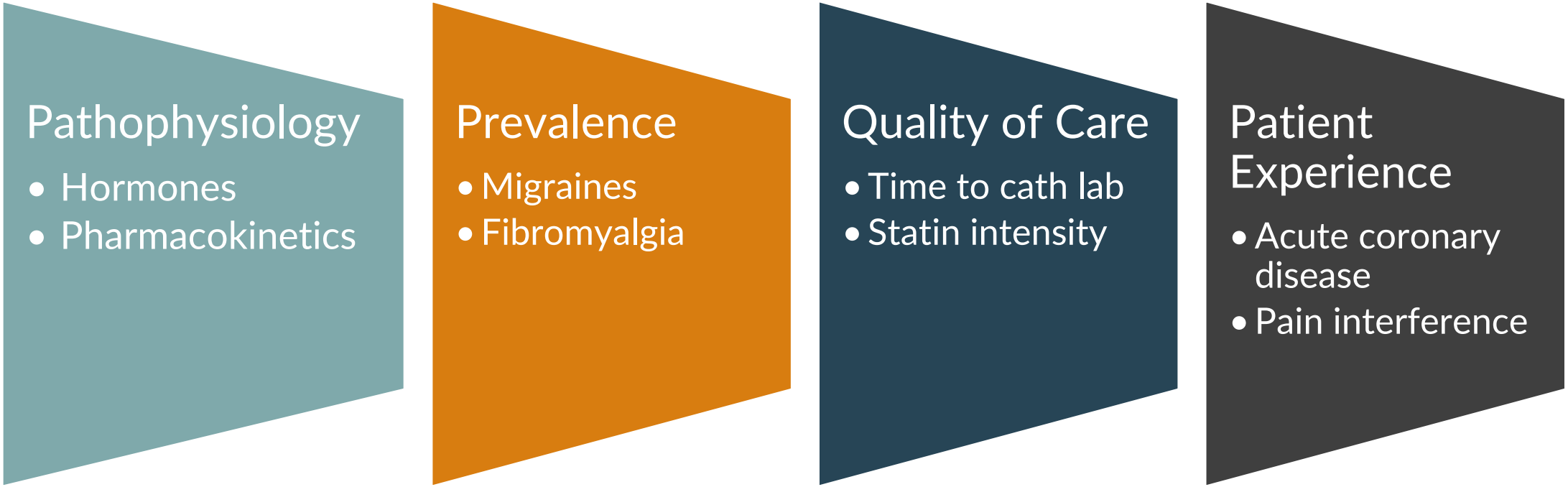
Recruiting women across the life of a study:
A VA Cooperative Studies Program Process Improvement Project

Karen Goldstein, MD, MSPH
Co-PI, Women's Enhanced Recruitment Process
Designated Women's Health Provider, Durham VA Health Care System
Investigator, Durham ADAPT

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

Research conducted predominantly among men can lack generalizability to women



What are the challenges to recruiting women Veterans into trials?

