



NIH Office of Research on Women's Health (ORWH)

# **CONCEPT CLEARANCE: ORWH U3 Research Program Expansion to Emphasize Understudied Conditions Relevant to the Health of Women**



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# Purpose: Expand Research on Conditions Historically Understudied That Affect Women

- U3 supplement program is an ORWH Signature Program, focusing on populations of women who are Understudied, Underrepresented and Underreported
- Expand ORWH support for conditions that affect women that remain Understudied
- Align with NIH Strategic Plan Goal 1: Advancing rigorous research that is relevant to the health of women



Objective 1.5 - Expand research on female-specific conditions and diseases, including reproductive stages, and maternal and gynecologic health



# Background

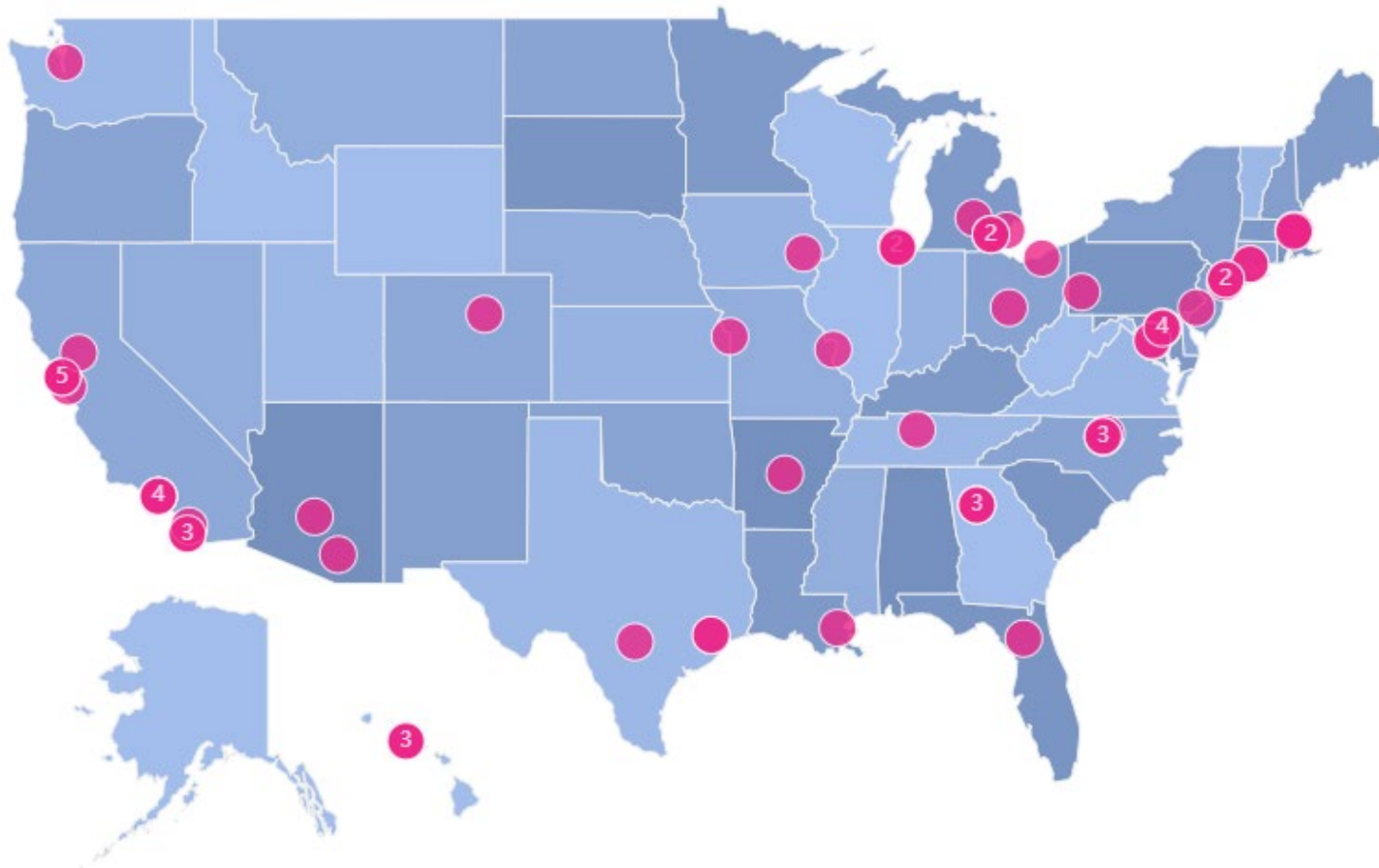


- The **U3 framework** was developed by ORWH to draw attention to the lack of research on persistent disparities in women’s health and healthcare and to support research and evidenced-based programs to address this gap.
