

**Electronic Health Record (EHR)-enhanced clinical communication and quality-of-life improvement in managing menopausal vasomotor menopausal symptoms (VMS)**

Submitted by:

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**Abstract**

The overall goal of this project is to evaluate the effectiveness of an EHR-facilitated clinical intervention to help improve control of vasomotor symptoms in menopausal women. Research objectives include 1) To develop, build, test, and implement an EHR-based set of activities to facilitate clinical communication around managing VMS, 2) To assess the impact of EHR-enabled VMS tools on practitioners and the clinical encounter, 3) To assess the impact of EHR-enabled patient engagement on clinical interactions around managing their VMS, and 4) To improve patient Health-related Quality of Life (QoL) in symptomatic menopausal women through better management of VMS. To address these questions, the project team will design and implement a robust, cluster-randomized clinical trial to test the effect of combining patient-generated VMS symptom information and quality of life into useful electronic dashboards for patients and practitioners, with practitioner decision-aids (based on best practice recommendations) and electronic health record tools that facilitate treatment actions. The study design allows for two experimental arms (patient-only intervention, and patient-practitioner intervention), both compared with standard care at baseline. The project is hubbed within a large Department of Obstetrics and Gynecology and with the Biomedical Informatics group of the University's acclaimed Clinical and Translational Science Institute. The project has the integral involvement of the Medical Center's enterprise-wide EPIC system (termed e-Record), guided by a project team of accomplished practitioners, statisticians, epidemiologists, informaticists, and qualitative researchers. Project results will be disseminated locally through both practice and research networks, and nationally at scientific conferences and in peer-reviewed publications.

## **Electronic Health Record (EHR)-enhanced clinical communication and quality-of-life improvement in managing menopausal vasomotor menopausal symptoms (VMS)**

### **I. Overall Goal and Objectives**

The overall goal of this project is to evaluate the effectiveness of an EHR-facilitated clinical intervention to help improve control of vasomotor symptoms (VMS) in menopausal women. This goal aligns with Pfizer's interests in addressing a care gap reflected by the high proportion of women whose menopausal symptoms are negatively impacting their quality of life though who are not presently receiving treatment for these symptoms. The project's goal also aligns well with the University of Rochester's new Strategic Plan that emphasizes innovation, population health, widespread integration of technology to improve care, and improving value. The Department of Obstetrics and Gynecology, the academic home for this project, constitutes a large practice group that serves a diverse population of women experiencing menopausal symptoms, has nationally- and internationally-recognized menopausal researchers, and has clinical champions with strong visibility around menopause-related issues among practitioners and the community. Further, the University of Rochester has had a large installation of EPIC (electronic health record system) since March 2011 with mechanisms for conducting the type of research proposed. That the Biomedical Informatics Group at Rochester's Clinical and Translational Research Institute<sup>1</sup> are involved in all aspects of this project leverages substantial technical resources in electronic health record-based research, study design, and dissemination.

#### **The objectives of this research include:**

- 1) To develop, build, test, and implement an EHR-based set of activities to facilitate clinical communication around managing VMS,
- 2) To assess the impact of EHR-enabled VMS tools on practitioners and the clinical encounter,
- 3) To assess the impact of EHR-enabled patient engagement on clinical interactions around managing their VMS, and
- 4) To improve patient Health-related Quality of Life (QoL) in symptomatic menopausal women through better management of VMS.

#### **I.a Theoretical Orientation**

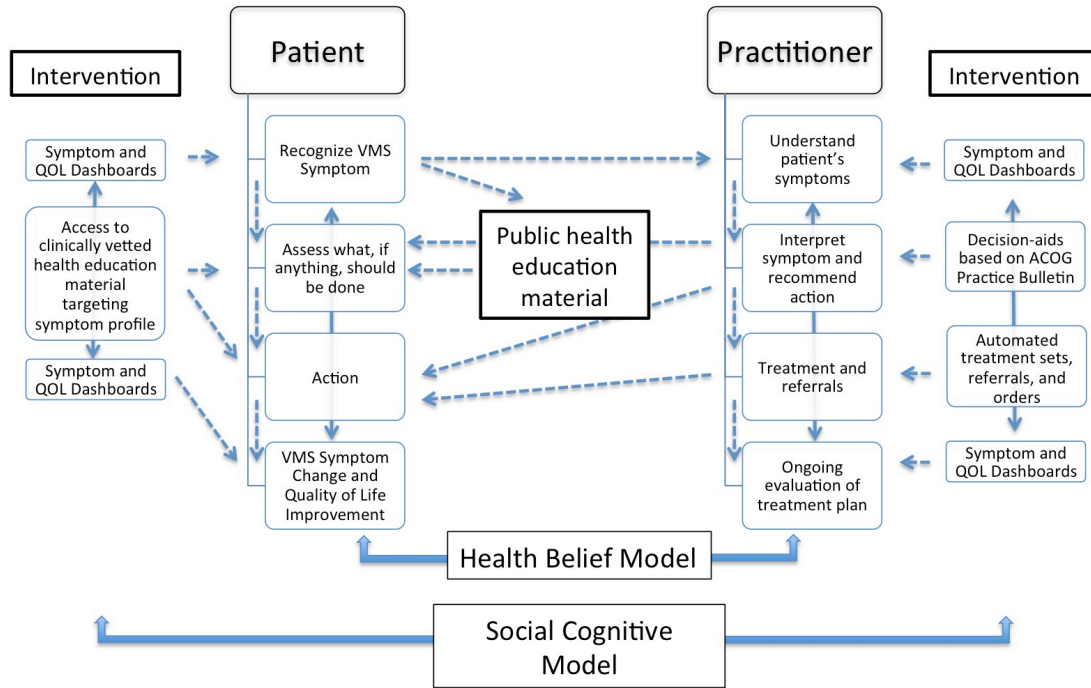
This project is guided by two intersecting health behavior theoretical models (see Figure 1). First, the classic Health Belief Model (HBM) attempts to explain and predict health behaviors, by focusing on the attitudes and beliefs of individuals (see Nutbeam et al. 2012). In this project both the patient and practitioner are guided by the Health Belief Model: they identify and

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assess risks, benefits, and options, and then act upon them. A woman must identify and recognize an experience as a “symptom” and she (and her practitioner), in turn, make an assessment of what, if anything, should be done about it. This project aims to help women better identify their symptoms with this information, which are then provided along with treatment recommendations to practitioners so they are better able to treat them.

Figure 1. Theoretical Model of VMS Behavior Change



This interaction between patient and practitioner is highlighted in a second theoretical orientation, Social Cognitive Theory. Social Cognitive theory posits that behavior change occurs due to a dynamic and reciprocal interaction of the person, environment, and behavior (Nutbeam et al 2012). Applied to this project, by improving a woman’s “information” environment with structured and effective information provided through public and clinical sources, that information and the involvement of the clinician in generating treatment options shapes her behavior (e.g. adopting recommended treatments).

The experimental design adopted in this project allows for manipulation of the information environment in three ways: first, by packaging detailed patient-generated symptom and quality of life data into actionable dashboards for both patients and for practitioners; second, through enhanced information targeting patient need (directed online health education material) and practitioner need (EHR decision-tools based upon best practice recommendations from ACOG); and finally, the bundled treatment options will be based on electronic algorithms incorporating the patient symptom profile and practitioner recommendation.

## II. Technical Approach

### II.a. Assessment of Need for the Project

The University of Rochester Medical Center (URMC) is the largest health care provider of inpatient and outpatient women’s health care in the Finger Lakes region, comprising a network of hospitals, primary care practitioners, and specialists. Because URMC uses EPIC (which accounts for the largest meaningful use market share among EHR providers in the USA),<sup>2</sup> the primary population of interest for this particular project is the population served by the extended URMC system. In the proposed population, women are seen primarily by obstetricians/gynecologists (68%) with remainder being served by Family Medicine and Internal Medicine practitioners.

