The VA Women's Health Practice-Based Research Network: Amplifying Women Veterans' Voices in VA Research

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INTRODUCTION

Abraham Lincoln founded the Department of Veterans Affairs (VA) "to care for him who shall have borne the battle, and for his widow and his orphan." While women have served in every U.S. military conflict since the American Revolution, the Veterans Health Administration (VHA) paid little heed to the specific needs of women Veterans for much of its early history.[1] In parallel, there was scarce research focusing on women Veterans; indeed, female gender was often an exclusion criterion in earlier research studies. In that era, women Veterans' voice in research was muted at best.

The landscape truly began to change in 2004 with the national VA women's health research agenda-setting conference.[2] The 5 years following that conference saw publication of more articles that focused on women Veterans or included women Veterans than in the prior 25 years taken together.[3]

Despite these achievements, the chasm between the existing evidence base and the needed evidence base remains wide. The number of women using VHA has doubled over the past decade,[4] and women new to VHA have distinctive health care needs.[5] Thus, there is pressing demand for research on best practices for this special population.[6]

VHA investigators increasingly are stepping up to this call. However, a major obstacle hampers their research efforts: with women constituting only 6 % of Veterans in VHA,[4] it is often impossible to recruit sufficient numbers of women at any one facility. For example, heart disease is the leading cause of death in women and a priority area in VA. Administrative data from 2009 indicate that only about 60 women (versus about 6,000 men) have a coronary artery disease diagnosis at a median-sized VA medical center ("facility") (Source: VHA Women's Health Evaluation Initiative, Women's Health Services, Patient Care Services). To recruit enough women with coronary artery disease who meet all other study entry criteria and agree to participate, an investigator typically would need to reach out to women at multiple facilities. However, conducting multi-site research at geographically dispersed locations is challenging.

In response, in June 2010, VA Health Services Research & Development Service (HSR&D) funded the VA Women's Health Research Network, composed of the VA Women's Health Research Consortium and the VA Women's Health Practice-Based Research Network (WH-PBRN).[7] (For contact information, see: http://www.hsrd.research.va.gov/for_researchers/womens_health/.) The focus of this paper is the WH-PBRN, designed to provide research infrastructure in support of multi-site women's health research through a network of partnered VHA facilities.

The WH-PBRN builds upon a tradition of non-VA PBRNs.[8] By collaborating across practice settings, PBRNs

make it feasible to recruit from a larger pool of prospective study participants, which is critical for VA women's health research. However, they also do much more. Because PBRNs are inherently clinician-centric, they "draw on the experience and insight of practicing clinicians to identify and frame research questions whose answers can improve… practice,"[9] they establish effectiveness of treatments and delivery systems when applied to real-world practices, and they provide a "laboratory" for testing health care innovations.[10] While VA has existing infrastructure for multi-site research in its Cooperative Studies Program (CSP), only the WH-PBRN specializes in multi-site *women's health* research and recruitment of *women* to multi-site, practice-based research studies. The WH-PBRN is thus able to add value because it fosters a community of researchers and clinicians with a special commitment to women Veterans and expertise about emerging areas in VA women's health clinical practice that require research attention. Front-line women's health clinicians on the WH-PBRN team are also expected to have greater credibility when interfacing with a patient population that may feel marginalized[11] or that may have trust issues related to prior trauma.[12] The WH-PBRN team works out the logistics of running research in the local clinic setting, streamlining recruitment of women and addressing the complexities of navigating clinic-based research with women Veterans. In addition, the WH-PBRN Coordinating Center in Palo Alto has been accumulating best practices for multi-site women's health research in VA, and thus is able to help researchers with approaches to multi-site project management, multi-site research administration, and practice-based research in VA clinics that care for women Veterans. Thus, the WH-PBRN is well positioned to accelerate women's health research in VA.

This paper describes two overlapping phases of development of the WH-PBRN: Phase 1, designing the core infrastructure; and Phase 2, building the network. We conclude with challenges and opportunities on the horizon.

