Women's Enhanced Recruitment Process (WERP)

Experience with Enhanced Recruitment of Women Veterans to a CSP Trial

VA HSR&D CyberSeminar: Spotlight on Women's Health Series
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Susan M. Frayne MD, MPH

Director, WH-PBRN and WHEI
HSR&D Center for Innovation to Implementation (Ci2i), VA Palo Alto Health Care System
Professor, Division of Primary Care and Population Health, Stanford University

Alyssa Pomernacki, MPH

National WERP Coordinator
Program Coordinator, Women's Health PBRN
HSR&D Center for Innovation to Implementation (Ci2i), VA Palo Alto Health Care System

Paula P. Schnurr, PhD

Executive Director, VA National Center for PTSD, White River Junction VA Medical Center Study Chair, CSP #591 Professor of Psychiatry, Geisel School of Medicine at Dartmouth

Poll Question

Are you considering submitting a research grant that oversamples women Veterans?

- Yes
- No
- Considering it

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Grant Huang, MPH, PhD, Director

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Marcus Johnson, MPH, MBA, MHA

CSP Coordinating Center, Palo Alto

Mei-Chiung Shih, PhD, Acting Director Jennifer Lee, MD, PhD, CMO

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Ying Lu, PhD, former Director

VA Women's Health Research Network

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Susan Frayne, MD, MPH (PBRN Director)

Diane Carney, MA

Alyssa Pomernacki, MPH

Andrea Nevedal, PhD

Karen Goldstein, MD, MPH (VA Durham)

Lori Bastian, MD, MPH (VA Connecticut)

CSP #591 National Team

National Center for PTSD

Paula Schnurr, PhD (PI)

Kate Chard, PhD (PI)

Joe Ruzek, PhD (PI) Kristina Caudle, PhD

TeChieh Chen, PhD

Claudine Louis, PhD

VA Women's Health Research Network

CSHIIP, VA Greater Los Angeles Elizabeth Yano, PhD, MSPH (Consortium Director)

Alison Hamilton, PhD, MPH (Engagement Director)

Ruth Klap, PhD

Acknowledgements Local WERP Teams

Hines

NODES Director: David Leehey, MD

NODES Manager: Conor McBurney, MPH

CSP #591 Local Site Investigator: Kelly Phipps Maieritsch, PhD Study/WERP Coordinator: Samantha Cymerman *and*

Cheryl Odle

WH-PBRN Site Leads: Sudha Bhoopalam, MD and

Karen Saban, PhD, RN

Minneapolis

NODES Director: Selcuk Adabag MD, MS

NODES Manager: Debra Condon, MSN, RN, CCRP

CSP #591 Local Site Investigator: Kyle Curry, PhD

Study/WERP Coordinator: Courtney Sellberg and

Jillian Wright

WH-PBRN Site Lead(s): Erin Krebs, MD, MPH

Houston

NODES Director: Panagiotis Kougias, MD NODES Manager: Emily Boeckman, MEd

CSP #591 Local Site Investigator: Su Bailey, PhD

Study/WERP Coordinator: Jade Heathman and

Vanessa Posev

WH-PBRN Site Lead: Rola El-Serag, MD

Palo Alto

NODES Director: Trisha Suppes, MD, PhD

NODES Manager: Karen Bratcher, RN, MSN, CCRC

CSP #591 Local Site Investigator: Steven Lindley, MD Study/WERP Coordinator: Kathryn Azevedo, PhD

WH-PBRN Site Lead(s): Nicole Grant, MD and

Jennifer Lee, MD, PhD

Long Beach

NODES Director: Timothy Morgan, MD

NODES Manager: Aliya Asghar, MPH

CSP #591 Local Site Investigator: Michael Hollifield, MD

Study/WERP Coordinator: Kala Harkin, MS and

Linda Nguyen

WH-PBRN Site Lead(s): Laurie Rudisill, RN, MSN and

Amarpreet Bath, MD

Salt Lake City

NODES Directors: Daniel Clegg, MD and

Jennifer Romesser, PsyD

NODES Manager: Kandi Velarde, MPH, CHES

CSP #591 Local Site Investigator: Jennifer Romesser, PsyD

Study/WERP Coordinator: Anthony Trumpy and

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WH-PBRN Site Lead(s): Lori Gawron, MD, MPH

Why Do We Need to Increase Opportunities for Inclusion of Women Veterans in VA Research?