<b>Age (years)</b>	<b>ICD9 627.2 Symptomatic menopausal climacteric states*</b>	<b>Estrogen/Combination Prescribed</b>	<b>Percent Prescribed</b>
45-54	1135	144	12.7%
55-64	853	163	19.1%

\* Source: University of Rochester CTSI, i2b2 Query and Analysis Tool applied to URMC’s e-Record population (51,904 outpatient women age 45-54 and 52,268 outpatient women age 55-64)

This project adopts the American College of Obstetricians and Gynecologists (ACOG) 2014 Practice Bulletin on Management of Menopausal Symptoms as outlining best practice, which includes both hormonal and non-hormonal treatments.

Shown in Table 1, overall only 15.4% of URMC outpatients with diagnosed symptomatic menopausal or female climacteric states were prescribed estrogen. As mentioned in the RFA for this initiative, this pattern may well illustrate an important gap in care for women who may benefit from hormonal therapy. This data suggests, perhaps, overall underuse of medical treatment for VMS symptoms, though insufficient data exists to confirm that interpretation. Therefore, the first phase of this project will be collect baseline data regarding VMS symptoms, quality of life, and clinical practice, providing a base for comparison of the proposed intervention. Note that the clinical diagnosis of approximately 2,000 women with VMS symptoms are from an overall population of more than 100,000 outpatient women in these age groups. The diagnosis code may well indicate an undercount of women presenting with these symptoms. The baseline period will help the team assess this potential undercount in coding.

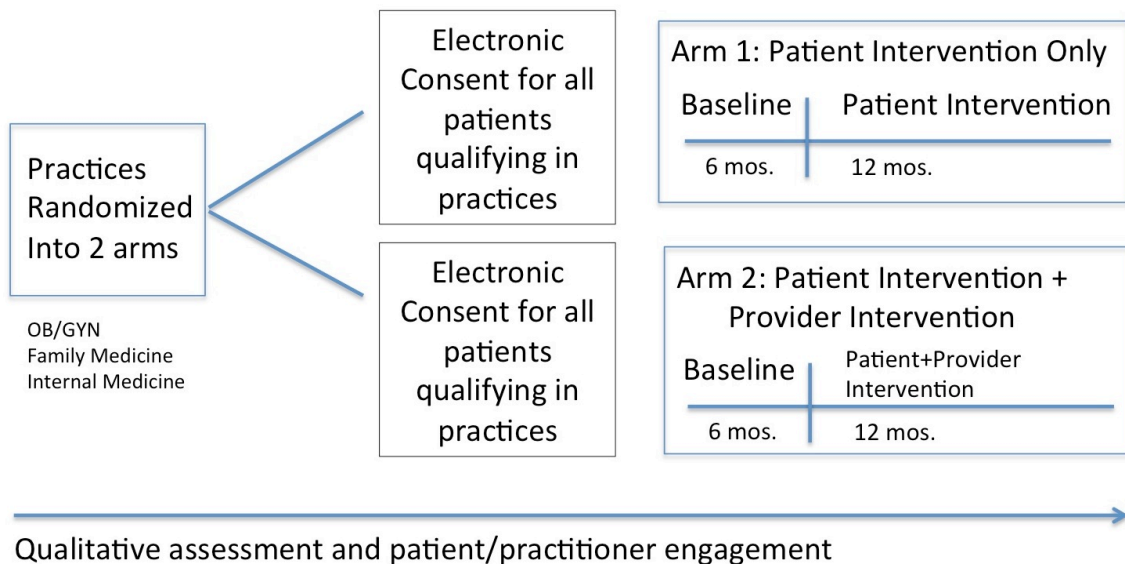
<sup>2</sup> EPIC is the top Electronic Health Record software for all categories of meaningful use (see “EHR Meaningful Use Market Share IndustryView | March 2014” available at <http://www.softwareadvice.com/medical/industryview/ehr-meaningful-use-market-share-2014/>)

**Target Population.** The target population for this study includes women age 45-64 without surgically-induced menopause and without known medical history that is contraindicated for care strategies outlined in ACOG’s 2014 Practice Bulletin on Management of Menopause Symptoms. Informed written consent will be obtained in two stages, first by enrolling URMC-associated OB/GYN, Internal Medicine, and Family Medicine practices into the study, and secondly by electronically notifying all women with scheduled primary care appointments in those practices of the study and obtaining informed consent. Because consent will be obtained electronically through MyChart, and since the intervention is deployed in part through MyChart, the study will may not be representative of non-MyChart users (who could have lower health and digital literacy, or perhaps internet access, than MyChart users). The University of Rochester’s Research Subjects Review Board (RSRB) will review and approve the project prior to recruitment.

**II.b. Project Design and Methods**

**II.b.i. Overall study design:** The study is designed as a cluster randomized trial to investigate the effects of two interventions, a patient-centered intervention and provider-centered intervention, on quality of life in symptomatic menopausal women and to compare these interventions with standard care identified in the baseline phase. This design will be supported by qualitative formative research and a qualitative process evaluation to help facilitate insight and engagement. The general study design is presented in Figure 2 and the overall flow of intervention is presented in Figure 3.

**Figure 2. Overall Study Design**



### *II.b.ii Rationale*

A randomized trial is necessary to establish whether or not an EHR-enhanced practitioner-targeted intervention offers advantages over 1) standard care measured at baseline, or 2) an intervention targeting only patient education. Because patients cluster in practices, the only option to eliminate an erroneous practice-effect is to conduct a cluster randomized trial. Also, because of the logistics of the interventions, practitioners cannot conceivably deliver care in one way (informed by EHR-enhancements) to one patient, and in a different way (without enhancements) to a different patient. Thus the model of the cluster randomized trial with practice as the unit of randomization is the optimal design. Further, the project team decided that symptom-appropriate health education information is warranted for all participants and should be part of standard care. So, all participants will form their own control during the baseline period (no interventions) and then all will receive the patient intervention. The experimental arm will then, in addition to the patient intervention, receive the practitioner (EHR) intervention.