Women-specific providers & clinics

10 years younger on average

More care in the community

10% total VA population

Caregiving social support

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

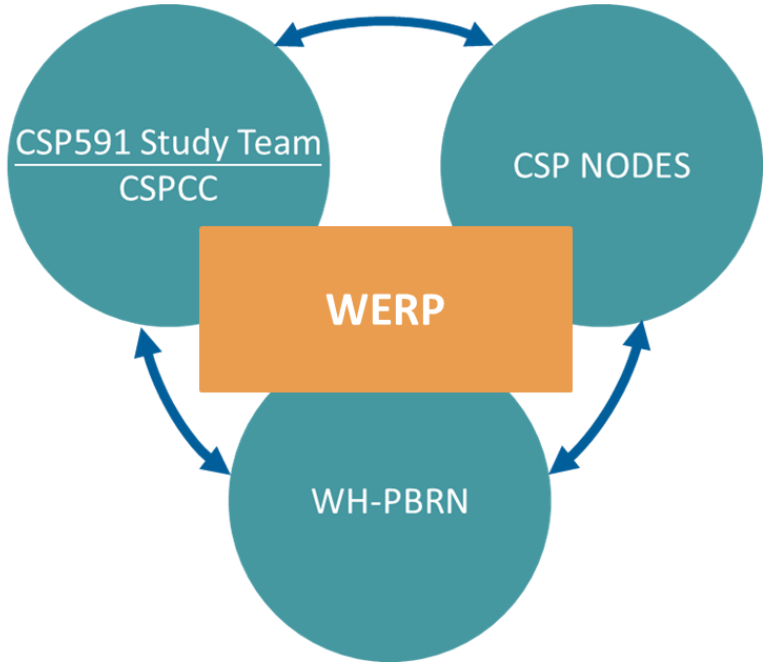
(PIs: Schnurr, Chard, Ruzek) 2016-2018

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

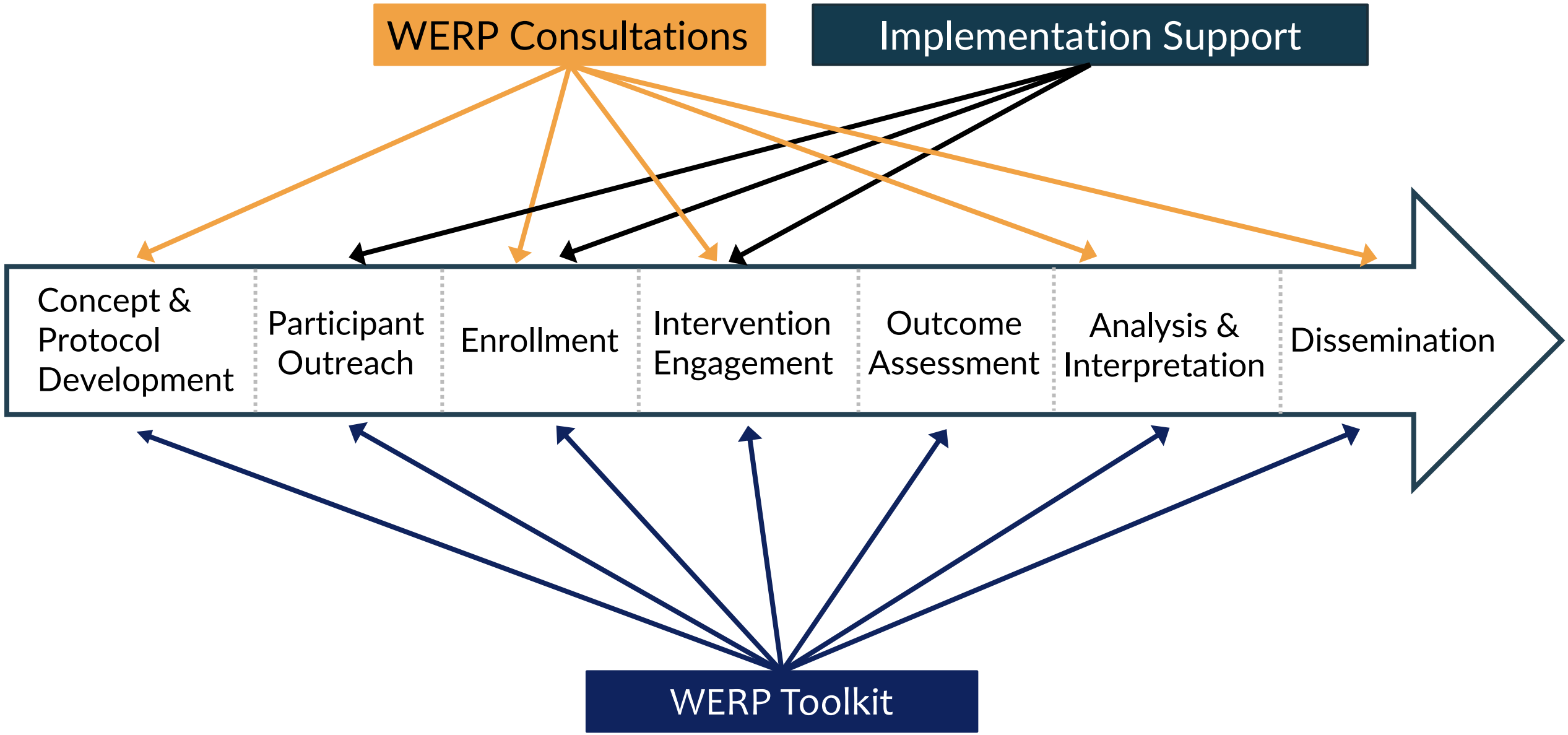
Motivators of participation

- 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 the majority of 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)

