



# **Recruiting women across the life of a study:** A VA Cooperative Studies Program Process Improvement Project

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Why it is important that  
women are well-represented  
in research?

# Research conducted predominantly among men can lack generalizability to women

## Pathophysiology

- Hormones
- Pharmacokinetics

## Prevalence

- Migraines
- Fibromyalgia

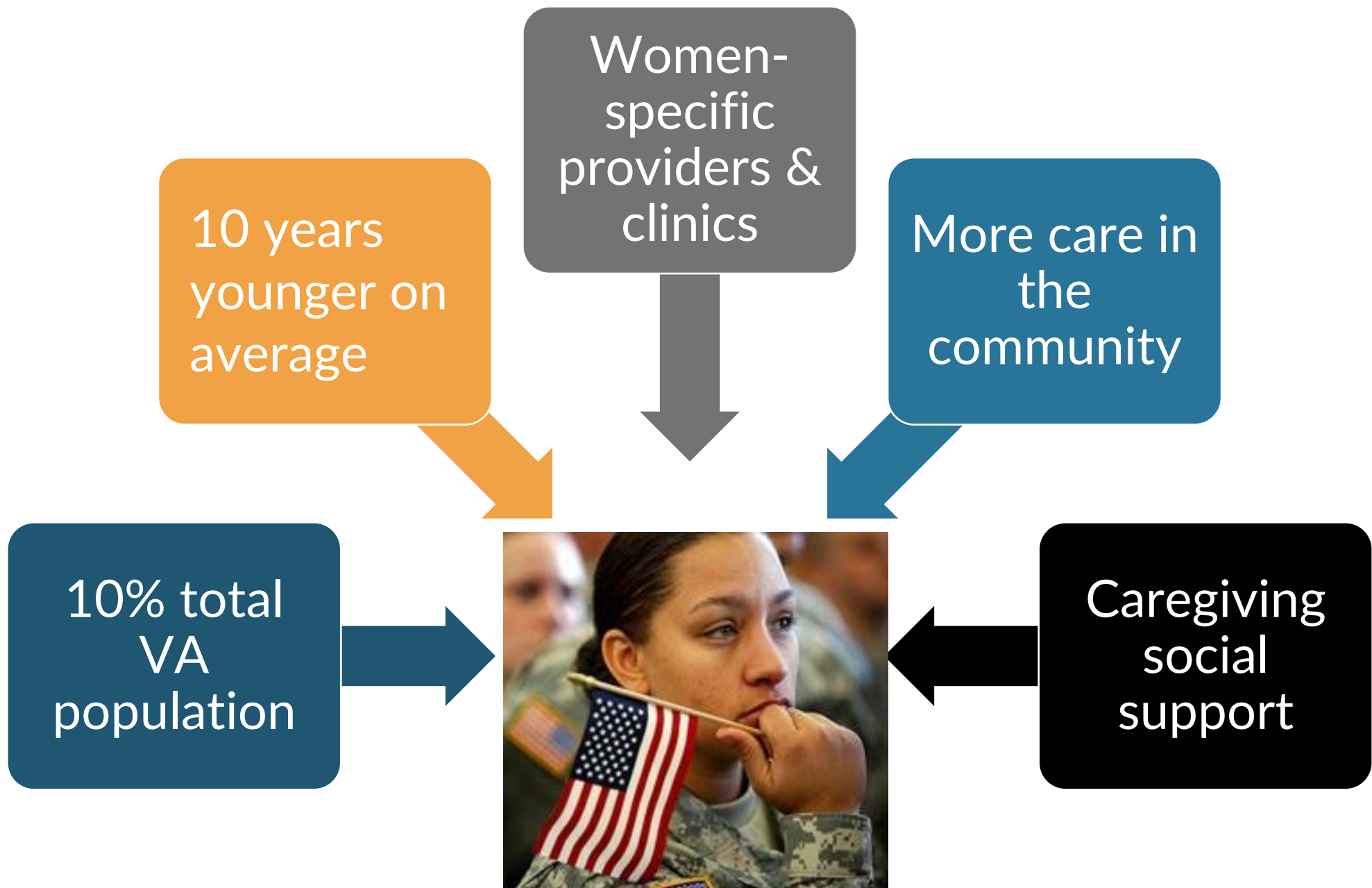
## Quality of Care

- Time to cath lab
- Statin intensity

## Patient Experience

- Acute coronary disease
- Pain interference

What are the challenges to recruiting women Veterans into trials?





