Web and Shared Decision Making for Reserve/National Guard Women's PTSD Care

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1.0 SPECIFIC AIMS:

"Women serving in the military are essential components of our Nation's success," Secretary of Veterans Affairs Eric Shinseki acknowledges (2011). "In honor of their service, VA is committed to providing women Veterans with quality care and preparing for their evolving needs." Indeed, women and OEF/OIF/OND Reserve/National Guard (RNG) war Veterans are among the fastest growing groups of new VA users. Women comprise 15% of the armed forces overall and 17% of RNG forces (Meehan, 2006). Of all recently discharged Veterans eligible for VA care, approximately half are RNG members (Deyton & Kang, 2008). RNG members appear to have higher rates of post-deployment mental health (MH) problems, including PTSD, with progressively increasing rates of MH problems at 3 and 12 month follow-up compared to stable rates for active component service members (Thomas et al., 2010). Unfortunately, the effects of military experiences, including combat, post-deployment readjustment, and sexual assault are not yet well characterized in RNG servicewomen. A recent study of both male and female Afghanistan combat Veterans found that around half (56%) report that post-deployment reintegration is difficult (Sayer et al., 2011). Yet, for a variety of reasons (e.g., stigma, prior military assault, VA care perceptions, established care prior to deployment) facilitating access to MH services for RNG OEF/OIF/OND female Veterans with PTSD is challenging and will require new approaches to outreach. Indeed, such approaches are urgently needed to mediate the severity of post-deployment MH conditions, alleviate concerns over MH diagnoses and interrupt the cycle of chronicity found in many with PTSD. A web-based interface tailored to consumer needs has the potential to promote active engagement by Veterans in their health care, a process shown to be effective in civilian populations. Furthermore, researchers have found that when patients are educated about their physical health conditions and treatment alternatives, shared decision-making results in better health outcomes. However, more studies are needed with MH care (Perestelo-Perez et al., 2011). The long-term goals of this project are to: 1) increase RNG servicewomen's knowledge about their own post-deployment adjustment, including PTSD, enhance PTSD self-management while decreasing stigma about readjustment and MH conditions; 2) improve non-VA user RNG servicewomen's willingness to access VA MH care for PTSD and evidence based psychotherapy (EBP); 3) revise an existing web-based interface, which is portable and can interface with My HealtheVet (MHV) and, 4) ultimately enhance RNG servicewomen's engagement with VA and with MHV so that VA non-users will be more likely to access VA care and current users will be more likely to receive the benefit of EBP for PTSD. The immediate goals of this study are 1) to understand female war Veterans' perceptions, preferences and barriers to EBP for PTSD; 2) augment our current web-based interface with this information to incorporate educational interventions specific to EBP for PTSD; and 3) test specific access routes to VA care in order to determine whether a concierge nurse case manager shared decision-making intervention can increase linkages to VA services for PTSD and initiation of EBP initiation for OEF/OIF/OND RNG post-deployment women Veterans compared to a more standard access route (outreach).

Specific Aim #1: Using focus groups, identify VA enrolled OEF/OIF/OND RNG female war Veterans' perceptions, preferences and identified barriers and facilitators to accessing VA MH services and EBP (including cognitive processing therapies and prolonged exposure therapy) for PTSD.

Hypothesis 1.a: OEF/OIF/OND RNG servicewomen with PTSD who differ in factors associated with access to care based on Aday and Andersen's (1974) model will identify different barriers and facilitators to VHA services for PTSD including EBP.

Hypothesis 1.b: With improved understanding of the consumer's perceptions of, or experiences with VA mental health care for PTSD and EBP, we can further tailor our existing web-based educational interface to better address the gap between PTSD care need and EBP access.

Specific Aim # 2: To evaluate the participants' perceptions of and satisfaction with the revised web-based interface and to evaluate and test differences in VHA initiation and use for those who screen positive for PTSD by randomly assigned route: 1) Study concierge nurse case manager (NCM) or 2) existing outreach.

Hypothesis 2.a: Web-based interface is a successful way to improve Veterans' post-deployment health education and VA access as demonstrated by web-intervention satisfaction survey and subsequent enrollment.

Hypothesis 2.b: Use of a nurse case manager to promote shared decision-making regarding PTSD services and EBPs will result in increased use of MH care and initiation of EBP for PTSD compared to outreach counselors.

RESEARCH PLAN

2.0 BACKGROUND

Women Frequently Choose not to use VHA Care:
Many women Veterans do not know that women's health care is even available in the VHA and are concerned with the quality of care that exists (Washington et al., 2007). Women exposed to combat are less likely to use VHA care because they believe it is male-oriented. When they do use VA care, they have lower opinions of VA health care facilities and more problems with doctors and staff (Kelly et al., 2008). High rates of military sexual trauma (MST) are reported by women pre-OEF/OIF and more recently in RNG populations with 15% of VA enrolled female Iraq/Afghanistan Veterans screening MST positive. MST is a major contributor to PTSD (Sadler et al., 2004; Street et al., 2007; Suris et al., 2004, Booth et al., 2011). These women are significantly less likely to believe they are safe from sexual harassment at the VHA compared to non-traumatized peers (Mengeling et al., 2011). Despite high use of services, women with MST are more likely to have less satisfaction with and poorer perceptions of VHA care than those without MST (Kelly et al., 2008).

War has Adverse Consequences on Relationship and Parenting:
Over 700,000 American children have had at least one parent deployed and few events are more stressful than having a parent or loved one deployed. In response, the VA has extended services to the families of war Veterans through marital & family therapy. The returning veteran must reintegrate into a family different than the one they left and they may have difficulty disengaging from combat and readjusting to family life, especially when redeployment is possible (Johnson et al., 2007). Returning women are demonstrating a higher risk for family readjustment problems as marriages of female troops are failing at almost three times the rate of male service members (Mulhall, 2009).

