

PEX 16-002

Evaluating Evidence-Based Quality Improvement of Comprehensive Women's Health Care
Implementation in Low-Performing VA Facilities

NCT03238417

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02. Specific Aims

Women Veterans (WVs) continue to represent the fastest growing segment of new users of the VA healthcare system, doubling their numbers in the past decade, with 10% of VA users being women by 2018. Their physical and mental health (MH) needs have proven to be more complex than their male counterparts, including a high rate of military sexual trauma (MST) that places them at greater risk of depression, anxiety and posttraumatic stress disorder (PTSD), while also complicating medical management and requiring gender-sensitive care environments. Most VA providers also have minimal exposure to women, creating deficits in needed knowledge and experience. Historical gaps in VA provision of women's health (WH) care have also resulted in WVs being more likely to be referred to community providers, adding to their care fragmentation and contributing to persistent gender disparities in VA quality of care and patient experience.

These trends have required multiple initiatives to change VA culture to be more gender-sensitive, set minimum standards for training and proficiency of designated WH providers, and delineate features of acceptable primary care clinic models that integrate gender-specific and MH services in "one-stop shopping" approaches. VA Women's Health Services (WHS) has led these efforts and set forth an updated VA policy on "Health Care Services for Women Veterans" (VHA Handbook 1330.01, May 2010), which seeks to systematically improve WVs' access to comprehensive healthcare services delivered by proficient providers and staff in environments that ensure WVs' safety, security and dignity. In the same year, WHS launched an annual Women's Assessment Tool for Comprehensive Health (WATCH) to evaluate Handbook implementation, and an external evaluation comprised of site visits to over 84% of VA medical centers (VAMCs). Together, these evaluation activities have documented substantial progress and informed strategic planning and decision-making in terms of policies and resources needed to improve VA WH programs nationwide.

However, the evaluations also found that traditional top-down policy implementation—even when leveraged by evaluation feedback and multilevel WH champions at the clinic, VAMC, VISN and national levels—has not been uniformly successful in achieving the tenets of VA policy on comprehensive WH care. WHS has begun to identify consistently low-performing VA facilities that would benefit from more focused organizational interventions. Based on previous success using evidence-based quality improvement (EBQI) as an implementation strategy that fosters local engagement and multilevel stakeholder activation around improvement goals, WHS will rollout EBQI in low-performing VA facilities starting in FY17. WHS's EBQI approach, which will be implemented by an already-approved contractor, builds directly on the bundle of activities being tested in one of the five WH CREATE studies (CRE 12-026), which itself was based on EBQI efforts in multiple VA randomized trials. These activities include local site visits designed to achieve consensus on QI targets, multilevel stakeholder engagement, external practice facilitation, local EBQI team training, and formative feedback, for which technical specifications have already been developed.

We have worked closely with WHS to design a convergent parallel mixed methods evaluation in the context of a dynamic waitlisted design to evaluate the effectiveness of EBQI implementation on achievement of comprehensive WH care in low-performing VA facilities. Building on our substantial prior experience implementing and evaluating EBQI in VA, we propose the following specific aims:

Aim #1: To evaluate barriers and facilitators to achieving delivery of comprehensive women's health care in the identified low-performing VA facilities;

Aim #2: To evaluate the effectiveness of EBQI in supporting low-performing VA facilities achieve improved:

- a. Organizational features (e.g., level of comprehensive services available, care coordination arrangements, PACT features implemented, environment of care improvements);
- b. Provider/staff attitudes (e.g., improved gender awareness, WH knowledge and practice);
- c. Quality of care and patient experience among WV patients; and,

Aim #3: To evaluate contextual factors, local implementation processes, and organizational changes in the participating facilities over time.

Evaluation results will inform strategies for optimizing future policy deployment and multilevel engagement strategies with the field, while also informing best practice diffusion. The focus on low-performing VAs will offer new insights, as these less-studied facilities may require uniquely concentrated and/or tailored efforts.

02a. RESEARCH PLAN (EVALUATION PLAN)

A. BACKGROUND

A1. Gaps in Comprehensive Care for WVs. Historically plagued by gaps in safety and privacy for women in VA facilities originally designed for men, with a workforce with little to no exposure to female patients, the VA has faced significant challenges in meeting WVs' complex care needs.^{1,2,3} Ensuring access to gender-specific care and a full complement of reproductive and gynecologic health services has also contributed to higher rates of community referrals among WVs, further fragmenting their care.^{4,5,6} These and other challenges have led to persistent gender disparities in VA care quality and patient experience.^{7,8}

Over a decade ago VA stood up a handful of comprehensive WH centers in response to Government Accounting Office findings of gaps in WVs' care, and subsequent legislation.⁹ WH clinics grew 8-fold over the next decade.¹⁰ However, only a fraction delivered comprehensive services like the original model programs, many focusing on gender-specific exams to help increase VA breast and cervical cancer screening rates.¹¹ Nonetheless, adoption of WH clinic models was associated with higher preventive practices and higher WV ratings of access, continuity, coordination, and satisfaction.^{12,13}

A2. VA Policy Aimed to Respond to Gaps in Care. In 2010, VA WHS launched a 5-year strategic plan to redesign the nation's healthcare delivery system for WVs, with guidance on required use of designated WH providers (DWHPs) for primary care (PC), acceptable PC model features with integrated MH and gender-specific care, and a set of required comprehensive services (VHA Handbook 1330.01, May 2010). Added were explicit expectations that all VA care environments must afford WVs a sense of safety/security, supply same-gender providers (if preferred), and address gender-sensitivity across the spectrum of VA services.