Phase 1: Designing the WH-PBRN's Core Infrastructure

Here we describe how the WH-PBRN operationalizes core infrastructure elements: mission, clinical practices, staff and governance, and communication.[9]

Mission. The mission of the VA Women's Health Research Network (the combined WH-PBRN/Consortium) is to *promote*, *support*, and *disseminate* practice-based research and quality improvement initiatives designed to identify and develop evidence-based approaches that improve the health and health care of women Veterans. To achieve this, it fosters collaboration among a community of researchers and clinicians across VHA and promotes a culture of continual organizational learning (Table 1).

The WH-PBRN *promotes* women's health research through various strategies. It outreaches directly to investigators, and enlists the support of VA research leadership to emphasize VA's requirement to include women in research[13] to grant applicants and reviewers. It profits from its tight affiliation with the Consortium, which generates a critical mass of VHA women's health investigators and which fosters a research pipeline leading toward the WH-PBRN.

The WH-PBRN also *supports* studies during the grant preparation phase and after grant funding, by providing guidance on management and administration of a multi-site, women's health practice-based study, and by ensuring ongoing maintenance of the network. While Principal Investigators are responsible for all aspects of study leadership (distinguishing the WH-PBRN from VA Cooperative Studies Program, which is designed and staffed to contribute to the actual conduct of major multi-site studies), an investigator can purchase supplemental services from the WH-PBRN Coordinating Center or from the sites to conduct specific study tasks. Site Leads at facilities selected for a study can serve as Site Investigator (to complete local research regulatory processes, to recruit local study participants from clinic settings already primed for engagement in WH-PBRN activities, and/or to conduct local study procedures), or can connect the study Principal Investigator with another appropriate local Site Investigator. Budgets for such study-specific roles are determined during the grant preparation process.

When a WH-PBRN study is completed, the Consortium takes the lead in *disseminating* findings, with support from the WH-PBRN. In particular, the WH-PBRN sites form a natural dissemination network.

Clinical Practices. At the heart of the WH-PBRN are its clinician collaborators. In more classical approaches to clinical research, investigators may drop into clinical settings for a fixed period to collect data. In contrast, the core principle of the WH-PBRN is that it represents a long-term partnership of clinicians and researchers who together strive to improve the health and health care of women Veterans. Powerful synergies arise from this bi-directional collaboration, which aligns the perspectives and experience of clinicians and researchers.

Staff, Governance and Communication. The WH-PBRN is led by its Director, and co-led by the Consortium Director. The WH-PBRN Coordinating Center is in Palo Alto's VA HSR&D Center of Excellence, and collaborates with three Divisions (providing expertise on clinical trials, post-deployment health, and health care delivery/quality improvement) and with the 37 local PBRN Sites. Communication is key to the success of this complex structure (Table 1).

Table 1. Design of VA Women's Health Practice-Based Research Network (WH-PBRN) Core Infrastructure