Mental Health Conditions (including PTSD) are Prevalent in Male and Female OEF/OIF War Veterans but Many either don't Seek VA Care or Complete Recommended Treatment:
Almost a third (32%) of OEF/OIF Veterans in the VA have received a mental health diagnosis. Eleven to twenty percent of US soldiers will develop PTSD secondary to their combat experiences, but most still don't seek care (Hoge et al., 2006). PTSD is the most prevalent mental health condition among these Veterans, followed by substance abuse (when non-dependent abuse of drugs and alcohol dependence syndrome are considered additively) and then depression (Deyton & Kang, 2008). In recent work, OEF/OIF servicewomen have been found to have high levels of combat exposures, only slightly lower than men. Yet, gender differences of the impact of these stressors, including post-traumatic stress symptoms, have been found to be minimal (Vogt, 2011). Many OEF/OIF studies have included comparisons between men and women and gender differences in MH symptomatology have shown insignificant differences (Street et al., 2009). A RAND study using a community sample of OEF/OIF war Veterans found rates of mental health disorders similar to VA populations but only half of those meeting criteria for current PTSD or major depression had sought help from a physician or mental health provider for a mental health problem in the past year (Tanielian & Jaycox, 2008). In a study of almost 50,000 Veterans with newly diagnosed PTSD, only a minority of Iraq and Afghanistan Veterans (9.5%) received the recommended number and intensity of VA MH treatment sessions within the first year (Seal et al., 2010)

Women and EBP:
Unfortunately, there is little data looking at gender differences across PTSD treatment outcomes. Litz et al. (2007) compared internet-based cognitive behavior therapy across male and female military service members with PTSD finding no differences in rates of treatment attrition between men and women (with analysis of gender differences in treatment outcomes not presented). The National Center for PTSD (Schnurr et al., 2007) implemented the first randomized clinical trial to assess PTSD treatment outcomes for active-duty and Veteran women. They found that women who received prolonged exposure (PE) therapy had a greater reduction of PTSD symptoms compared to women receiving present-centered therapy. Indeed, women in the PE group were relatively more likely to no longer meet PTSD diagnostic criteria. Most prior studies in civilian populations have focused on PTSD treatment of women with sexual trauma and demonstrated similar success (Foa et al., 1991; Foa et al., 2005; McDonagh et al., 2005). Notably, combat is the second greatest risk for PTSD in the United States following rape (Kessler et al., 1995). Epidemiological studies have demonstrated that women with PTSD are almost twice as likely to have depression and anxiety disorders as men with PTSD (Breslau et al., 1997).

Informed Patient's are More Likely to Engage in and Be Satisfied with Their Care:
Information plays a critical role in helping patients to be more aware of their treatment options and effective self-care strategies (Rogers, Entwistle, & Pencheon, 1998). Considerable evidence suggests that patients who are better informed about their health/mental health conditions and treatment tend to have more favorable outcomes across a variety of domains. For example, a lack of knowledge about PTSD, its causes, and available treatment services have been identified as important barriers to help-seeking among Veterans (Sayer et al., 2009). Conversely, having adequate information about one's medical condition is associated with better adherence to treatment recommendations (Detmer et al., 2003; Karaeren et al., 2009). In addition, patients who are better informed tend to be more satisfied with their care (Detmer et al., 2003; Deyo & Diehl, 1986; Jabbar, Casey, Schelten, & Kelly, 2011) and experience reduced uncertainty and anxiety regarding treatment (Detmer et al., 2003; Jensen, Madsen, Andersen, & Rose, 1993). Patient-provider communication patterns involving more information sharing on the part of the provider have also been associated with greater patient satisfaction, knowledge, and adherence (Hall, Roter, and Katz, 1988) as well as better subjective (self-rated health), behavioral (functional status), and objectively-measured health outcomes (e.g., blood pressure and blood glucose levels; Kaplan, Greenfield, & Ware, 1989)

The accumulating data supporting a link between patients' level of understanding of their medical conditions and various health outcomes combined with an increasing trend toward more patient-centered models of care have led to efforts to facilitate patient education and informed decision making. Collectively, these findings suggest that well-informed patients tend to be more satisfied with their care, are more engaged in and adherent to treatment recommendations, and experience better health outcomes.

Online Mental Health Screening and Interventions Promote Veteran Engagement in Care:
OEF/OIF combat Veterans enrolled in VA care have reported a preference to seek readjustment services or information over the internet or web (53%) and virtually all (97%) had internet use, with most (70%) using it daily (Sayer, 2010). The majority of OEF/OIF Veterans are computer-literate, and many use the internet as a daily part of their lives (Needham, 2008). Improving education about resources could help these Veterans obtain appropriate evidence-based care. There is a recent and growing precedent of web-based interventions in high risk populations, including identification of mental health conditions (such as depression, substance abuse, PTSD) and focus on behavior change to promote patient engagement in care (Wantland et al, 2004; De Salvo et al., 2007; Khasanshina et al., 2008; King et al., 2009; NIDA, 2009). Research investigating internet treatment of PTSD (Litz et al., 2004) suggests that there may be greater follow through with internet-based approaches, which further supports the need for finding creative ways of safely extending education and services beyond traditional methods. Online feedback is already being provided to active component soldiers and DoD on topics ranging from assessments (e.g., pre-and post-deployment deployment health) to educational resources (e.g. care promotion).

Shared Decision Making Improves MH Care Outcomes and Patient Satisfaction:
In the past decade there has been growing interest in shared decision-making (SDM), in which clinicians and patients engage in a decision-making process together, discuss treatment preferences, and reach agreement about treatment choice (Joosten et al., 2008). Such a participatory care model of decision making is a central theme of many evidence-based psychosocial MH treatments and a core component of the chronic care model (Woltman, 2011). Improved health outcomes and patient satisfaction of MH consumers have been associated with SDM (Woltmann et al., 2011). Both men and women report improved patient satisfaction with SDM and MH care receipt (Swanson et al., 2007). In addition to greater satisfaction, improved self-management of mental health conditions has been found (e.g., greater follow-through with treatment plans, and improved therapeutic alliances with clinicians (Mahone et al., 2011)). To our knowledge, no prior research has investigated SDM and PTSD in Veteran populations. However, the fit is logical given PTSD is a chronic care need and feeling powerless is a key element of PTSD symptomatology.

Preliminary Work:
Focus groups for our recent HSR&D funded study of OEF/OIF RNG servicewomen (8 groups, 5 Mid-Western states, N=39). Our qualitative data suggests that women have significant mental health consequences (PTSD, depression, substance abuse) from deployment exposures which further confound their return to relationship and parenting roles. Thematic coding of transcripts revealed that (1) almost all of the participants had received no information regarding their VA eligibility for services or how to access VA services (48 references in 7 of 8

groups), and (2) that post-deployment adjustment, including depression and PTSD symptoms as well as family re-adjustment, was one of the most frequently noted concerns (51 references in all 8 groups). **The majority of our focus group participants didn't know their post-deployment symptoms were treatable mental health conditions that influence readjustment.**

The quantitative findings from the cross-sectional phase of this study (N= 665) indicates that most RNG servicewomen (79%) did not use mental health care in the past year despite mental health problems at rates consistent with other studies, and that RNG women who did use mental health services were more likely to seek mental health care outside of the VA (15%) instead of within (7%). Conversely, most (82%) endorsed the belief that mental health care counseling and services work, and were less likely to think that VA mental health professionals would not understand their problems (9%) than private care mental health professionals (23%). A fourth of participants reported that mental health care would cost them too much money. **Thus, despite their belief that mental health counseling can help them and that VA mental health care providers could better understand their problems, they chose to not seek care or to do so privately** at a financial cost. This incongruity indicates the existence of barriers to access and unaddressed concerns which are not yet adequately understood.

