CALL FOR SUBMISSIONS

To a Special Supplement to Women's Health Issues

Topic: Examining Sex/Gender Differences in VA Clinical and Health Services Research

Underrepresentation of women in clinical research studies can impair efforts to inform patients, providers, and policy makers. To address this concern, rules requiring the inclusion of women in studies were implemented to generate study results that would provide evidence of efficacy applicable to this important subgroup of patients. The U.S. Government Accounting Office (GAO) has recently reported results of a review of NIH-funded clinical trials demonstrating that, while most studies have shifted to accommodate this requirement, very few go on to publish results by sex/gender. As it has been over two decades since the institution of this policy, the implications for interpretation and generalizability have likely become more prominent. Several highly publicized consequences of the lack of such reporting (e.g., cardiovascular diagnosis and treatment) further highlight the importance of the need to understand sex/gender differences in clinical research studies.

Women Veterans are the fastest growing segment of new users in the VA healthcare system. The Department of Veterans Affairs sponsors a large number of clinical and health services studies that include this subpopulation. Yet, prior reviews have identified few published VA trials reporting findings by sex/gender to provide definitive results specific to women Veterans. Furthermore, the relatively smaller number of women Veterans at any one location within the VA makes recruitment of sufficient numbers of women Veterans an additional challenge in study design. The goal of this supplement is to stimulate interest and disseminate new VA research findings related to sex/gender differences and/or methodological considerations for prospective VA studies aiming to include enough women to enable the conduct of sex- and gender-based analyses.

Submissions to the *Women's Health Issues* supplement on **Examining Sex/Gender Differences in VA Clinical and Health Services Research** should provide insights for clinicians, educators, researchers, and policymakers, as well as patients and their families, regarding when and how research results may vary by sex and/or gender of Veteran participants and, in turn, how those differences (or lack thereof) relate to care for Veterans and the nation. The supplement is being sponsored by the Cooperative Studies Program (CSP), a division within the VA Office of Research and Development.

DEADLINE EXTENDED: All manuscripts must be submitted by **August 31, 2018 at 5pm Pacific Time.**

We seek manuscripts reporting on methodological considerations and/or analyses of sex and/or gender differences from VA sponsored clinical studies. Particular emphasis is placed on clinical trials (using the International Committee of Medical Journal Editors/World Health Organization definition of "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes") and other primary data on the following topics, though others may also be considered:

- Medical condition treatments
- Mental health, including substance use disorder, treatments
- Health behavior change
- Pharmaceuticals
- Rehabilitation
- Trial methodology related to the study of sex and gender differences (e.g., recruitment strategies)

Well-conducted studies that analyze results by sex or gender and do not find differences are also welcome. Because women Veterans represent a minority of VA Healthcare System users, we acknowledge that many studies will not be powered to allow for subgroup analyses. We encourage the publication of appropriate exploratory analyses for studies that have sufficient numbers of women to allow for these. We will not consider administrative data analyses unless a particular case can demonstrate applicability to outcomes research for women. Please consider reviewing the resource listed at the bottom of this call for submissions for additional

information about appropriate methodology for sex- and gender-based analyses. Investigators from all branches of research are welcome; submitted research does not need to have been conducted within the CSP.

All submissions will be peer reviewed to assess their rigor and contribution to the scientific literature and to the contribution of the body of work on sex and gender differences in Veteran health and healthcare delivery.

Submissions should be no longer than 4,000 words, with frugal use of tables and figures and a structured abstract of no more than 250 words. All articles must include an "Implications for Practice and/or Policy" section. (See instructions for authors on the *Women's Health Issues* website, http://www.whijournal.com/content/authorinfo, for further details about submission requirements.)

After initial screening, selected articles will undergo *Women's Health Issues* editorial and peer review process. All submissions for this supplement should be submitted through the *Women's Health Issues* standard on-line submission process but will need to be designated for this special supplement.

To submit your manuscript, go to https://www.evise.com/profile/#/WHI/login and either log in or create an account. For the Article Type, select "VA Clinical Research Outcomes" from the drop-down menu. If you have any questions about WHI or the submission process, contact managing editor Liz Borkowski at whieditor@gwu.edu.

Resource on gender/sex-based analyses:

https://orwh.od.nih.gov/research/sex-gender/methods-and-techniques

Planning committee

Karen M. Goldstein, MD, MSPH Durham VA Health System, Durham Duke University Karen.Goldstein@va.gov

Elizabeth M. Yano, PhD, MSPH VA Greater Los Angeles Healthcare System UCLA Fielding School of Public Health Elizabeth.yano@va.gov

Ruth Klap, PhD
VA Greater Los Angeles Healthcare System
Ruth.Klap@va.gov

Grant Huang, MPH, PhD
Cooperative Studies Program Office of Research & Development, VA Central Office,
Grant.huang@va.gov

Lori Bastian, MD, MPH VA Connecticut Healthcare System, West Haven Yale University Lori.bastian@va.gov