Component	Key infrastructure elements
Mission	Promote women's health (WH) research • Direct outreach to investigators (e.g., presentations and national cyberseminars; detailing researchers at diverse national scientific and professional society meetings; website postings; media events; manuscripts describing the WH-PBRN capabilities; reminders of WH-PBRN availability/value prior to each grant proposal submission deadline) • Enlist support of VA research leadership in emphasizing VA's requirement to include women in research to grant applicants and grant reviewers • Enlist support of Site Leads to recruit investigators interested in writing new grants that capitalize on WH-PBRN use • Closely collaborate with VA Women's Health Research Consortium, a concurrent initiative using training/education, mentorship, provision of technical assistance and dissemination in order to cultivate existing WH researchers and recruit investigators new to WH and/or interested in adding women to studies; the Consortium also actively fosters movement of research portfolio through "research pipeline" from small scale studies toward more complex multi-site studies appropriate for the WH-PBRN Directly support WH research studies • *Through grant preparation phase* (e.g., discuss study topic and alignment with national WH research priorities; explore utility of WH-PBRN for the proposed project; examine methodological aspects of inclusion of women in planned research; provide WH-PBRN site information for suitable studies; broker site-level participation; provide WH-PBRN facility-level, provider-level and patient-level descriptive data and information about prior work in the WH-PBRN, for inclusion in proposals) • *During study implementation phase* (e.g., provide guidance on multi-site project management—such as secure data transmission across sites, staff training procedures for cross-site standardization and protocol adherence, multi-site subject tracking, etc.; provide guidance on multi-site project regulatory and compliance issues—such as use of local vs. Central institutional review board (IRB), research engagement, national unions, consent form version control, etc.; provide guidance on practice-based research—including minimizing research-related disruptions to the flow of patient care, identifying clinic space for study procedures, enlisting support of facility-level leaders, etc.; ongoing Network maintenance) • *Direct study participation (in selected cases)* (e.g., creation of study cohorts and mailing lists from national VHA databases; centralized data entry; local site involvement in subject recruitment and performance of study procedures, etc.) Disseminate research findings • Disseminate through Consortium (e.g., cyberseminars, conferences, journal supplements); through researchers and clinicians in WH-PBRN member sites; through national Steering Committee (inclusive of VHA leadership and private sector experts); through national VHA WH and other senior leaders and offices
Clinical Practices	Bi-directional collaboration between researchers and clinicians (including research-clinicians) • Clinicians perform array of functions (e.g., alert researchers to emerging topics needing research attention; provide feedback on proposed research procedures; assist with subject recruitment; help researchers interpret findings; integrate new research findings into clinical practice and policy, and inform clinical colleagues of the new findings) • Researchers perform array of functions (e.g., develop new research projects with robust methodologies that respond to priority areas in VA WH research identified by front-line clinicians; solicit feedback from front-line clinicians during grant preparation phase, study roll-out, and data analysis; communicate research findings to clinicians and policy-makers)
Staff and Governance	• WH-PBRN led by a Director, co-led by collaborating Consortium Director, both within strong HSR&D centers; WH-PBRN also co-located with Health Economics Resource Center and Cooperative Studies Program Coordinating Center (clinical multi-site trial capability) • WH-PBRN Coordinating Center staffed by PBRN Program Manager, Local Coordinator and Research Assistant; supported by off-campus expertise in clinical trials, post-deployment health and health care delivery/quality improvement (organized in Divisions) • Bimonthly calls with WH-PBRN Site Leads with structured agendas and interactive conference call capability to enhance engagement
Communication	Engage in multi-level WH-PBRN operations and strategic planning through regular contacts • *Coordinating Center team, Management Committee* (adds Consortium), *Executive Committee* (adds divisions), and *PBRN Advisory Board* • *Steering Committee* (comprised of national leaders in VA research, national leaders in VA WH policy and clinical care, nationally recognized PBRN expert, nationally recognized communications expert, senior VA WH investigators, research leaders from outside VA and women Veteran representatives) • *VHA Women's Health Services*, which sets national VA WH policy • *WH-PBRN Site Leads* (from the 37 sites) (e.g., communicate information, provide training on research methods and on WH-PBRN policies, plan new projects, and build a national community of WH-PBRN leaders) • *Local site meetings* (e.g., research/clinical staff, intermittent meetings with facility leaders)

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Phase 2: Building the Network

The WH-PBRN started with four founder sites: Palo Alto, Greater Los Angeles, Iowa City and Durham. This reflected a deliberate decision to initially design the structure and address logistical issues at a small number of sites, each with an experienced clinician-investigator at the helm, prior to expansion. However, the intention from the outset was to increase the number of WH-PBRN sites, so as to grow the

pool of women Veterans with a chance to participate in research, augment geographic representativeness and heterogeneity of patient populations, reduce risk of burn-out among clinicians and patients at any one facility, and maximize opportunities for a growing cohort of women's health investigators to collaborate with colleagues and assume site-level leadership roles in major research initiatives.

A call for applications in October 2011 yielded 33 new Member Sites accepted into the WH-PBRN, resulting in a total network size of 37 geographically dispersed sites as of January 2012 (Fig. 1). Based on national VHA administrative data, one in every three women Veteran VHA patients—or over 100,000 women Veterans—receives care in a WH-PBRN Member Site.