### *II.b.iii Intervention Description*

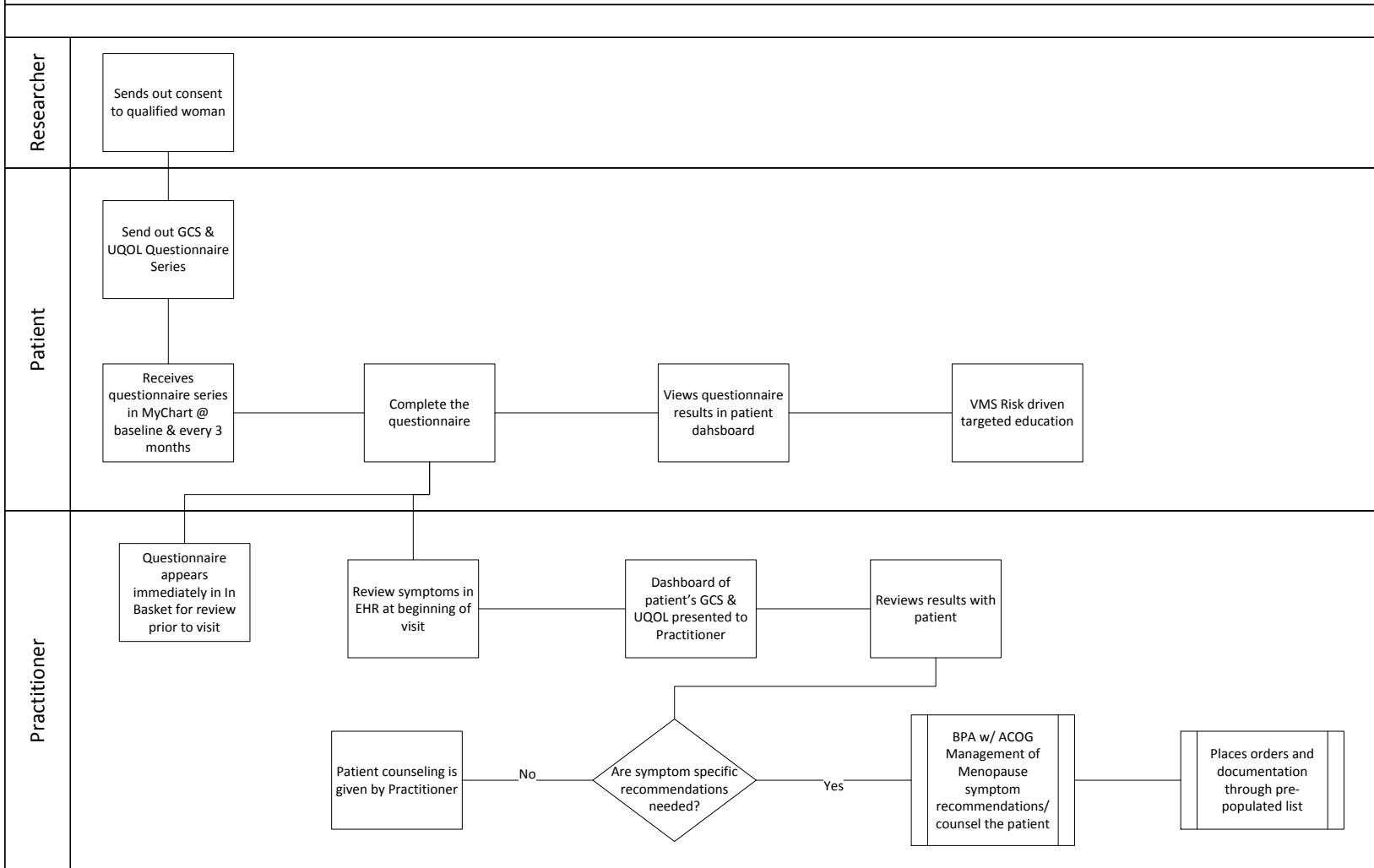
The two intervention arms (Figure 2) include: 1) “Patient Intervention” only (includes patient symptom and quality of life assessments, feedback through a dashboard to patients, and access to targeted practitioner-vetted educational materials), and 2) the Patient Intervention plus the “Practitioner Intervention” (practitioner has access to EHR-enhanced care supports with patient assessment dashboards tailored for clinical use, tools to facilitate use of ACOG Practice Bulletin, and pre-planned orders and documentation). All patients seeking care from an enrolled practitioner will receive the intervention appropriate to the group for which that practitioner was assigned. The Intervention Flow is shown in Figure 3.

Patient Intervention. Patients will be asked to complete at standard intervals and before clinical visits two instruments: The Greene Climacteric Scale (GCS) and the Utian Quality of Life Questionnaire (UQOL).

The Greene Climacteric Scale is one of the most widely used scales for measuring menopausal symptoms, and has demonstrated excellent reliability and validity (Greene 1998). This VMS symptom measure consists of 21 items scored on a 4-point Likert scale (0, not at all; 3 extremely), that measure four categories of symptoms a) psychological symptoms; b) somatic symptoms; c) vasomotor symptoms and d) sexual dysfunction.

The Utian Quality of Life Questionnaire is a commonly used tool for clinical research and practice in perimenopausal women and has demonstrated high reliability and validity (Utian et al 2002). This measure consists of 23 items scored on a 5-point Likert scale (1, not true of me; 5, very true of me) that measure four components of quality of life (QOL): occupational QOL, health QOL, emotional QOL, and sexual QOL.

Figure 3: Intervention Flow



**Key:**

GCS – Greene Climacteric Scale

UQOL – Utian Quality of Life Scale

BPA – Best Practice Advisory (an active decision support alert)

ACOG – The American College of Obstetricians and Gynecologists

The information from these two scales will be summarized back to women on a dashboard summarizing and highlighting their responses, in addition to presenting the individual components of the scales. Online health education materials that have been vetted by the project's clinical team to assure quality and consistency with the ACOG Practice Bulletin on Managing Menopausal Symptoms will be linked with women's scores on the two scales. As such, the recommendations they receive will be targeted to their VMS symptom and QOL profiles. The actual content and presentation of these dashboards and feedback mechanisms will be developed and tested in the qualitative formative stage of the project to assure usability and participant acceptability.

Practitioner Intervention. The practitioner intervention will include several components (Figure 3). First, practitioners will have access to the woman's VMS symptom and quality of life information detail (question-specific) within e-Record (EPIC). Second, information will be summarized in a Care Dashboard for the practitioner to help them identify potential concerns, and to interpret and act upon the information. Third, practitioners will have easy access to VMS-specific EHR-actions (e.g., automatic documentation, pre-planned order sets, prescription sets) that enhance adherence with the ACOG Technical Bulletin. As with the Patient Intervention, the design and usability details of the Practitioner Intervention will emerge from the qualitative formative phase that involves practitioners. Note, given the experimental design, that all enrollees receive the *Patient* Intervention, but only enrollees who are patients of practitioners in the *Practitioner* Intervention arm will receive care that results from clinical EHR-enhanced activities.

#### *II.b.iv Analytic Plan*

Power Calculation. The proposed study will enroll patients from 12-15 practices. These practices will be randomly assigned to the two intervention arms as described previously, stratified by size and practice type. For both arms, all patients will receive standard care during the first phase. During the second phase, Arm 1 will receive the patient intervention only and Arm 2 will receive the patient intervention along with the practitioner invention. Patients will be recruited in the study during both phases. Those enrolled in the first period will be followed up either until completion of the study or until drop out, whichever occurs first. With 200 subjects enrolled in each phase across practices assigned to the arm in which patients receive the first intervention during the second phase, the study will have more than 80% power to detect a standardized difference (Cohen's effect size) of 0.3 in the UQOL change relative to baseline (see "Statistical methods" section below for a definition of this outcome variable) using a two-sided *t*-test with a 5% significance level. We expect the study to have higher power or be able to detect smaller effect size because change in UQOL will be measured at several time points. Randomization of practices will be stratified by practice size to assure comparable groups.

Statistical methods. The primary objective of the statistical analysis is to determine whether either of the two interventions that will be tested improves quality of life in symptomatic menopausal women through better management of VMS compared to standard of care. The primary outcome variable that we will use to compare interventions will be the UQOL score. In



all statistical analyses, we will treat this score as a continuous variable. For each patient, the UQOL score will be determined at baseline and during subsequent assessments. We expect that these assessments will occur every three months on average. At baseline, the UQOL score will be determined before intervention. Thus, because of randomization, there should be no difference in UQOL at baseline, regardless of phase and intervention received. Our primary statistical analysis will focus on change in UQOL relative to baseline, measured repeatedly over time in each patient and described using multi-level linear mixed effects models to account for within-patient and within-practitioner dependencies. These models will include the following covariates (or any subset of these, if deemed more appropriate) as fixed effects: baseline UQOL, the type of intervention received when UQOL was determined (a three-level categorical variable), time from baseline (defined as the difference between the time at which UQOL was evaluated and the time at which the patient entered the study). To test whether the rate of improvement differs by practice or arm, we will also consider including interaction terms (the most important ones being time  $\times$  practice and time  $\times$  treatment). Other interactions will be considered, for example: time  $\times$  time and time  $\times$  treatment  $\times$  practice. Two levels of random effects will be introduced in the model. One level will describe potential dependencies between observations performed in the same patient. This will be accomplished using patient-specific random intercepts and random coefficients for the variable time. The significance of these random effects will be assessed using a likelihood ratio test on the associated variance components, accounting for the fact that variances are constrained to be positive when determining the asymptotic distribution of the test. A second level of random effects will describe potential dependencies induced by practitioners. Our plan is to include these random effects as practitioner-specific random intercepts. Modeling assumptions will be thoroughly checked. For example, the assumptions of normality of the error terms and of the random effects will be examined by inspecting the distribution of the conditional and unconditional residuals using normal probability plots. Scatterplot of residuals will be examined to assess the linearity assumption. If any assumption appears violated, we will either modify the model or transform the data. We expect the probability of an observation to be missing to increase over time due to attrition. We will investigate whether other variables is associated with the probability that any observation misses. Once an appropriate model will have been developed, we will compare interventions using likelihood ratio tests. Point estimates of model parameters will be reported along with their standard errors and 95% confidence intervals. All significance tests will be two-sided (with the exception of the likelihood ratio tests for variance components) and conducted at the 5% significance level. All statistical analyses will be conducted using SAS, R or Matlab.