Findings from our recently completed Mental Health QUERI RRP (N=131) indicated that **RNG servicewomen completing online screening have substantial post-deployment mental health and readjustment concerns**. Nine post-deployment online screens (for PTSD, depression, substance abuse, prescription drug abuse, military sexual trauma (MST), traumatic brain injury (TBI), family readjustment, combat exposures) were implemented. Less than 1% (n=1) of participants screened negatively for all mental health issues and deployment trauma exposures (recognizing the probable selection bias of participation). The maximum number of positive screens by any individual was 8/9. Most (48%) participants had 3-4 positive screens, while 29% had 1-2 positive screens and 22% had more than 4 positive screens. More importantly, using the VA screen for PTSD, **41% screened positive for PTSD**. Most participants (95%) screened positive for combat trauma exposures, half met the VA screening criteria for MST, and 10% the VA screen for TBI. Thus, the mental health care needs of this group are substantial.

In this study, **RNG servicewomen reported our web-based MH screening and tailored educational intervention for post-deployment readjustment provided needed education they felt they otherwise would not have received (48%), decreased MH stigma (32%) and improved access as two-thirds indicated they would subsequently seek MH care (38% VHA and 26% non-VA care).** Participating women endorsed the online interface for improving subsequent access to mental health care. **Almost a third (32%) reported that the tailored information they received reduced their discomfort with seeking care, 38% indicated that they would subsequently seek assessment from a VA provider, and 26% would do so from a non-VA provider.** The online method of education was shown to be a preferred source of information by users. The majority of participants (74%) indicated they preferred to receive VA information through e-mail and 66% routinely use the internet to seek health information. Most (74%) participants would recommend this web-based educational interface to other military women.

It is important to note here that in our reproductive health study (N=1,002), we found that **women who use the VA had more positive perceptions of VA services and gender specific care compared to non-users,** recognizing that 88% were already VHA users (Mengeling, 2011). Consequently, if we are able to decrease care barriers through our web-based interface and NCM intervention, post-deployed RNG women Veterans may be more likely to identify mental health care needs, initiate care more immediately, and subsequently address post-deployment mental health care issues using VA services.

In summary, our preliminary work illustrates the complex needs and barriers to MH care faced by RNG servicewomen. Our proposed study is appropriately directed at better understanding and addressing access to and engagement in mental care in general and EBP in particular for RNG servicewomen with PTSD. We are building on our existing web-based interface to determine whether it can generate interest in accessing VA and EBP for PTSD so that women will be interested in enrolling in the study comparing access routes. Moreover, we can determine the effectiveness of a NCM using shared decision-making at increasing access to VA mental health services and EBT for PTSD.

Conceptual Framework:
Health disparities are "differences in the incidence, prevalence, mortality, and burden of disease and other adverse health conditions that exist among specific population groups in the United States" (NIH, 2002). Disparities in health attributed to harmful health exposures (e.g., combat or rape in military) or to factors related to limited access to health care (e.g., barriers to care while deployed or VA access) are considered inequities (Peters & Evans, 2001). Although racial/ethnic minorities and low-income groups have traditionally been the focus of health disparities research, we propose that military women, as VA treatment minorities, deserve this consideration. The identification and elimination of health disparities associated with female Veterans with PTSD is important because they are avoidable, unfair, and can affect our entire society (Woodward & Kawachi, 2000). The two-year costs of major depression and PTSD (including treatment costs, lost productivity and costs associated with suicide) for those deployed to OIF/OEF on June 30,2008, were simulated to be close to $925 million. If Veterans suffering from the disorders were all treated with evidence based treatment, policy simulations suggest that the savings generated would be $138 million (Kilmer et al., 2011). We will use Aday and Andersen's (Aday & Andersen, 1974) framework for assessing equity in access to health care. Aday and Andersen identified three groups of factors that affect service use: predisposing, enabling, and need characteristics. This framework will be a guide to the key domains that will be queried in the Phase 1 focus groups with regard to barriers and facilitators to mental health care and, moreover, VA evidence-based psychotherapy. Specific factors that affect service use include: *predisposing* (e.g., military rank, number of deployments), *enabling* (e.g., age, insurance, employment, rurality, VA care sites- primary care, MH, community-based outpatient clinic (CBOC)) and *need* (e.g., medical and mental health co-morbidities) characteristics.

3.0 SIGNIFICANCE
Impact of the Findings
While it is apparent that female OEF/OIF/OND RNG Veterans are at significant risk of PTSD and other post-deployment MH problems, only a minority of these women seek VA MH care. This is despite believing mental health care can be helpful and that VA clinicians will understand their problems. This gap between need for and use of VA PTSD services suggests that further research is needed to understand specific barriers to VA MH care and VA PTSD EBP. It is also currently unknown if women Veterans who have participated in PTSD EBP and are considered "drop outs" have actually had therapeutic benefit and/or are using community resources that fit their unique preferences (e.g., clergy support, Vet centers). Thus, our proposed research will provide valuable insights about this population's perceptions of VA MH services and of PTSD EBP and their evolving use of VA and other community resources to address PTSD and other post-deployment MH needs.