A3. Evaluation of Comprehensive Care Policy Implementation. WHS contracted with a private sector firm from 2010-15 to gauge progress towards full Handbook implementation through site visits that included interviews with approximately 20 individuals/groups, case discussions, facility tours, and a review of program-related documents. Each VAMC's capabilities were then scored (from "needs development" to "highly developed") through focused team consensus sessions across 33 Handbook-related domains. Site visits concluded with closing conferences with leadership, followed by Site Visit Summary Reports and Score Cards for each site. WHS received dashboard updates for distinctively high- and low-end performers on program components and capabilities by facility and VISN.

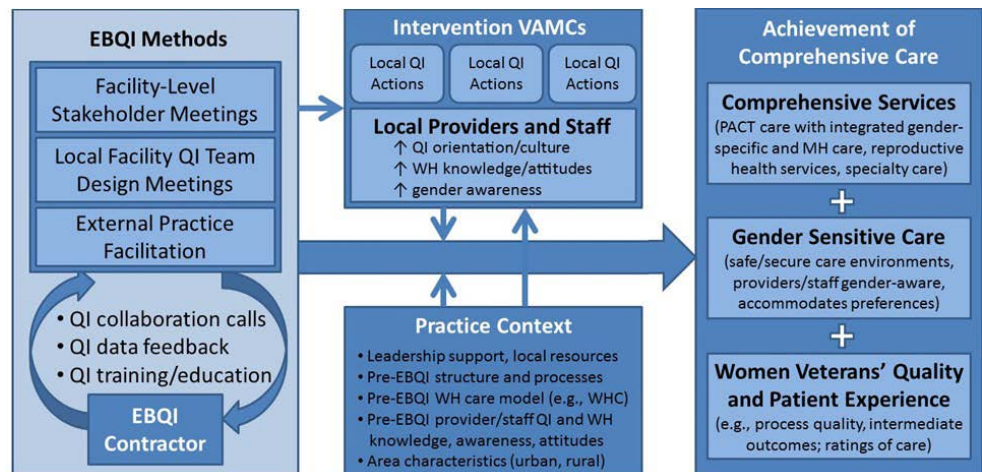
Major problematic findings included gaps in organizational structure (e.g., WV Program Managers being assigned collateral duties, precluding focus on policy-mandated roles and responsibilities), inadequate oversight or planning, major gaps in privacy/security in exam rooms, limited cross-coverage for key WH roles, environments not welcoming to women, gaps in comprehensive care in community-based outpatient clinics, staffing insufficiency (including below-standard staffing ratios, high panel sizes, limited WH experience/training), and limited efforts to improve cultural competency and gender sensitivity of staff.

A4. WHS/HSR&D Collaboration to Accelerate Comprehensive Care Implementation. WHS has long been funding the applicant HSR&D investigators and their colleagues to conduct evaluation activities of WVs' health conditions and use (e.g., WV Sourcebooks), needs and experiences (e.g., National Survey of WVs), and evaluations of VA WH programs (e.g., telegynecology). In 2012, WHS funded the applicant team to conduct a national expert panel to define gender-sensitive comprehensive care to improve its measurement.¹⁴ WHS then worked with us as primary partner for the WH CREATE, a partnered collaborative research initiative funded by VA HSR&D to use research to further accelerate implementation of comprehensive care for WVs.¹⁵ All five CREATE studies launched in early 2013, including a national organizational survey of comprehensive care arrangements based on the panel results, and a 12-VAMC trial of an EBQI approach to tailoring Patient Aligned Care Teams (PACT) to the needs of WVs. The WH CREATE is an integral initiative supported by the VA WH Research Network (WHRN), which the Blueprint for Excellence cited as central to accelerating innovations in VA WH care (Transformational Strategy 7.2.g).

A5. WHS Main Evaluation Goals. WHS seeks a partnered evaluation of their rollout of EBQI as a new strategy for improving quality of WH care in consistently low-performing VA facilities. Building on early evidence of EBQI's promise in activating local teams and leadership around WH PACT improvements, WHS asked for technical specifications to enable contracting for EBQI. They then asked us to adapt our WH PACT EBQI evaluation methods—specifically, key stakeholder (KS) interviews, provider/staff surveys, and

analysis of secondary data—to determine the ways in which EBQI may help low-performing VAs improve quality of care.¹⁶ In our WH PACT study, these methods and measures have revealed new information on WVs' needs and experiences, elucidated implementation barriers, and helped identify actionable provider/staff attitudes and knowledge gaps.

A6. Conceptual Framework for Evaluation. We have adapted our conceptual framework from the WH PACT trial for the proposed evaluation (**Figure** below).¹⁶ In this evaluation, a contractor working under technical specifications for EBQI (*far left column*) will: 1) convene facility-level stakeholder meetings; 2) facilitate local facility-level QI team design meetings; and 3) provide external practice facilitation through within- and across-facility QI collaboration calls, QI data feedback and QI training/education. Initial results of EBQI implementation will include local QI actions (e.g., strategic project activities, structured QI proposals, and multilevel review in advance of conduct), and improved provider and staff QI orientation, WH knowledge/awareness, and gender awareness (*middle column, top*). These actions will occur in the context of each VAMC's leadership support, local resources, pre-EBQI WH care model and staffing, pre-EBQI provider and staff QI and WH experience, awareness and attitudes, as well as area characteristics (e.g., urban/rural location) (*middle column, bottom*).