Susan Frayne, MD, MPH

The Need for Inclusion of Women in VA Research

- Like other federal agencies, VA requires inclusion of women in research
- Women historically under-represented in VA research
 → insufficient evidence base to guide their care
- Rapidly growing number of women Veterans
 - However, low # of women Veterans at any one VA
 - Single-site studies typically cannot recruit enough women to yield meaningful conclusions.

Source: Yano EM et al. Integration of women veterans into VA quality improvement research efforts. JGIM 25(Suppl 1):56-51, 2010; Source: Women's Health Evaluation Initiative (WHEI):

https://www.womenshealth.va.gov/WOMENSHEALTH/docs/WHS Sourcebook Vol-IV 508c.pdf







VA HSR&D Funded Infrastructure to Build Women's Health Research Capacity

(for more detail, see HSR&D CyberSeminar $11/5/\overline{18}$)



(2010-present)

WH Research Consortium (Yano/Klap)



WH Practice Based Research Network (Frayne/Carney)

- Training, mentorship
- Methods support
- Research development
- Dissemination support

- ↑ recruitment of women
- ↑ multisite research
- Engage local clinicians, leaders
- ↑ implementation/impact

Multilevel Stakeholder Engagement (Hamilton)

Accelerate implementation of research into practice and policy

VA Women's Health PBRN: Overview

- National network of 60 VA facilities partnering to promote and support the conduct of multi-site research/QI
 - About WVs and/or their health care
 - Seeking to over-sample women to make gender analyses possible
- WH-PBRN Site Lead at each facility
 - Primed for PBRN research to improve health/health care of WVs
 - Connected with local clinicians, leaders, researchers
- National PBRN Coordinating Center
 - Promote local site development/grow the network
 - Support researchers conducting PBRN studies
 - Close collaboration with Consortium/Engagement arms





Opportunities for Synergies with VA Cooperative Studies Program (CSP)

Cooperative Studies Program (CSP)

- CSP is a division of VA ORD (since 1972)
 - Plans and supports VA investigator-initiated large multicenter clinical trials and epidemiology studies
- CSP tradition of enlisting under-represented groups in VA research
 - Example: the SELECT trial

SELECT Trial

Prior Initiative to Increase African American Accrual

- Multi-site prostate cancer prevention trial (SELECT)
- Enhance recruitment of African-Americans
 - Expanded eligibility criteria
 - Sought sites with prior success recruiting minorities
 - National infrastructure for minority recruitment
 - Minority Recruitment Enhancement Grants
 - Awarded to 15 sites
 - Impact
 - 1 odds of African American recruitment vs. comparison sites
 - Boosted recruitment: 10% pre → 15% post

CSP Network of Dedicated Enrollment Sites (NODES)

- Consortium of VA medical centers (VAMCs) that have teams (Nodes) in place dedicated to conducting CSP studies to enhance the performance, compliance and management of CSP multi-site research.
- Expected outcomes:
 - Increasing study enrollment rates
 - Enhancing participant safety
 - Developing standardized procedures & best practices for conducting clinical trials
 - Providing local insights in the design and execution of studies
 - Improving the overall efficiency of CSP research

http://www.research.va.gov/programs/csp/nodes.cfm

CSP NODES ↔ WH-PBRN Collaboration



CSP NODES All Overlap with PBRN Sites: Opportunities for Synergies...!