### **III. Evaluation Design**

As described previously, this study is primarily powered to detect a 30 percent change in UQoL and secondarily powered to detect change in VMS in menopausal women. While the main study is a cluster randomized trial, it is supplemented by a substantial qualitative and formative component to obtain practitioner and patient input into the design of the intervention. Further, patients and practitioners are queried regularly throughout the study to ascertain the impact of the intervention on their care parameters (length of visits, documentation requirements, etc).

The study team includes experts in statistical design, epidemiology, clinical care, and biomedical informatics. Additional detail regarding measurement and evaluation of the project's objectives follows.

### **III.a. Overview of Outcomes Evaluation**

**Objective 1:** *To develop, program, test, and implement an EHR-based set of activities to facilitate clinical communication around managing VMS.*

EHR Build: Adapting Darer's approach to EHR innovation in clinical care (Darer 2014), the core intervention of this project is a cluster of action tools that support elimination of care gaps (see Silow-Carroll 2012). To do this, we will create an intervention that starts with a set of structured questionnaires built into MyChart that: 1) obtains consent from eligible women, 2) implements the Greene Climacteric Scale (GCS) to assess symptomatology (see Greene 1998), and 3) implements the Utian Quality of Life Scale (Abraham et al 2014). Automated algorithms will convert GCS and UQOL data into visual dashboards accessible to patients and practitioners along with practice recommendations appropriate to the GCS and UQOL interpretations based upon the ACOG Management of Menopausal Symptoms Practice Bulletin (2014). Notations of the GCS and UQOL results will be placed in an appropriate documentation location, triggering practitioners to address these issues at the next visit. Women will have access to their own results of the GCS and UQOL through MyChart, and upon completion and enrollment will receive linkages to ACOG and Menopause Society patient-information sources, University of Rochester PeriFacts Bulletins addressing menopause, and guest columns on menopause from *Rochester Women* authored by co-investigator Dr. James Woods. At the clinical encounter, practitioners in the experimental group will discuss the woman's results to the GCS and UQOL and will present appropriate treatment recommendations from the ACOG Practice Bulletin. Practitioners will initiate appropriate automated orders for treatment based on their clinical encounter with women. Basic fields will be included in the EPIC record to document fidelity in implementation of the intervention as appropriate to the practitioner's assigned group.

Provider Training: All practitioners participating in this project will participate in two one-hour training sessions organized by Dr. Dye and Dr. Woods. The content of this provider education will include discussion of risk assessment and measurement using MRS and UQOL, ACOG Practice Bulletin treatment recommendations, and Patient Communication about Menopause. The EHR build will be tested using usability testing techniques and will be iteratively developed until the project team reaches consensus on the tools, presentation dashboards, and practice recommendations. After the build consensus is reached, the intervention will be tested with non-participating practitioners to identify final usability issues and issue the final build.

Objective 1, qualitative component: The success of the intervention depends in large part on practitioner willingness to engage in the patient's GCS and UQOL generated recommendations, documentation, and automated orders in the EHR. To maximize practitioner engagement and improve the EHR build, semi-structured focus groups will be conducted with practitioners during the first phase of the project. We will use a

purposeful sample of practitioners across a variety of practices and ages until redundancy is reached. Practitioners will first be asked open-ended questions about their attitudes regarding integrating into the EHR the patient surveys and AGOG recommendations. They will then be asked specifically about their reactions to prototypes of the EHR build. A similar approach will be taken with focus groups of target patients, except with a focus on repackaging the measurement tool results (Green Climacteric Scale and the Utian Quality of Life), focusing upon women's interpretation and understanding of the results, and comments on education sources to which they will be referred. A trained qualitative researcher will conduct the focus group with a research assistant taking notes. All focus groups will be recorded with the permission of participants. The audiotape of the discussions and the participant observer's notes will be analyzed using the constant comparative method by two investigators (Krueger 1994).

**Objective 2:** *To assess the impact of EHR-enabled VMS tools on practitioners and the clinical encounter.*

Practitioners in practices participating in this study will receive a brief generalized automated survey in their EPIC In-Basket at baseline and every three months assessing their experience with providing clinical care to women around VMS that particularly assesses length of visits, time spent answering questions for patients outside of clinical encounter, time spent writing up notes, and transparency of documentation (see Darer 2012, Delbanco et al 2010).

Objective 2, qualitative component: Based on practitioner survey responses, a purposeful sub-sample of practitioners (varying in engagement and satisfaction with intervention) from the EHR enhanced arm will be recruited to participate in semi-structured focus groups. The objective of this process evaluation is to better understand how practitioners interact with the intervention and if they find it a helpful addition to their current standard of care. The findings from this analysis will be used to better understand the overall findings of the intervention and how and if the intervention can be disseminated or improved. A trained qualitative researcher will conduct the focus groups with a research assistant taking notes. All focus groups will be recorded with the permission of participants. The audiotape of the discussions will be transcribed and coded. Two investigators will independently and systematically reviewed transcripts to identify themes and sub-themes unique and similar across all groups. Systematic coding scales included frequency (the number of times that the topic appears in the analysis), convergence (whether the topic extends across subject classification groups), and intensity (the emotion and importance of topic to the speaker) of the data elements. Using an iterative process, these themes will be revised until a consensus is achieved among the two investigators. We will use NVivo, a qualitative data analysis software, to manually record and compare coding of transcripts.

**Objective 3:** *To assess the impact of EHR-enabled patient engagement on clinical interactions around managing their VMS*

Patients in both groups will be triggered every three months from baseline to assess whether or not they: understood their health and medical conditions better, took better care of themselves, remembered the plan for their care better, were better prepared for their visits, felt more in control of their health care, were more likely to take medications prescribed (e.g. see Darer 2014, Delbanco et al 2010).

Objective 3, qualitative phase. A purposeful sample of patients from both study arms will be recruited to participate in telephone interviews about their experience. The objective of this process evaluation is to better understand patients' experiences filling out the questionnaires, their clinical interaction with their physician, and (for those in the Practitioner Intervention arm) if they believe the intervention improved their quality of care. The findings of this qualitative analysis will provide important insight into the perceived impact of the intervention from the patient's perspective.

**Objective 4:** *To improve patient Health-related Quality of Life in symptomatic menopausal women through better management of VMS.* Patients enrolled will be triggered to repeat the GCS and UQoL every three months from baseline, to document both absolute change from baseline and relative change from each quarter. We will implement final intent-to-treat analysis ascertaining if UQoL changed over time and if that change can be attributed to the interventions in this project.

### **Summary of Outcomes Evaluation**

Assessment of provider and patient metrics will occur at the intervals described in Section E, and are modeled on the OpenNotes evaluation (Darer 2014, Delbanco et al 2010). All data is gathered through EPIC and MYCHART, designed by the project team and analyzed by the project team in coordination with a biostatistician. To control for a variety of external factors, we have included a phase of standard care (at baseline) and two intervention arms, and will measure fidelity of the intervention as implemented. The study is powered to detect an estimated 30% improvement in the UQOL index from baseline to one year post-enrollment. Participant engagement will be managed directly through examining access/portal use metrics, responses to quarterly experience assessments, and through the qualitative evaluation.