# What is WERP?

# WERP goal statement

To create enhanced opportunities for women Veterans to participate in VA clinical trials through facilitating study design choices and study team actions that promote the inclusion of women.

# VA Cooperative Studies Program Trials evaluate interventions that have the potential for sex-based differences

**Aspirin as prevention in unstable angina.**  
Lewis et al. NEJM. 1983

Women may manifest CVD differently

**Herpes zoster vaccine**  
Oxman et al. NEJM. 2005

Women are more likely to develop shingles

**Chlorthalidone vs. HCTZ for HTN-CVD.**  
Ishani et al. NEJM. 2022

Women have more electrolyte disturbances while on diuretics than men



# Findings from WERP

# CSP #591 Comparative Effectiveness Research in Veterans With PTSD

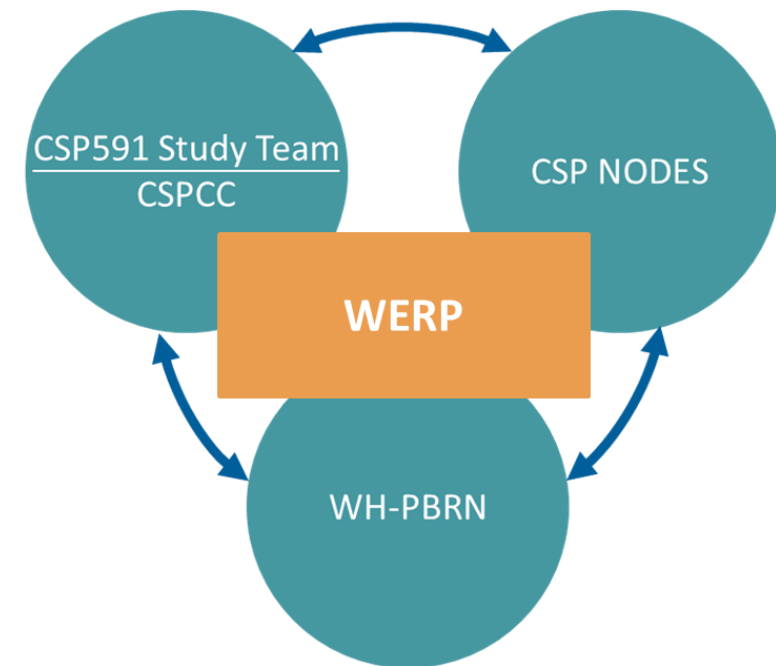
(PIs: Schnurr, Chard, Ruzek) 2016-2018

## Goals:

- Increase recruitment of women to CSP #591 at NODES sites
- Identify best practices for recruiting women Veterans, using CSP #591 as a “case study”

The WERP team was integrated within the CSP #591 national study team and worked to develop enhanced recruitment procedures specifically for this trial.

A part-time, local WERP Coordinator was embedded in the local LSI team and specifically focused on local recruitment of women to CSP #591.



# CSP #591 Comparative Effectiveness Research in Veterans With PTSD

(PIs: Schnurr, Chard, Ruzek) 2016-2018

## Successful recruitment

- CSP #591 was able to achieve high recruitment: women were 21% of participants at WERP sites

