IMPLEMENTATION OF TAILORED COLLABORATIVE CARE FOR WOMEN VETERANS (CCWV)

An EMPOWER QUERI Project

Protocol Component A & B

Funding Agency: QUE 15-272

Principal Investigator/Study Chair: Alison B. Hamilton, PhD, MPH

June 22, 2020

Abstract

Project Background: Women Veterans are the fastest growing segment of Veterans Health Administration (VHA) users. This dramatic growth has created challenges for VHA. Rates of depression, anxiety, and mental health comorbidity are disproportionately high among women Veterans. Furthermore, a high rate of women Veterans' attrition from VA care, along with organizational barriers to care, substantiate that organizational changes are needed in order to engage and retain women Veteran VHA users in evidence-based, patient-centered care.

Project Objectives: The **E**nhancing **M**ental and **P**hysical health **o**f **W**omen through **E**ngagement and **R**etention (EMPOWER) QUERI addresses VHA Blueprint for Excellence Strategy 6, by advancing "personalized, proactive, patient-centered" care models, and Transformational Strategy 7.2.g by implementation of innovative care models in women Veterans' health care." The EMPOWER QUERI Program is designed to improve women Veterans' engagement and retention in evidence-based care for mental health. To achieve this impact goal, we propose a cohesive portfolio of projects with the following aims: (1) To use an evidence-based implementation strategy that emphasizes local tailoring of care models, multilevel stakeholder engagement, and systematic evaluation of complex implementation processes in order to enrich organizational capacity for innovations in women Veterans' VHA health care; (2) To implement personalized, proactive, patient-centered innovations in VHA women's health that are acceptable, feasible, satisfactory, relevant, and effective for both providers and patients, thereby encouraging women Veterans' engagement and retention *and* sustainability of the innovations; and, (3) To generate implementation "playbooks" for our partners that are scalable and serve as guidance for future implementation of a broader array of evidence-based women's health programs and policy.

Project Methods: "Implementation of Tailored Collaborative Care for Women Veterans" will evaluate implementation of an evidence-based collaborative care model tailored to enhance provider- and system-level capabilities to address women Veterans' anxiety and depression treatment needs, thereby improving organizational primary care-mental health integration (PC-MHI) effectiveness and women Veterans' engagement and retention in PC-MHI. The study will use a modified stepped wedge design and will apply the evidence-based Replicating Effective Programs (REP) implementation strategy. Mixed methods implementation evaluations will focus on investigating primary implementation outcomes of adoption, acceptability, feasibility, and reach. Multilevel stakeholder engagement will be prioritized. Program-wide organizational-, provider-, and patient-level measures and tools will be utilized to enhance synergy, productivity, and impact. As a coherent program of women's health implementation research and quality improvement, the proposed EMPOWER QUERI will constitute a major milestone in achieving BPE strategies and realizing women Veterans' engagement and, ultimately, empowerment in our VHA system.

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List of Abbreviations

1. EMPOWER.....Enhancing Mental and Physical health of Women through Engagement and Retention
2. PCMHI……...……Primary Care-Mental Health Integration
3. PCP……..……..Primary Care Provider
4. MH…….…….…….…… Mental Health
5. CCWV…….……Collaborative Care for Women Veterans
6. WATCH…….……Women's Assessment Tool for Comprehensive Health
7. CALM……Coordinated Anxiety Learning and Management
8. PACT……..……VA's Patient-Aligned Care Teams
9. WH……Women's Health
10. WHS…….Women's Health Services
11. GLA…….……..Greater Los Angeles
12. NCP……...National Center for Disease Prevention and Health Promotion
13. BPE……..……...Blueprint for Excellence
14. EMR…….……..Electronic Medical Record
15. REP……...……..Replicating Effective Programs
16. TECH……Tool for Evaluating Research Implementation Challenges
17. WHRN……..……..Women's Health Research Network
18. PBRN……Practice-Based Research Network
19. DART……Data Access Request Tracker

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Protocol Title:
IMPLEMENTATION OF TAILORED COLLABORATIVE CARE FOR WOMEN VETERANS (CCWV)

NOTE: Component A (approved 12/27/2016) involves Key Stakeholder VA Staff Participants, and will be coordinated by the PI at Greater Los Angeles VA Healthcare System. Component B involves Patient Human Subjects and additional sites outside of Greater Los Angeles VA.

1.0 Study Personnel

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Introduction

BACKGROUND

Almost half (48%) of women Veterans have at least one mental health (MH) condition,[1] with depression as the most common MH condition among women Veteran VA users (24% in FY14), followed by PTSD (14%) and anxiety (8%). Depression and anxiety are substantially more prevalent among women Veterans than men.[2] Women Veterans are also more likely than men to have comorbid MH conditions, and they are more likely to have experienced military sexual trauma (MST)[3-4] and intimate partner violence (IPV)[5] Like their male counterparts, women Veterans tend to have complex mental health needs. However, in contrast with men, a significant proportion of women's symptoms, losses, and treatment contraindications may be related to reproductive phases and experiences, gendered trauma histories, and gender role responsibilities.

Women Veterans' distinctive MH needs challenge the organization to appropriately connect women to MH providers who understand their unique vulnerabilities, and to support their navigation of often fragmented MH care options offered across VA primary care (PC) and MH settings. Depending on the VA site, women may have access to integrated MH care in general PC clinics, in a separate portion of a general PC clinic set aside for women, or in stand-alone women-only clinics, with variable access to women-only care options and same- gender providers when preferred. MH clinics may have no special arrangements for women, or may have some providers to whom women are preferentially assigned. At a few sites, women-only MH clinics may be available, or if the site has a comprehensive women's PC clinic, full-service specialty MH care may be co- located.[6] Such highly variable models of MH care delivery in PC and MH further challenge the system to engage women in services in a timely manner, and to support their retention in care.

Collaborative care models have a strong evidence base for enhancing patient engagement and retention in PC-based MH care for depression,[7-9] and the VA has extended application of collaborative care to many other mild to moderate conditions, including anxiety disorders and alcohol misuse. The VA's approach to integrated MH involves collaborative care with two components: co-located MH professionals who are integral components of the PC team, and MH care management.[10] While co-location has been achieved at many sites, implementation of care management has been limited, especially in women's clinics. The VA endorses three collaborative care models that emphasize different elements of care management: Behavioral Health Lab,[11] White River Junction,[12] and Translating Initiatives in Depression into Effective Solution (TIDES).[13] A recent report on Integrating Mental Health into VA's Patient-Aligned Care Teams (PACT)[14] suggests that further work should be directed at understanding the advantages and disadvantages of each approach, and suggests moving away from branded approaches, toward blended models with local tailoring.

VA policy specifies that MH services must be provided in a manner that recognizes that gender-specific issues can be important components of care. With attention to gender-specific

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concerns, collaborative care is a promising model to improve PC-MH integration for women Veterans. We propose implementation of tailored "Collaborative Care for Women Veterans" (CCWV) that encourages local blending of elements from VA-approved models with a PC-friendly evidence-based, computer-assisted cognitive behavioral treatment (CBT) platform for anxiety and depression.[15]

RATIONALE

The rationale for this project is based on five fundamental premises: 1) PC and MH care for women Veterans are complex and diverse (as described above); 2) anxiety and depression among women Veterans can and should be treated in PC; 3) improvements are needed in PC-MHI for women in these complex care structures and settings; 4) collaborative care *designed for women Veterans* would benefit the VA, providers, and women Veterans themselves; and 5) blended models of existing collaborative care models or components, with some enhancements, are needed in order to fit with local WH structures, needs, and resources.

Anxiety and depression among women Veterans can and should be treated in the PC context. Since 2007, Primary Care-Mental Health Integration (PC-MHI) in VHA has evolved into a requirement at all VHA medical centers and large community-based outpatient clinics.[16] VA WH policy now requires that basic mental health services be provided in the same physical location as women's primary care, whether in a gender-neutral primary care clinic, in shared separate space in the gender-neutral clinic, or in a separate WH center. In addition, WH clinics must have co-located MH and social work services. Assessment and psychosocial treatment need to be available in women's PC for MH disorders, including depression and problem drinking, within the parameters of PC-MHI.

Improvements are needed in PC-MHI for women in VA's complex WH care structures and settings. Women's Assessment Tool for Comprehensive Health (WATCH) data provided to us by our WHS primary partners indicates that roughly 63% of VA healthcare settings (including medical centers and community-based outpatient clinics) have availability of PC-MHI such that a woman can "see a PC-MHI provider when clinically indicated…whenever this clinic is open to see patients on a timely, same-day basis." Unpublished interview data from several of our team's qualitative key informant studies suggest that MH services available in women's PC (or in an adjacent women's MH clinic) tend to be longer-term specialty MH services (as opposed to PC-MHI assessments and brief therapies) as well as women-only treatment groups, particularly for MH problems associated with MST experience. Informants have tended to report good communication between PC and MH providers, with "warm hand-offs" and curb-siding easily occurring in the clinic, but without a care management component to assess and triage the more and less severe cases to appropriate services.

True integration of MH supports for PC-based management of mild to moderate MH conditions may be overshadowed by co-located specialty MH services for more serious conditions. On the

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other hand, when women receive their PC in mixed-gender general PC clinics, women's proportional minority creates challenges to provision of integrated services that can provide choice of women-only and same-gender provider services when desired, and may limit access to integrated MH providers experienced in working with the unique trauma experiences of women in the military. Varying care arrangements and varying needs for gender-specific choices make the "glue" of a care management process very important to help women Veterans access appropriate services, while also making care management more difficult to implement.

Furthermore, work from the VA Women's PBRN[17] indicates that depression and PTSD are associated with women's strong preferences for designated women's mental health services, as well as treatment within the PC setting. According to a recent national survey of women Veterans, access to MH care for these conditions is good, but nearly half of respondents reported that VA MH services do not fully meet their needs.[17] Our WH, MH, and PC partners have urged us to use this QUERI implementation research opportunity to improve PC- MHI for women Veterans with depression and anxiety.