### **III.b Dissemination**

Scientifically, results from this project will be presented at national conferences and will be submitted for peer-reviewed publication. We will target, specifically, methodological journals interested in the impact of electronic health record-based interventions, and also in clinical journals interested in whether or not VMS symptom management can be impacted by clinician-oriented intervention. Internal to the University of Rochester's technical environment, the EPIC team will share the methods, operationalization, and impact of this project with EPIC leaders in other disciplines who may wish to take a similar approach in their own clinical research using e-Record. Additionally, Dr Woods will share the project's findings with other local, regional, and

state practitioners who work with women of menopausal age. The project’s findings will further be integrated with the PeriFACTS continuing education system (which Dr Woods directs) which will provide the most comprehensive local outlet for results.

### III.c Innovation

This project is innovative in its design and approach. After conducting a detailed literature search, we have not identified another cluster randomized trial that randomized practitioners to intervention groups and assessed VMS symptomatology over the course of one year. As described earlier, there are inherent biases in not randomizing practitioners in research where patient outcomes are assessed though the main target for intervention is a clinical, practice-based one. Secondly, this project is uniquely situated in an ideal context of a large e-Record installation in a complete medical institution, with the integral involvement of practitioners and informaticists, placing the study at the center of where the University’s research capacity and clinical care intersect.

### IV. Detailed Workplan and Deliverables

This project’s timeline (Table 2) is anticipated to be 24 months, with four months for build planning, implementation, and testing, one month for training, staggered randomization and enrollment (estimated for six months), and follow-up for twelve months. Three main deliverables guide this project that reflect the project’s logic model: the Interventions are developed and built, the cluster randomized controlled trial (the primary source of information for this project) is developed and implemented, and the information from the RCT is analyzed, interpreted, and disseminated.

<b>Table 2: Timeline</b>		<b>Month of Project</b>																								
<b>Overview of Deliverables Timeline</b>		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	
<b>1. EHR Build/ Intervention Development</b>																										
<b>2. RCT Developed and Implemented</b>																										
<b>3. RCT Evaluated and Disseminated</b>																										
<b>Deliverables Timeline Detail</b>																										
Finalizing team members																										
All-hands team meeting (monthly)																										
IRB Approval and Registration																										
Practitioner focus groups to inform intervention																										
Patient focus groups to inform intervention																										
Intervention build prototyped																										
<b>Deliverable 1: Intervention build finalized</b>																										
Practices recruited																										
Practices randomized																										
Consent created in MyChart																										
Patients recruited																										
Baseline measurement of GCS/ UQoL																										
Repeated measures GCS/ UQoL (Every 3 months)																										
<b>Deliverable 2: Implementation of Full RCT Protocol</b>																										
Qualitative Process Evaluation																										
Data management and quality control																										
Statistical analysis																										
Conference Presentation																										
<b>Deliverable 3: Develop and Submit Manuscripts</b>																										

**Deliverable 1: EHR Build and Intervention Development.** While the project team members have ideas about the EHR intervention (e.g., dashboards, clinical practice reminders, decision-aids), the details and usability of the intervention needs to be tested with patients and practitioners. Thus, the qualitative phase will begin immediately with concept and prototype testing and focus grouping to refine and finalize the electronic interventions in the first quarter (by month four) of the project. Because the trial begins with a baseline phase (no intervention) that consists solely of assessment deployment (without feedback to patients), the builders will have up to six additional months to finalize and integrate the final interventions into the e-Record (EPIC) system.

**Deliverable 2: RCT Developed and Implemented.** The main focus of the project in the cluster randomized controlled trial of the electronic interventions, with two arms (patient intervention only, and patient-practitioner intervention). Explained earlier, the study questions necessitate this design given the lack of systems independence of practitioners belonging to the same practice (that is, all practitioners in a particular practice use the same system for all patients, making simultaneous implementation of a variety of electronic interventions confounded). As such, practices will be recruited for this study (estimated 12-15 practices) and subsequently randomized. All patients within each practice meeting eligibility criteria within the six month window of recruitment will be approached electronically to obtain consent to participate. MyChart (the patient interface with EPIC and their practitioner) will be deployed with the GCS and UQOL instruments to consented participants repeated at three month intervals throughout the project. The actual trial is expected to last for 18 months of the project period, with two months in the first quarter for additional planning and administrative procedures.

**Deliverable 3: RCT Evaluated and Disseminated.** The final analysis for the project will occur in the last quarter, together with manuscript generation and conference abstract submission (dissemination). However, the project team will be conducting evaluation activities from the start of the project period through: 1) the ongoing qualitative formative and process evaluation, 2) ongoing data and enrollment management and data quality reviews, and 3) anticipatory statistical analysis and analytic plan development.

**Administration and Management.** The project will be managed daily by the Project Coordinator and the Principal Investigator. An all-hands team meeting will meet monthly throughout the project so all project team members are apprised of progress and involved. Regular meetings will be held with subgroups assigned to particular tasks. The project team will use ASANA ([www.asana.com](http://www.asana.com)) to organize and share material relating to the project. The project will also form part of the standing agenda for the CTSI Biomedical Informatics team, in the event that other informatics resources need to be accessed for unforeseen technical circumstances and to provide a backup management structure in the event of an emergency. The PI and Project Coordinator will cooperatively complete all RSRB (IRB) requirements, trial registrations, and other administrative and regulatory aspects of the project. The PI and Project Coordinator will meet at least weekly to review the project's progress, and the Project Coordinator will also attend the weekly CTSI Biomedical Informatics team meetings.

## References

- Abraham, L., Pinkerton, J. V., Messig, M., Ryan, K. A., Komm, B. S., & Mirkin, S. (2014). Menopause-specific quality of life across varying menopausal populations with conjugated estrogens/bazedoxifene. *Maturitas*.
- American College of Obstetricians and Gynecologists. (2014). ACOG Practice Bulletin No. 141: management of menopausal symptoms. *Obstet Gynecol*, *123*, 202-216.
- Darer J. Disruptive Innovation and Data-Driven Care. University of Rochester Department of Medicine Grand Rounds, June 2014.
- Delbanco, T., Walker, J., Darer, J. D., Elmore, J. G., Feldman, H. J., Leveille, S. G., & Weber, V. D. (2010). Open notes: doctors and patients signing on. *Annals of internal medicine*, *153*(2), 121-125.
- Green J. Constructing a standard climacteric scale. *Maturitas* 1998; 29:25-31.
- Krueger RA. Focus Groups. 2<sup>nd</sup> ed. Thousand Oaks, CA: Sage Publications, 1994.
- Nutbeam D, Harris E, Wise M. Theory in a Nutshell: A Practical Guide to Health Promotion Theories (Third Edition). Australia: McGraw-Hill, 2012.
- Silow-Carroll, S., Edwards, J. N., & Rodin, D. (2012). Using electronic health records to improve quality and efficiency: the experiences of leading hospitals. *The Commonwealth Fund*, *17*, 1-38.
- Utian WH, Janata JW, Kingsberg SA, Schluchter M, Hamilton JC. The Utian Quality of Life (UQOL) Scale: development and validation of an instrument to quantify quality of life through and beyond menopause. *Menopause* 2002; 9(6):402-10.

## **V. Organizational Detail**

### Organizational Capacity

This project will be led by the University of Rochester Medical Center's Department of Obstetrics and Gynecology. Dr. Timothy Dye, Professor of OB/GYN, Pediatrics, Medical Informatics, and Public Health, and serves as Associate Chair for Research in the Department of OB/GYN, will serve as PI, and Dr. James Woods, Professor and Chair Emeritus will serve as Co-Investigator. Dr. Dye also leads Biomedical Informatics in the Clinical and Translational Science Institute (CTSI), which along with the Division of Medical Informatics will form the technical team for the project. Dr. Woods is a world-recognized leader in OB/GYN patient-provider communication, menopause research, and obstetrical and gynecological practice. Drs. Dye and Woods will be supplemented by other professorial and technical staff in implementing this work.