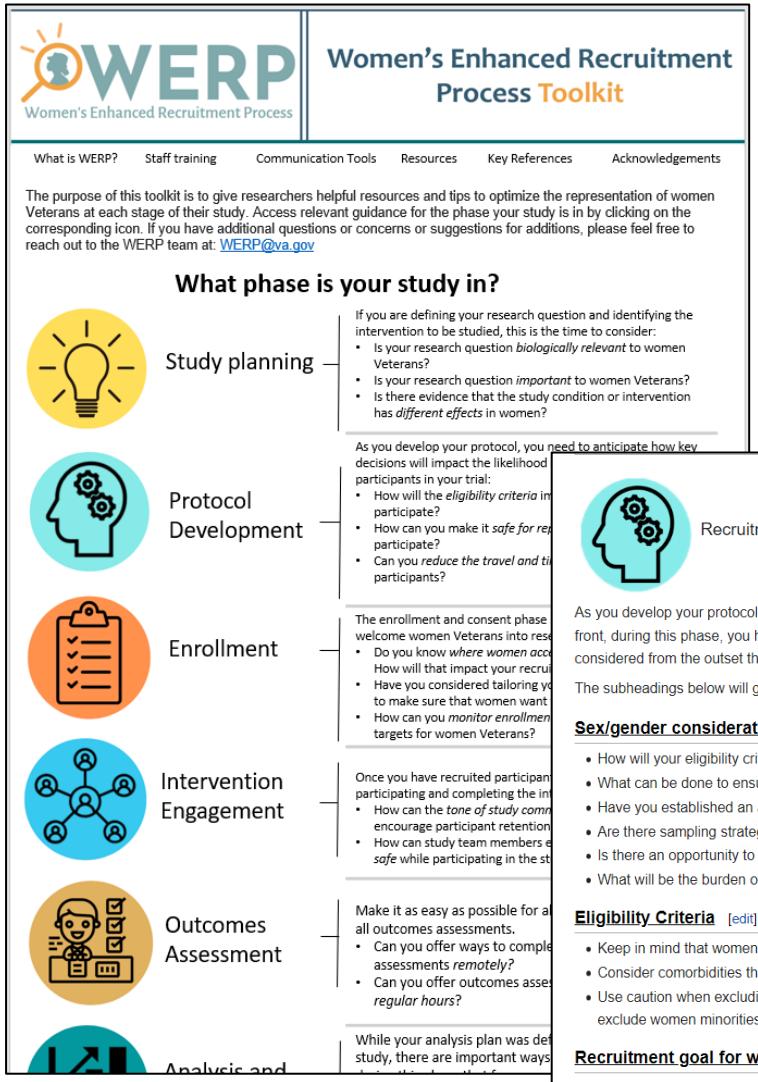
Partnered engagement

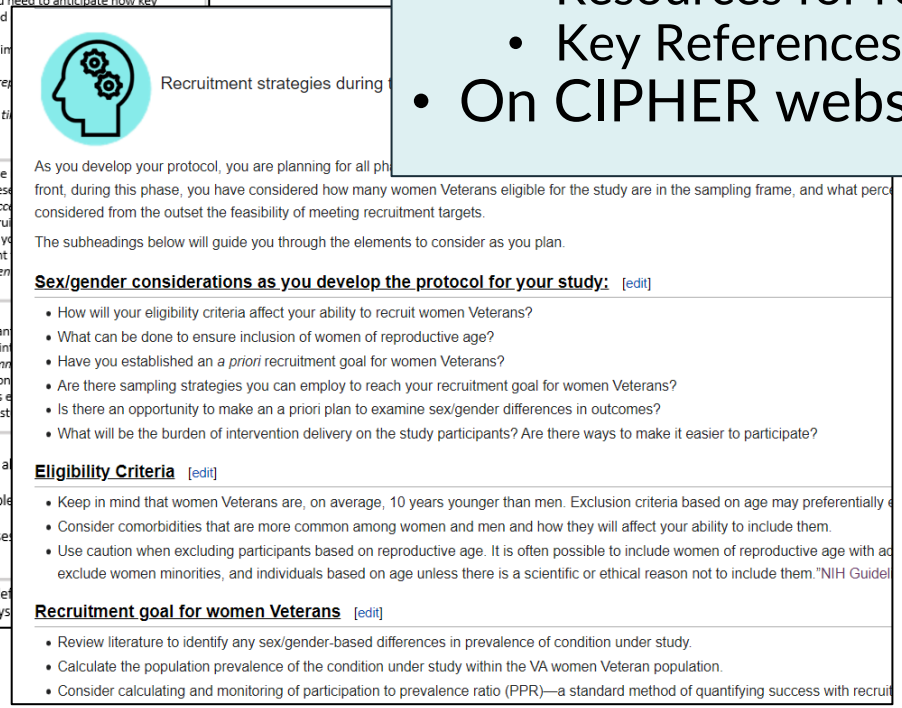
- Identify relevant local stakeholders

Site level engagement

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

WERP Toolkit





- 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