Collaborative care *designed for women Veterans* with depression and anxiety would benefit the VA, providers, and women Veterans themselves. Numerous similar models of collaborative care have been tested, primarily for care of depression in primary care settings, both outside the VA,[18-19] and in military[20] and VA[11, 12, 21] populations. A 2006 meta-analysis found that collaborative care is more effective than standard care in improving depression outcomes in the short and longer terms, and concluded that future research needs to address the implementation of collaborative care.[7]

The overall higher MH burden among women Veterans, and greater complexity of presentations, adds to the challenges of tailoring care management to meet women's needs. Models based on treating one MH condition, such as depression, tend to exclude patients with more complex issues. Our recent work has found that over one-quarter (27%) of women Veteran VA users have two or more MH conditions. Though depression is the most common MH diagnosis among women Veterans, depression very often presents together with anxiety disorders; in fact, depression-plus-anxiety and depression-plus-PTSD are tied for the two most prevalent co- occurring MH conditions among women Veterans.[1] Therefore, collaborative care management models that incorporate PC-friendly transdiagnostic brief treatment options for co-morbid presentations may be particularly suited to women Veteran populations. In addition, for those women whose MH needs exceed what can be offered in PC, strategies to support engagement in specialty care (especially when women-only settings are not available), as well as strong stepped care and referral management components will be important.

Because of the need for transdiagnostic and flexible models to meet women's MH needs, we propose to enhance existing VA models with elements of another collaborative care management model, Coordinated Anxiety Learning and Management, or CALM. CALM is a flexible, patient preference-driven model for multiple anxiety disorders (panic, generalized anxiety, social anxiety, PTSD) and depression in PC. Evidence for the effectiveness of CALM

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comes from a large (n = 1004) randomized controlled effectiveness trial, in 17 US primary care clinics with 71% women.[15,22] Women receiving collaborative care showed larger reductions in anxiety, greater improvements in mental health functioning, and larger reductions in days of restricted activity than women receiving usual care, while men showed no differences in these measures. Women receiving the computer-assisted CBT (which used disorder-specific treatment modules) attended more sessions of psychotherapy, completed more modules of therapy, expressed more commitment, and viewed psychotherapy as more helpful than did men.[23] Although Veterans were not the focus of the CALM trial, past trials using cognitive behavioral strategies for anxiety and depression in VA PC clinics have demonstrated the value of the general approach.[24] Importantly, the effectiveness of CALM was strongly related to level of engagement; outcome was predicted by completing exposures and homework and attending more frequently.[25] CALM's care management components closely mirror those emphasized in VA-approved models described above, including screening and initial assessments using structured instruments; regular monitoring of treatment adherence and side effects using a standardized protocol; patient education and activation; decision support using a protocol to determine patient preference for medication vs a brief computer-assisted CBT-based therapy or both; a stepped care protocol supported by regular brief assessments and a patient tracking system; and assistance with referral to specialty care when appropriate. Our ability to incorporate elements of CALM for CCWV is strengthened by many key factors: 1) the CCWV Co-PI, Dr. Lang, was involved in the original CALM trial and is an expert on the CBT platform; 2) one of the main CALM developers, Dr. Craske, has guided our study design and is a member of our Strategic Advisory Group; 3) CALM is currently being evaluated in a VA HSR&D CREATE hybrid type III implementation study, and the research team has agreed to share with us their VA-tailored version of the web-based CBT platform as well as their implementation results; 4) the lead of the CALM implementation evaluation,[150] Dr. Curran, is a nationally recognized implementation scientist and will also serve on our Strategic Advisory Group; and 5) one of our key partners, the PC-MHI National Medical Director, Dr. Post, strongly endorses our incorporation of CALM, indicating in his letter that this project will take existing PC-MHI programs "to a new level."

2.0 Objectives

SPECIFIC AIMS

Our specific aims are to:

1. In four PBRN sites, blend and tailor existing primary care-based collaborative care models with an evidence-based CBT platform to provide evidence-based, patient-centered collaborative care for women Veterans (CCWV) with anxiety and/or depression;
2. Implement the tailored CCWV in the four PBRN sites; and

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3. Evaluate CCWV implementation using a modified stepped wedge design and conduct an implementation-focused evaluation to further refine CCWV to facilitate future spread.

Achieving these aims will help achieve VA comprehensive PC policies for women Veterans and VA MH Strategic Analytics for Improvement and Learning (SAIL) performance goals of population coverage, continuity of care, and experience of care.

Our secondary aims focus on factors that empower Women Veterans to engage in and benefit from collaborative care. Specifically, we will evaluate a) effects of patient activation and engagement with care on retention in and experiences of CCWV, and b) changes in MH symptoms, patient activation, health-related quality of life, and care experiences as a function of participation in CCWV. We hypothesize that a) more highly activated women and women with greater increases in activation will demonstrate better retention in care and report better care experiences, and b) symptoms, patient activation and quality of life will improve as a function of CCWV participation.

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3.0 Resources and Personnel

STAFF			PROJECT ROLE		STUDY ACTIVITIES				
Staff	**Degree**	**Site**	**Role (Level)**	**Description**	**Access to PHI**	**Obtain Informed Consent**	**Recruit-ment**	**Conduct Interviews**	**Perform Data Analysis**
Hamilton, Alison	PhD, MPH	GLA	PI	Ensure that study procedures are followed to collect implementation evaluation data that contributes to an understanding of the implementation outcomes, as well as patient-level data that will inform secondary aims related to clinical outcomes. Oversee the study team, administrative components, project management, human subjects, data collection, data quality, analysis, dissemination of findings, and preparation of the final report.	Y	Y	Y	Y	Y
Huynh, Alexis	PhD, MPH	GLA	Collaborator (Implem eval/stats)	Provide both qualitative and quantitative data collection support and analysis in the implementation evaluations. She will also be the statistical analyst who runs the stepped wedge model. She will contribute to the Implementation Core, particularly to cross-project analyses and manuscripts.	Y	Y	Y	Y	Y
Moreau, Jessica	PhD	GLA	Implem eval	With mentorship from Dr. Hamilton, Dr. Zuchowski will coordinate and lead qualitative data collection and analysis. She will ensure that data collection and analysis are conducted in a systematic and efficient way. In Year 5, she will participate in the cross-QUERI analyses and in preparation of manuscripts, presentations and reports.	Y	Y	Y	Y	Y
Canelo, Ismelda	MPA	GLA	Admin support	Manage QUERI project staff and keep the team aware of projected timeline milestones, budgetary issues and compliance requirements, as well as evaluation activities and progress as needed. She will also coordinate the scientific activities of the study and provide administrative and regulatory support. She will also work to ensure the project stays on track according to the Gantt chart through effective project coordination, documentation and meeting arrangements with the PIs and the SAG.	N	N	N	N	Y
Oberman, Rebecca	MSW, MPH	GLA	Project Director	She will meet with leadership and the Implementation Team and liaison with the participating sites. Ms. Oberman will evaluate implementation progress and problem-solve implementation issues with the site staff and leadership throughout implementation. She will be responsible for the day-to-day central project activities, including oversight of research, implementation, and interfacing with VHA personnel. At the sites, she will be in	Y	Y	Y	Y	Y

				close communication with the care managers and the Research Assistants. She will complete research assessments as needed. She will collaborate with the PI and research team on data analyses, including the qualitative data analyses. Ms. Oberman will assist with reports and development of the CCWV Implementation Playbook. She will work to disseminate project findings through relevant VA workgroups. She will manage the CIRB and DSMB reports for this multi-site study. She will also prepare and collate all study related materials (surveys, interview guides). Ms. Oberman will devote 20 hours per week over the course of the entire QUERI Program.					
Jackson, LaShawnta	DrPH, MPH	GLA	Project Director	Dr. Jackson will meet with leadership and the Implementation Team and liaison with the participating sites. She will evaluate implementation progress and problem-solve implementation issues with the site staff and leadership throughout implementation. She will be responsible for the day-to-day central project activities, including oversight of research, implementation, and interfacing with VHA personnel. At the sites, she will be in close communication with the care managers and the Research Assistants. She will complete research assessments as needed. She will collaborate with the PI and research team on data analyses, including the qualitative data analyses. Dr. Jackson will assist with reports and development of the CV Toolkit Implementation Playbook.	Y	Y	Y	Y	Y
Brunner, Julian	PhD	GLA	Stats	Mr. Brunner will support the stepped wedge analysis.	Y	Y	Y	Y	Y
Than, Claire	MPH, CPhil	GLA	Stats	Ms. Than will support the stepped wedge analysis.	Y	Y	Y	Y	Y
Chrystal, Joya	MSW	GLA	Implem. Eval	Ms. Chrystal will conduct qualitative data collection and analysis, and participate in the cross-QUERI analyses and in preparation of manuscripts, presentations and reports.	Y	Y	Y	Y	Y
Schweizer, Catherine Amanda	PhD	GLA	Implem. Eval	Dr. Schweizer will provide both qualitative and quantitative data collection support and analysis in the implementation evaluations.	Y	Y	Y	Y	Y
Dyer, Karen	PhD	GLA	Research Assoc.	Dr. Dyer will conduct qualitative data collection and analysis, and participate in the cross-QUERI analyses and in preparation of manuscripts, presentations and reports.	Y	Y	Y	Y	Y

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SITE: Palo Alto

STAFF			PROJECT ROLE		STUDY ACTIVITIES				
Staff	**Degree**	**Site**	**Role (Level)**	**Description**	**Access to PHI**	**Obtain Informed Consent**	**Recruit-ment**	**Conduct Interviews**	**Perform Data Analysis**
Kimerling, Rachel	PhD	Palo Alto	Co-I	Given her expertise in measurement of women's preferences for care as well as other key measures related to patient engagement (e.g., patient activation), support the Implementation Core. In Year 1 she will contribute to the consolidation of the cross-Program measures, ensuring that members of the team are trained in the measures and that they are integrated appropriately for use in the projects. As the first sites launch, she will monitor the data collection activities, ensuring quality and consistency and she will conduct preliminary analyses to ascertain the integrity of the data. She will continue to provide measurement support, and then in Year 5 will contribute substantially to cross-Program analyses and dissemination of findings.	N	N	N	N	Y
Wiltsey-Stirman, Shannon	PhD	Palo Alto	Co-I	With her strong background and training in implementation science, Dr. Wiltsey-Stirman will support the implementation evaluation efforts in the CCWV implementation research project. Because her focus is on implementation of evidence-based treatments, she will provide the team with unique expertise regarding implementation challenges and solutions, and will participate in the use of the TECH. In addition, she will provide consistent support to the Implementation Core, lending her expertise in sustainability of evidence based care models to the team.	N	N	N	N	Y
Carney, Diane	MA	Palo Alto	PBRN liaison	Ms. Carney's responsibilities on this project will be consultative in nature. She will serve as the PBRN liaison on the Implementation Core. Considering that all projects will occur in PBRN sites, it is imperative that we have a liaison who can provide contacts, information, and connections as well as support for the overall emphasis on multilevel stakeholder engagement.	N	N	N	N	N