The US Government Accountability Office (GAO, 2011) summarized key barriers to VA mental health care as stigma, lack of understanding or awareness of MH care, logistical challenges to accessing MH care, and concerns about VA's care, such as concern that VA services are primarily for older Veterans. Our proposed web-based interface and concierge NCM address each of these barriers by moving beyond traditional avenues for engaging this population and providing needed EBP. A successful online educational program tailored to individuals' needs for specific MH services may represent an effective and relatively low cost approach to provide more immediately responsive education to address PTSD and other common post-deployment MH conditions. Web-based screening using existing VA screens has the potential to improve VA interface and care engagement. Women Veterans concerned about MH stigma can determine if they meet screening criteria for PTSD, or other post-deployment MH conditions, within the privacy of their homes, and if they screen positive, they can find out if and how these conditions are treatable. Furthermore, RNG female Veterans participating in our pilot web-based post-deployment education program indicated they were more likely to respond honestly to screening questions in their own home and own timeframe. Thus, women using web-based screening may have more valid screens and become more engaged in their own care. Furthermore, women who may have challenges with VA access, e.g. because of rurality, transportation, work or childcare demands, may prefer web-based screening and education to provide on demand access to information. Paired with NCM telephone follow-up to explore their PTSD care options and facilitate more informed choices, women may demonstrate a greater willingness to overcome barriers to face-to-face care.

From a VA resource perspective, web-based screening with results available to clinicians behind the VA firewall on the intranet (or ultimately through MHV) alleviates unnecessary clinician time to implement and score screens. Women Veterans who do not screen positively for PTSD or MH conditions will consequently not

unnecessarily utilize MH services. Women Veterans who do screen positively will have the added impact of web-based educational modules so that they arrive at their initial PTSD or MH appointment more informed and can ultimately be more goal directed, thus resulting in more efficient clinician interface. In short, the proposed educational interface and nurse care manager intervention holds the potential to engage women early after returning from combat in an effort to mediate the severity of post-deployment PTSD and other mental health conditions, interrupt the cycle of chronicity found in many war Veterans, blunt the development of multiple mental health co-morbidities associated with PTSD, address family readjustment concerns, and facilitate self-initiated care seeking. The VA collaborative care model for treating depression in primary care has demonstrated the effectiveness of NCM in roles that interface with and educate Veterans to be partners in their own care (Cheney et al., 2011). Given this success, such an approach appears very promising for facilitating access to VA MH care for PTSD, as well.

Implications for Policy and Practice, Feasibility of VA Adoption:
This study has direct implications for women's mental health care education practice and policy. Interventions that this proposal plans to deliver are readily and/or relatively inexpensively importable into existing VA care delivery with next step implementations readily feasible. Our NCM intervention can be a FTEE neutral undertaking as Patient Aligned Care Team (PACT) models of care currently have NCMs in key roles as points of contact as do Women's Health Care and MH Care clinics that are already interfacing with female RNG Veterans and their post-deployment needs. Consequently, our proposed research can provide standardized shared decision-making protocols that will facilitate the care of female RNG Veterans with PTSD. This NCM interface has the potential to improve patient engagement in PTSD care and EBP. Furthermore, while the proposed web interface and shared decision-making intervention is currently directed at RNG women Veterans post-deployment, there are clear implications for expansion to other populations or health concerns. At a policy level, there are unique benefits to multiple partners who have stakes in different facets of our evidence-based implementation of web-based education and screening interface and shared-decision making interventions. It should be noted that the NCM will be a complementary role with existing OEF/OIF/OND outreach counselors who focus on educating returning Veterans about their VA eligibility, facilitating enrollment and subsequently appointment scheduling as needed in a variety of areas..

Deliverable	**VA Portability/Adoption**	**VA Benefit/Sustainability**	**Partners that Benefit**
Web-Based Post-Deployment Readjustment Screening and Educational Intervention	Immediately implementable, i.e., accessible as is from anywhere (web-based). Next Steps: 1. *My Healthe Vet* (MHV) integration: (MHV Diseases and Conditions Center, MHV My Recovery Plan). 2. *Phone Applications.*	1. Low cost to translate to care. 2. Improves access to information for Veterans with potential barriers, e.g., rural employed, caring for children, and can be accessed in the privacy of home. 3. Promotes convenient VA interface and education with RNG, a population that might not otherwise access VA MH or EBP. 4. Replace clinician-administered screening with web-based screening. Maximizes efficiency by comprehensively screening and accurately triaging Veterans who are or are not in need to appropriate services, e.g.,	Office of Mental Health Services Office of Primary Care Services National Center for PTSD Office of Rural Health Women Veteran's Strategic Healthcare Group Women's Health Innovation Office Office of Family Services, Women's Health and Military Sexual Trauma OEF/OIF/OND Outreach Teams

		EBP. 5. VA Promotes Accurate education and available VA health care services, e.g., EBP for PTSD and gender-specific care.	Non-VA Partners: Vet Centers, Veteran Service Officers, Veteran Groups
NCM Manualized Shared Decision-making Protocol	Adoption by NCM within: 1. Patient Aligned Care Teams (PACT) 2. Mental Health Service 3. Women's Health Clinic	FTEE Neutral NCM point of contacts will not change but with this protocol NCMs will efficiently be able to use a standardized method to implement treatment triage and support informed consumer-based decision making about PTSD treatment benefit and options, e.g., EBP.	

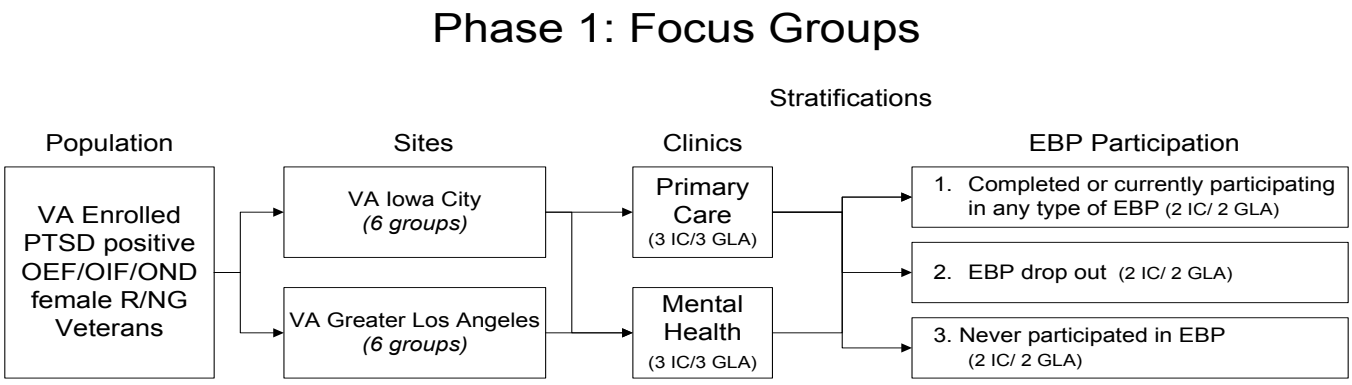
Participation by Partners:
Findings from this study will be immediately relayed to the partners who will be able to take action accordingly. As VISN MH Medical Director, co-Investigator Dr. Brian Cook will assist with these communications. He and PI Dr. Anne Sadler have routine interface (weekly and monthly, respectively) with different facets of Office of Mental Health Services (OMHS) in their roles as VA MH administrators. Partners include OMHS (S. Batten); OMH Operations (M. Schohn); NCPTSD (M. Friedman and P. Schnurr); Primary Care Program Office (G. Schectman); VISN 23 (J. Murphy) and MH QUERI (J. Kirchner). In addition to a briefing version of the final report, we plan to write a technical monograph to summarize the study outcomes and recommendations. Offices with special interest that we will also inform include partners: Mental Health Program (T Zeiss., Ph.D), the Women Veterans Strategic Healthcare Group (P. Hayes, Ph.D., Chief Consultant), the Director of Family Services, Women's Mental Health, and Military Sexual Trauma (S. McCutheon, Ph.D., R.N.), the Director of Web Services, (K. Weingardt, Ph.D).