## Positive Veteran-centric feedback

- 100% of women were satisfied with the way they were approached to participate

## Motivators of participation

- Helping other women Veterans: leading reason women joined

## Recruitment strategies identified

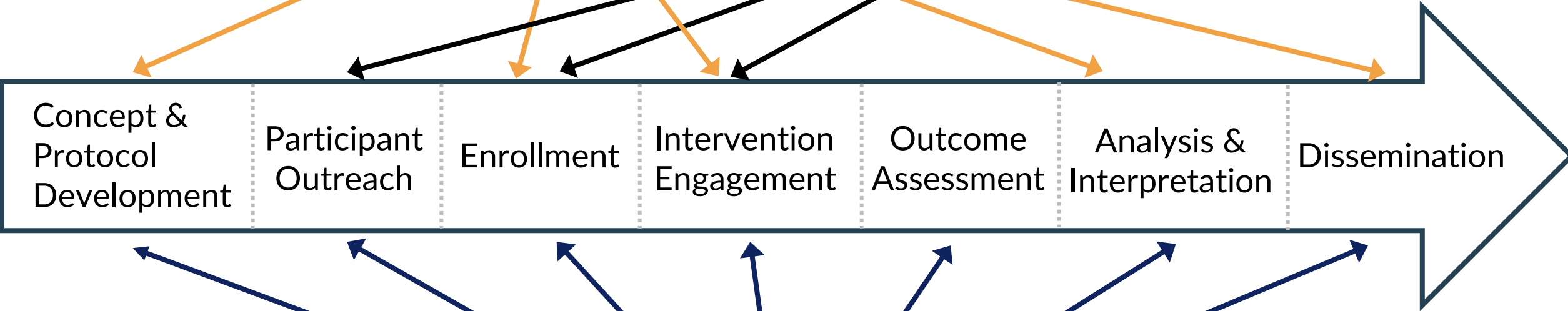
- Incorporated into preliminary training materials



What are we doing currently?