### **University of Rochester Medical Center**

One of the nation's top academic medical centers, the University of Rochester Medical Center forms the centerpiece of the University's health research, teaching, patient care and community outreach missions. Over the last five years, the UR School of Medicine and Dentistry has received almost \$1.3 billion in total research funding. The School ranks in the top quartile of U.S. academic medical centers in research funding from the National Institutes of Health, attracting nearly three times the federal funding received by the medical schools in Albany, Syracuse and Buffalo combined. The University's health care delivery network— UR Medicine — is anchored by Strong Memorial Hospital - an 800-bed, University-owned teaching hospital which sustains specialty programs that consistently rank among the best in the nation according to *US News & World Report*.

While this project is not limited to practitioners in the URMIC OB/GYN Department, the Department does provide about 70 percent of care to women with VMS seen at the University, which is the larger provider in the region. The Investigators will engage the Practice-Based Research Network and the OB Practice Network to access additional practitioners who provide primary care to women with VMS. Nested within the Department of OB/GYN will enhance the project's research environment, access to clinical research resources, and will facilitate communication through existing in-person, on-line, and written mechanisms. Further, the project may involve some of the residents and medical students being taught in the Department, providing a research learning experience for future practitioners and women's care practitioners.

The EPIC system is maintained by the Division of Medical Informatics, headed by Dr. David Krusch, also a Co-Investigator of this effort. Dr. Dye's team in the Biomedical Informatics group of the CTSI works closely with Dr. Krusch's team in Medical Informatics to implement research interventions using EPIC and its associated projects. With the technical team nested within the investigator team and fully resources, there is little risk that the priority of this project will delay implementation or research attention. Dr. Dye's team also works closely with the Department of Biostatistics to provide analytic services.



## Staff Capacity

**Timothy De Ver Dye, PhD** will serve as Principal Investigator for this project. Dr Dye is Professor and Associate Chair for Research in the Department of Obstetrics and Gynecology at the University of Rochester, and also serves as Director of Biomedical Informatics for UR's Clinical and Translational Research Institute. Dr Dye has extensive experience with clinical and translational research with an emphasis on women's and children's health, and has overseen numerous large-scale informatics projects that integrate with hospital systems. Specifically for this project, Dr Dye will liaise with the Pfizer team, will oversee the project team's development and implementation of the proposed research, and will lead in the dissemination of findings. As an epidemiologist and anthropologist with expertise in biomedical informatics, Dr Dye is well-suited to relate to all aspects of the proposed research.

**Project Coordinator.** A part-time project coordinator will be hired/ assigned to coordinate all aspects of the study, working closely with Dr Dye and project team members to assure that project plans are developed and implemented efficiently. The Project Manager will also serve as the main interface for project reporting and compliance, both with Pfizer and with the University of Rochester's internal systems. The University of Rochester's CTSI maintains a robust professional development organization of research study coordinators (Study Coordinators Organization for Research and Education "SCORE") that provides networking and training opportunities. This project will first access the SCORE group with this opportunity, only recruiting externally in the unlikely event that an existing SCORE study coordinator with strong informatics background cannot be identified. The Coordinator will be Master's prepared, with clinical / clinical research experience, and demonstrated informatics and EHR experience, preferably in the context of primary care and women's health.

**James Woods, MD** will serve as Co-Investigator for this project. Dr Woods is Professor and former Chair of the Department of Obstetrics and Gynecology at the University of Rochester, and has extensive expertise in women's health, clinical research, and menopausal care. Dr Woods is deeply involved with continuing professional education as Editor-in-Chief of *Perifacts*, subscribed by over 11,000 ob/gyn nurses and physicians across the U.S. Dr Woods also writes a monthly article on Menopause Medicine and produces a monthly feature for *Rochester Woman* magazine on menopause. He is a significant opinion leader in Rochester and will work with **Kalin Warshoff N.P.**, who is a nurse practitioner clinician specializing in women's health, providing content expertise, testing EHR prototypes, reaching out to other participating practices, overseeing training of practitioners implementing the interventions, and vetting health education materials for the patient component of the intervention.

**Ollivier Hyrien, PhD** will serve as the project's methodologist and biostatistician. Dr Hyrien is Associate Professor of Biostatistics and Computational Biology at the University of Rochester, and has overseen the design and statistical analysis of many randomized trials of clinical interventions. Dr Hyrien will oversee the operationalization of the study design including randomization of practices, statistical management of study enrollment, and will conduct all analyses of study data.

**Miriam Weber PhD** will serve as the psychometrician for the project, in particular overseeing the operationalization and deployment of the Greene Climacteric Scale and the Utian Quality of Life Scale. Dr Weber, an Assistant Professor of Neurology at the University of Rochester, will work closely with Dr Hyrien around analysis of the scales and subscales generated from these instruments, and will assist the EPIC build team in presenting the results of these instruments in a valid and concise manner to practitioners in the Practitioner Intervention. Dr Weber is an experienced clinical researcher who has published extensively on menopause and quality of life, and will bring that experience to this project as the expert on menopausal symptom and quality of life measurement and analysis.

**Margaret Demment PhD** will oversee the qualitative assessment and patient/ practitioner engagement components of this project. Dr Demment is an epidemiologist and Senior Research Associate with the Clinical and Translational Research Institute (CTSI) at the University of Rochester. Dr Demment has experience organizing and conducting formative and evaluative qualitative research and with integrating qualitative research methods into quantitative designs (mixed methods). Dr Demment will work closely with Dr Dye and Dr Woods to assess patient and practitioner experience with the interventions of this project, and with Mr Tatro and Dr Darer to assess optimal intervention development.

**Adam Tatro, MSN** is the lead informaticist for the project and will oversee development and implementation of the EHR builds, including MyChart questionnaire development and EPIC dashboards for clinicians. Mr Tatro has extensive experience in both clinical and research informatics and is the Lead Informaticist for the CTSI at the University of Rochester. In this capacity, he routinely interfaces with the EPIC technical staff (locally, nationally, and at other institutions) and is familiar with EPIC functionality and operations. Mr Tatro will coordinate the EPIC Programmer and the technical development team to assure appropriate development and implementation of data capture, feedback, and display of all project information. Finally, Mr Tatro will work with Dr Demment to conduct usability testing with pilot groups to assure that the interventions are acceptable and sensitive to patient and practitioner needs.

**Jonathan Darer MD MPH** is Chief Innovation Officer at Geisinger Health System and an experienced clinical informaticist. Dr Darer, a primary care physician at Geisinger, has extensive experience adapting EPIC electronic health record systems for optimal clinical use and for clinical care improvement. Dr Darer will advise the team on intervention design and implementation, and will assist with interpretation of findings and patient/ practitioner evaluation. His extensive experience with patients and practitioners around electronic health record innovation will assist the project in maximizing the potential of the EPIC system.

**EPIC Programmer.** A part-time EPIC programmer will be hired/ assigned to program all builds, reports, and interfaces as required for the project. The Programmer will serve as the main liaison with the Division of Medical Informatics staff responsible for EPIC implementation at the University of Rochester and will assure that all project development and programming is in compliance with University and EPIC standards and requirements.



Timothy De Ver Dye, PhD  
Professor of Obstetrics and Gynecology  
Director, Biomedical Informatics  
Clinical and Translational Science Institute  
University of Rochester School of Medicine and Dentistry  
265 Crittenden Boulevard  
Rochester, NY 14642-0708

September 9, 2014

Dear Tim,

We are excited about your application to Pfizer entitled "Electronic Health Record (EHR)-enhanced clinical communication and quality-of-life improvement in managing menopausal vasomotor menopausal symptoms (VMS)." This project which aims to provide patient-generated information to practitioners in an informative way will better target the clinical encounter. With enhancements as described to our e-Record system, clinicians will likely benefit from streamlined bundling of treatments and referrals. The University of Rochester will support this project by ensuring that the resources, personnel, and facilities required to bring this worthwhile project to fruition are at your disposal. We wish you the best of luck with this project.

Sincerely,

A handwritten signature in cursive script that reads "Brenda Kavanaugh".