4.0 RESEARCH DESIGN AND METHODS

Methods:
We propose a mixed-methods study building upon the HSR&D Women's Practice Based Research Network (PBRN) to leverage the research infrastructure and the research and clinical relationships already in place to optimize the successful completion of this study. To the PBRN sites (Iowa, North Carolina, California -2 sites) we will also add Minneapolis, the EBT4PTSD CREATE site. This established PBRN and CREATE network will also facilitate access to VA services and enhance safety for study participants. This study will include two phases. ***Phase 1*** will use focus groups to build on our knowledge from community sample focus groups with prior HSR&D funded research and to take advantage of VA computerized health records to identify VA enrolled RNG servicewomen diagnosed with PTSD post-deployment. Focus groups will characterize predisposing, enabling and need factors associated with both PTSD/EBP access facilitators and barriers as well as better define this group's unique perceptions of mental health care and EBP treatment preferences (e.g. type, timing following deployment, concurrent MH treatments). ***Phase 2*** will include (a) modification of our current web-based screening and educational interface from focus group findings, and (b) a comparative study with a community sample of RNG women screening positive for PTSD who are randomly assigned by the web interface to one of two VA access routes: 1) a study-specific nurse case manager (NCM) who will use shared decision-making to assist with local VA PTSD/MH evaluation and treatment in the Veteran's locale, or 2) OEF/OIF/OND outreach coordinators in place nationally at every VHA facility.

Aim #1: Using focus groups, identify VA enrolled OEF/OIF/OND RNG female war Veterans' perceptions, preferences and identified barriers and facilitators to accessing VA MH services and EBP (including cognitive processing therapies and prolonged exposure therapy) for PTSD.

Phase 1: This phase will build upon knowledge that we gained from focus groups implemented for a prior HSR&D funded study. Topics we generally addressed in these groups included RNG service women's perceptions of VA care and access to care. The majority of women in these focus groups did not use VA health services.



Setting: In order to obtain samples that are diverse (e.g., rural vs. urban, race/ethnicity, CBOC utilization) and improve VHA generalizability, focus groups will be held at the Greater Los Angeles (GLA) and the Iowa City (IC) VA Health Care Systems. The focus groups will be held in conference rooms at the respective VAs so that the groups are readily accessible and in a familiar environment.

Participants: Potential focus group participants will be identified through VA administrative databases at the respective medical centers. Focus group participants will be delimited to OEF/OIF/OND Reserve and National Guard (RNG) servicewomen with PTSD who have returned from deployment in Iraq or Afghanistan within the prior 24 months. Focus groups will be composed of women who have had at least one VA encounter within the preceding 18 months. Participation inclusion, described in the informed consent, will be limited to those with no disabilities that would impair their ability to provide consent and participate in the groups. Following chart review and consultation with evidence-based coordinators at each VA site, three focus groups with RNG women will be held for each specialty care group (Primary Care and specialty mental healthcare [MH]) according to EBT participation: 1) current or completed EBP, 2) EBP drop out, 3) never participated in EBP. Two VA sites (Greater Los Angeles and Iowa City) will be used, for a total of 12 focus groups (2x3x2). These data will be used to modify our current web-based tailored educational interface with modules specific to VA MH and PTSD/EBT perceptions and post-intervention satisfaction survey questions. Prior to implementation, the modified web-based interface will be pilot tested in a sample of 20 OEF/OIF/OND RNG women within two years post-deployment to Iraq or Afghanistan and within our study catchment areas (per Defense Manpower Data Center (DMDC) data) regardless of VA enrollment.

Feasibility: We verified sufficient participant availability for Phase 1 using administrative data (2011) at the IC VA using these eligibility criteria. We found that more RNG women with PTSD are seeking care in mental health (n=161) and have a greater range of visits than those seen in primary care (n=82). The GLA VA has an even larger women Veteran population.

Focus Group Process: Following IRB approval, participants will be recruited by US postal mail with a goal of 6-8 participants in each group. In order to participate they must be willing to be audio-recorded in the focus groups after being informed about the ways that their personal identities are not associated with the audiotapes and the strict security protocols that are followed to maintain confidentiality and data security. The population of Veterans meeting inclusion criteria is of sufficient size at each center that we do not anticipate recruitment difficulties. However, we will have alternative options such as semi-structured interviews or recruitment follow-up with a telephone protocol or recruitment by clinician referral. The 1.5 hour focus group sessions will be led in Los Angeles by Dr. Hamilton, a qualitative expert, and Dr. Sadler, who is well experienced in performing