Our evaluation activities map directly to this conceptual framework using a formative evaluation framework designed to identify the potential and actual influences on progress and effectiveness of implementation efforts.¹⁷ For example, we will evaluate the EBQI contractor's implementation of EBQI methods (*first column*) under **Aim #1** as a developmental evaluation stage (e.g., degree of less-than-best practice, determinants of current practice, barriers/facilitators and feasibility/perceived utility). Under **Aim #2**, we will conduct a progress-focused evaluation of EBQI effectiveness on achievement of comprehensive care (right column), monitoring impacts and indicators of progress toward goals, with feedback to WHS and the EBQI contractor. **Aim #3** will cover two types of evaluation. First, we will conduct an implementation-focused evaluation (also known as process evaluation) to examine discrepancies between EBQI implementation plans and how the EBQI contractor actually operationalizes them, helps identify influences we might otherwise have not considered, will enable us to describe experiences of those undergoing EBQI implementation, and will consider the context in which facilities participate (12-month key stakeholder interviews [§B4a] will be especially important). Second, we will use results from all of the other evaluation stages to conduct an interpretive evaluation (24-month key stakeholder interviews will be key here).

B. METHODS (EVALUATION PLAN)

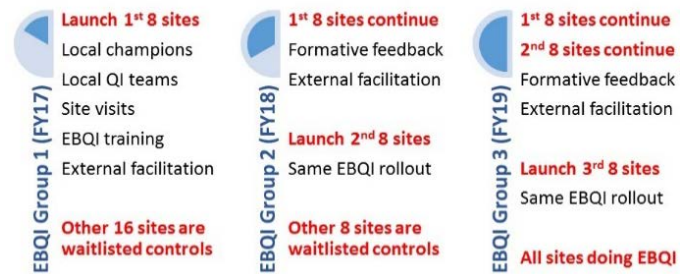
B1. Evaluation Plan Overview

We will conduct a convergent parallel mixed methods evaluation^{17,18} in the context of a dynamic waitlisted design to evaluate the effectiveness of EBQI implementation on achievement of comprehensive WH care in low-performing VA facilities. For **Aim #1 (developmental evaluation)**, we will rely on key stakeholder interviews (§B4a), organizational surveys (§B4b), and administrative data (§B4d) at baseline and ahead of each phased implementation launch of another wave of VA facilities. For **Aim #2 (progress-focused evaluation)**, we will use organizational surveys (§B4b), provider/staff surveys (§B4c), and secondary data on WVs' quality of care and patient experience (§B4d). For **Aim #3 (implementation-focused & interpretive evaluations)**, we will re-interview Aim #1 key stakeholders, with a focus on implementation processes and organizational changes at 12 and 24 months (§B4a).

B2. Evaluation Design

The choice of a dynamic waitlisted design is based on WHS's plans for staged EBQI implementation at no more than eight VA facilities per year for the next three years for a total of 24 facilities. This randomized "roll-out" implementation design has very good statistical properties, including higher power than traditional wait-listed designs¹⁹ and less vulnerability to external, uncontrolled factors.²⁰ EBQI implementation will commence in Year 1 (FY17) in eight randomly selected facilities (Group 1), with the remaining 16 facilities serving as waitlisted controls. In FY18, eight of these waitlisted controls will be randomly selected for EBQI implementation (Group 2), leaving the remaining eight as waitlisted controls in FY18, which will begin EBQI implementation in Year 3 (Group 3).

Figure 1. Staged EBQI Implementation



B3. Study Population and Sampling Strategy

In the first 30 days of FY17, with input from WHS and the evaluation team, the EBQI contractor will analyze prior site visit assessment data (Booz-Allen-Hamilton FY16 report), local VA facility self-assessment data (WATCH) (**Appendix 2**), and selected performance measures to identify the lowest-performing VAs (bottom 25-30%) of previously assessed sites nationwide and by VISN. In FY17Q1, WHS will make the final site selection decision (n=24 VA facilities) that will be the focus of EBQI implementation and evaluation.

B4. Data Sources, Measures and Data Collection Approaches

The proposed data sources are a direct result of WHS input on and preferences for evaluation design, and their experience with these sources under the WH CREATE and previous evaluations we have conducted with and for WHS. In particular, the evaluation will substantively benefit from use of existing instruments from the WH CREATE, including the national VA organizational survey modules noted above (CRE 12-038) (including national secondary data on quality metrics and patient experience) and the WH PACT trial (CRE 12-026) (including KS interview guides and provider/staff surveys). Below we describe each evaluation data source's sampling plans, measures, and data collection procedures.