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SITE: San Diego

STAFF			PROJECT ROLE		STUDY ACTIVITIES				
Staff	**Degree**	**Site**	**Role (Level)**	**Description**	**Access to PHI**	**Obtain Informed Consent**	**Recruit-ment**	**Conduct Interviews**	**Perform Data Analysis**
Lang, Ariel	PhD, MPH	SD	Co-PI	Co-PI of the CCWV project and will be responsible for overseeing implementation at the San Diego PBRN site, as well as contributing to the broader scientific effort, in particular, overseeing implementation of the collaborative care protocol, with expertise in the CALM CBT platform. She will provide supervision and training as needed to clinical staff who provide the CBT.	Y	Y	Y	Y	Y
Jeanne Maglione	MD	SD	Co-I	Psychiatrist with experience in PCMHI, she will be the San Diego site liaison and responsible for facilitating research and implementation at the San Diego PBRN site, as well as contributing to the broader scientific effort, in particular, overseeing implementation of the collaborative care protocol.	Y	Y	Y	Y	Y
TBN		SD	Research Assistant	Carry out activities including recruitment, screening, consent, survey and qualitative interviews	Y	Y	Y	Y	N
TBN		SD	Site Coordinator	Manage Local Site CIRB submissions and local site R&D submissions. Assist in research activities as needed including recruitment, screening, consent, survey and qualitative interviews.	Y	Y	Y	Y	N

SITE: San Antonio

Erin Finley	PhD, MPH	San Antonio	Implem core	Oversee the implementation evaluations. Leading role in development, drafting, and dissemination of the Implementation Playbook.	Y	N	N	Y	Y

SITE: Salt Lake City

Catherine Chanfreau,	PhD,	Salt Lake City	Implem core	Dr. Chanfreau will lead the data extraction from CDW, will be part of the implementation evaluation team, and will oversee the data extraction and measures construction for the impact, access, and other measures for implementation monitoring and feedback to the sites, as well the overall trial.	Y	N	N	Y	Y

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Co-Investigators involved in design and interpretation and dissemination, accessing only de-identified data, include: Anne Sadler, RN, PhD (Iowa City VA) and Jennifer Strauss, PhD (Durham VA).

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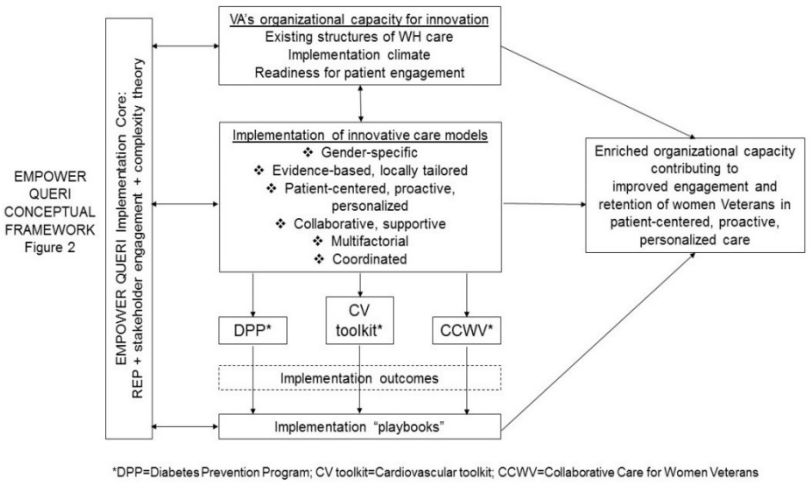
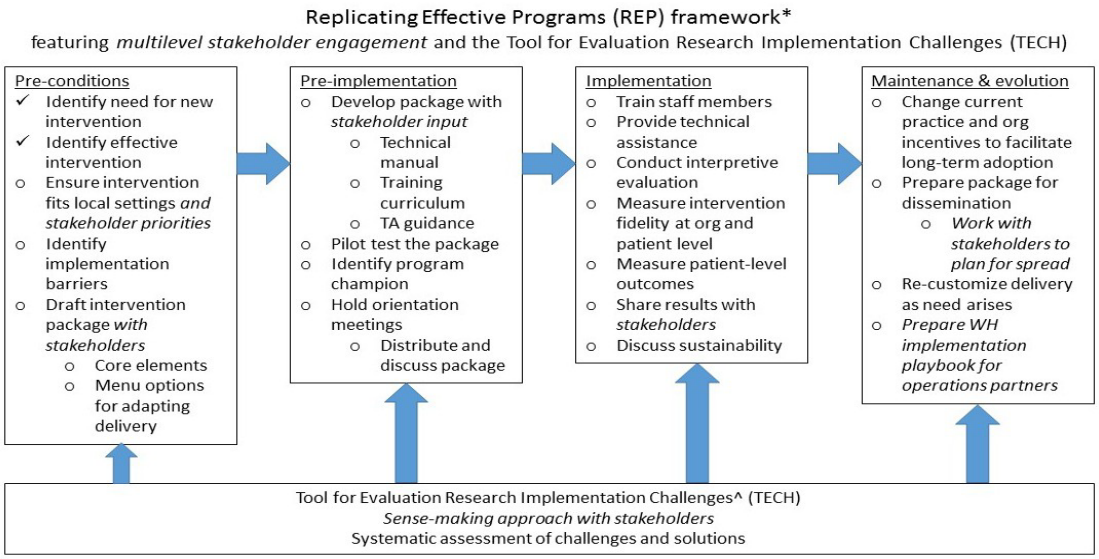
4.0 Study Procedures

This study is part of a larger EMPOWER QUERI project focusing on innovation in care for women Veterans at VA. Project stakeholders include staff and leadership as subjects and/or key informants. Products include development of an innovative approach for addressing implementation of a care model that addresses anxiety and depression for woman Veterans.

5.1 Study Design

EMPOWER QUERI Conceptual Framework. This QUERI Program focuses on strengthening WH organizational capacity for innovation in patient-centered care, using an Implementation Core and three projects as a collective platform for examining how particular characteristics of care models contribute to providers' ability to utilize the models and to patients' engagement and retention in the models. As depicted in our conceptual framework (Fig. 2), the Implementation Core forms the backbone of our program, and relies on an evidence-based implementation strategy, Replicating Effective Programs (REP), and emphasizes multilevel stakeholder engagement and complexity theory. The Core will examine organizational capacity for innovation in the context of local WH care arrangements, which we know to be quite diverse, as well as implementation constructs such as climate and leadership, and novel constructs such as organizational readiness for patient engagement and implementation citizenship. Knowledge of organizational capacity will inform implementation of innovative care models that address anxiety and depression. Implementation outcomes will contribute to development of Implementation Playbooks—brief, user-friendly summations of implementation targets, processes, outcomes, and recommendations for scale-up and spread.[26] Together, these activities will contribute to our ultimate goal of enriching VHA's organizational capacity to engage and retain women Veterans in patient-centered, proactive, personalized evidence-based care.





EMPOWER QUERI Implementation Strategy: Replicating Effective Programs (REP). We will use REP[13] across all projects to maximize the implementation science knowledge that will be generated by a common approach. Grounded in theories of Diffusion of Innovation and Social Learning, REP was selected because of its strong evidence base and application in VHA health services research.[27] It also provides a phased *framework* for implementation, with different discrete implementation strategies being employed in different phases. REP's demonstrated effectiveness in promoting uptake of evidence-based practices allows us to focus on its application in varied settings and care models. Use across all projects will allow for further testing and expansion of the framework, particularly through our emphasis on multilevel stakeholder engagement and incorporation of complexity theory. The REP framework consists of four phases (Fig. 3): pre-conditions, pre-implementation, implementation, and maintenance/evolution. Careful attention is paid to intervention packaging during pre- conditions and pre- implementation; training, technical assistance, and fidelity assessment during implementation; and recustomizing during maintenance/evolution.

During each phase, local context is paramount, with varying deployment of the intervention depending on local priorities, needs, and resources. One of our implementation science goals will be to track the relative importance of each discrete strategy in each phase at each site and across sites, as well as in each project and across projects, to inform user-friendly, implementation practice "playbooks" for our partners.

Enhancing REP with Multilevel Stakeholder Engagement and Complexity Theory. REP was originally designed to guide dissemination of evidence-based practices in community-based organizations. Kilbourne and colleagues[27] note that "it was not designed to address multilevel barriers to implementation," so they enhanced REP with facilitation, using implementation experts as external facilitators to provide guidance for overcoming implementation barriers. Interestingly, outcomes were favorable for enhanced REP for their primary implementation outcome of uptake (i.e., completed contacts with Veterans with serious mental illness who had been lost to care), but not for increased

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utilization of services by patients who had dropped out of care.[28] This prompted us to consider alternate REP enhancements that are 1) more focused on participatory action[29] within complex adaptive systems[30] in VHA WH clinical settings,[31] and 2) potentially more effective in increasing patient engagement. Accordingly, we draw on complexity theory and multilevel stakeholder engagement (Fig. 3). Complexity theory postulates that outcomes in complex adaptive systems are nonlinear and unpredictable; it is a highly relational theory, examining how multiple agents involved in implementation interact in complex ways and "make sense" of implementation in different ways.[32] This emphasis on incorporating multiple perspectives and differing priorities is consistent with our VHA WH roadmap to delivering gender-sensitive comprehensive care for women Veterans,[33] which suggests that multilevel stakeholder engagement is key to improving women Veterans' health care.

We will operationalize complexity theory through use of the Tool for Evaluating Research Implementation Challenges (TECH),[34] which was designed to systematically assess impacts of implementation challenges and guide potential solutions. Simpson and colleagues recommend this tool under three pre-conditions: 1) "implementation adaptations are expected due to the emergent nature of complex research settings;" 2) the research environment needs to encourage "spontaneous emergent solutions" and creativity; and 3) all research team members must be empowered to participate. Our approach, where all stakeholders are integral to achieving the impact goal, supports these pre-conditions.