The expansion process successfully engaged sites with diverse patient populations. For example, based on national VHA administrative data for women Veterans using a WH-PBRN facility as their main source of VA care in FY2009 (Source: VHA Women's Health Evaluation Initiative, Women's Health Services, Patient Care Services), the proportion of women Veterans of childbearing age (45 years or younger) varies substantially across WH-PBRN facilities (from 26 % to 56 %), as does the proportion of women with rural residence (from 1 % to 83 %). In contrast, across facilities, most women use primary care services (range 80 % to 92 %), making VHA primary care settings an excellent venue for recruitment. Similarly, a large proportion receive mental health care (range 30 % to 45 %): this is important since women's mental health care remains a major focus of VHA research.[3]

Site Leads are a heterogeneous group: 76 % provide clinical care (primarily primary care or mental health care) to women Veterans, 97 % have ever conducted institutional review board (IRB)-approved research, 76 % have ever been Principal Investigator of a funded study, 76 % have ever participated in a clinical Quality Improvement project, and 49 % have ever led a clinical Quality Improvement

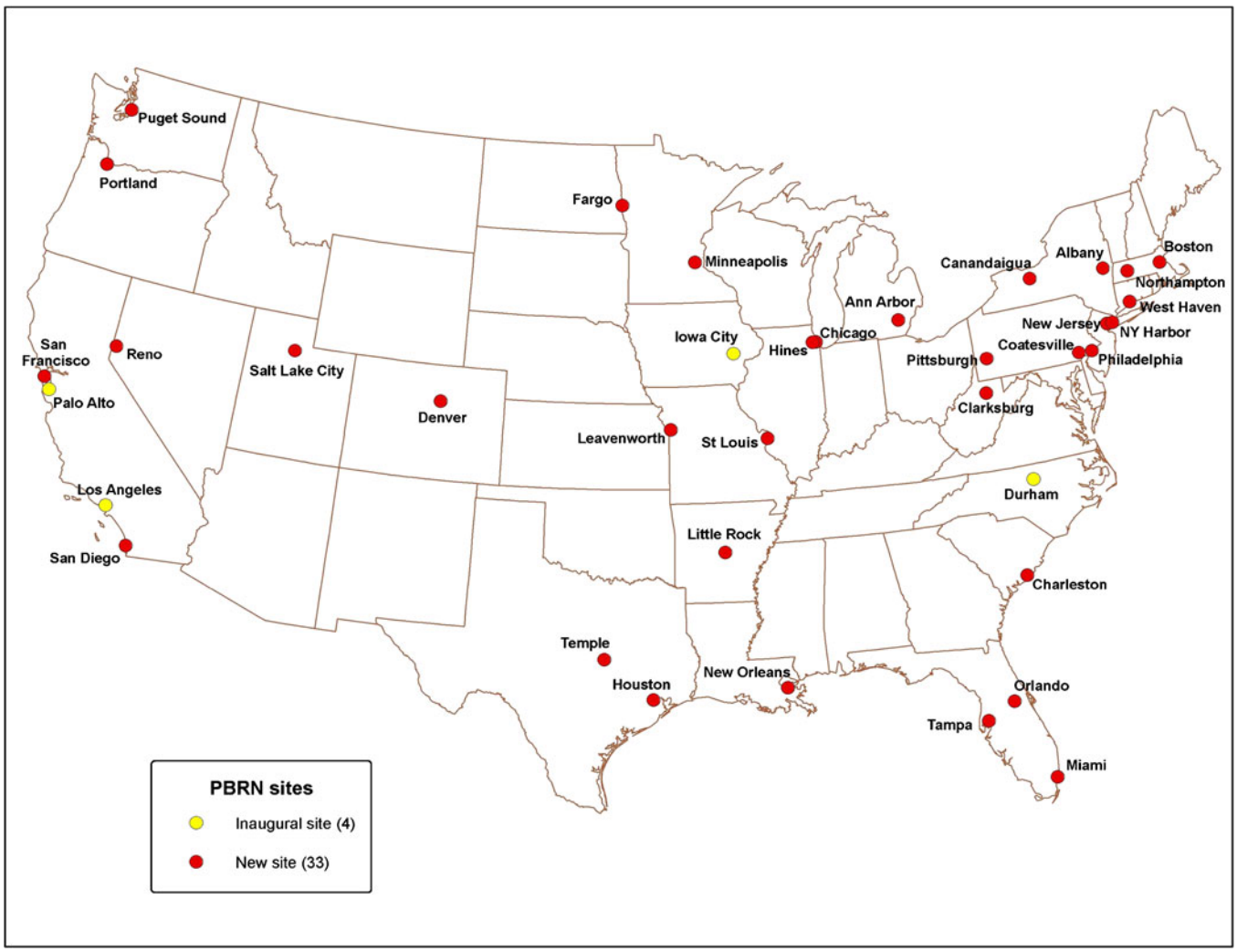

Figure 1. VA women's health practice-based research network sites, as of January 2012.

project (characteristics of Site Leads as of January 2012, based upon self-report by Site Lead). This provides options for investigators seeking Site Leads with specific skills for a proposed study. For example, one investigator might be seeking a physician with prescribing authority, whereas another might seek a local investigator with demonstrated expertise in qualitative research methods.

WH-PBRN Member Sites together are fairly representative of VHA as a whole, including 37 of the 140 VHA medical centers nationally, and 17 of the 21 VISNs (VA regions). The main difference is that 62 % of WH-PBRN facilities versus 21 % of all facilities nationally have an HSR&D research center. While this could affect generalizability of study findings, it offers the advantage of leveraging existing infrastructures at established HSR&D research centers to promote success of early PBRN studies.

Challenges Facing the WH-PBRN