Facility	WH-PBRN Site	CSP NODES Site
VA Palo Alto Health Care System (Palo Alto, CA)	X	X
Edward Hines Jr. VA Hospital (Hines, IL)	X	X
Minneapolis VA Health Care System (Minneapolis, MN)	X	X
Portland VA Medical Center (Portland, OR)	X	X
Michael E. DeBakey VA Medical Center (Houston, TX)	X	X
VA Salt Lake City Health Care System (Salt Lake City, UT)	X	X
VA San Diego Healthcare System (San Diego, CA)	X	X
VA North Texas Health Care System (Dallas, TX)	X	X
VA Long Beach Healthcare System (Long Beach, CA)	X	X

Women's Enhanced Recruitment Process (WERP)

Goal: Develop and test a Women's Enhanced Recruitment Process in the context of a specific study, CSP #591 (Pls: Schnurr, Chard, Ruzek)



CERV-PTSD (CSP #591): An Ideal Context to Test Women's Enhanced Recruitment Processes

Paula Schnurr, PhD

CERV-PTSD (CSP #591)

Co-chairs: Paula P. Schnurr PhD, Kathleen M. Chard PhD, Josef I. Ruzek PhD VA Cooperative Studies Program



Comparative Effectiveness trial comparing two effective treatments for PTSD:

- Prolonged Exposure (PE) vs Cognitive Processing Therapy (CPT)
- PE and CPT both effective treatments for PTSD, and have been rolled out via VA-wide provider training programs

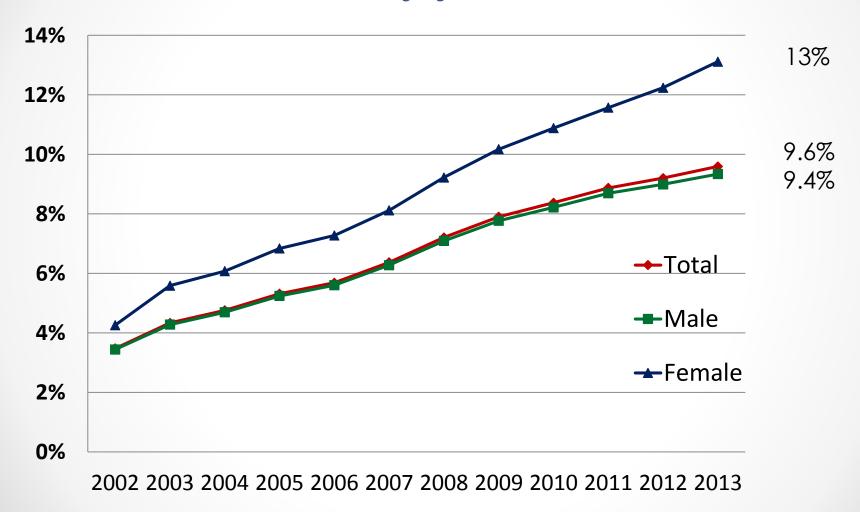
17 participating study sites

 6 are NODES + WH-PBRN sites: Hines, Houston, Long Beach, Minneapolis, Palo Alto, Salt Lake City

- 7 are WH-PBRN sites without a NODES
- 4 have neither WH-PBRN nor NODES



Veterans in VHA with a diagnosis of PTSD, by year



Study Objectives

- Primary: Compare effectiveness of PE and CPT for reducing PTSD symptom severity
- Secondary: Compare effectiveness of PE and CPT for:
 - reducing comorbid mental health problems and service utilization
 - improving functioning and quality of life
- Tertiary: Examine whether discrepancy between preferred and assigned treatment reduces effectiveness
- Exploratory: Examine differential predictors of treatment outcome