WERP Consultations

Implementation Support



Concept & Protocol Development

Participant Outreach

Enrollment

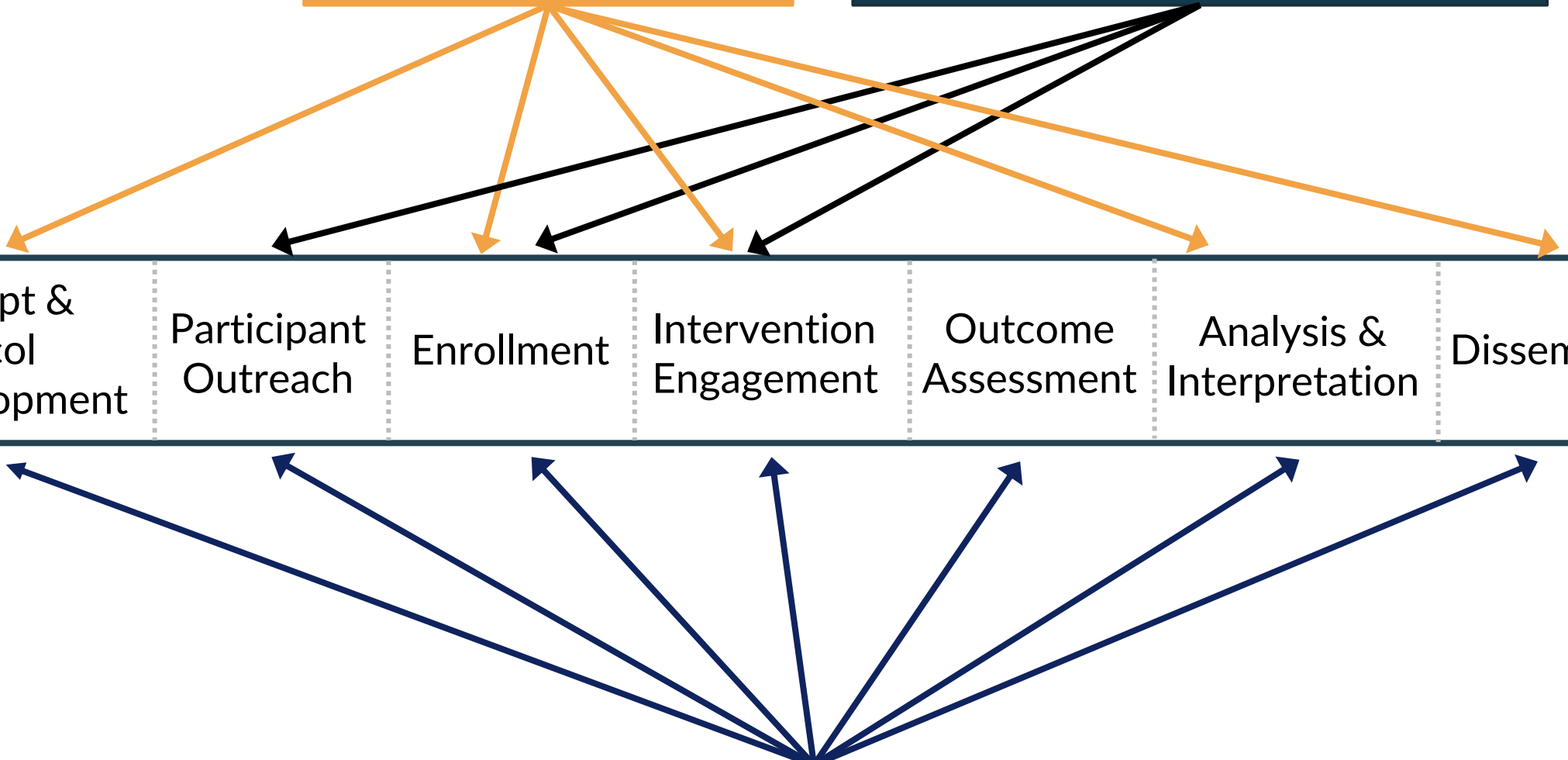
Intervention Engagement

Outcome Assessment

Analysis & Interpretation

Dissemination

WERP Toolkit



# Consultation Report Example:

## Trial Design Considerations

Trial Design considerations	
Design consideration	WERP recommendation
A priori recruitment goal for women	
Eligibility criteria	N/A
Inclusion of reproductive age women	Unlikely given condition under study.
Sampling strategy	If recruitment relies on referral from [REDACTED], there is the potential to bias against inclusion of patients less likely to make it to specialists which could reduce the pool of potentially recruited women. Could consider adding administrative data to identify women or men and women for recruitment. If pulling recruitment pool from administrative data, study team could consider preferentially having study teams contact women first.
Stakeholder engagement	Study team could consider obtaining input from key stakeholders to inform recruitment strategies, variable intervention aspects, interpretation, and dissemination. Relevant stakeholders for women’s health would include women Veteran program managers, women’s health medical directors and designated women’s health providers. In particular, if the study team seeks input from primary care providers, including
	designated women’s health providers who see <u>the majority of</u> women Veterans in the VA is recommended. One possibility for obtaining input is through existing Veteran engagement groups which would generally include women Veterans.
Site Level engagement	CSP node sites now have a WERP coordinator with time dedicated to support CSP studies at their sites around recruitment and inclusion of women. Please have your LSI teams connect with their WERP coordinator as relevant. (See attached document “CSP sites and WH resources”).  Some study sites also have VA women’s health practice-based research network (PBRN) site leads who are point of contacts for women’s health research more generally at their VA facility. If you are interested in collaborating with PBRN site leads, PIs should contact Diane Carney (Diane.Carney@va.gov) to be connected to specific site leads (See attached document “CSP sites and WH resources” to see which sites are Women’s Health PBRNs).

### Sampling strategy

- Suggestions for reaching more women (e.g., preferentially contact women first)

### Partnered engagement

- Identify relevant local stakeholders

### Site level engagement

- Local women’s health experts
- VA Women’s Health Practice-Based Research Network site lead

# WERP Toolkit

**WERP**  
Women's Enhanced Recruitment Process

**Women's Enhanced Recruitment Process Toolkit**

What is WERP? Staff training Communication Tools Resources Key References Acknowledgements

The purpose of this toolkit is to give researchers helpful resources and tips to optimize the representation of women Veterans at each stage of their study. Access relevant guidance for the phase your study is in by clicking on the corresponding icon. If you have additional questions or concerns or suggestions for additions, please feel free to reach out to the WERP team at: [WERP@va.gov](mailto:WERP@va.gov)

**What phase is your study in?**

- Study planning** (Lightbulb icon): If you are defining your research question and identifying the intervention to be studied, this is the time to consider.
  - Is your research question *biologically relevant* to women Veterans?
  - Is your research question *important* to women Veterans?
  - Is there evidence that the study condition or intervention has *different effects* in women?
- Protocol Development** (Head with gears icon): As you develop your protocol, you need to anticipate how key decisions will impact the likelihood participants in your trial:
  - How will the *eligibility criteria* impact participation?
  - How can you make it *safe for research* participation?
  - Can you *reduce the travel and time* for participants?
- Enrollment** (Clipboard icon): The enrollment and consent phase welcome women Veterans into research.
  - Do you know *where women access* care? How will that impact your recruitment?
  - Have you considered tailoring your approach to make sure that women want to participate?
  - How can you *monitor enrollment* and retention targets for women Veterans?
- Intervention Engagement** (Network icon): Once you have recruited participants participating and completing the intervention.
  - How can the *tone of study communication* encourage participant retention?
  - How can study team members ensure the *safety* of participants while participating in the study?
- Outcomes Assessment** (Person with checklist icon): Make it as easy as possible for all participants to complete outcomes assessments.
  - Can you offer ways to complete assessments *remotely*?
  - Can you offer outcomes assessments during *regular hours*?
- Analysis and Reporting** (Bar chart icon): While your analysis plan was developed, there are important ways to ensure that your findings are...