B4a. Key Stakeholders (KS). Semi-structured qualitative interviews will be conducted at baseline for all sites (Aim #1), as well as immediately prior to the EBQI launch of Groups 2 and 3. Interviews will be conducted at all sites at 12 months post-EBQI launch; in Group 1, interviews will also be conducted at 24 months. Sampling Plan: For Aim #1, we will work with the EBQI contractor to identify facility-level KS (e.g., quadrad member, PC director, WH medical director, WVPM, QI/system redesign lead; n~6/facility) and VISN-level KS (e.g., VISN director, VISN Lead WVPM, VISN system redesign lead; n~4/VISN). We will also interview WHS leaders and EBQI contractor personnel to evaluate leadership and implementation processes. We will adapt KS selection based on the QI targets established at initial EBQI site visits (e.g., add a MH director if the QI project targets MH). For Aim #3, we will seek to re-interview the same KS as in Aim #1, but will pursue replacement personnel in the event of turnover and/or position changes over time. Measures: The Aim #1 baseline interview guide (**Appendix 3**) includes questions about the structure and delivery of usual care for WVs, barriers and facilitators to achieving delivery of comprehensive WH care, what (if any) improvements are underway in WH and/or for WVs, familiarity with performance metrics, access to metrics by gender, experience with QI, local culture, perceptions of the care environment, and engagement. The Aim #3 12- and 24-month interviews will assess any changes in care for WVs (staffing, structure, etc.), details of completed/in progress QI projects, perspectives on critical components of EBQI, and anticipated sustainability of local improvements and QI methods. Data Collection: Under the supervision of Dr. Hamilton (Co-PI), KS interviews will be conducted by telephone, recorded and professionally transcribed. Transcripts will be reviewed and edited for accuracy.

B4b. Organizational Surveys. We will use key informant organizational surveys at baseline, 12- and 24-months among the 24 participating VA facilities, in addition to annual administered WATCH surveys from WHS (Aim #2a). For Year 1 (FY17), we will rely on national organizational survey modules that will be fielded in Quarter 1 (Q1) as part of a WH CREATE study (Rose & Yano, Co-PIs, CRE 12-038) (**Appendix 4**). For Years 2 and 3 (FY18-19), we will re-administer the same surveys, adapting selected domains in relation to EBQI targets of participating VAs. Sampling Plan: All 24 participating VA facilities, including modules for PC directors, WH medical directors, MH directors and WV Program Managers (WVPMs). We

will use the tailored design method to identify named respondents for each module.²¹ Additional key informants (e.g., chief of medicine) may be considered in subsequent waves if local EBQI targets warrant it. **Measures:** We will include measures of *leadership support*,²² *local resources* (e.g., sufficiency of time, personnel, equipment),²³ *practice structure* (e.g., WH care model, staff mix, referral arrangements), *service availability*,²⁴ *care coordination arrangements* (within and outside VA), *ability to engage in QI* (e.g., barriers to QI, data access by gender), *gender-sensitivity of environment* (e.g., privacy), *local challenges* (e.g., provider shortages, hiring difficulties, practice chaos),^{25,26} *facility type* (e.g., size, academic affiliation, urban/rural), and *EBQI activities*.²⁷ **Data Collection:** We will field surveys through REDCap, a VA-approved web survey vendor.

B4c. VA Providers/Staff Surveys. We will use web-based provider/staff surveys at baseline, 12- and 24-months. **Sampling Plan:** We will obtain lists of local providers and staff using the same protocol used previously to identify PC and WH providers/staff, drawing a census from Primary Care Management Module (PCMM) data for each participating facility (including PACT teamlets and larger PACT teams [e.g., pharmacists, social workers]). In the 12-VA WH PACT trial, this approach yielded 775 providers and staff across urban and rural VAMCs; we anticipate identifying roughly twice as many personnel in the 24-facility evaluation. If other work units are prioritized by WHS (e.g., MH provider/staff), we will adapt the same approach but using VA PAID and other administrative sources, with local sample validation. **Measures:** We will include measures of *EBQI exposure/participation* (e.g., awareness, hours spent, local buy-in), *QI orientation/culture* (e.g., perceived cooperation among managers/providers/staff, communication effectiveness, culture fostering flexibility, participative decision-making),^{28,29,30} *gender sensitivity* (e.g., awareness, knowledge, attitudes, self-assessment of WH proficiency),³¹ *practice context* (e.g., leadership norms, organizational readiness to change, job satisfaction, burnout),^{32,33,34} and *provider/staff characteristics* (e.g., age, gender, race, ethnicity, staff type, clinician type, DWHP, proportion of WVs in panel/clinic, board certification, years in VA) (**Appendix 5**). **Data Collection:** Consistent with prior procedures, we will send pre-notification emails, then email invites with an embedded survey weblink, Q&A, and endorsement letters from WHS and local leadership. Email reminders will include a hardcopy option.

B4d. VA Administrative Data. We will pull secondary data on WV-specific VA quality of care and patient experience, in addition to utilization patterns and other administrative data. **Sampling Plan:** Each VA data source (e.g., chart-based External Peer Review Program [EPRP] quality metrics; Survey of Healthcare Experiences for Patients [SHEPs]) has its own sampling plan, limiting our latitude and also statistical power as WVs are not currently sufficiently over-sampled at the facility-level. For *quality metrics*, we will address this by applying existing programming code from WHS for generating EPRP-like measures on the population of WVs seen in each participating facility from the Corporate Data Warehouse (CDW). We will also obtain comparable CDW-derived metrics from the National PACT Evaluation team for PACT Compass-like measures (e.g., average wait time, non-face-to-face visit use). For *survey metrics*, we will explore aggregated SHEPs data by Group (1/2/3) and over time, and examine contextual differences in the sample of WVs seen in the 24 participating facilities compared to VAs of similar facility complexity. Because the sample of low-performing facilities has not yet been identified, we cannot as yet estimate available sample sizes. **Measures:** CDW-derived metrics will include process measures of *quality for diabetes and cardiovascular disease* (e.g., lipid screening) care and *intermediate outcome measures* (e.g., glycemic and lipid control). SHEPs metrics will include access, continuity, coordination, courtesy and overall satisfaction with VA care. PACT Compass-like measures include additional measures of *access* (e.g., average wait time, % enrolled in PC-MH integration [PC-MHI]), *continuity* (% of visits with PACT team providers), *coordination of care* (e.g., emergency room use) and *non-face-to-face access* (e.g., secure messaging; telephone visits; group visits). We will include *utilization measures* on PC, WH, MH, specialty care visit rates, in addition to hospital and emergency room use each year. We will also include area measures (e.g., urban/rural location, academic affiliation, facility complexity score). **Data Abstraction:** We will pull data from CDW through VINCI and/or obtain data elements directly from WHS for use in evaluation.