Women's Enhanced Recruitment Process (WERP) *Goals*

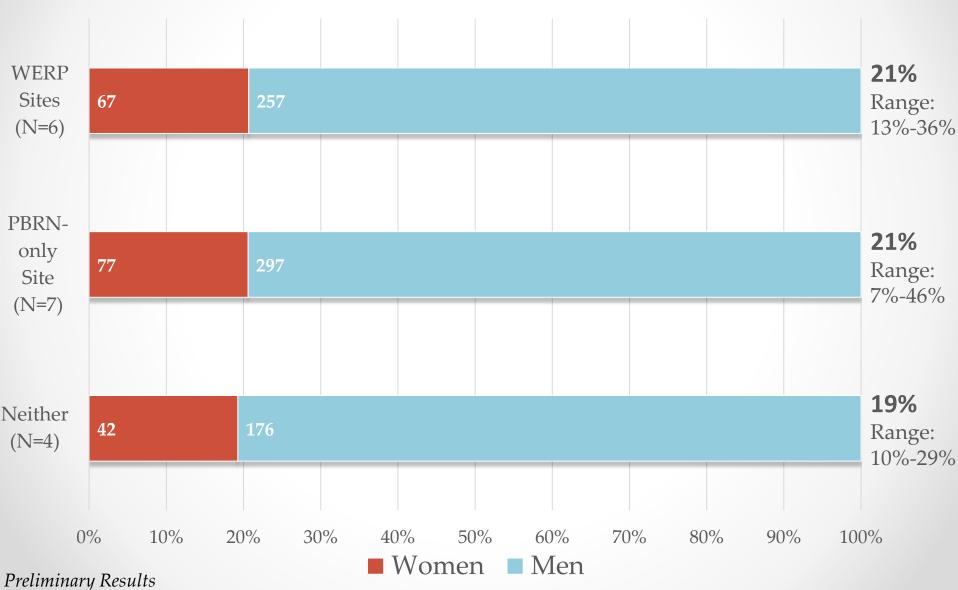
- Increase recruitment of women to CSP #591 at NODES sites
 - Maximize recruitment
 - Learn what is achievable
 - Secondarily seek to increase enrollment of women Veterans at non-WERP sites
- Identify best practices for recruiting women Veterans, using CSP #591 as a "case study"

WERP: Recruitment Rates

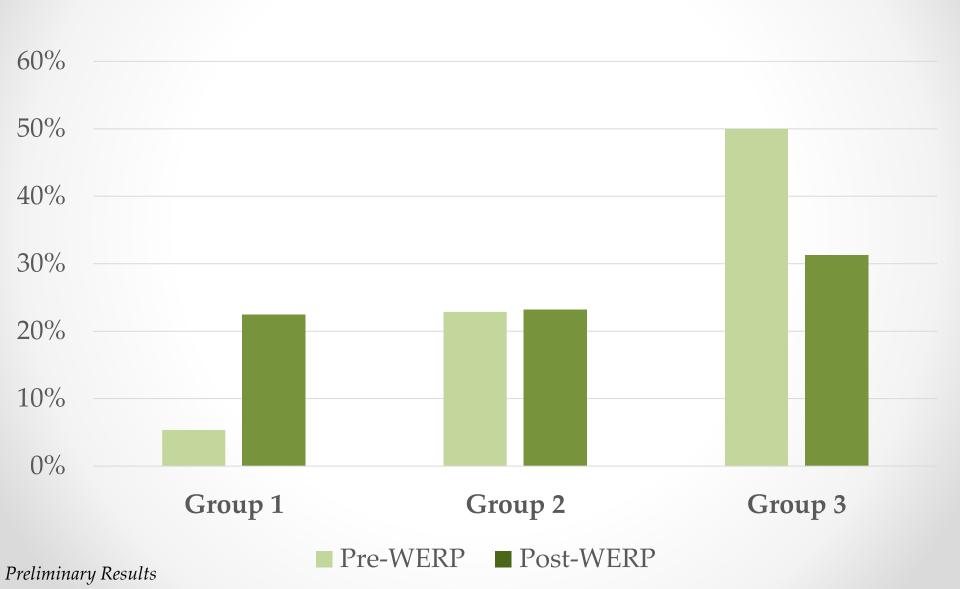
Women Veterans as a % of CSP #591 Participants, overall:

1 in 5

Women Veterans as a % of CSP #591 Participants, by site type



Women Veterans as a % of CSP #591 Participants, WERP Sites Only, pre/post WERP



WERP: Design and Activities

Alyssa Pomernacki, MPH

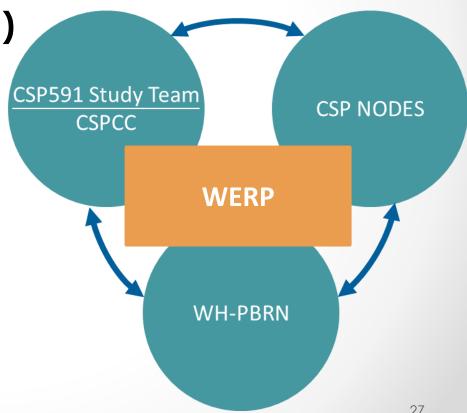
Roles / Coordination at Local Site

Capitalizes on Synergies: CSP/NODES + WH-PBRN + CSP #591 Study Team

- WERP Site Coordinator (SC) ~ 1 day per week of time
- NODES Director

Local Site Investigator (LSI)

WH-PBRN Site Lead



Women's Enhanced Recruitment Process (WERP) Activities

- Development of enhanced recruitment procedures for CSP 591
- WERP site activities
 - Monthly meetings, local presentations, mailings, recruitment
- Program evaluation
 - Veteran Feedback Form (VFF)
 - Qualitative Interviews with research study staff
- Toolkit development:
 - Synthesize lessons learned around recruitment of women
 - Amass resources relevant to inclusion of women

WERP: Lessons Learned So Far

Best practices for recruiting women Veterans The Veteran's Voice

- Veteran Feedback Form (VFF) Goals
 - Provide study participants with an opportunity to explain:
 - Why they participated in the study
 - Reflect upon their perspectives about the recruitment process

Best practices for recruiting women Veterans The Veteran's Voice

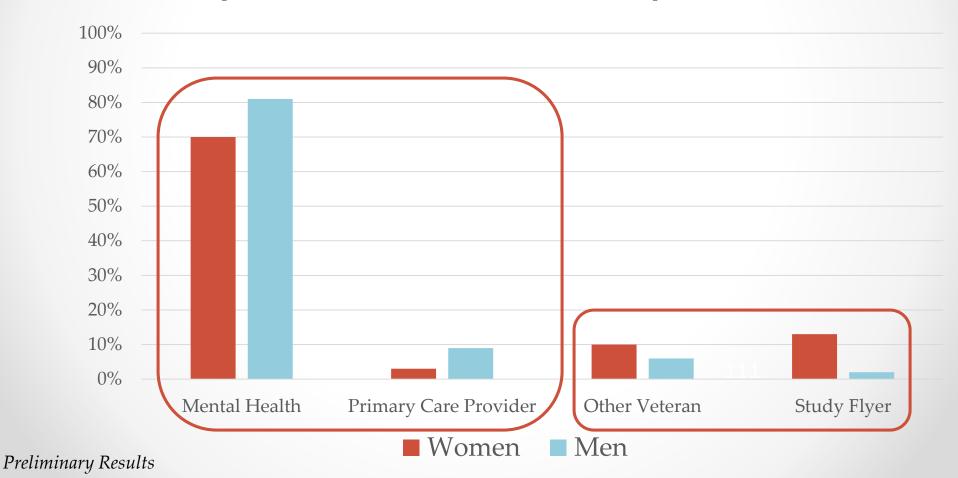
Veteran Feedback Form (VFF) Methods

- 2-page survey included in packet of instruments completed by study participant
- Some items adapted from Ohio State University instrument
- Examined gender differences in Veterans' preferences around participation in a clinical trial

Best practices for recruiting women Veterans The Veteran's Voice Veteran Feedback Form

N= 40 women; N=144 men

Where did you first hear about this study?