Brenda Kavanaugh  
Associate Director  
Office of Research and Project Administration  
University of Rochester

Stephen Dewhurst, PhD  
Vice Dean for Research  
Associate Vice President for Health Sciences Research

MEDICINE of THE HIGHEST ORDER

Timothy De Ver Dye, PhD  
Professor of Obstetrics & Gynecology, Pediatrics, Public Health Sciences, & Medical Informatics  
Vice Chair (Research), Obstetrics & Gynecology  
Director, Biomedical Informatics  
Clinical and Translational Science Institute  
University of Rochester School of Medicine and Dentistry

September 2, 2014

Dear Tim:

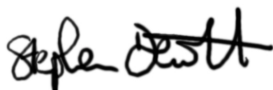
The University of Rochester (UR) School of Medicine and Dentistry (SMD) is pleased to support your application to Pfizer to conduct electronic health record research to improve patient and clinical experience managing vasomotor symptoms for women in menopause.

The research as proposed aligns well with the UR SMD's new Strategic Plan that emphasizes innovation, population health, widespread integration of technology to improve care, and improving value. The Department of Obstetrics and Gynecology, the academic home for this project, constitutes a large practice group that serves women experiencing menopausal symptoms, has nationally- and internationally-recognized menopausal researchers, and has clinical champions with strong visibility around menopause-related issues among practitioners and the community. Further, the University of Rochester has had a large installation of EPIC (our electronic health record system) since March 2011 with mechanisms for conducting the type of research proposed.

The grant application appropriately is centered with the Clinical and Translational Science Institute's Biomedical Informatics team working closely with our Medical Informatics Division (which runs the University's EPIC system), Biostatistics and Computational Biology on study design and statistical analysis, and of course our strong Department of Obstetrics and Gynecology.

As Vice Dean for Research at the School of Medicine and Dentistry, I will do whatever I can to encourage others to conduct practical, EHR-based research using rigorous methods working with you and your team. I look forward to learning of this project's progress and extending those learnings to the intersection of our research and clinical mission, an intersection directly addressed by EHR-related research activities.

Sincerely



Stephen Dewhurst, Ph.D.  
Vice Dean for Research, School of Medicine and Dentistry  
Associate Vice President for Health Sciences Research  
University of Rochester

## SCHOOL OF MEDICINE AND DENTISTRY

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### Department of Obstetrics and Gynecology

Eva K. Pressman, MD  
Henry A. Thiede Professor and Chair



September 1, 2014

Timothy De Ver Dye, PhD  
Professor of Obstetrics and Gynecology  
Associate Chair for Research, Obstetrics and Gynecology  
University of Rochester School of Medicine and Dentistry  
265 Crittenden Boulevard  
Rochester, NY 14642-0708

Dear Tim,

As the Chair of the Department of Obstetrics and Gynecology at the University of Rochester, I am very pleased to endorse your application to help improve care to women through creative uses of the electronic health record.

We have been using EPIC for several years and research projects such as the one you and Dr. Woods (our former chair) propose will help our physicians connect more strongly with the potential of e-record to strengthen the care experience. Vasomotor symptoms in menopausal women is a common condition we see in providing care; indeed this area can be easily overlooked in the context of other screening and clinical activities and your study will help us explore the best way to package patient-generated information for clinical use.

Further, I think that since you're using educational materials to expand women's knowledge of menopause that have been vetted (and in some cases, created by) our clinicians will help steer patients toward useful and accurate resources rather than leaving them to navigate the internet without guidance. In many ways, this project can be seen as an example for other studies based on using the electronic health record as a mechanism to improve care.

This project will be housed in our Department in collaboration with your informatics team at the Clinical and Translational Research Institute (CTSI). This project is also a great example of the intersection of informatics and clinical care for women, and the team you've assembled (which includes Dr Woods and other clinical providers) will help assure that your work is relevant and visible to clinicians. Our Research Division will provide whatever support necessary to facilitate this project and I think, since the project is embedded within a clinical department, there is a great potential that the project will be successful.

I think your project could provide a wonderful opportunity to help us see whether or not the electronic health record can provide unique opportunities to facilitate evidence-based care. That you are using the new ACOG Practice Bulletin from January 2014 on Managing Menopause Symptoms

as a base for clinical recommendations and information will certainly help us achieve that. On behalf of our department, I endorse this project, support your efforts and look forward to working with you on this important initiative.

Sincerely,

A handwritten signature in black ink, appearing to read 'Eva K. Pressman', written over a light grey rectangular background.

Eva K. Pressman, M.D.  
Henry A. Thiede Professor and Chair of Obstetrics and Gynecology

Karl Kieburtz, MD, MPH  
Robert J. Joynt Professor in Neurology  
Director, Clinical & Translational Science Institute  
Senior Associate Dean for Clinical Research

September 2, 2014

Timothy De Ver Dye, PhD  
Professor of Obstetrics and Gynecology, Pediatrics, Public Health Sciences, and Medical Informatics  
Director, Biomedical Informatics  
Clinical and Translational Science Institute  
University of Rochester School of Medicine and Dentistry  
265 Crittenden Boulevard  
Rochester, NY 14642-0708

Dear Tim,

I write to express my strong support for your application to Pfizer to develop a patient-based clinical intervention that integrates patient-generated information with evidence-based clinical recommendations for providers. Despite the potential revolution in care that is possible with electronic records, we don't often have EHR-based research examining the potential impact. Your randomized trial will allow us to properly evaluate the impact of these creative interventions and will contribute to the scientific literature, as well as informing our own local adaptation of EPIC.

As the Director of the Clinical and Translational Science Institute at the University of Rochester, I am very glad to see our informatics team under your leadership committed to such work. As you know, e-Record provides a potentially very rich resource for clinical researchers, but we don't often examine the use of e-Record as a basis for changing practice, or for improving patient engagement (both of which you propose to do). Since this project is closely connected with the CTSI, it will benefit from a research-focused environment which includes substantial expertise in the conduct of randomized trials, a methodology that I am pleased to see you've selected to evaluate this intervention. The CTSI serves as the research engine for the University of Rochester and is part of the vibrant NIH-funded CTSA network nationwide. As such, this project will have visibility within a wide audience of interested scientists, clinical researchers, and informatics groups.

I fully support your inclusion of several of our informatics team members in this proposal. The project design makes great use of their skills, experiences, and relationships within the electronic health record operations groups at the University. Further, I think working with partners in the Department of Biostatistics and Computational Biology, and importantly with Dr Jonathan Darer at Geisinger Health System (a true trailblazer in innovative electronic health record development), together with experienced clinicians from the Department of Obstetrics and Gynecology, will create a wonderful opportunity for collaborative success with this work.

Sincerely,



Karl D. Kieburtz, MD, MPH

September 2, 2014

To: Timothy De Ver Dye, PhD  
Professor of Obstetrics and Gynecology, Pediatrics, Public Health Sciences, and Medical Informatics  
Director, Biomedical Informatics  
Clinical and Translational Science Institute  
University of Rochester School of Medicine and Dentistry  
265 Crittenden Boulevard  
Rochester, NY 14642-0708

Dear Tim,

I am pleased to support your application to Pfizer entitled *Electronic Health Record (EHR)-enhanced clinical communication and quality-of-life improvement in managing menopausal vasomotor menopausal symptoms (VMS)*.

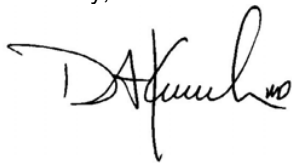
As you know, I head the Division of Medical Informatics at the University of Rochester and am responsible for overseeing our institution's installation of EPIC enterprise-wide. We transitioned to EPIC several years ago and our use is now widespread with well over one million patients managed in the system.

This research that you propose will serve as a model for other researchers at the University who wish to learn from electronic record enhancements that could well improve care. The widespread use of EPIC is an incredible opportunity for us to improve care and provide effective clinical experiences for patients.