- The **U3 supplement** program highlights the intersectional experiences of women, exploring the ways in which socially determined categories – like race and gender – overlap and interact to create different outcomes for individuals and communities.
- The **U3 program** has supported research on many understudied conditions

Notice of Special Interest (NOSI): Research on the Health of Women of Understudied, Underrepresented and Underreported (U3) Populations (Admin Supp Clinical Trial Optional)  
Notice Number: NOT-OD-22-031



# Current and Previous ORWH U3 Projects



- FY2017-2021
- 71 projects have been funded
- 16 ICs (HD, MD, GM, AG, HL, AR, AI, DA, ES, MH, DK, CA, NR, AT, DC, TR)
- For FY21, 12 applications funded across 9 ICs

<https://orwh-stage.cit.nih.gov/womens-health-research/interdisciplinary-research/u3-interdisciplinary-research/projects>



# Chronic debilitating conditions

## Women's Health Conference (WHC)



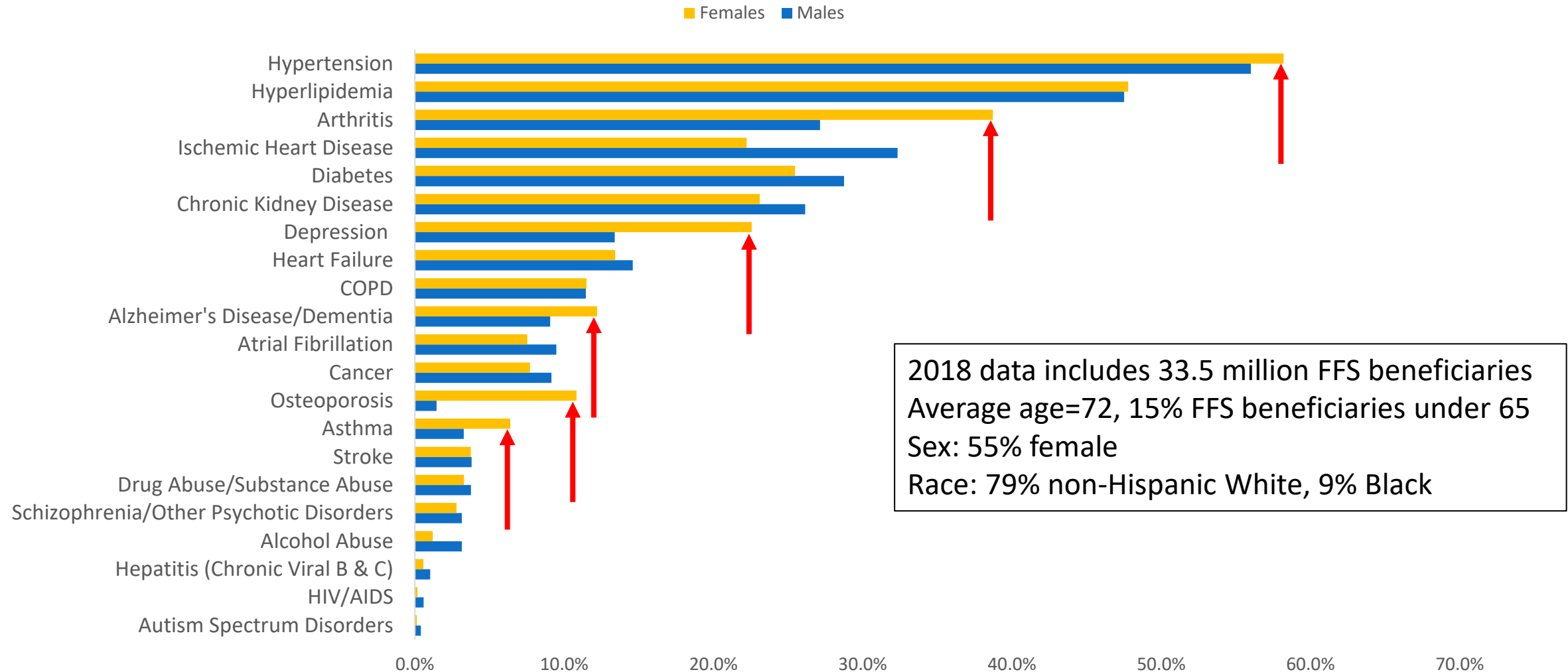
Advancing NIH Research on the Health of Women: A 2021 Conference