B5. Evaluation Analysis Plan

B5a. Qualitative Analyses (Aims #1 and #3). Analysis of KS interviews will initially focus on data reduction³⁵ to use findings rapidly and iteratively to inform WHS oversight, support EBQI implementation, and prepare deliverables. Specifically, using an approach designed by this component lead (Hamilton) (**§C1**), all interviews will be summarized using a template informed by the interview guide topics (**Appendix**

3). Summaries will be organized into matrices to compare and contrast findings across roles, sites, and levels (e.g., facility, VISN). In our extensive experience, this data reduction approach is sufficient for generating formative feedback reports to sites and presentations to partners and other stakeholders. The approach will also help generate a preliminary codebook, to be used for more in-depth analysis of the KS interviews using ATLAS.ti, a qualitative data analysis software program that allows for fluid “interaction” of data across types and sources. Initially, a top-level codebook will be developed for the baseline interviews based on the semi-structured interview guide.³⁶ Using a constant comparison analytic approach, this codebook will be elaborated upon based on emergent themes and adjusted as each round of interviews is completed.³⁷ Interviews will be compared within facility, across facilities, and over time. These approaches and groupings are easily facilitated within ATLAS.ti, which has the capacity to group data in multiple ways and which allows for maximum efficiency in navigating a complex narrative dataset. In baseline transcripts, we will identify commonly shared knowledge about the structure and delivery of WH care, barriers and facilitators to delivering comprehensive care, as well as pre-implementation knowledge of and experience with QI. In 12- and 24-month KS interview data, we will identify factors that facilitated and impeded EBQI and what changes (if any) were observed in WH care delivery and quality. Consistent with our implementation-focused evaluation in the WH-PACT trial, we will explore which EBQI components are of particular value in improving care and examine clinic and provider characteristics associated with varying levels of EBQI effectiveness and achievement of comprehensive care.

B5b. Quantitative Analyses (Aim #2). To assess effectiveness of EBQI implementation on comprehensive care achievement, we will use data from the organizational surveys (**\$B4b**), provider/staff surveys (**\$B4c**) and administrative data on quality and patient experiences (**\$B4d**). **Dependent Variables:** We will examine multiple outcome measures as dependent variables: 1) multiple individual measures of comprehensive care achievement, including levels of WH service availability (as noted in VHA Handbook 1330.01), integration of and access to gender-specific and MH care, and other related measures that capture different domains of comprehensiveness; 2) gender-sensitive care delivery, including organizational and provider/staff level measures; and 3) quality of care and patient experience measures. For comprehensive care achievement, we will include as dependent variables the individual measures, and we will also examine approaches to creating an aggregated ordinal score of the individual measures. We will prioritize the final set of dependent variables in consultation with WHS. **Independent Variables:** The primary regressors of interest will be EBQI exposure (i.e., level of implementation) and time. We will examine the potential moderating effects of practice context and provider/staff knowledge/attitudes (e.g., determine EBQI effects in high vs. low leadership support sites). We will use multiple linear or logistic regression to evaluate EBQI effectiveness. Where appropriate we will adjust for covariates, account for clustering of patients by site, and mitigate bias due to non-response or loss to follow-up through the use of enrollment/attrition weights. Covariates used for adjustment will include patient factors (e.g., facility casemix, proportion of WVs seen), provider/staff factors (e.g., DWHP availability, readiness), and organizational factors (e.g., resource sufficiency, facility size). Clustering by site will be accounted for by fitting hierarchical regression models with random intercepts for the sites (e.g., using SAS PROC Mixed).³⁸ We will evaluate the goodness-of-fit of a given regression model using standard diagnostics (e.g., Mallow's statistic (C_p)).³⁹ To adjust for potential non-response bias and loss to follow-up over time for the provider/staff survey samples, we will apply enrollment weights using available characteristics of eligible providers/staff and attrition or “inverse probability of inclusion” weights estimated using an appropriately specified logistic regression model.⁴⁰ We will use multiple imputation methods to replace missing values among covariates⁴¹ with hot-deck methods used for imputation as needed.⁴² We will estimate site-level effects using the hierarchical regression models with random intercepts for sites. While our sample of sites (24) is small for the estimation site-level effects, EBQI trials of fewer sites have noted significant effects.⁴³

B6. Potential Obstacles and Solutions

B6a. Timing of Data Collection. The evaluation's launch will be reliant on identification of low-performing VAs and WHS's introduction of EBQI plans with facility and VISN leadership. Once navigated, we will brief leaders of participating VAs regarding the evaluation, work with locally identified contacts, and begin sample development (KS, provider/staff). KS interviews will begin as soon as practicable, as will baseline administrative data extraction. Provider/staff surveys, however, will have to undergo review by the National Center for Organizational Development's Organizational Assessment Sub-Committee (OASC) as the evaluation meets the criteria of VA employees across 10+ sites. While no FY17 blackout dates have yet

been published, we will be required to accommodate them. As with prior work, we will also submit the surveys for national Union review, with a 30-day review period.