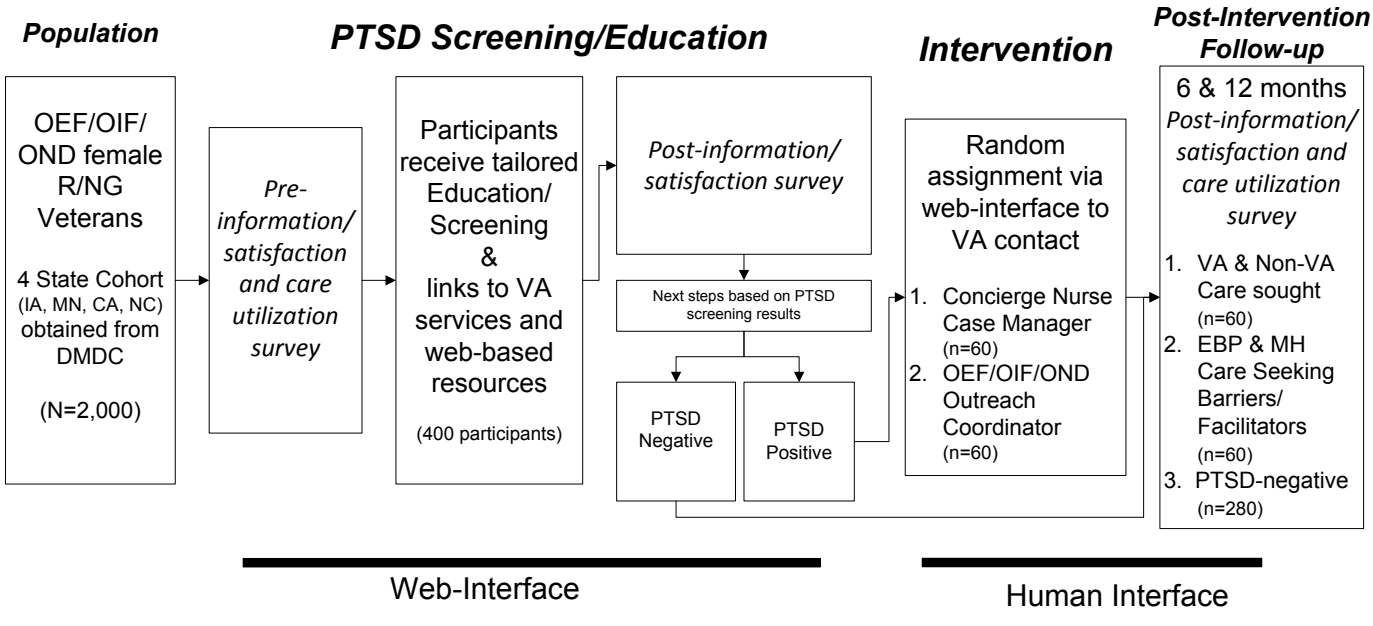
focus groups with RNG servicewomen. Participants will be reimbursed $30.00.and refreshments will be provided. Women who contact the research coordinator to affirm focus group participation will receive an additional $10.00. A protocol will be in place to address any mental health emergency or safety issues that may arise, but noting that this research team has experienced no adverse outcomes from prior focus groups with RNG servicewomen post-deployment.

Qualitative Analysis: The Aday and Andersen (Aday & Andersen, 1974) framework for assessing equity in access to health care will be a guide to the key domains that will be queried in the Phase 1 focus groups with regard to barriers and facilitators to VA mental health care and, moreover, EBP. Our initial analytic approach to the focus group data will use the constant comparison method, whereby we use open coding to identify salient issues and concerns raised by the participants across all of the groups. These open codes will be examined by the investigators in order to develop themes that pertain to the majority of focus group participants, with a focus on addressing the specific aims of the study (rather than all emergent themes). These themes will also be analyzed for their potential "fit" with the Aday and Andersen model, i.e., their relevance to the concepts of predisposing, enabling, and need characteristics. Assuming that there will be some degree of fit between emergent themes and conceptual domains, each conceptual domain will be summarized with reference to its applicability to refinements to the intervention as well as overall implementation processes. Focus groups will be digitally recorded and the Iowa City CADRE Qualitative Team will complete verbatim transcription. ATLAS.ti, a qualitative data analysis software program, will be used to assist this process. A codebook will be developed initially by the focus group co-facilitators with subsequent co-investigator independent coding of manuscripts from each of the focus groups specific to EBP participation (current or completed, never used, drop-out) and ultimately team consensus of codebook themes.

Aim # 2: To evaluate the participants' perceptions of and satisfaction with the revised web-based interface and to evaluate and test differences in VHA initiation and use for those who screen positive for PTSD by randomly assigned route: 1) Study concierge nurse case manager (NCM) or 2) existing outreach.

Phase 2:
Phase 2 of the study will involve 5 Steps: 1) Web-based pre-interface survey; 2) web-based screening and tailored education and resource links; 3) post-interface satisfaction and intended care survey; 4)random assignment to concierge nurse case manager versus in place OEF/OIF/OND outreach workers 5)post-intervention follow-up.

Phase 2: Web-based Interface & Concierge Intervention



Setting*:* The study will be based in Iowa City but implemented by mail and web to the RNG servicewomen in PBRN and CREATE study states in order to utilize our already established directory of resources and relationships. The concierge NCM will be based in Iowa City and perform interventions by telephone with toll free Veteran access available. There will be pre-study briefing with key VA staff (OEF/OIF/OND Outreach Counselors, Women Veteran and MST Coordinators) within each of these states. The existing infrastructure of the PBRN and CREATE relationships and resources will assist us to provide optimal subject education and access to VA care.

Participants: Participants will be delimited to RNG servicewomen returning from deployment within the 24 months preceding study participation to PBRN and CREATE study states (California, Iowa, North Carolina and Minnesota) and who have no disabilities that would interfere with their capacity to complete a web-based survey.

Sampling: Subjects will be selected through the Defense Manpower Data Center (DMDC) with which Dr. Sadler has a successful working relationship. Our previous work, on which this study builds, used military e-mail as the sole method of contact. We learned several lessons: (1) RNG servicewomen only sporadically checked their military e-mails which was problematic for recruitment; (2) feedback from participants told us that e-mailing a traditional IRB study invitation and informed consent (6-7 pages) was a participation deterrent; (3) we were unable to follow up with non-responders and determine a true response rate because our original QUERI sampling specifications to DMDC did not request additional information. Consequently, we have revised our protocol for recruiting: (1) we have increased the recruitment and follow-up duration; (2) we have worked with our IRB and Pharos Innovations (developer of the web-based program) to streamline the subject information and consent process; and (3) we have thus revised our DMDC registry requirements to sample potential participants with both e-mail and postal mail. Our respondents will be contacted initially by postal mail with study materials and web-based study link and notification that an e-mail is being mailed the same week for their convenience. Non-responders will be re-contacted in 10 days following initial mailing. DMDC is able to provide sociodemographic and military information (e.g. age, marital status, race, rank, number of deployments) that will subsequently allow us to compare study participants with refusers and non-responders. This will facilitate follow up and better analysis of the generalizability of findings. Web-based interface participants will be reimbursed $30.00 for their participation.