TECH, which has been used successfully in VHA and community studies, is codified into a series of interactive steps: identifying challenges (e.g., through observing day-to-day dynamics, listening to complaints, asking questions, etc.), interpreting the challenges in weekly meetings, generating and testing solution strategies, and, if necessary, addressing regulatory issues. Solution strategies are developed through open dialogue among the team members as well as others who might have perspectives on potential solutions. Although applicable to many different types of research, TECH is especially useful for research in complex adaptive systems as a tool for addressing unexpected challenges in systematic and collaborative ways.

Multilevel Stakeholder Engagement in the EMPOWER QUERI. Our QUERI capitalizes on our seasoned team of implementation scientists, health services researchers, and clinicians, supported by a stellar Strategic Advisory Group. Furthermore, we have the distinct advantage of being buttressed by the VHA HSR&D Women's Health Research Network (WHRN), which is comprised of the Women's Health Research Consortium and the Women's Health Practice-Based Research Network (PBRN; §3.3.1), and a research aim on multilevel stakeholder engagement. Our entire team is associated with the WHRN (with EMPOWER QUERI PI Hamilton also being one of the WHRN PIs). In fact, this QUERI was developed with consistent input from the PBRN Site Leads (some of whom are on our team: Bean-Mayberry (PI), Mattocks, Sadler), and the projects will all be conducted at PBRN sites (Frayne LoS). Moreover, our QUERI proposal has been strengthened from its inception by invaluable input of women Veterans themselves. Specifically, a newly forming Women Veteran Patient Advisory Council has agreed to serve as an implementation partner for this QUERI Program

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(Gottke LoS); Dr. Hamilton will serve as an advisor to the Council and will use principles of patient engagement in research[33] to guide collaboration and involvement of the Council.

EMPOWER QUERI Methods

Setting: Women's Health Practice-Based Research Network (PBRN). The PBRN provides a research infrastructure for investigators seeking to increase inclusion of women in VHA research or conduct multi-site women's focused research in VHA. Comprised of 37 VAMCs that see one-third of women Veteran VHA users, the PBRN helps investigators overcome the challenges of multi-site studies through engagement of Site Leads with established working relationships with local clinicians and facility leadership. Site Leads have received implementation training, and have developed across-site relationships through regular national calls and technical support organized by the PBRN Coordinating Center in Palo Alto (Frayne LoS).

Modified Stepped Wedge Study Design for Implementation Trials. We will use stepped wedge designs, which rely on sequential roll-out to participating sites over time, while using other sites as controls until they begin implementation. Consistent with our substantial prior experience using these designs in VHA and armed with complexity theory's recognition of nonlinearity of implementation, we will use *modified* stepped wedges (rather than randomized) given their suitability for studying implementation. This design acknowledges that sites are heterogeneous, face multiple constraints, and, as a result, are ready to adopt interventions at different rates. The modified design explicitly considers the timing of implementation spread and addresses the statistical issues introduced by lack of randomization in implementation starts and processes. We will analytically compensate for the design by collecting patient-, provider-, and site-level data that may be associated with timing of the adoption of each intervention.

We will include three levels in our hierarchical stepped wedge models: (1) patient,(2) time of intervention (i.e., when a provider starts using the intervention), and (3) site. Outcomes of interest are measured for all patients at each site within the given intervention time period. We will include four PBRN sites in each of our two implementation trials

Data collection will occur in each of the REP phases (e.g., pre-conditions for 6 months, pre-implementation for 6 months, implementation for 15 months, and maintenance/evolution for 4 months). Similar to previous modified stepped wedge studies, implementation initiates with PCPs. Figure 4 depicts Site A initiating at Quarter 3, Site B at Quarter 4, and so on, with three PCPs at each site, each quarter, for a total of 81 PCPs. The PCPs "turn on" (i.e., use the template in the CV project; refer to the care manager in the CCWV project) as they switch from pre-implementation to implementation.

Modified stepped wedge designs make efficient use of all data available for within-site and between-site comparisons. For the within-site comparison, sites act as their own controls in an evaluation that compares sites pre- versus post-implementation. The comparison examines sites as they cross-over from control to intervention states. The between-site comparison evaluates the intervention period for a site vs. all other intervention and control periods for all sites. By having these two types of

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comparison, the design improves on the validity of the evaluation of the intervention, by accounting for historical time trends that may occur outside of the intervention and for site contextual characteristics that may affect site performance.

We will use a modified stepped wedge design to evaluate the implementation in four VA Women's PBRN sites (Frayne LoS). In the context of the modified stepped wedge design, the intervention is "turned on" when a PCP at a site makes her/his first referral to the CCWV care manager (see below).

In Year 1, we will begin the REP pre-conditions phase in one VA Women's PBRN sites. We will continue through the phases over the course of four years, with a 15-month implementation phase in order to ensure adequate time to evaluate implementation and sufficient numbers of Women Veterans being exposed to CCWV. Three additional PBRN sites will be "stepped in" during Year 2at appropriate intervals over time. According to the REP framework and complexity theory, all sites will be encouraged to adapt and tailor set-up and delivery of CALM according to their local resources and care configurations.

REP Implementation Phases

Pre-conditions (Aim 1): The need for CCWV has been established and the review of effective interventions has been conducted (see above). To ensure that the care model fits local settings and stakeholder priorities, the PI and Co-Investigator Dr. Oishi will visit the sites and meet with the local team to discuss local structures, care models and processes, educational needs, as well as elements of the proposed CCWV and tailoring options that we have conceptualized (Table 3). Using the TECH, the local team will discuss options for CCWV implementation and anticipated barriers to implementation. Also during this phase, interviews and surveys will be conducted with all consenting key stakeholders, with the exception of patients who will be interviewed and surveyed in the implementation phase (see below).

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Table 3. Elements of Collaborative Care for Women Veterans (CCWV)

Care management Functions	CCWV Element	Local Tailoring Options
Initial MH assessment of patients referred by PCP	Care manager conducts baseline MH assessments, medication history, and other relevant information collection	Site designates a local MH care manager (RN or social worker) who conducts some or all care management functions; sites choose from VA-approved assessment packages
Women with positive assessments offered treatment choice	Treatment choices for anxiety, depression, and PTSD are medications, primary care-based CALM CBT, or both	Site chooses integrated MH providers according to local availability (psychologist; social worker) for training in CALM CBT

Care management Functions	CCWV Element	Local Tailoring Options
Women with severity or complexity requiring specialty treatment assisted to access specialty resources	Care manager inquires about preferences for gender-specific services and provider gender; facilitates connection to most congruent locally available specialty services, and makes a warm handoff if possible; care manager follows up with patient to check on any missed appointments or group sessions	Referral can be made to co-located or distant specialty services as available at the site; care manager is familiar with locally available gender-specific groups and providers most experienced in treating women; same gender provider options identified ahead of time
Systematic monitoring of symptoms and treatment emergent problems	Care manager uses structured MH assessments for depression, anxiety disorders, and alcohol problems as well as symptom and side effects checklists to monitor treatment response; follows up to assure medication and/or CBT session compliance	Sites choose from VA-approved follow-up assessment options; site can choose to involve peer support for telephone check-in with patient and in-person chaperoning and escorting to various services
Patient education and activation	If the patient has chosen medication, care manager provides basic patient education and activation relevant to the primary diagnosis; if CBT is chosen the care manager facilitates connection to an integrated provider trained in CALM	Site decides which materials from available care management programs care manager will offer; if in the scope of practice of the locally chosen care manger (e.g., MSW) the care manager may be trained to provide CALM CBT
Decision support	Care manager uses a stepped care protocol under supervision of a local psychiatrist to determine when decisions to increase or change treatment options are needed and to collect information to assist the primary care provider in making adjustments	Decision support templates may be locally selected from VA-approved options; sites choose a supervising psychiatrist who may be co-located or based in specialty mental health depending on local circumstances

Site 1: Because this project's Co-PI (Dr. Lang) is based at the San Diego PBRN site, we have already laid the groundwork for implementation at this site, in collaboration with the PBRN Site Lead, Dr. Meredith Barnes, who is the WH Medical Director. VA San Diego is an interesting and complex site at which to implement CCWV, because PC is delivered in two locations (La Jolla and Mission Valley) that serve both men and women, with 41 designated WH providers across the healthcare system. These two locations differ in their PC-MHI teams, with one having a clinical psychologist, a nurse case manager, and a part-time (1/8) psychiatrist; and the other having two psychologists, a nurse case manager, a part-time (6/8) psychiatrist, and psychology trainee time (approx. 40 hours/week). Unless the PCP is prescribing him/herself, most PC patients with MH needs are referred to the Anxiety Disorders Clinic or the Mood Clinic, unless the diagnosis is PTSD, in which case women are referred to the women's trauma clinic. *These clinics all have waiting lists.* MH providers at the two PC sites have expressed to the co-PI that CCWV would be an important and needed addition to the services currently provided, especially in that, for those who need a higher level of care, it can provide a "bridge" to that care and may even circumvent the need for such care if desired outcomes are achieved through CCWV. This site has a strong peer support specialist program, led by the Local Recovery Coordinator who has expressed her support for this study and will actively "market" the availability of female peer support specialists to the WH PCPs and patients. Of note, across the two PC clinics from Oct 2014 – Apr 2015, there have been 688 unique encounters in primary care by women with anxiety or depression. This substantiates that we will have sufficient numbers of women at this site to ensure that at least 130 will be referred to the CCWV care manager (see power analysis section) and will complete the baseline measures.

Pre-implementation (Aim 1 cont.): At each site, a local CCWV champion will be identified by the Site Lead when s/he signs onto the project. The CCWV package will be further developed and locally tailored, with attention to training and technical assistance needed at each site. Once prepared, the package will be piloted locally to ensure that it works as intended with local systems and processes. In order to use the CALM CBT platform, we are collaborating with Dr. Curran (see LoS) who will provide us with a VA version of the platform when it is ready (their CREATE study). Using the TECH, any challenges with pilot implementation will be discussed and addressed by the team. When the team determines that challenges have been sufficiently addressed, orientation meetings will be held with the broader clinic, where the CCWV package will be distributed, discussed, and marketed.