In response to a congressional request to address NIH efforts related to women's health research, ORWH, on behalf of the ACRWH, hosted an event on October 20, 2021, titled "Advancing NIH Research on the Health of Women: A 2021 Conference."

- Key Topics included the following:
  - (1) rising maternal morbidity and mortality rates;
  - (2) increasing rates of chronic debilitating conditions in women; and
  - (3) stagnant cervical cancer survival rates.

# Chronic conditions that disproportionately affect women

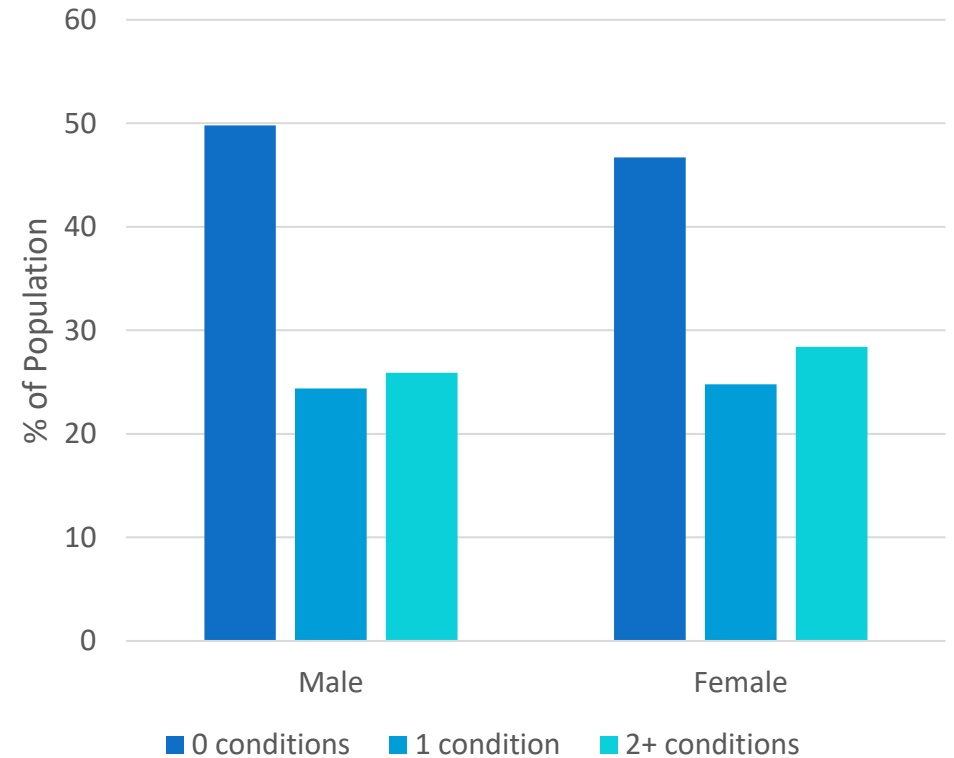
Prevalence of Chronic Conditions among Fee-for-Service Beneficiaries by Sex: 2018