Sample Size***:*** Taking into account a conservatively estimated e-mail only response rate (15%) and response rates based on letter contact and phone follow-up (48% - 70%), we conservatively estimate a 20% response rate using e-mail and letter recruitment and therefore will request a sample of 2,000 women from DMDC to achieve a final sample size of 400. Assuming conservatively that 30% of the sample will screen positively for PTSD (45% of RNG women participating in our original QUERI web-based screen met criteria for PTSD), this will allow us to have at least 120 women with a positive screen for PTSD.

Phase 2 Intervention Process: The web-based interface provides online screening scores and individually tailored educational and referral information to participants (see appendix for current version). Following IRB approval, potential subjects will receive a postal mail invitation and information summary. This will be followed within the same week by an e-mail summary of the project and invitation to complete an online tailored questionnaire that will be administered using software developed by Pharos Innovations Corporation. In the email, potential subjects will be provided with an embedded web link and a subject identification number that can be used to access the online survey/educational interface. A consent document will be included in the initial survey screens prior to beginning the survey. The survey and responses will be maintained on a secure server behind the VA firewall. The web-based pre-screening survey will query prior and current VA utilization and their reasons for accessing it or not, knowledge about post-deployment VA eligibility and services and satisfaction with VA care, a brief check list of barriers and facilitators to VA MH care and to EBP (gathered from focus group information), and non-VA MH service use.

The web-based screens will include the following:

1. PTSD - VA Post-Traumatic Stress Disorder (PTSD) Screen
2. Sexual Trauma - VA Military Sexual Trauma Screen
3. Combat Exposure - Exposures to Combat Screen (Hoge et al (2009)
4. Domestic Violence - American College of Obstetrician and Gynecologist domestic violence screen
5. Family Readjustment- developed from PI's focus groups from another HSR&D funded study
6. Substance Abuse - AUDIT-C Substance Abuse Screen (VA screen)
7. Prescription Drug Abuse- DoD Survey of Health Related Behaviors modified for web
8. TBI - VA Traumatic Brain Injury (TBI) Screen, modified to include more descriptive questions
9. Depression - Physician's Health Questionnaire (PHQ-9) depression questions

Even though the focus of this study is on PTSD, these additional screens are necessary because of frequent comorbidities with PTSD and also to inform the NCM regarding the comorbid conditions. In our preliminary study of this web-interface, most participants completed the screening and education on the same day (92%). Those who did finish the interview on the same day had an average completion time of 26 minutes (median of 17 minutes), ranging from 8 to 221 minutes.

Participants can finish the survey in one or multiple occasions. Those who sign on for more than one occasion can go directly to the last completed question. Participants who screen positive for PTSD or other mental health disorders/concerns will be given immediate web-based feedback about the domains for which they screened positively. On-line notification for those who meet screening criteria for PTSD or other conditions will include an indication to the participant of the importance of face-to-face evaluation, education about each mental health domain there is a positive screen for, and links to contact information for OEF/OIF/OND outreach personnel and VA services in their geographic region to facilitate access to care. Educational materials will include information about what PTSD or the mental health or adjustment concern is, what to expect, how commonly it occurs, treatment options, and what treatments are available in the VA. Key information about PTSD EBP will be provided. Following completion of questions and access to educational information, participants will be asked to complete the post-intervention information and satisfaction survey online. The VA Crisis Hotline toll free number available 24 hours a day will be provided.

All contact professionals and PBRN/CREATE sites will be involved prior to study initiation, educated about this study, and engaged in facilitating outreach and care. It is noteworthy that our research team's studies that use focus groups and telephone interviews with more intensive questions about sexual assault in RNG populations have not resulted in any subsequent clinical emergencies. Women who have no positive screens will be able to access the same educational information and web links if they choose to. The web-based post-screening survey immediately following the screening and education interface will be revised from our original web-and semi-structured survey to include satisfaction with information about VA MH and EBP for PTSD that they receive in the web education intervention. We will also repeat the check-list of barriers and facilitators to VA MH care and to PTSD EBP tailored from the participant's prior responses to determine if the web-based intervention altered their perceptions. We will also query those who are PTSD positive and who are not engaged in PTSD EBP and other MH care whether they intend to seek care as a result of their participation and why or why not. Participants will be reimbursed $30.00 for the time and effort to complete the web-interface and pre-and post-surveys. If they complete the web-interface and pre and post surveys within two weeks following their initial postal or e-mail invitation then they will receive an additional $10.00. In order to receive subject reimbursement, participants will be asked to provide their names and social security number to the coordinator through a toll-free number. These data and linkage study ID number will be maintained in a locked and limited access research network electronic file behind the VA firewall. With these subject identifiers we are able to access participant VA records, given subject IRB consent. VA health services utilization will be obtained from all consenting participants in this phase of the study, including initiation of mental health services (either in primary care or specialty care) and extent of participation in EBP. Participation will be measured by self-report of EBP engagement, type, and number of sessions. This will be validated by VA electronic chart review.

Random Assignment to Route of VA PTSD EBP Access: As indicated in their IRB informed consent document for study Phase 2, RNG women Veterans who screen positive for PTSD will be randomly assigned by the web interface to one of two conditions: 1) a study-specific nurse NCM using shared decision-making to assist with