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."*

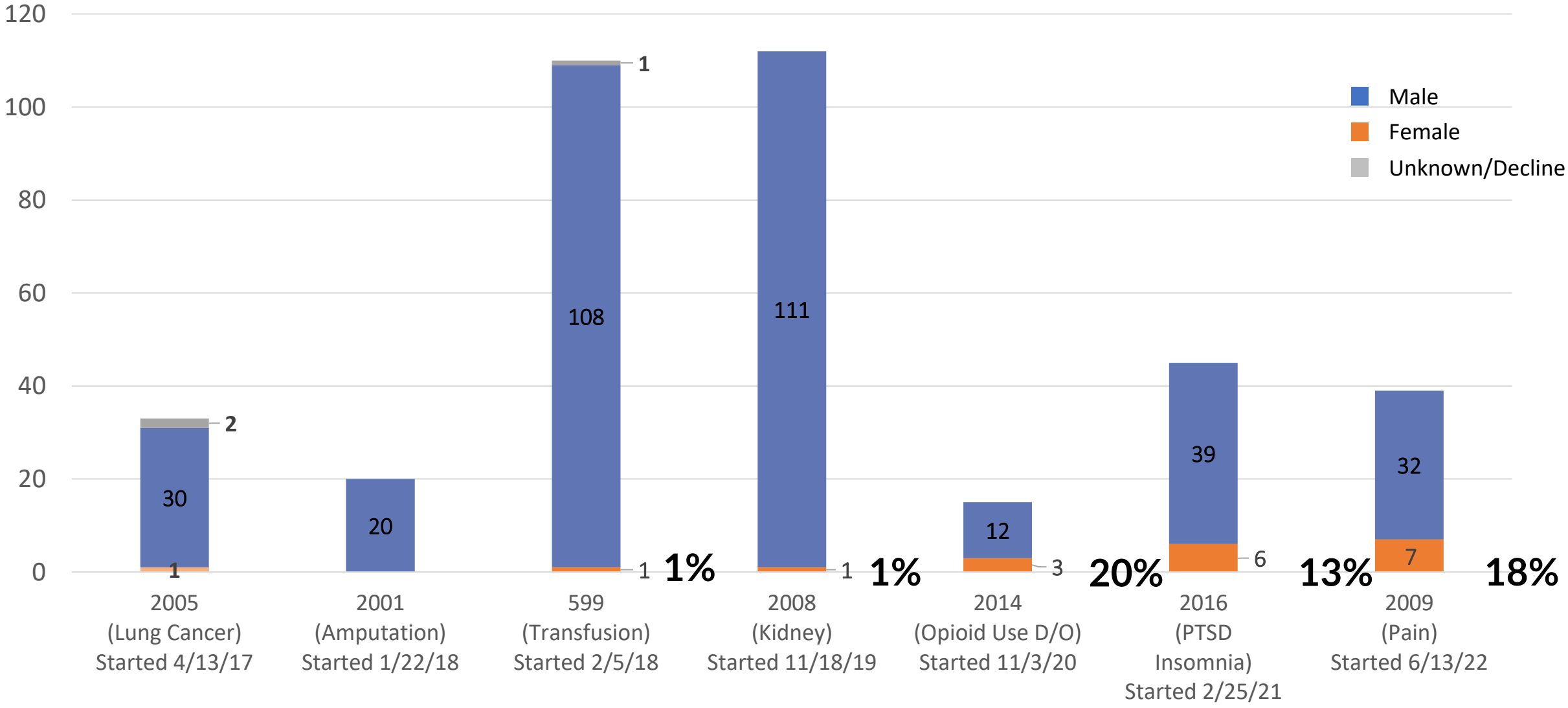
– local study coordinator

"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

WERP
Women's Enhanced Recruitment Process

- 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