B6b. Timing and Unit of Randomization. The EBQI contractor was recently approved (8/22/16), enabling an early start on site selection. WHS has agreed to allow us to randomly allocate up to eight VA facilities of the 24 low-performers in Year 1, up to eight VAs of the remaining 16 in Year 2, with the remainder getting EBQI exposure in Year 3. If the EBQI contractor does not meet contract deliverables, evaluation activities may be delayed to accommodate their processes. Fortunately, the contractor (Atlas Research) has a strong track record with VA and specifically WHS. We plan to proceed with the evaluation even if not all contracted-for activities occur, enabling us to still address our evaluation aims. Low-performing facilities may also suffer from leadership gaps, provider and staff burnout, and other structural and management issues that may complicate their engagement in evaluation activities. We have experience working with VHA, VISN and VAMC leaders in multilevel research and evaluation, but will consider site replacement, depending on the circumstances.

B6c. Survey Feasibility and Subject Burden. Based on prior experience, we anticipate high participation rates in the KS interviews (96% completed interviews in the WH PACT trial), chiefly in light of the caliber of interviewers, the comfort and trust they routinely engender, and the open offer to not record sensitive dialogue as needed. Even so, we plan on 30-minute rather than 60-minute interviews to reduce subject burden while also increasing feasibility of rapid deliverable generation. We have achieved 85-100% response rates (RRs) on our past PC, WH and MH organizational surveys,^{44,45,46,47} but lower rates for subspecialists (e.g., average 60% RR for cardiology, neurology, oncology chiefs).⁴⁸ We have divided the organizational surveys that will be used here into modules to minimize respondent burden for any one key informant, while ensuring that the most knowledgeable respondent is asked. We anticipate the lowest RRs for providers and staff, given competing demands, but will use approaches similar to those used by the VISN 22 PACT Demo Lab (>60% RR), including local leader survey endorsements, incentives/perquisites (if available), and aggregated feedback.

C. RESEARCH TEAM AND RELEVANT EXPERIENCE

C1. Key Participants. Elizabeth Yano, PhD, MSPH will serve as the proposed WHS/QUERI PEC Director. A healthcare epidemiologist, Dr. Yano has conducted numerous VA program evaluations since the 1980s and taught program evaluation in the UCLA Executive MPH program for 15 years. She directs the VA HSR&D Center for the Study of Healthcare Innovation, Implementation & Policy, which is the only HSR&D Center with WH as a primary focus area, and WHRN (SDR 10-012), to accelerate intervention, implementation and high-impact (I³) research. This work led to development of the WH CREATE (**\$A4**), for which she serves as Director and PI of the WH PACT trial noted above (CRE 12-026). Alison Hamilton, PhD, MPH, is a nationally known medical anthropologist and expert in implementation evaluation. She is the Center's Associate Director for Implementation Science and directs the EMPOWER QUERI (QUE 15-272), including leadership of a stepped-wedge trial to gender-tailor PC-MHI. She led implementation evaluations for collaborative care models for schizophrenia (EQUIP) and depression (Hep-TIDES), and the VISN 22 PACT Demo Lab, all of which used EBQI methods. She is also a PI of the WHRN (focused on multilevel stakeholder engagement) and a CREATE study on determinants of WVs' attrition, using a convergent parallel mixed methods design (CRE 12-019). Danielle Rose, PhD is a health services researcher with expertise in organizational theory and organizational determinants of VA quality. She is PI of the WH CREATE study of impacts of variations in comprehensive care on WVs' quality and experience (CRE 12-038), and leads medical home neighborhood evaluation in the VISN 22 PACT Demo Lab. Sabine Oishi, PhD, MSPH, is a psychologist with extensive survey expertise and leadership of partnered VA evaluations of WVs' needs around PC-MHI, trauma, and eating disorders, including national assessments of gender-sensitive MH care arrangements (MHS) and WVPM needs (WHS). Katherine Hoggatt, PhD, is an epidemiologist and VA HSR&D Career Development Awardee focused on substance use disorders (SUD) treatment. She co-leads secondary analyses of VA data on alcohol screening, and is PI of a new HSR&D IIR to improve validity of VA SUD performance measurement. She is also Co-I leading secondary analyses of VA EPRP and SHEP data for the Office of Health Equity (OHE)/PEC at the Center.