That you've included adequate funds and personnel in your application to oversee the EPIC builds that are required to implement the intervention will help us not have to reassign our existing staff and will allow sufficient attention for your project's needs. I can assure you that our team will provide whatever we can to help facilitate this work.

eRecord (as our local installation of EPIC is termed) was heralded at its inception as an opportunity to enhance communication between practitioners and patients, to help practitioners distill and interpret large amounts of clinical information, and to facilitate best practice. Your project will help us demonstrate all of these features applied to a very important clinical area that crosses disciplines. I look forward to participating in your project and helping others learn from this experience and move e-record-based research forward.

Sincerely,



David A. Krusch, MD, FACS  
Chief Medical Information Officer  
Director, Division of Medical Informatics  
Professor of Surgery and Informatics  
University of Rochester School of Medicine and Dentistry

**University of Rochester Medical Center**

601 Elmwood Avenue, Box SURG • Rochester, New York 14642 • Phone: (585) 275-5027  
David\_Krusch@urmc.rochester.edu



Center for Experiential Learning



MEDICINE *of* THE HIGHEST ORDER

August 31, 2014

Timothy D. Dye, PhD

Professor of Obstetrics and Gynecology, Pediatrics, Public Health Sciences, and Medical Informatics  
Associate Chair for Research, Obstetrics and Gynecology  
Director, Biomedical Informatics  
Clinical and Translational Science Institute  
University of Rochester School of Medicine and Dentistry

Dear Dr. Dye,

It is with great enthusiasm that I write a letter of support for your grant submission entitled “**Electronic Health Record (EHR)-enhanced clinical communication and quality-of-life improvement in managing menopausal vasomotor symptoms (MVS)**”. This is a very important project that has the potential to contribute to the evidence base and our understanding of how the electronic health records can be mobilized to facilitate patient education, patient centered care and impact health outcomes.

This proposal complements work being done at the University of Rochester both in the spheres of utilization and impact of the electronic health record and in healthcare delivery changes that encompass patient and family centered care principles. As I understand your overall aim, your project will evaluate the effectiveness of an EHR-facilitated clinical intervention to help improve control of vasomotor symptoms in menopausal women. Over the past five years the institution has rolled out two simultaneous initiatives that have been aimed at preparing our clinicians and workforce to adopt the electronic health record and patient and family centered care. Now, with project such as yours, we can begin to measure impact on health outcomes when technology is harnessed to expand healthcare beyond our traditional point of care practice sites.

As the Assistant Dean for Interprofessional Education and a member of the Executive Board for our Institution for Innovative Education, I have a very strong interest and passion for work in this domain. The relationship between technology and humanism is a top educational priority for our medical center and is reflected as such in our current strategic plan. Most recently I was awarded the Josiah Macy Faculty Scholar Award to study and implement an intervention to train our workforce in utilization of the electronic health record to enhance and engage patients and their families. I am also the Director of the Center for Experiential Learning that serves as the educational delivery system within the medical center and is deeply invested in online education, outreach and supporting educational interventions that lead to behavior changes in healthcare delivery performance.

The electronic health record has changed how healthcare communicates, coordinates and collaborates care with patients. It has also created a perception and real sense of increase in workload and task change for providers. We need to study these changes. As a researcher, educator and administrator I believe your very important work will make an impact in our understanding of how the electronic health record impacts care delivery and patient outcomes.

I look forward to future collaborations both in research and in practice, and hearing the news that your project was funded!

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Peyre', with a long horizontal flourish extending to the right.

Sarah E. Peyre, EdD  
Assistant Dean, Interprofessional Education  
Director, Center for Experiential Learning  
Associate Professor of Surgery  
School of Medicine and Dentistry  
Assistant Professor of Nursing  
University of Rochester



Timothy De Ver Dye, PhD  
Professor of Obstetrics and Gynecology  
Director, Biomedical Informatics  
Clinical and Translational Science Institute  
University of Rochester School of Medicine and Dentistry  
265 Crittenden Boulevard  
Rochester, NY 14642-0708

September 3, 2014

Dear Tim,

I am very pleased to serve as a Co-Investigator on your application to Pfizer entitled "Electronic Health Record (EHR)-enhanced clinical communication and quality-of-life improvement in managing menopausal vasomotor menopausal symptoms (VMS)." We have discussed the project numerous times and we welcomed your team's visit to our clinical site to better understand how primary care is provided for women experiencing menopausal symptoms. Control of VMS is critically important as the American population ages, and tries to understand the complexity of how we as care providers make treatment decisions. This project that provides patient-generated information to practitioners in an informative way will better target the clinical encounter. And with enhancements as described to our e-Record system, clinicians will likely benefit from streamlined bundling of treatments and referrals.

Our practice indeed is one of the largest primary care practices in Rochester serving women of menopausal age. As a result, I have developed considerable visibility as a clinical expert on treatment of menopausal symptoms and, importantly, have provided a wide range of public education materials for local and national audiences. For example, as Editor in Chief of an internet journal enjoyed by over 11,000 ob/gyn nurses and physicians across the U.S., I write a monthly article on Menopause Medicine. I also produce a monthly feature for Rochester Woman magazine on menopause, and have authored numerous public and professional educational documents for area hospitals on the topic.

Kalin Warshoff, a nurse practitioner at our site, and I will be pleased to form your team of clinical experts for this project. I am certain, based on my recent experience as Chair of the Department of Obstetrics and Gynecology, that you will have cooperation from URMC-affiliated practices in family medicine, internal medicine, and of course obstetrics and gynecology. With the high quality team of researchers you have assembled, plus the commitment of the Institution's EPIC team, this project is poised for successful implementation.

Sincerely,

James R. Woods, Jr., MD  
Professor and Chair Emeritus  
Department of Obstetrics and Gynecology  
University of Rochester

Center for Clinical  
Innovation  
M.C. 30-65  
100 North Academy Avenue  
Danville, PA 17822  
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Jonathan Darer MD, MPH  
Chief Innovation Officer  
Director, Center for Clinical Innovation  
Geisinger Institute for Advanced Application

GEISINGER  
HEALTH SYSTEM

September 3, 2014

Timothy De Ver Dye, PhD  
Professor of Obstetrics and Gynecology, Pediatrics, Public Health Sciences, and Medical Informatics  
Associate Chair for Research, Obstetrics and Gynecology  
Director, Biomedical Informatics  
Clinical and Translational Science Institute  
University of Rochester School of Medicine and Dentistry  
265 Crittenden Boulevard  
CU 420708

Re: Electronic Health Record (EHR)-enhanced clinical communication and quality-of-life improvement in managing menopausal vasomotor symptoms (MVS)

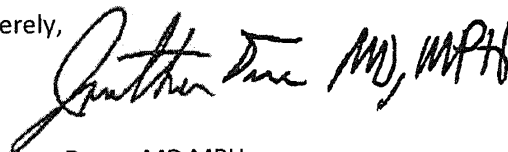
Dear Dr. Dye,

On behalf of Geisinger Health System, I am pleased to offer my enthusiastic support towards the Pfizer proposal titled, *Electronic Health Record (EHR)-enhanced clinical communication and quality-of-life improvement in managing menopausal vasomotor symptoms (MVS)*. I am committed to supporting the University of Rochester-led team to develop health information technology-enabled processes to improve care for women as they transition through menopause. In this proposal, we will seek to engage women and their providers in designing, testing and evaluating innovation in the management of vasomotor symptoms and collaboratively contributing to scholarly papers.

As the Chief Innovation Officer and Director of the Center for Clinical Innovation, I coordinate and lead initiatives to engage patients and families through the use of health information technology as well as leverage the use of technology to improve the quality of care. Our current priorities include expanding the OpenNotes initiative, seeking to build trust and enhance patient and family self-efficacy through increased transparency and access to provider documentation, incorporating patient self-reported data into routine clinical operations, and building software applications to support population care.

Collectively, the Geisinger team has all of the relevant experience and skills needed to successfully contribute to this work. Thank you, and let me know if you have any questions.

Sincerely,



Jonathan Darer, MD MPH