- Target audience: national and local study staff
- Toolkit contains:
  - Suggested strategies to support inclusion of women Veteran participants in each study phase
  - Tips and examples for developing inclusive study materials
  - Resources for research staff training
  - Key References
- On CIPHER website → Partners → WERP

**Recruitment strategies during protocol development**

As you develop your protocol, you are planning for all phases of your study. In the front end, during this phase, you have considered how many women Veterans eligible for the study are in the sampling frame, and what percentage of those women Veterans are considered from the outset the feasibility of meeting recruitment targets.

The subheadings below will guide you through the elements to consider as you plan.

**Sex/gender considerations as you develop the protocol for your study:** [\[edit\]](#)

- How will your eligibility criteria affect your ability to recruit women Veterans?
- What can be done to ensure inclusion of women of reproductive age?
- Have you established an *a priori* recruitment goal for women Veterans?
- Are there sampling strategies you can employ to reach your recruitment goal for women Veterans?
- Is there an opportunity to make an *a priori* plan to examine sex/gender differences in outcomes?
- What will be the burden of intervention delivery on the study participants? Are there ways to make it easier to participate?

**Eligibility Criteria** [\[edit\]](#)

- Keep in mind that women Veterans are, on average, 10 years younger than men. Exclusion criteria based on age may preferentially affect women Veterans.
- Consider comorbidities that are more common among women and men and how they will affect your ability to include them.
- Use caution when excluding participants based on reproductive age. It is often possible to include women of reproductive age with additional considerations, such as excluding women minorities, and individuals based on age unless there is a scientific or ethical reason not to include them."NIH Guide for Industry and Sponsor Information to Expedite Preclinical, Clinical, and Translational Research, 2017

**Recruitment goal for women Veterans** [\[edit\]](#)

- Review literature to identify any sex/gender-based differences in prevalence of condition under study.
- Calculate the population prevalence of the condition under study within the VA women Veteran population.
- Consider calculating and monitoring of participation to prevalence ratio (PPR)—a standard method of quantifying success with recruitment.

# Academic Detailing

Provide guidance to CSP:

- National study teams at study kickoff
- Local site study teams for multi-site CSP studies



# Examples of strategies recommended



Align recruitment activities to locations that women receive care within VA

ex: comprehensive women's health clinics



Reduce in-person burden for enrollment and intervention



Review eligibility criteria to avoid inadvertent exclusion of women



Include images and messages on recruitment materials that resonate with women

# Other WERP activities to date

- Developed training materials and guidance for delivering trainings
- Working with CSP to improve regular reporting of sex and gender for all participants
- Produced review of the literature on strategies to recruit women to trials

*“I feel like a lot of the barriers you come across with women are kind of at a level that **has to be addressed more by the study design...** it's just kind of hard to do much as a study site, unless it comes more from the top.”*

