted from the EMR to assess for documentation of discussion of symptoms at visits; two team members will abstract data from each encounter using standardized forms and will discuss and resolve any discrepancies before a final determination is made.
Secondary process outcomes—evaluation, treatment, referral for vulvovaginal symptoms
Rates of pelvic examination (EMR-based and patient-reported): Investigators will review records abstracted from the EMR to assess whether a pelvic exam was performed to evaluated vulvovaginal symptoms at clinic visits. Patient surveys administered within one week of clinic visits will also assess whether a pelvic examination was performed.
Rates of condition-specific diagnoses (EMR-based): Investigators will review abstracted records for diagnoses of "postmenopausal atrophic vaginitis," "vulvar atrophy," and other diagnoses made at visits. Diagnosis rates will also be tracked through the UCSF Academic Research Department's EMR-based cohort selection tool, which automatically imports ICD-9 billing codes and allows tracking by patient characteristic, date, and practice location (see attached letter of support from Doug Berman, Director of Academic Research Systems).
Prescribed or recommended treatments (patient-reported and EMR-based): Web-based patient surveys administered within one week of patients' clinic visits will assess whether patients were prescribed any treatments (such as systemic or vaginal estrogen therapy) or advised to use non-prescription treatments (such as non-hormonal vaginal moisturizers). Investigators will also review abstracted EMR records to assess for documentation of any treatments, again using standardized forms and resolving differences between reviewers.
Perceptions of shared treatment decision-making (patient reported): Web-based patient surveys administered within one week of clinic visits will include a modified version of a

validated shared decision-making questionnaire, the SDM-Q-9,[11] which assesses the degree to which patients perceive their providers as involving them in decision-making about treatment for a health issue (in this case, VVA symptoms). Consistent with usual scoring for this measure, higher scores indicate greater shared decision-making about treatment.
Secondary patient and provider satisfaction outcomes
Patient satisfaction with the impact of the intervention: Patients completing web-based surveys within one week of their clinic visits will be asked to rate the impact of the portal-based intervention on 1) perceived quality of care received for their vulvovaginal symptoms, and 2) their overall satisfaction with their clinic visit, using a 5-point Likert scale
Provider satisfaction with the impact of the intervention: Providers will surveyed at the end of the trial period and asked for feedback on their experience with the intervention and its impact on quality of care, practice efficiency, and the patient-provider relationship.
Secondary symptom and quality of life outcomes
Severity of vulvovaginal symptoms (patient reported): Patients will complete a second web-based survey one month after their visits, which will include self-assessment of change in the severity of their vulvovaginal symptoms along a 4-point Likert scale (none, mild, moderate, and severe), according to the FDA guidance on assessment of symptoms.[10]
Quality of life impact of symptoms (patient reported): Web-based patient surveys sent one month after visits will include a new structured self-report questionnaire, the Day-to-day Impact of Vulvovaginal Aging measure, recently developed and validated by Drs. Huang and Kuppermann to assess impact of postmenopausal vulvovaginal symptoms on: 1) activities of daily living, 2) emotional well-being, 3) sexual function, and 4) self and body image (see Appendix C for abstract submitted for presentation at the International Society for the Study of Women's Sexual Health, summarizing measure development process).

6.C.4. Statistical analyses and sample size estimates

Statistical analyses: Generalized estimating equation (GEE) logistic regression models clustered by provider will be developed to assess group differences in the proportion of patients who report discussion about their vulvovaginal symptoms with their providers, as the primary process outcome. Models will be adjusted for practice team and for any patient- or provider-level characteristics that are not adequately distributed between groups. Additional models will be developed to examine intervention effects on secondary process outcomes including the proportion of patients that undergo pelvic exams, receive a condition-specific diagnosis, are prescribed pharmacologic or other treatments, and are referred for further evaluation. Additionally, change in the severity and quality-of-life impact of patients' vulvovaginal symptoms during the month after their visits will be modeled using GEE linear regression models. In the event that symptom severity and impact scores are non-normally distributed (i.e., Shapiro-Wilk tests for normality of the residuals from initial models significant at $p < 0.01$), these score outcomes will be transformed prior to analysis. In the case of missing data from web-based surveys or chart abstraction, multiple imputation of missing data will allow models to be fit to all available data and will invoke the relatively mild assumption that the data are *missing at random*, conditional on modeled variables.