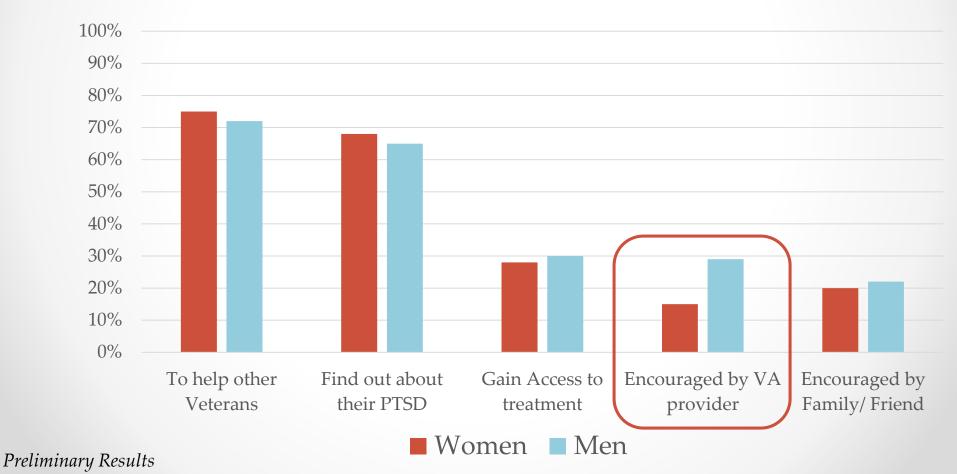


Best practices for recruiting women Veterans The Veteran's Voice

Veteran Feedback Form

N= 40 women; N=144 men

Why did you decide to take part in this study?



Best practices for recruiting women Veterans The Veteran's Voice Veteran Feedback Form

N= 40 women; N=144 men

- Satisfaction with how you were approached to be in study?
 - 100% women were satisfied or very satisfied
 - 88% men were satisfied or very satisfied

Best practices for recruiting women Veterans The Veteran's Voice Veteran Feedback Form

N= 40 women; N=144 men

What did you like about the way your were approached?

- "I felt pleased to be asked for my input"
- "I liked how it was emphasized that I would be able to help other veterans or people [with] the condition that I have"

What could we have done better?

- "I think it would be beneficial to give flyers out in some of the groups where women veterans are attending."
- o "The word is not getting out that [this] research is available

to the average vet...."

Program Evaluation: Qualitative Interviews Goals

- Understand experiences around recruitment and retention of women Veterans
 - Recruitment/retention strategies
 - Challenges enrolling women into research
 - Suggestions for improvement

Program Evaluation: Qualitative Interviews <u>Methods</u>

Data collection

- 42 participants (out of 54 contacted) from Jan-May 2018
- Semi-structured telephone interviews
- ~30-60 minutes
- Audio recorded and transcribed

Analysis

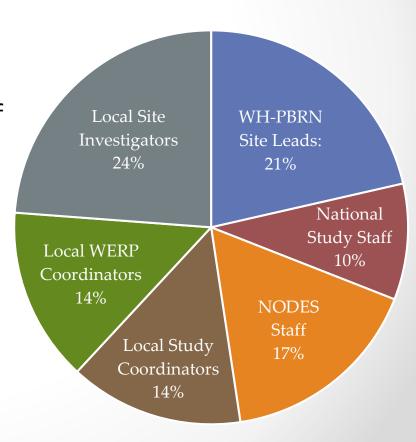
- Rapid analysis of interview transcripts
- Summarized in a matrix
- Consensus based coding

Program Evaluation: Qualitative Interviews Sample

• Site-Level:

Across 15 of 17 CSP #591 Sites

- NODES (WERP) sites (n=6)
- WH-PBRN only (n=7)
- Neither: (n=2)
- National CSP#591 Study Staff



What STRATEGIES have worked well recruiting women Veterans? Qualitative Interviews

- Finding "Champions," nurturing relationships to facilitate buy-in, integrating into clinic "flow"
 - "The best referrals came when there was clinician buy-in and the clinician gave the participant a heads up and actively encouraged the participant to participate."
 - "We had a built-in kind of referral system through the MST coordinator. She was a huge help in sending us referrals."

Helping other women Veterans

o "The women that signed up were very invested because of the way we presented it: 'We can't look at what's going to be helpful and effective for female Veterans if you don't participate in research. So your participation is not only going to help hopefully you, but really to help [what] we can do for other female Veterans as well.' I found that to be very effective as a rationale that the female Veterans really attach to."

What CHALLENGES has your site experienced trying to recruit women? Qualitative Interviews

Multiple studies recruiting from a small pool

- "There were too many ...programs that were competing for that same population base."
- "I think the [women's health] stakeholders are burdened with many requests for their women"

Recruiting women Veterans is complex

"I think they have a lot of comorbidities, so I think ...that they
just need a lot of attention with a lot various health issues."