Implementation (Aim 2): The implementation phase will begin at one PBRN sites and will last a total of 15 months to ensure adequate time for patient Exposure to the care model as well as implementation evaluation and reach. CCWV will spread to three additional PBRN sites in the following years. PBRN representatives will be trained in CALM. Field notes will be taken during the training and minutes will be kept of all conference calls and meetings. Notes will be analyzed using ATLAS.ti and will be interpreted in conjunction with other evaluation data as described below. During regular implementation meetings, TECH will be used to assess and address implementation challenges.

Procedures: Once training is complete and sites are ready for implementation, women Veterans with possible depression and/or anxiety disorders will be referred by their PCP (or other referring provider) to the locally identified CCWV care manager, who will also conduct local case finding activities to identify women Veterans who may benefit from care management. The care manager will then complete a clinical evaluation to identify the disorder of primary clinical focus (Panic Disorder with or without Agoraphobia, Social Anxiety Disorder, Generalized Anxiety Disorder, Posttraumatic Stress

Disorder, depression). CCWV is an innovative care model that is proactive, patient-centered and personalized to each woman that has an appointment with the care manager. Specifically, the care manager assists the patient in deciding which type of treatment she wants to pursue (CBT, medication, or both). During or shortly after the initial meeting with the care manager, each woman will be asked by the RA if she is willing to participate in our research project, meaning that she will be asked to complete a brief written battery of measures (§3.3.3.3) and a short qualitative interview at baseline (after the first or second visit with the care manager) and at six-months post-baseline. Women who enroll after the baseline window will not be eligible for baseline survey measures; however they can participate in interviews. Participants who enroll in research after the baseline period, and any women who are otherwise unable or unwilling to complete the written surveys, will be invited to consent to participate in other components of the research (i.e., qualitative interviews, , data obtained from medical record).

For women who choose CBT, the CALM-trained provider will then meet with the patient weekly to review the CALM CBT modules. The program includes five general modules (introduction, psychoeducation, self- monitoring, breathing retraining and relapse prevention), and three other modules that are customized to each anxiety disorder (cognitive restructuring, in vivo exposure and interoceptive exposure), which are tailored to each anxiety disorder. Depression modules are also available. The CALM CBT platform is a computer-assisted delivery system. The provider sits with the patient in front of the computer and directs the individual to review the appropriate material, clarifying and individually tailoring. The program contains educational material as well as skills training and exposure exercises. The entire program is typically completed within eight 60-minutes sessions.

Maintenance and Evolution: The last phase in this framework allows us to take the feedback and make modifications to our implementation process to enhance CCWV adoption, fidelity to the REP framework, and dissemination to future sites. Sharing these details with stakeholders using TECH informs the current implementation process and sustainability for the future. The four REP phases allow us to account for each step of the guided implementation strategy. Finally, the interchange between these phases and the implementation process components provide an in-depth understanding of whether CCWV implementation requires further adaptation and customization prior to broader VA dissemination. During this phase, the research team will collaborate with the local implementation teams to develop points for the CCWV Implementation Playbook.

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Risk to Subjects

This study involves both Veteran (520 total across sites) and VA Staff participants (60 total across sites).

Veteran Involvement and Characteristics

This 4-site project aims to inform the VA regarding implementation of collaborative care for women Veterans (CCWV). The study is primarily focused on implementation outcomes such as adoption, acceptability, feasibility, satisfaction, and reach, as well as patient engagement and retention; patient clinical outcomes (symptoms, etc.) though examined, are secondary. After IRB approval, at each participating site, we will enroll approximately 130 women Veterans who are referred by their primary care provider (PCP) or another referring provider to the CCWV care manager. Any woman referred to the care manager (and therefore initially screening positive for anxiety, depression, and/or PTSD) is eligible to participate. We will stop consenting enrollees once we have reached up to 80 women who have had an encounter with the care manager and who consent participate in the research, in order to complete data collection with 65 women at each site. Our goal is to have 260 women total (across the 4 sites) engaged in care management over the course of the study. Participation in CCWV consists of completion of the surveys, interviews, and access to relevant medical record data.

Routine Clinical Care versus Research. Meeting with the care manager and participating in Coordinated Anxiety Learning and Management (CALM), being followed by the care manager for medication adherence, psychiatric treatment and medication, or other mental health treatments are routine clinical care available to any woman Veteran seen at a participating primary care or women's health clinic. Consenting to research involves completing the research surveys, research interviews, and granting permission to access selected medical record data as part of an evaluation of the implementation outcomes and secondary clinical outcomes described above. Participants who enroll in research after the baseline period, and any women who are otherwise unable or unwilling to complete the written surveys, will be invited to consent to participate in other components of the research (i.e., qualitative interviews, data obtained from medical record). Patients do not have to consent to participating in research in order to receive routine clinical care with the care manager.

Provider / VA Staff Involvement and Characteristics

We will recruit approximately 15 VA staff members per site. Staff members from each site will comprise primary care providers, care managers, MH providers, social workers, and administrators (e.g., Primary Care Chief, MH Chief). Given the diversity of VA staff, this sample will include women, men, and members of minority and ethnic groups. This array of providers and staff will allow varied perspective on the CCWV care delivery process at each site.

Potential Risks

Risks are minimal.

For patients, study assessments will include potentially sensitive questions and information about mental and/or physical health symptoms, thus there is risk for embarrassment and negative effects on

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patient subjects if sensitive information was improperly disclosed and used in a discriminatory fashion against the individual. It is also possible that patients may become upset or triggered when asked about mental health concerns and exposures, or that suicidal thoughts may be revealed during questionnaire completion or during interviews. Additionally, individuals' social security numbers will be collected in order to obtain data from VA databases and to collect data from patient medical records. If disclosed, this information could cause negative financial or legal consequences. Recruitment may also involve the risk of coercion if the Veteran perceives that refusal might threaten care or benefits.

For staff participants, because these studies ask questions about organizational issues at the clinic where they are employed, there is risk for embarrassment and negative effects on subjects if sensitive information was improperly disclosed and used in a discriminatory fashion against the individual.

However, given the safeguards against improper disclosure and steps we are taking to ensure protection of sensitive information as detailed below, the likelihood of any disclosure is minimal.

Adequacy of Protection from Risk

Procedures to safeguard against adverse events. All data collection protocols will include procedures whereby research staff members report problems with the data collection, concerns about risk to subjects or others, or unusual occurrences during the collection. These allow project leaders an opportunity to quickly review and respond to any possible concerns or adverse effects.

Informed consent. Research participants are advised of the voluntary nature of participation and research subjects are informed of their right to withdraw from the project at any time. Each participant receives a verbal and written description of the study. The Principal Investigator and delegated research team members are available at all points of the study to answer questions and to explain assessment procedures, uses to which the data will be put, and confidentiality of data.

Mandatory reporting safeguards. Procedures to prevent violation of confidentiality are limited by the mandatory nature of legal reporting requirements. Subjects are informed in the consent document and verbal consent process that their responses to the surveys and interviews are confidential, except:

"1) If we need to protect you or others from harm. An example of this is if you want to hurt yourself or others. In that case, we will give information about you to others that is needed to protect you or others from harm.

2) If you tell us about the abuse of a child or of an elderly person, or if you tell us about being abused yourself. In that case, we must report this to a supervisor, who may report it to the authorities."

Data safeguards. Before analysis of the data, all identifying information will be removed from the data. No information that could identify study subjects will be published or presented. Data will be reported only in the aggregate. Identifiable data will be stored separately from coded data sets. Access to identifiable study data will be restricted to research teams on a need-to-know basis.

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The CALM CBT program that will be used by care managers who work with patients choosing this option will be accessed from a secure website behind the VA firewall. No mental health information recorded in the program during CALM CBT sessions, including mental health assessments, will be accessed for research purposes. We will document which modules were used for each participating patient as a way of tracking the most useful and effective content for this population.

Discomfort with assessment, intervention procedures or disclosure safeguards. During the course of participation in the study, a subject could feel uncomfortable answering the survey or interview questions. All interviewers will be trained in the assessments and with sensitivity to the issues to be discussed. All subjects are informed that they may choose to skip any questions that they find uncomfortable or withdraw from the study at any time.

For patients who consent to be surveyed, the 30-45 minute surveys are handed to the participant by the RA, and will be completed in a private room in the VA clinic setting at each site. The RA will check for completeness as well as suicidality items before participant leaves. Qualitative interviews will be conducted in person in a private room or by phone.

Staff interviews will be conducted over the phone or in person in a private room.

Response procedures for adverse events are described in Section 6 Reporting (below).

Staff training safeguards. As required, all research staff will be credentialed by their VA Healthcare System's research service, and will successfully complete all required trainings. Clinical staff provide routine clinical care. Research staff will meet with their local study supervisor (the Site Lead or the Project Director) on a regular basis for supervision, ongoing monitoring of interactions with subjects, and problem solving. Research and clinical staff are trained to identify events that would fall under mandatory reporting guidelines, such as harm to self or others. The PI will be available at all times by cell phone. When the PI is not available, the PI will delegate this responsibility to another qualified, credentialed staff member.

Potential Benefits of the Research to Subjects and Others

Although individual subjects do not benefit directly, there are potential benefits to human subjects from participation. Participants may be able to impact the development and future dissemination of the care models for women with anxiety and/or depression at their own or other VA sites. They may also be able to provide feedback on care in the clinic where they receive services or are employed, which may affect their treatment or working environment in the future if this model is widely adopted.

5.2 Recruitment Methods

This study involves both Veteran **Patients** (n=260; 65/site) and VA **Staff** participants (n=60; ~15/site).

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Patients. Patient subjects will be recruited after making contact with the CCWV care manager via referral from their provider or other staff. The care manager will introduce the research study, and if the person wishes to find out more about the study and possibly participate, the care manager will introduce the Veteran to the RA (if available), ask the Veteran to complete the Research Candidate contact form, add research staff as an additional signer on their CPRS note to automatically notify research staff of interested individuals, or contact the RA through another secure HIPAA-compliant route such as phone call or encrypted email to relay the Veteran's referral information. . The RA will check in with the care manager frequently to learn when women Veterans have been referred, as well as respond to notifications from the CPRS system, phone calls, and encrypted emails. Using a visit-based sampling method, patients are eligible during their first or second visit with the care manager during the 15-month implementation period. The patient will be informed about the details of research participation and asked if they would like to participate in the project. If they agree, the written or verbal (if by phone) informed consent process will be conducted. Patients that are past the enrollment window (i.e., 1st or 2nd visit with care manager), or otherwise unable or unwilling to participate in surveys are still eligible to complete qualitative interviews.