Despite these successes, several challenges face the nascent WH-PBRN. First, its very success is also a challenge: as investigators increasingly approach the WH-PBRN with prospective new studies, growth and development of the infrastructure must keep pace with demand, while aligning scope of services offered with available resources to assure that investigators have realistic expectations for what the WH-PBRN can provide. Likewise, communication systems need to become increasingly robust to keep pace with the influx of studies and expansion of sites, and clear delineation of the roles of study investigators, site investigators, and WH-PBRN Coordinating Center staff will be critical.

Second, building upon the enthusiasm of researchers and clinicians at the geographically dispersed sites will be key, so as to assure that these busy professionals with competing priorities remain engaged over time. When approached about participation in multiple simultaneous studies, it will be important for the Site Lead to ensure buy-in from clinical teams about the feasibility of juggling these projects prior to agreeing to participate, to reduce risk of burn-out among clinicians and women Veterans at the site. Site Leads and clinicians in general are likely to value the opportunity to contribute to the research process and build their research portfolios, to attend Cyberseminars describing findings from practice-based research, to participate in or lead Quality Improvement initiatives, and to join a national community of professionals with a shared commitment to women Veterans.

Third, sustaining the WH-PBRN will require ongoing infrastructure funding, an issue that PBRNs nationally rate among their greatest challenges.[10,14,15] This will likely involve a hybrid approach drawing upon diverse funding streams.

Opportunities for the Future

With 37 sites on board, studies underway, new research projects in various phases of review and preparation, QI projects in development, and core operational procedures established, the WH-PBRN is poised to support VA's commitment to accelerating women's health research. Over the next few years, the WH-PBRN will in particular emphasize conduct of high-impact studies, intervention and implementation research studies, and studies that focus on women or that have gender comparisons as an aim. These efforts are timely, given that the Secretary of Veterans Affairs has made "improvements to care and services for women Veterans" a priority area.[16]

The practice-based orientation of the WH-PBRN binds it to front-line clinicians and to the women Veterans we serve. This initiative should help overcome the historical underrepresentation of women Veterans in research, expanding the evidence base that guides clinical practice and policy, and assuring that VA research heeds the voices of women Veterans.

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