Sample size estimates: Sample size estimates are based upon assumptions including 80% power, two-tailed alpha = 0.05, 80% response rate for on-line surveys, and logistic regression models testing group differences. Planned analyses will include multiple imputation and use all available data, resulting in increased power. Rates of spontaneous discussion about vulvovaginal symptoms in the control group are assumed to be low for any given visit (i.e., <25%). For this intervention, our goal is to improve discussion rates to at least 50%, for an absolute improvement in discussion rates (i.e., effect size) of greater than 25%. We estimate that a sample of 75 providers and 192 symptomatic patients will allow for us to detect the following effect sizes, depending on discussion rates in the control group and within-provider correlation of this outcome:

Rates of discussion in control group	Minimum detectable effect size associated with varying levels of within-provider correlation of outcomes					
	0.1	0.12	0.14	0.16	0.18	0.2
15%	22.1%	22.5%	22.9%	23.3%	23.6%	23.0%
20%	23.3%	23.7%	24.0%	24.4%	24.7%	25.1%
25%	24.0%	24.4%	24.8%	25.2%	25.5%	25.9%

6.D. Future dissemination

Our EMR-based patient assessment instruments, follow-up patient education materials, and provider advisory bulletins represent exportable products that can promote use of the EMR to support evaluation and treatment of menopause-related vulvovaginal symptoms nationally. If this intervention is found to be effective, we propose to assemble an exportable tool kit and disseminate it through two approaches: 1) a national sample of academic organizations and professional societies focused on women's health, primary care, and treatment decision-making, and 2) regional and national networks of practices and healthcare delivery systems currently using EPIC.   Project faculty have current leadership positions or are active within the Society of General Internal Medicine, American Geriatrics Society, the International Society of the Study of Women's Sexual Health, the American College of Obstetrics and Gynecology, and the Society for Medical Decision-Making. Dissemination will occur through presentations and publications in meetings and journals associated with these organizations. Additionally, any successful results of this project will be formally presented to the MyChart Steering Committee at the UCSF Medical Center, along with MyChart teams at other University of California medical centers, with the goal of promoting broader roll-out of the intervention in practices using Epic.

7. Potential issues and alternative strategies

Why not focus on providing in-depth education to providers about VVA symptoms? We appreciate that one potential strategy for improving management of vulvovaginal symptoms is to design in-depth educational interventions to improve providers' knowledge about the importance and management of these symptoms. However, this would address only one barrier to evaluation and treatment of symptomatic VVA in primary care, and may have limited potential to bring about meaningful and sustained change in primary care practice as long as other, more pervasive system-level barriers are not addressed. In this proposal, we have

chosen to take another approach--one that is based on using information technology to promote systematic screening as well as provide practice support *directly at the point of care*. Although this approach may differ from traditional education-based strategies, we believe that it has a unique potential to change clinical practice in ways that are scalable and sustainable within large organizations that use EPIC and other electronic medical record systems.

<u>Why not focus on change in patients' symptoms or quality of life as the primary outcome?</u> Our long-term goal is to improve patients' quality of life related to VVA symptoms, and we plan to collect data on change in the severity and impact of patients' symptoms as secondary outcomes in this project. However, we recognize that symptom severity and impact can be influenced by a wide array of factors that are not related our proposed intervention, such as variability in patients' responses to clinical treatments, development of side effects from treatments, and/or changes in patients' life circumstances that affect their experience of vulvovaginal symptoms. Rather than conducting a traditional clinical trial directed exclusively at improving clinical and quality-of-life outcomes of VVA, our project is directed at changing underlying *processes of care* for symptomatic VVA. As a result, the primary outcome and many secondary outcomes of this project are *process outcomes*, designed to assess whether the intervention is effective in fundamentally changing the way VVA symptoms are assessed and managed.