For patients who enroll after the baseline window and will only be invited to consent to participate in other components of the research (i.e., qualitative interviews, data obtained from medical record) by phone, after receiving information about interested Veterans from the care manager, the RA will mail the interested Veteran a written information sheet about the study that contains all the elements for informed consent and HIPAA, including information about audio recording.. The RA will wait one week before calling the Veteran to check if they have received it. If they have received it, the RA will discuss the details of research participation with the Veteran and if the Veteran would like to participate, the RA will review the written information sheet and conduct a verbal consent process that includes reviewing all the elements of consent and the HIPAA, and verbal consent will be recorded at the time of interview for these patients.

Staff. A total of 60 to 80 VA Staff participants will be recruited from 4 sites. Staff participants will be recruited from women's health clinics that are using a WH PACT model of care. To obtain the staff sample, we will work with each site's PBRN Site Lead and/or Site Representative to develop a list of eligible individuals (and their contact information), who meet the staff categories we would like to include. The study PI and/or the Site Lead will present the study to local staff and administrators via email and/or phone call. Staff members will be emailed an invitation to participate in an initial interview, which will be collected at the time of the initial interview. This email will also inform the participant that their participation includes three semi-structured interviews, either in person or over the phone, that will take 30 minutes each, the initial interview in the next few weeks, the second interview 10-12 months later and the final interview about a year later (the expected duration of their participation will be a total of 3 years). The recruitment process will include informing potential staff participants about the study, who is conducting it, why the individual was selected for recruitment, and how the information gathered will be used. Potential staff participants will be informed that their participation is entirely voluntary and their decision about participation will not affect their employment, merit, or promotion. After explaining

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the study, if the staff member is interested, the GLA research staff will schedule an appointment, or local staff may help schedule in-person interviews with visiting GLA research staff. We will also inform the participant that in 10-12 months, unless they ask us not to, we will contact them again regarding participating in a similar follow-up interview to document events across time.

5.3 Informed Consent Procedures

Patients. For patients who enroll during the baseline period and complete the written surveys, we will obtain a signed HIPAA authorization to access patient medical records. The informed consent process will include informing potential subjects about the study, who is conducting it, why the individual was selected for recruitment, that their participation in the research will be entered in their medical record, how the information gathered will be used, and about the patient participant payments. Payments include $20 voucher for each of two surveys and, $10 voucher for each of the interviews at baseline and six months post-baseline.

Patients who enroll after the baseline window will only be invited to consent to participate in other components of the research (i.e., qualitative interviews, data obtained from medical record). We will request a waiver of HIPAA in entirety from this subset of patients and a waiver of documentation of consent from this subset of patients, as these components may be conducted by phone. After receiving information about interested Veterans from the care manager, the RA will mail the interested Veteran a written information sheet about the study that contains all the elements for informed consent and HIPAA, including information about audio recording. The RA will wait one week before calling the Veteran to check if they have received it. If they have received it, the RA will discuss the details of research participation with the Veteran and if the Veteran would like to participate, the RA will review the written information sheet and conduct a verbal consent process that includes reviewing all the elements of consent and the HIPAA, and verbal consent will be recorded at the time of interview for these patients.

Potential subjects will be informed that their participation in the research is entirely voluntary, and that if they choose not to participate, there will be no effect on the care they receive. Methods for how subjects' identity and collected data will be protected will be discussed. Patients will be asked if they understand the nature of their participation, and will be asked to describe their understanding of participation.

Staff. A request for waiver of documentation of consent will be requested as affirmative response to the email invitation will constitute informed consent and verbal consent will be recorded at the time of interview. After a response has been received, enrolled staff members will be scheduled for an interview with a member of the research team.

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5.4 Inclusion/Exclusion Criteria

Staff

Inclusion Criteria: VA staff affiliated with women's health care. Given the diversity of VA staff, we expect this will include women, men, and members of minority and ethnic groups.

Exclusion criteria: Non-VA staff.

Patients

Inclusion Criteria: female VA patients who are referred to the care manager for further mental health assessment and/or care.

Exclusion criteria: Non-VA patients; less than 18 years of age; anyone who is unable to provide consent.

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5.5 Study Evaluations

Qualitative Data Collection:

Staff Interviews: To understand clinic organization, provider and staff roles, existing care arrangements for women Veterans, and perceived acceptability and feasibility of the CCWV program from key participants (VA staff, including WH primary care providers, nurses, clinical staff and health coaches); we intend to recruit approximately 15 staff per site who will be asked to complete a brief interview. Participation will consist of three 30-minute qualitative interviews (pre-, mid-, and post-implementation) conducted in-person or over the phone by a research staff member. We will evaluate the pre-implementation interviews (approximately five months into the pre-conditions phase); perceptions of interim implementation processes and outcomes (approximately six months into the implementation phase) and summative perceptions of implementation and potential for spread (last two months of the maintenance/evolution phase). The mid-implementation assessment will evaluate the progress and implementation barriers and facilitators to CCWV implementation and be used to continue to tailor the implementation. Final interviews will re-evaluate baseline domains, and will follow-up on CCWV implementation and sustainability.

Ethnographic field notes will be taken by research team members *throughout implementation* to capture aspects of the context of implementation and otherwise unmeasured aspects of usual care. The two anthropologists on the QUERI Program (Hamilton and Moreau) will provide training on writing field notes. Also, minutes will be recorded for all project meetings (including trainings) and conference calls. In addition, substantive emails and other communications regarding implementation will be archived and analyzed.

Quantitative Data Collection: The measures will be compiled into a written questionnaire for patients. Participants will be asked to complete brief questionnaires during or near the same time as the qualitative interviews.

Information from and about Veterans:

Sources of patient data for this project include (1) Data obtained from medical records including utilization of MH and CCWV services, psychiatric medications, MH diagnoses, relevant patient history (i.e., MST), and symptom measures completed with care manager and obtained from medical record; (2) information provided by patient participants via surveys (baseline and six months) and interviews (baseline and six months; and (3) CALM modules accessed and/or completed. (

After consent, all enrolled participants in each project who enroll during the baseline window will complete a 30-45 minute survey, delivered in-person by a research assistant (RA) at baseline and six-months post-baseline. The surveys focus on patient activation, health-related quality of life, satisfaction with treatment, and project specific measures. In addition, a subset of approximately 45 women Veterans in each study will also be asked to complete an additional 30-minute qualitative interview with a research staff member at baseline and six months post-baseline. The participant will be asked to

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complete a hard copy, which the RA will send via fax to a monitored fax machine at GLA to enter into the database. Participants who enroll in research after the baseline period, and any women who are otherwise unable or unwilling to complete the written surveys, will be invited to consent to participate in other components of the research (i.e., qualitative interviews, , data obtained from medical record), which may be conducted primarily by phone.

Patient semi-structured interviews will be coded only with a study ID, digitally audio-recorded, and uploaded to a secure VA server behind the VA firewall. If recording consent is denied, the researchers will take hand written notes, which will be securely transported and stored as described below until they are transcribed into an electronic format. When desired by the patient or the interviewer, or to accommodate the cognitive needs of the subject, the survey or interview can be performed at two or more sessions. At the end of the implementation period we will obtain utilization history through the Data Access Request Tracker (DART) system, conducting chart review in the VA Informatics and Computing Infrastructure (VINCI) environment.

5.6 Data Analysis

Qualitative Analysis: All semi-structured interviews will be digitally recorded on an VA-approved audio device. The interview content will be transcribed in order to assure that interviewer notes have accurately and fully captured interview content. Approved staff from the VA Salt Lake City (VASLC) will transcribe the CCWV audio files. The VASLC has a Professional Transcription Service available to VA sites and monitored by their own IRB. The CCWV] audio recordings to be transcribed by VASLC staff will be labeled by the subject's unique alphanumeric code and saved behind the VA Firewall in CCWV's secure shared project folder on GLA VA share drive. The VASLC transcription staff will be given access to a sub-folder within CCWV's secure project folder. Approved study staff will place a copy of the audio files in this folder for an approved VASLC transcriptionist to access for the purposes of transcription. The VASLC transcriptionist will transcribe each interview verbatim and save the completed transcript in the sub-folder using the same alphanumeric code. No data (audio files, in process transcripts, or completed transcripts) will leave the GLA VA secure research server. As completed transcripts become available, approved study staff will move these files from the transcription sub-folder into another sub-folder that is only accessible to study staff, where they will be stored and accessed for qualitative analyses.

Transcripts will be reviewed, edited for accuracy, and summarized by members of the research team. Consistent with our team's approach across multiple projects, matrix analysis methods[35] will be used for rapid turn-around of the results[36] to share with our Strategic Advisory Group. In-depth analysis of the qualitative data will be conducted 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.[37] Using a constant comparison analytic approach, this codebook will be elaborated upon based on emergent themes, and it will be adjusted as each round of interviews is reviewed. Interviews will be compared within each clinic, across clinics, and over time. Additional sources of qualitative data (i.e. meeting minutes, field notes, and archival information) will also be included in the data set and will be coded

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separately and in relation to the interview data. These multiple approaches and groupings are easily facilitated within the software program, which has the capacity to group data in multiple ways and which allows the qualitative researchers maximum flexibility in negotiating a complex narrative dataset. Of note, the EMPOWER QUERI qualitative team has been working together for over five years; all described analytic procedures are well- established and all members of the team have expertise with qualitative data analysis and dissemination of results.

In the pre-conditions transcripts, we will identify clinic organization, provider and staff roles, existing care arrangements for women Veterans, and perceived acceptability and feasibility of the CCWV program. We will synthesize this information with patient survey data to create baseline summaries of care as usual, and to tailor our marketing and implementation strategies for use at the sites. In mid-implementation interview data, we will identify factors facilitating and impeding implementation of the care model, and strengths and weaknesses of the model as implemented. We will assess the extent to which components of the model are being implemented, and which components are efficient and easy to incorporate into routine care. We will explore whether particular components appear to be of limited value in improving care and examine clinic and provider characteristics associated with varying levels of care model implementation and effectiveness. In post-implementation interview data, we will take a summative approach to characterizing overall experiences of and perspectives on implementation, with a particular focus on recommendations for scale up and spread.[55]

For providers, we will track changes in perceptions about the utility and impact of CCWV on clinical practice from pre-conditions to maintenance. We will also be interested in the experiences of the care managers and other stakeholders with regard to working specifically with women, eliciting their preferences, providing the CBT, and coordinating with MH providers. For patients, we will compare and contrast data from those who selected different treatment options. In order to evaluate the patient impact of CCWV, we will assess changes in patient perceptions of their MH symptoms, self-efficacy, activation, health-related quality of life and functioning. We will also collect information on demographics, trauma history, health care, mental health care, and experiences of care.