C2. Experience with Partnerships with VA National Program Offices. Dr. Yano's entire VA tenure (since 1989) has continuously involved partnered research and evaluation with National Program Offices, starting with evaluation of VA's first demonstration project on VA PC global academic care teams, which informed

VA's National PC Directive (1994). She then led the national evaluation of its implementation (1996), and launched her HSR&D career by evaluating PC practice features associated with VA quality (MPC 97-012, 1997-99). She continued her partnership with the VA PC Office and then Office of Quality & Performance to evaluate organizational influences on quality using the VHA Clinical Practice Organizational Survey linked to VA performance measures (2005-07) and National VA PC Survey (2008-09). She evaluated VA's quality transformation to generate lessons for evidence-based management (IIR 06-087, 2007-10), and used the PC practice data to evaluate determinants of colorectal cancer screening (CRS 02-163), smoking cessation treatment (IIR 04-308), racial-ethnic disparities in quality (IAA 08-087), and medical home impacts pre-PACT (IIR 09-082). She led the PC Program Office's efforts to better understand factors underlying medical home readiness by analyzing ACP Medical Home Builder scores for over 850 VA PC practices in 2009 and 2011. She later co-led the PC Program Office funded VISN 22 PACT Demonstration Lab, treating the entire Lab as a stepped wedge trial of EBQI's impacts on PACT innovations, provider/staff outcomes and quality.

Dr. Yano's VA WHS partnership has a comparable track, starting with her Under Secretary-funded survey of WVs' health programs (2001), and an evaluation comparing/contrasting VA and Dept. of Health & Human Services' WH centers (2003). She pioneered use of expert panel methods to engage Program Office leaders in the review and policy feedback on HSR&D-funded studies of WVs' ambulatory care use (GEN 00-082), impact of practice structure on WVs' quality of care (IIR 04-036), and impacts of structural changes on quality over time (IAE 07-170). Dr. Yano's partnered work evolved into annual WHS-funded multi-project agreements since 2009 for a broad base of evaluation projects, including leadership of a national VA expert panel on gender-sensitive comprehensive care, strategies for tailoring PC-MH integration to WVs' needs, among others. WHS also funds a CREATE-level program manager and EBQI work in the WH PACT trial.

Dr. Yano's evaluation team has similar partnered evaluation expertise, including Drs. Hamilton (WHS, MHS, National Center for Disease Prevention and Health Promotion (NCP), Office of Patient-Centered Care & Cultural Transformation [OPCC&CT]), Rose (PC, WHS), Oishi (WHS, MHS), and Hoggatt (OHE). Ms. Ismelda Canelo has been project director for partnered evaluations for 17+ years.

C3. Roles & Tasks of each Evaluation Team Member. Dr. Yano will direct the PEC, overseeing aims' achievement and working directly with WHS and the EBQI contractor on all evaluation phases. Dr. Hamilton will oversee the interviews under Aims #1 and 3, consistent with her collaboration with Dr. Yano on the WH-PACT trial and VISN 22 PACT Demo Lab, and will serve as Co-PI. She will finalize the KS interview guides; guide sample development; lead selected interviews; supervise qualitative staff (Chrystal, Dyer); and oversee and participate in coding, quality review and analysis. Dr. Rose will oversee organizational survey design, administration, and oversee analysis (Brunner) (Aim #2a). Dr. Oishi will lead the provider/staff survey work, with support for web-survey procedures (Simon) and sample development and survey analysis (Than) (Aim #2b). Dr. Hoggatt will lead administrative data acquisition and analysis with the support of a statistical analyst (Brunner) (Aim #2c). All leads will participate in report and manuscript preparation in their respective areas. Ms. Canelo will serve as the PEC project director, organizing work tasks laid out in the Gantt chart (**Appendix 6**), coordinating project meetings and managing sample development, data collection procedures, data cleaning and management, as well as transcription services, with assistance of the research assistant (Chow). Work will be coordinated through weekly PEC staff meetings and biweekly data collection and later analysis meetings for the qualitative and quantitative teams.

C4. Local Resources Supporting Evaluation Team. The PEC will reside organizationally within CSHIP, while benefiting from the infrastructure, professional networks, and research teams of the VA WHRN (Yano, Hamilton, Frayne, PIs), WH CREATE (Yano, Director), EMPOWER QUERI Program (Hamilton, Director), and the Office of Health Equity PEC (Hoggatt, Co-I). This collaborative context will enable cross-coverage and technical support to PEC team members. CSHIP is heavily leveraged by partner-funded initiatives as well as two QUERI Programs (EMPOWER and Care Coordination), providing an unusually strong environment of implementation scientists brought together in biweekly work-in-progress seminars. CSHIP has also launched Implementation and Improvement Cores supporting development and testing of dissemination tools and EBQI implementation strategies in the context of VAMC and VISN level initiatives.

D. MANAGEMENT PLAN AND TIMELINE

D1. Management Plan. The core team (Yano, Hamilton, Rose, Oishi, Hoggatt, Canelo, Brunner) will meet weekly, with biweekly Aim-specific meetings focused on evaluation sub-aims (e.g., KS interviews). Monthly

WHS calls already underway will continue throughout the PEC's evaluation period, with additional emails and calls arranged to meet Partner information needs and obtain WHS review/input. We will also participate in regular WHS calls with the EBQI contractor (see *Organizational Chart* in **Appendix 7**). Drs. Yano and Hamilton will attend 1-2 of the initial in-person EBQI meetings and join initial site engagement calls.

D2. Timeline/Deliverables. We will deliver written quarterly reports and briefings to WHS throughout the evaluation, consistent with current practices in annual WHS Memoranda of Understanding (MOUs). The FY17 MOU has already been finalized and will be signed before QUERI PEC review but for a reduced scope of work. Deliverables (below) will be appended to the MOU in Quarter 1 (Q1) if the PEC is awarded.