Women are busy!

- "Younger Veterans certainly had more logistical barriers consistent with what we see in other studies in the research, either working, child care"
- "...if there was a sick child they were the one that had to take off work"

What CHALLENGES has your site experienced trying to recruit women? Qualitative Interviews

Local cultural issues around treatment for women

o "I did find that a few of the providers were – I don't want to say overprotective of the women in their programs, but I will say they were a little more cautious about referring them to us"

Unwelcoming setting for women Veterans

- "I'd have to go to a clinic area which, there's like five men's bathrooms and one women's bathroom."
- Color: the clinic is [a depressing color]. The men in the waiting room need to behave. There are women who have babies and the bathrooms do not have accommodations to change a diaper..."

What CHALLENGES has your site experienced trying to recruit women? Qualitative Interviews

- Not always able to accommodate female provider preference
- Identifying where the women Veterans receive care
- More flexibility to recruit outside the mainstream
 - "I wish we could be more flexible with how we communicate, I wish we could do research using online surveys... I think if we improve or technologic interfaces, giving people more options... Just trying to make it easier and more time efficient for busy people."

What SUGGESTIONS do you have to improve recruitment? Qualitative Interviews

Increase awareness about women Veterans' recruitment

- "...we definitely could've talked about it more and gotten people excited about looking for women who were good candidates for the study."
- "when I told [women] that this study was a part of an initiative to increase women enrollment, they were surprised, but pleasantly surprised, that there was a research [study] that even cared that much to try and increase female enrollment."

Address participant's logistical barriers

"If you're thinking about competing demands and how little time you have, to add something else to your plate can be a big challenge and so I think trying to identify those aspects of studies where patients really can see, "Oh, this would be good for me."

What SUGGESTIONS do you have to improve recruitment? Qualitative Interviews

Building relationships with clinicians and staff

- "Getting to know staff and explaining to them why we're recruiting and getting them on board, like medical assistants and nurses can be really helpful because that's kind of like the warm handoff where they can encourage patients who they know to participate."
- "Presenting at provider team meetings is always important...
 so that the provider can actually explain that to the patient.
 And also, we do a lot of myth-busting and dispelling rumors
 about research."
- "You can't just kind of like pop in; you have to reside, you have to be a presence."

Putting it All Together WERP Toolkit

- National WERP Toolkit: available for dissemination soon!
 - Sample gender-tailored recruitment materials (e.g.: letter, opt-in/opt-out form, brochure, flyers, telephone script)
 - Guidance on finding and selecting pictures of diverse women Veterans
 - IRB approach to incorporate focus on recruitment of women Veterans
- Local WERP sites have also developed local toolkits
 - Local tips, resources, contacts for local women's health stakeholders

Thank you for your efforts to ensure that women Veterans are represented in VA Research!







Resources

- HSR&D Women's Health Research
 - Includes searchable women's health literature database and searchable women's health research portfolio
 http://www.hsrd.research.va.gov/for_researchers/womens_health/
- Women's Health Evidence Synthesis Reports
 http://www.hsrd.research.va.gov/publications/esp/women-vets.cfm

 http://www.hsrd.research.va.gov/publications/esp/women-vets.cfm
- Women's Health Issues Supplement <u>http://www.whijournal.com/content/supplements</u>
- Women Veterans Sourcebook Volume 4
 https://www.womenshealth.va.gov/latestinformation/publications.asp
- CyberSeminar series
 http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/catalog-archive.cfm?SeriesSortParam=y&SeriesIDz=56##Archived

Contact Information:

Women's Health Research Network

Consortium

Elizabeth Yano PhD, MSPH (<u>elizabeth.yano@va.gov</u>)
Ruth Klap PhD (<u>ruth.klap@va.gov</u>)

PBRN

Susan Frayne MD, MPH (<u>susan.frayne@va.gov</u>)

Diane Carney MA (<u>diane.carney@va.gov</u>)

Stakeholder Engagement

Alison Hamilton, PhD, MPH (alison.hamilton@va.gov)