8. Schedule of work and deliverables

	Project month											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Create draft electronic instruments and materials	X	X										
Obtain IRB approval for alpha- and beta-testing		X	X									
Deliverable: confirmation of IRB approval			X									
Adapt electronic materials for MyChart platform			X	X	X							
Pre-testing (alpha testing) of electronic materials				X	X	X						
Deliverable: summary of pre-testing results							X					
Beta-testing and refinement of workflows								X	X	X		
Obtain IRB approval for cluster randomized trial								X	X			
Enroll patients into cluster randomized trial										X	X	X
Web-based surveys to collect outcomes data										X	X	X
Chart abstraction to collect outcomes data										X	X	X
	Project month											
	13	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
Deliverable: 10 patients enrolled in trial	X											
Enroll patients into cluster randomized trial	X	X	X	X	X	X	X	X	X			
Web-based surveys to collect outcomes data	X	X	X	X	X	X	X	X	X			
Chart abstraction for collect outcomes data	X	X	X	X	X	X	X	X	X			
Data cleaning, analysis, and interpretation										X	X	X
Prepare abstracts, presentations, manuscripts										X	X	X
Deliverable: study report sent to sponsor												X

<div align="center">**Organizational information**</div>

A. Overview

We have assembled a multidisciplinary project team with complementary expertise in menopausal and genitourinary medicine, quality improvement, and dissemination and implementation research. To accomplish the proposed work, project team members will draw upon the extensive resources and infrastructure of the University of California San Francisco to conduct research and quality improvement activities related to women's health.

B. Institutional environment

University of California San Francisco (UCSF)
As the only University of California campus dedicated exclusively to health studies, UCSF has a long, diverse, and successful history of excellence in clinical research. The UCSF School of Medicine is consistently ranked among the top 5 medical schools in the United States by *US News and World Report*, is ranked fourth for research, and third in National Institutes of Health (NIH) funding. Five departments and programs – Internal Medicine, Obstetrics & Gynecology, Anesthesiology, Neurosurgery, and Social Science – have ranked number one in NIH funding, and many of the clinical programs are near the top of their categories in the *US News and World Report* rankings (AIDS/HIV ranks first, Women's Health second, Internal Medicine second, Primary Care fourth, and Family Medicine fourth). In 2008, UCSF was one of the first 12 academic institutions selected to be part of the NIH's national Clinical & Translational Science Institute (CTSI) consortium, with the goals of increasing the number and quality of training programs and enhancing infrastructure to promote high quality, original research.

Women's Health at UCSF
Since 1996, UCSF has had one of 20 US Department of Health and Human Services-designated Centers of Excellence in Women's Health, led by School of Medicine Vice Dean, Nancy Milliken, MD. The Center emphasizes a multidisciplinary approach to improving women's health by recognizing the importance and interdependence of clinical care, research, leadership development, education, and partnering with communities. The major research component is the UCSF Women's Health Clinical Research Center, which has brought disparate research groups previously spread across multiple UCSF campuses together under one roof at the Mount Zion campus of UCSF. The Center provides the infrastructure for these groups to conduct multidisciplinary research in areas including: menopausal symptoms, urinary incontinence, pelvic floor dysfunction, diabetes, breast health, cognitive decline and dementia, HIV in women, osteoporosis, hormone therapy, polycystic ovarian disease, and perinatal risks.

General Internal Medicine at UCSF
Under the leadership of Dr. Eliseo Perez-Stable, the Division of General Internal Medicine at UCSF is nationally recognized for its clinical research, training programs, and clinical service. Currently, the DGIM practices follow approximately 23,500 patients making >40,000 annual visits, and administrative and clinical data are available from the medical center's electronic medical record system and other databases to promote quality improvement and research. UCSF has one of the largest research programs in general internal medicine in the

country, and includes over 20 faculty with funded projects spanning a range of topics including clinical epidemiology, dissemination and implementation research, aging/geriatrics, genetic epidemiology, health disparities, tobacco control, cancer prevention, health informatics, behavioral medicine, and health policy topics. The Division's research and training programs encompass ~10,000 square feet of space on the Laurel Heights and Mt. Zion campuses, with work areas for research faculty and other space committed to support staff, including programmers and administrative and computer support. Facilities also include conference rooms, telephones with teleconferencing capacity, copying and fax machines, modern line computers, audio-visual equipment, and other support resources.

Appendix A: List of references cited

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