FY17: In Q1, we will work with WHS and the EBQI contractor to finalize operational criteria for classifying low-performing VA facilities. We will review the draft KS interview guide (**Appendix 3**) and provider/staff surveys (**Appendix 5**) with WHS, incorporating WHS and other subject matter experts' feedback as requested. WHS has already approved the organizational survey modules for FY17 (**Appendix 4**); these will be fielded in Q1. WHS will launch facility leadership introductions (including notification of evaluation plans), affirming participation, after which we will randomly allocate sites to EBQI (n=8) or waitlisted control (n=16). We will support contractor training in EBQI technical specifications in collaboration with WHS, document training, and develop a template for use in monitoring EBQI procedures used.

In Q2, WHS and the EBQI contractor will identify local champions and evaluation contacts for our use in identifying KS and launching baseline interviews across all sites. Organizational survey data will be cleaned and a report of initial frequencies provided to WHS. Provider/staff surveys will be submitted to OASC when released by WHS, after which we will submit them for national Union review; endorsement letters will be drafted for WHS review, and adapted to fit local contexts and needs, while we simultaneously obtain and begin validating sample lists. We will also pull and analyze the administrative data for participating sites.

In Q3, we will deliver KS summaries to WHS, while beginning to conduct the more in-depth ATLAS.ti analyses. We will finalize the provider/staff surveys following OASC and Union review, program them in REDCap, and launch survey administration by the end of Q3. We will conduct an organizational analysis of the 24 participating low-performers compared to higher performers of similar complexity.

In Q4, we will provide results for Aim #1 (barriers/facilitators) to WHS in the form of presentations and summary reports for each group of sites. We will finish provider/staff survey follow-up, with concurrent data cleaning and quality checks, followed by analysis and reporting to WHS of baseline evaluation findings for Aim #2. We will generate an annual report for WHS, summarizing evaluation findings across all data sources for FY17.

FY18: In Q1, we will randomly allocate the next 8 VA facilities to EBQI, update the KS sample, and launch the second wave of KS interviews, focusing first on baseline for newly allocated EBQI VAs. We will restart the OASC and national Union review procedures, adapting to FY18 blackout dates, and launch the second wave of the organizational surveys.

In Q2, we will continue with KS interviews, including WHS and EBQI contractor interviews and extending the KS sample to accommodate EBQI targets in Group 1 (e.g., MH leads). We will update the provider/staff survey sample lists, and work with site-level evaluation contacts on sample validation and updated cover letters as needed (i.e., to accommodate leadership changes). By the end of Q2, we will deliver KS summaries and organizational survey findings. We will launch the second wave provider/staff surveys in Q2. We will also pull a second year of administrative data, and provide WHS with a summary report on changes.

In Q3, we will finish the provider/staff survey wave, clean the data and deliver an initial summary report. KS analysis will continue. KS contrasts between Year 1-2 will be reported, in addition to early findings regarding Aim #3 contextual factors and implementation processes based on both waves. Additional organizational analyses with linked administrative data for Aim #2 will also be reported (e.g., variations in resource sufficiency by large and small low-performers).

In Q4, organizational changes based on KS interviews and organizational surveys between Years 1 and 2 overall and by EBQI vs. waitlisted controls will be reported to WHS. We will deliver a second annual report for WHS, summarizing findings across evaluation data sources for FY18, with notable FY17 comparisons.

FY19: In Q1, the EBQI contractor will launch EBQI in the remaining low-performing VA facilities. We will again update the KS sample as needed, and launch the third and final wave of KS interviews and again

extend the KS sample to accommodate EBQI targets in Groups 1 and 2 that will have had two and one year of EBQI, respectively. We will start with the baseline KS interviews for Group 3, followed by the KS follow-up interviews for Groups 1 and 2, which may carry over into Q2. We will again repeat OASC and Union review, and launch the third and final organizational survey wave.

In Q2, we will complete the KS interviews, and initiate rapid KS analysis. We will update the provider/staff sample for the third wave, repeat sample validation steps with participating sites, and prepare endorsement letters once again, and launch the survey by the end of Q2. By the end of Q2, we will also provide WHS with the third wave of KS summaries and an organizational survey summary in the quarterly report.

In Q3, we will continue conducting the more detailed qualitative coding for the annual report and completion of Aim #3 by Q4. We will deliver a summary of organizational changes over all three survey waves to WHS, as well as an initial provider/staff survey summary for the third and final wave. KS contrasts by year will be highlighted as well. We will pull and analyze administrative data, aiming for as many months of data as possible for the summative evaluation as part of Aim #2.

In Q4, we will report time trends related to Aim #1 (developmental evaluation), as well as summative results for Aim #2 (progress-focused evaluation) and Aim #3 (implementation-focused and interpretive evaluation) to WHS. We will include an appraisal of EBQI's potential utility for related WHS initiatives and its sustainability and spread.

In addition to these partner-focused deliverables, we plan to submit the protocol to *Implementation Science* for publication, as we did with the WH PACT EBQI trial, and pursue other traditional dissemination routes through scientific journals and presentations. We will also prepare brief summaries for WHS e-newsletters to the field when appropriate, provide briefings to participating sites' leadership at the VAMC and VISN levels on findings over the course of the evaluation, and offer national briefings to other relevant Program Offices (e.g., MHS, PC, NCP, OPCC&CT) based on evaluation findings and WHS recommendations and requests. With WHS, we will also disseminate findings to WVs, through existing WV Councils affiliated with WHRN and the WH CREATE, consistent with our Veteran engagement work.

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