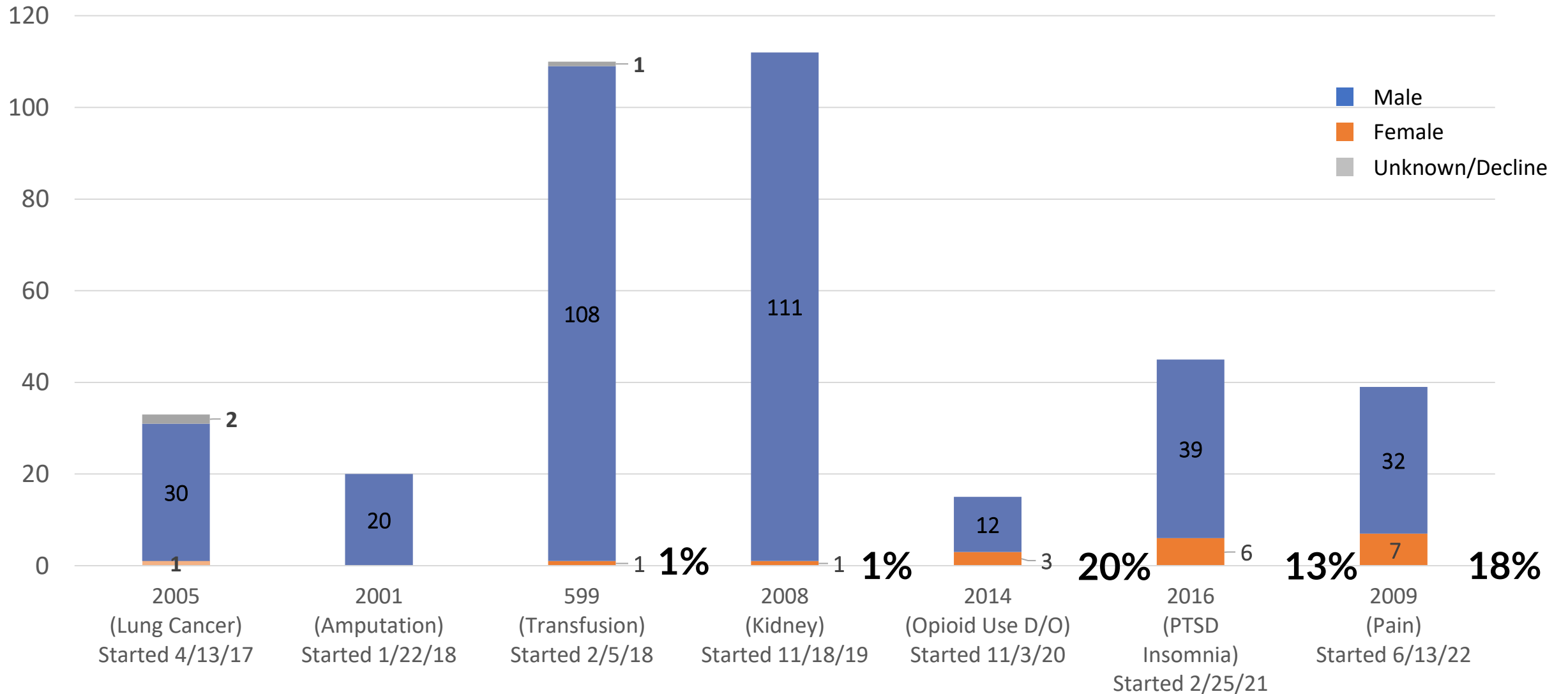
*– local study coordinator*

*“It's an important population and you definitely want to make sure that [women] are reflected in the research, and that **when we do find results it's going be applicable to them too...**When you have the recruitment deadlines it can make it hard to target that [recruitment] effort, because you're just so desperate to get anyone. You wish you could spend more time doing it...”*

*-local study coordinator*

# Preliminary CSP Recruitment by Gender Across Studies at WERP study sites\*

## December 2021 - December 2022



\* Data may be incomplete due to study turnover or unreported to WERP

# Lessons Learned



Changes in recruitment priorities needs leadership support

Start planning for inclusion of women with study design

Track participation of women throughout a study at each site

Engage with local women's health experts

# Acknowledgements

- CSP #N0011
- Susan Frayne, co-PI
- Susan Alton-Dailey, Durham WERP program coordinator
- Alyssa Pomernacki, Palo Alto WERP program coordinator
- Diane Carney, PBRN program coordinator, Palo Alto
  
- Dr. Grant Huang
- Marcus Johnson
- CSP study teams

# Resources

- Goldstein, K.M., Kung, L.C.Y., Alton Dailey, S. *et al.* Strategies for enhancing the representation of women in clinical trials: an evidence map. *Syst Rev* **13**, 2 (2024).

<https://doi.org/10.1186/s13643-023-02408-w>

- WERP Toolkit - VA Phenomics Library

[https://cipherwiki.va.gov/phenotype/index.php?title=WERP\\_Toolkit](https://cipherwiki.va.gov/phenotype/index.php?title=WERP_Toolkit)