local VA mental health and PTSD evaluation and treatment in the Veteran's locale, or 2) OEF/OIF/OND outreach coordinators in place at every VA. A toll-free number will be provided to participants assigned to the NCM with information that they can initiate contact and that they otherwise will be telephoned by the NCM within 2 weeks following completion of the post-intervention survey. Pharos Innovations (web-interface developer) will provide immediate notification to the study NCM of participants who are assigned to each group and she will be able to access web results of participant study screens. Upon telephone contact with the participant, the concierge NCM will engage the patient and by telephone administer a 17 item PTSD Checklist (PCL) developed by the National Center for PTSD to assess the presence of DSM-IV criteria for PTSD. She will use the PCL-S that allows identification of a specific traumatic event. This will assist with PTSD validation and allow for individualized referral. The NCM will then follow shared decision making protocols for specific domains (Joosten et al., 2008). Domains include (pending focus group augmentation): 1) Actively reporting all information and PTSD treatment possibilities to the patient/consumer. The NCM can recommend an option but PTSD treatment and therapy are decided jointly; 2) Encourages the patient to discuss preferences and form their own judgment regarding the harms and benefits of PTSD treatment/EBP options; 3) Makes sure that the information exchange is two-way between patient and NCM; 4) NCM informs partner or key family members who the Veteran includes in the telephone interface in the PTSD treatment decision-making process; 5) Informs Veteran about routes of access to VA or if already enrolled ways to access PTSD EBP and facilitates as needed and actively links with care; and 6) Addresses barriers and facilitators checked by the Veteran on her web-based interface and assists the Veteran in addressing these (e.g., education regarding night clinics, transportation). The NCM will review all PTSD treatment options, including pharmacotherapy and site specific options, e.g. unique groups. Subjects will be educated about the efficacy, risks and benefits, duration of each treatment option. Participants are welcome to re-contact the NCM on our toll free number for further questions and assistance with care initiation or transitions during the duration of the study. However, the NCM will not initiate further follow-up. The study concierge NCM, Linda Niebes, R.N., M.S. will build on her own skills as a career Army nurse and prior OEF/OIF outreach counselor. She will be trained in the intervention protocol by PI (AGS) and co-I (MV) who are MH care professionals with unique clinical and research expertise specific to this intervention. NCM model fidelity and tools developed (manual, check lists for PTSD and MH utilization, satisfaction) will be guided by consultant J. Smith, who has expertise specifically useful to this with his work with the VA's Translating Initiatives for Depression into Effective Solutions (TIDES) project in his QUERI implementation expert role. It should be noted that the NCM will use VA/DoD Clinical Practice Guidelines for The Management of PTSD (http://www.healthquality.vagov) for assistance with patient education, management, and tracking utilization specific to EBP but also other PTSD treatment interventions documented on the treatment checklist tracking utilization in post-intervention follow-up. Use of PBRN and CREATE study sites will allow NCM interface with PC, WHC, and MH teams already sophisticated about and engaged in evolving women's health care and research. This existing infrastructure of relationships and resources will facilitate the successful implementation and evaluation of the NCM linkage intervention. Traditional OEF/OIF/OND outreach counselors educate returning Veterans about their VA eligibility, facilitate enrollment and subsequent appointment scheduling. The NCM will have a complementary role in that her interventions will be specific to PTSD and EBP treatment.

Post-Intervention Follow-up: Women who screened positive for PTSD and were randomly assigned to NCM or usual OEF/OIF/OND outreach VA PTSD treatment access route will be contacted by the study research coordinator by telephone at 6 and 12 months following web-based interface. The study coordinator will use an IRB approved call contact protocol varying times of day and days of week (used successfully by this team) and ask willing participants brief questions using computer-assisted telephone interview data collection. Satisfaction with access route and consumer feedback regarding these will be assessed. Those who did not engage in VA MH or EBP will be queried to determine if they have sought non-VA care for their PTSD, including EBP, and current factors influencing needed PTSD services. Using DMDC data, this group will be compared to VA users with regard to access and military characteristics (e.g. rank, number of deployments) in addition to web-based screening data. Women who did engage in VA MH or EBP will be asked about their experiences and satisfaction with EBP and VA care. VA service use will be validated by electronic records. Participants will be also asked about their current satisfaction with the effectiveness of the web-based interface and subsequent utilization of educational links. Non-users will be asked about current barriers to VA and MH services and again offered assistance with access to VA care and EBP if desired. We will use DMDC data to provide comparison to women who initially screened positive for PTSD. Women completing the 6 and 12 month follow-up interviews will be reimbursed $15.00 for each completed interview.

Sample Size Analysis and Statistical Plan: The pre- and post-satisfaction surveys integrated within the Phase 2 web-based interface will be analyzed to estimate prevalence of post-deployment mental health concerns, pre-interface knowledge and current health care use, and post-interface knowledge, satisfaction, and participants' intentions to seek services for mental health care needs identified through the web-based screening. Descriptive statistics will be used to analyze individual items and mean scores on each of the various screens. Estimated power for within group mean differences (i.e., paired t-tests) based on the smaller of the two groups (i.e., N=400: 120 PTSD positive/280 PTSD negative) and assuming a conservative variance=2 and a mean difference of .5, then power=97%. A larger sample size n=280), a smaller observed variance, or a larger observed mean difference would all provide additional power. The power to detect mean differences between groups (120 PTSD positive v. 280 PTSD negative) assuming a conservative variance=2 and a mean difference is calculated to be of .5, then power=90%. Power estimates for differences in proportions are expectedly lower but are estimated to be over 90% to detect medium effect sizes (>.4) and 54% to detect small (>.2) effect sizes. Using nQuery 4.0 for power calculation, we found we can detect a 25% difference in the proportion of women with mental health service use (which can be measured for all participants using VA databases) comparing NCM with existing outreach with 81% power using a simple test of proportions. Using logistic regression for the dependent variable of mental health service use and adjusting for covariates such as comorbid substance abuse, depression, and other post-deployment problems, we estimate that we can detect an odds ratio of 2.3 with 84% power or 2.0 with 76% power for NCM vs existing outreach. Given the appealing and personal nature of the concierge NCM, we believe we will find a large OR of these magnitudes.

OMB Considerations*:* Our QUERI RRP that serves as the foundation for this CREATE proposal was exempt from OMB review since the survey and collection of information being conducted was in connection with research to prevent a clinical disorder (identified as a basis for exemption under 5 CFR 1320.3). We anticipate that this will be the case with this study as it addresses prevention of chronic PTSD entrenchment and associated mental health or social issues (e.g., depression, substance abuse, marital or family maladjustment). We readily obtained OMB exemption for our HSR&D and DoD funded studies with similar domains in OEF/OIF/OND servicewomen.

Study Feasibility: We know that this study is feasible as DMDC has identified that there are currently 3,000 Reserve and National Guard (RNG) servicewomen who have returned in the past two years from deployment to Iraq or Afghanistan from the PBRN-and CREATE associated study states of California, Iowa, North Carolina and Minnesota. Of these nearly all (99.5%) have a postal address and 93% have an e-mail address.

This study is also feasible because of our successful relationship with Pharos Innovations, the corporation that assists with the web-based implementation and has a dedicated research server behind the VA Firewall. Pharos follows standards for Section 508 compliancy, therefore allowing future accommodation of Veterans with disabilities should there ultimately be a MHV interface about how to access care generally and emergently.

We plan to refer to this project with a different title during study implementation in order to make it more engaging and easy to remember. Our title "Web and Shared Decision Making for Reserve/National Guard Women's PTSD Care" will be replaced with the following working title:

Encouraging ***V***et ***E***ngagement: ***P***articipation in ***T***reatment with ***S***hared ***D***ecision Making
(EVE-PTSD)