Quantitative Analysis: We will use the modified stepped wedge design to evaluate the implementation across the providers at four sites. CCWV will be defined as “turning on” when a provider refers a patient to the CCWV care manager. We will model the effect of CCWV implementation on referral rates, while controlling for organizational level, provider level and patient level covariates.

In addition to project key personnel, the overall EMPOWER QUERI Implementation Core will be involved in data analysis. The Implementation Core is directed by Dr. Hamilton (EMPOWER QUERI PI), an experienced and highly trained implementation scientist. She will be supported by a seasoned team of Co- Investigators, many of whom also have implementation research experience. Drs. Hamilton and Moreau will lead the qualitative analysis. The implementation core personnel are supported by several internationally recognized implementation scientists on the Scientific Advisory Group, including Drs. Curran, Mittman, and Yano.

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Impact-focused evaluation: Secondary aims for the project focus on factors that empower Women Veterans to engage in and benefit from care. We will use generalized linear mixed models (GLM) to evaluate a) cross-sectional relationships of patient activation, health-related quality of life, and care experiences at enrollment, with provider and site characteristics, adjusting for patient social and demographic characteristics; and b) prospective changes in patient activation, health-related quality of life, and care experiences from enrollment to 6-month follow-up, adjusting for patient, provider, and site characteristics. We will also construct multi-level mediation and moderation models to explore whether engagement-related factors such as patient activation, strength of treatment preferences, or the communication subscale of the CAHPS are associated with greater benefit from or satisfaction with care.

Power Analysis: Our goal with the power analysis was to ascertain the number of providers who would need to "turn on" the intervention (i.e., the number of referrals to the CCWV care manager), as well as the minimum number of patients that would need to be exposed to the care model. Consistent with our modified stepped wedge design, the power analysis presented here is for a 3-level hierarchical linear model where patients are clustered within PCPs within sites. In the final analysis structure, patients are the Level 1 units, the timing of PCP template use/referrals represent Level 2 units, and sites are the Level 3 units. The number of patients who completed the care model sessions out of all patients referred). The outcome is binary (referred/retained vs. not), and measured at the patient level (Level 1). Treatment effect is measured at Level 2, i.e., timing of when the PCPs turn on. Parameters required for calculating power are: alpha (α) = 0.05, sample size of patients clustered within referring PCPs (n) = at least 260 (based on prior work), the number of sites (K) = 4, the Plausible for Retention among those with low utilization (PI) = 5% to 85%, and Effect Size Variability (ESV) = medium or 0.05. Based on the resulting power curve, we need at least 8.78 (rounded to 9) referring PCPs per site to achieve power at 0.80. Our power analyses assume that the treatment effect is linear over time, i.e. patients that are retained longer have proportionally better outcomes. While selected details of the resulting dose response curve may vary, sensitivity analyses demonstrate a reasonable approximation enabling detection of treatment effects.

In addition to project key personnel, the overall EMPOWER QUERI Implementation Core will be involved in data analysis. The Implementation Core is directed by Dr. Hamilton (EMPOWER QUERI PI), an experienced and highly trained implementation scientist. She will be supported by a seasoned team of Co- Investigators, many of whom also have implementation research experience.

5.7 Withdrawal of Subjects

The PI may terminate a participant in the study at any time if the study participant does not meet enrollment criteria or does not comply with study requirements, e.g., keeping scheduled appointments with the interview team.

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Participants may withdraw at any time with no consequences.

Information obtained up to the time of participant withdrawal or termination may be used in the data analysis.

5.0 Reporting

Although we do not expect our project to elicit distress among participants, it is possible that some patient participants will experience distress at the recall of certain experiences. Interviewers will be trained to respond to indications of distress by redirecting the participant to another area of the interview guide. Should the participant continue to indicate distress, the interviewer will ask the participant if she/he needs to speak to a mental health professional; local contact information of such professionals will be available to all interviewers and will be utilized if necessary.

Under any adverse circumstance, the Coordinating PI will notify local PIs of any actions taken in response to the indication of distress, and regarding any unanticipated serious adverse events. In addition, the IRB will be notified according to guidelines if there is an adverse event.

The site PI and, in her absence, the Co-Principal Investigator will differentiate serious from non-serious adverse events. Upon discovery, all research-related deaths will be immediately and verbally reported to the CIRB and the Principal Investigator followed by written notification within 5 working days after being made aware of the death. All local serious unanticipated (unexpected) adverse events that are related to the research will be reported to the Central IRB within 5 working days. Unanticipated problems that represent a risk to participants and/or others will be reported to the CIRB and the coordinating center within 5 working days. Protocol deviations that substantively affect subjects' rights or safety, or potentially compromise facility human research protection will also be reported to the Central IRB within 5 working days. An annual report summarizing all adverse events and unanticipated problems/protocol deviations that did not require immediate reporting will be prepared and reported to the Central IRB at the time of continuing review.

Response procedures for adverse events

Discomfort with disclosure. Research staff who collect survey and interview data will be trained on how to respond to embarrassment or discomfort in an appropriate and compassionate manner. Participants will be encouraged to contact the care manager, site PI or other research staff in the event of a potential adverse reaction that occurs as a consequence of their participation in the survey or interview. They will receive specific written (in the form of a study description and contact information) and verbal instructions during the study consent procedures about how to do so, if needed.
Mandatory reporting. One adversity a participant may encounter is the possibility that staff must report to authorities instances of physical abuse or neglect of a child, dependent or elderly person; or threat of physical harm to the subject or others. To anticipate these concerns, the study has established

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procedures and guidelines to respond to risk disclosures and crisis situations. Staff will be trained to recognize risks or crises that require immediate reporting response.

We expect that discussion of some of the mental health issues during the course of the research assessments may possibly result in some emotional or psychological stress. If that does occur, the RA or interviewer will stop the research process, check on the patient, and inform the patient that she will call the PI or designated local clinical staff contact (e.g., care manager) for assistance.

Each of the possible adverse events is described below, including background, criteria for emergency action, and non-emergency action.

1) Suicidal ideation or intention to harm self

If a subject endorses thoughts of self-harm when responding to assessments or makes a spontaneous disclosure to the research assistant or interviewer at any time, research staff will follow the procedures below:

a. Emergency: in the rare instance that an individual is in imminent danger and needs emergency medical or mental health services, research staff will adhere to their medical center's policies and procedures for managing and reporting such events including, if appropriate dialing 911 or the local police.

b. Non-emergency: If a subject spontaneously reports that they are thinking of killing themselves or taking their life, for example:

1. "I'm thinking about suicide/killing myself"

2. "I feel like I want to kill myself"

3. "I wish I were dead"

4. "I wish my life were over"

5. "I can't go on" or "I feel I can't go on"

The research staff person will say, "You seem to be having a difficult time. If you think this is an emergency, we can call 911. If you think you need help with this problem, you can talk to your VA clinician or go to the VA emergency room." The research staff person will contact the designated VA clinician. The clinician will follow standard clinical care guidelines, assessing a level of suicidality and establishing a safety plan as needed

The research staff person will call either the PI or their delegate within one hour of this incident. They will determine what further action is needed.

2) Intent to harm others

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Research staff will not be probing for this information and it is not part of any of the research tasks. Sometimes threats may be voiced spontaneously. If this is a vague statement about intent to harm others and it is not an easily identifiable person, and does not communicate clear intent, capable means or immediate intent to do so, the research staff person will redirect the subject to the task at hand. However, if the subject makes a specific threat to a reasonably identifiable person, then the research staff person will remind the subject about the limits of confidentiality, and follow these procedures:

a. Emergency: In the rare instance that an individual is in imminent danger and needs emergency medical or mental health services, the research staff will adhere to their medical center's policies and procedures for managing and reporting such events including, if appropriate dialing 911 or the local police.

b. Non-emergency: If a subject reports intent to commit harm to others that is a non-emergency in nature but that still communicates a reasonably identifiable person, clear intent, capable means or an immediate intent to do so, the research staff person will contact the PI within one hour and will complete an incident report the same day. In addition, the research staff person will talk to the subject to express concern and encourage him/her to tell someone. They will determine what further action is needed.

3) Child or dependent abuse/neglect

Research staff will not be probing for this information and it is not part of any of the research tasks. However, if a subject discusses that a child, dependent or elder is being sexually, physically, or verbally abused or there is evidence of neglect (e.g., young child left alone for hours), then we will follow these procedures:

a. Emergency: In the rare instance that a child or dependent is in imminent danger, the research staff will adhere to their medical center's policies and procedures for managing and reporting such events including, if appropriate dialing 911 or the local police.

b. Non-emergency: If there is a report or incident of child or elder abuse that is non-emergency in nature, the research staff person will consult with the PI or delegate by phone within one hour of the incident and will complete a written incident report the same day.

Consulting with the VA Research Service, and VA legal representatives as needed, we will review what is known about each situation and will assess the legal and ethical characteristics of each situation. If it is determined that the study has a legal or ethical obligation to report the incident, we will do so. Reporting procedures of the VA Research Service will be followed for each incident.

6.0 Privacy and Confidentiality

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Assurance of Patient Safety

The local site research staff will be in regular communication with the research team at the main site and are responsible for monitoring patient safety at the participating sites. The Project Director will monitor research operations of the project and oversee patient safety. All research staff will be experienced in working with women Veteran patients and will be closely supervised by the study local site PI. Since a Data Safety Monitoring Board (DSMB) is required for multi-site studies, we plan to utilize the central HSR&D DSMB for further oversight. The DSMB provides an ongoing evaluation of the study's progress including patient accrual and retention, monitoring of adverse events, and the adequacy and efficiency of the analysis plan to discern outcomes that might require study modifications, or result in early cessation of the study due its benefits or harms. In terms of patient safety, the DSMB will evaluate all adverse and serious adverse events, by control and intervention site, including all hospitalizations and deaths.

Data Security

VA Research staff use VA computers to collect and analyze study data; either desktop or laptop computers with the VA image installed and managed by the local Information Resource Management department. All laptops are encrypted with VA-approved FIPS 140-2 certified encryption software to ensure that if laptops are ever lost or stolen, no data could be removed. Laptop computers are never removed from VA grounds without supervisory approval and a VA Property Pass approved by the VA research service. Thumb drives are never used as long-term storage of data with identifiers. If a thumb drive is needed to transfer data from one computer to another, only a VA-approved thumb drive with the proper encryption software would be used after obtaining authorization from the local ISO.

VA staff practice regular and secure data backup procedures. Computer users "lock" their workstations when not actively in use, and office doors are closed and locked when staff members are not present. Hard copies of sensitive data are stored separately from identifiers in locked filing cabinet in a locked office. All research staff have access to a secure VA server managed by the HSR&D CSHIIP. This server is behind the VA firewall and provides individual storage space for each project, and for each member of the study teams. VA staff regularly backup data stored on computers to this server to protect those data in the case of an original data failure. This server is backed up incrementally on a daily basis with full backup occurring monthly. Backups go to a tape library and the tapes are rotated on a quarterly basis and stored in the safe located in the ISO's office at the Sepulveda campus.

This server also provides a means to transfer data between local and non-local research staff. Project folders can be created where any approved individual on the VA intranet can gain access through their approved VA login to a project server folder. This allows secure data transfers over short and long distances with the smallest risk of accidental data disclosure. Only staff that are listed on delegated authorities for the project through the CIRB, are credentialed by Research, have completed all required data security training, and are approved by the CSHIIP will be given access to the research project folders on the research server. Staff may only access this folder by using their VA login on a VA computer behind the VA firewall. Access to these files is immediately revoked for staff members who leave the project.

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Data Collection Procedures

Staff data includes a masterlist, consents, and audio and transcription from interviews. Patient data includes a masterlist, consents, surveys, audio and transcription from interviews, CALM web-tool data, and data extracted from medical records.

A series of identification (ID) numbers will be generated for all patient and staff participants. A 4 digit study ID code will be generated for each participant and project staff will maintain a link file that contains the following for each participant: ID code, gender, name, site, and wave number. This is how the 4 digit study ID codes will be generated for each participant: 1st digit=wave #, 2nd digit=site #, Last 2 digits= random # for unique respondent code. For staff, the linking file will contain: ID number, gender and name. This link file will be stored on a secure VA server behind the VA firewall. All information linking subject identifiers to their data will be destroyed in accordance with the VA Records Control Schedule and guidance from the Central IRB.

Data from all participants will be collected in a private office at each site or private room by phone by a trained member of the project team. Project staff will maintain a link file that contains for each subject or participant: (a) for patients: ID number, subject name, last four of the social security number; (b) for staff: ID number and name. This link file will be stored on a secure VA server behind the VA firewall.

Consents are also collected in paper form and list patient subject's name and social security number (no SSNs are collected from staff participants). The paper consents will be stored in a locked file cabinet within a secured room at the local site. A limited number of authorized project staff have access to these consent forms. The study master list has the subject ID number, SSN, full name and contact information. This master list is only accessible to the PI, co-PI, and limited project staff. The master list is stored on a VA desktop or encrypted laptop and a backup copy is stored on a VA server behind the VA firewall.

Social security numbers are not collected from staff participants; we are only collecting their VA contact information.

Patient survey responses will be coded with the study ID and recorded directly into a survey program running on a VA computer and stored in a project-specific folder on the CSHIIP secure server.
The VA CALM web-tool stores information entered by the patient during CALM CBT sessions (e.g., behavioral goals) and also tracks scores on mental health assessments such as the PHQ-9 that may be completed during sessions for follow-up over the course of participation. The VA version of CALM was developed for the on-going CREATE CALM project (PI, Dr. Michael Cucciare, Little Rock VA) and have been made available to the CCWV project on a secure VA server in Little Rock for use by care managers during CALM CBT sessions with patients.

Patient information collected in the CALM web-tool is considered part of routine clinical care, and will be stored on a single-secure VA server at North Little Rock VA.

Audio and Transcription from Interviews. All staff participants and a subset of patient participants will also complete a semi-structured interview with a research staff member. With the participants' permission, the interviews will be recorded on VA-approved devices and uploaded to the project-

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specific folders. Data on patient participants extracted from VA data systems, will also be stored in project folders. Paper data collected will be entered and verified, and securely stored in a locked cabinet in a locked office at the local HSR&D site.

Any paper data collected from participants will have only the subject's ID number and no identifying information. No data will be collected outside the VA. Paper data containing PHI is never left out on unattended desks.

Data Transportation Procedures

If paper data and audio recording devices need to be transported between sites they will be securely carried in VA locked bags. Once on site, they will be secured in a locked file cabinet in a secure room.

Data Transmission Procedures

Paper surveys from local sites may be faxed to GLA. Local staff will coordinate with GLA staff to arrange a time when the fax machine can be monitored by GLA project staff to secure the data. The qualitative interviews will generate digital voice files, which are considered identifiable. To minimize risk, during recorded interviews subjects will only be identified using their project ID number, and subjects are instructed not to state any names or other identifying information in their interviews. These audio files will be uploaded from recorders to the secure server The transcription company will be informed not to transcribe any identifying information accidentally disclosed in interviews. Any identifying information found in voice files from the qualitative interviews is accidental and rare; no identifying information will be found in transcripts. The study team downloads the transcription files to the project-specific folders on the VA server behind the VA firewall. Once they have been downloaded and verified, the transcription company destroys the copies on their own server.

Access, Storage and Handling of Secondary Data

In addition to surveys and interviews, other outcome data will be extracted from national VA data systems, and patient medical record charts. Data from VA electronic data systems will initially include patients' social security numbers (SSN) along with any other identifiers, since these are used to assure that the data matches the project participants. We will merge the extracted data with our existing research data. Once the data have been checked to ensure the merge has been successful, within the shortest possible time period, the SSNs will be removed from the analytic data file and stored in a link file kept in a separate, high security folder on secure VA server. Each subject will already have been assigned a project ID number that does not contain any identifiers. The subject's ID number will replace the SSN in the files. All information linking subject identifiers to their data will be destroyed in accordance with the VA Records Control Schedule and guidance from the CIRB.

VA records data will be obtained from CPRS, DSS or CDW. In order to obtain data, the project team will work with a list of SSNs of patients consented and enrolled in the study. Project or VA-certified database analysts will be given this list of SSNs and will then run a query to extract the needed data, either working in the VINCI platform or downloading the data to a temporary folder on the CSHIIP

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secure server. Extracted data will be placed into our secure folder on the local CSHIIP server and coded for analysis. This data will always remain behind the VA firewall.

All the above data are stored and backed up on a secure VA server. Computer users “lock” their workstations when not actively in use and office doors are locked when staff members are not present. Hard copies of sensitive data are stored in a separate locked filing cabinet in a locked office.

Special consideration and precautions will be taken with regard to sharing information provided by individual employees with supervisors and co-workers. While general information derived from employee interviews related to relevant clinical practices, resources, quality improvement activities, and barriers/facilitators will be shared with other site participants in aggregate or synthesized form, detailed information that would allow identification of individual employee responses will not be shared with supervisors of the employees or their co-workers.

7.0 Communication Plan

The CCWV team is comprised of a PI (Hamilton) with strong implementation science and mixed methods expertise, a Co-PI (Lang) with an exceptional background in CALM, CBT, and trial research, and several Co- Investigators who are subject matter experts in both women Veterans’ MH and implementation science. Of note, one of our Co-Investigators, Dr. Strauss, is also the National Women’s Mental Health Program Manager, thus providing our project with a direct and consistent link to one of our key partners (WMHS; McCutcheon LoS). Drs. McCutcheon (WMHS) and Post (PC-MHI) are highly supportive of our approach to further developing collaborative care for women Veterans. Dr. Post, in particular, has guided our team in our conceptualization of blending models and incorporating elements of CALM. Reflecting their strong commitment to the proposed work and important policy-relevant information to be gained, these partners have worked closely with us to develop this study and will remain active partners throughout the course of this work. They are eager for the CCWV Implementation Playbook to guide future PC-MHI efforts.

The project headquarters will be at the VISN 22 HSR&D CSHIIP offices in Los Angeles. Alison Hamilton, PhD, MPH, is a medical anthropologist at the Greater Los Angeles VA, and Associate Research Anthropologist at UCLA. She will provide leadership of this study as the coordinating PI and will be responsible for all aspects of this project.

The Coordinating Principal Investigator will be responsible for informing local sites of protocol changes, reporting compliance issues related to CIRB and VA research service requirements, for reporting

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progress of research at least annually, and for reporting any injuries or other unanticipated problems involving participants or others.

Local Site leads are responsible for obtaining local approvals, complying with local policies, including notifying local facility directors of research engagement.

Each local site lead will ensure that the study is being conducted according to the IRB-approved protocol. Issues will be discussed with the Corresponding PI.

Each local site will hold its own regular meeting. Site leads will be responsible for tracking local events, complying with local reporting requirements, and reporting all events to the Coordinating PI.

On a regular basis, Dr. Hamilton will meet with Local Site leads. On a monthly basis, calls will be held with all leads to ensure cross-level synergies and consistency in qualitative approaches to data collection and analysis. Enrollment, data collection, and administrative issues will also be discussed. Issues may include IRB, protocol changes, informed consent, and HIPAA.

Any events that may impact the conduct of the study or the safety of participants will be reported by local staff to the Coordinating PI within 1 business day. This includes any SAEs, Unanticipated Problems, concerns about protocol deviations, and any interim results that may impact the conduct of the study.

Although we do not anticipate any SAEs/UAPs if any safety issues (SAEs or UAPs) arise, they will be reported to the Coordinating PI within 1 business day. The PI will follow CIRB reporting guidelines and collect relevant information. Data collection occurs at one point in time; therefore, it is unlikely we will become aware of any SAEs. If we become aware of any SAEs, we will collect the information by phone. Issues or interim results that may impact the conduct of the study will be reported by the Coordinating PI to Local Site PIs on weekly calls.

Sites will be informed when the study is over and they are no longer engaged in research. The coordinating PI will report to CIRB. Local Site PIs are responsible for reporting to local authorities.

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