2018 data includes 33.5 million FFS beneficiaries  
 Average age=72, 15% FFS beneficiaries under 65  
 Sex: 55% female  
 Race: 79% non-Hispanic White, 9% Black

# Multimorbidity

- Multimorbidity is the co-occurrence of two or more chronic diseases in one individual
- Multimorbidity is more common in women
  - Not just “more symptoms”, but also “atypical” symptoms
  - Worse responses to first-line treatments
- Interactions between conditions are poorly understood in women

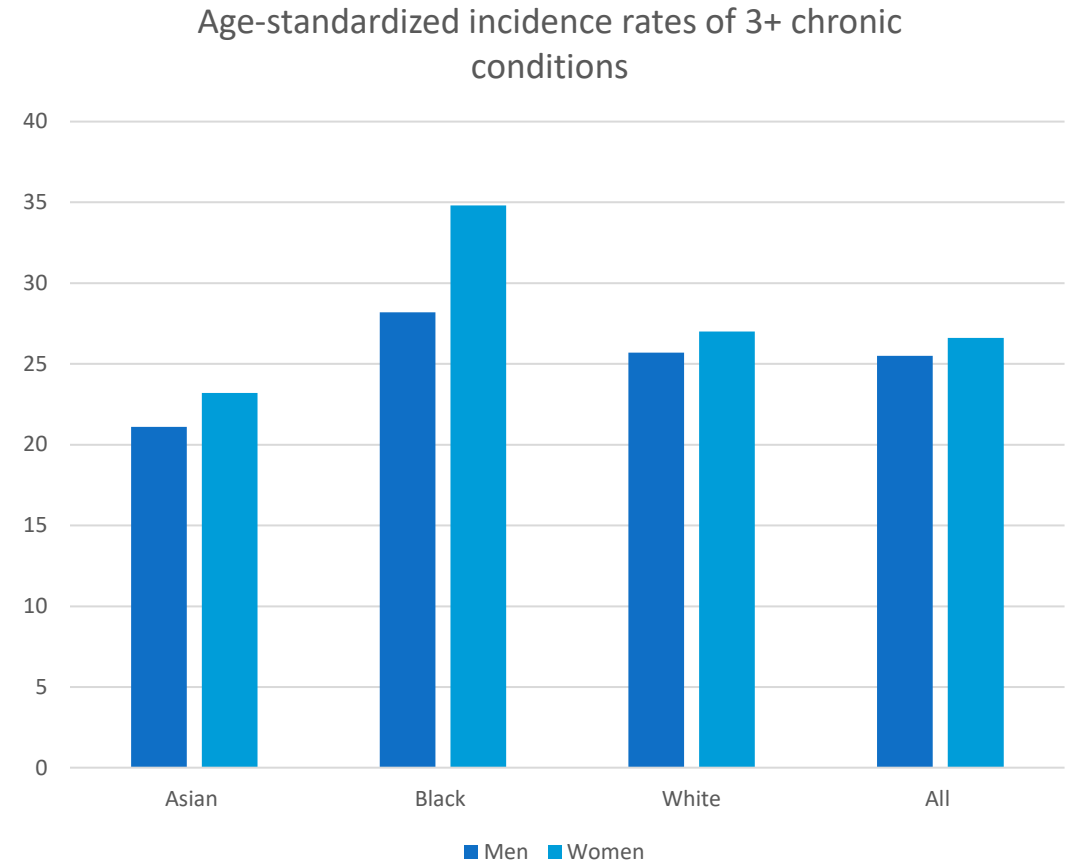


Boersma P, Black LI, Ward BW. Prevalence of Multiple Chronic Conditions Among US Adults, 2018. *Prev Chronic Dis* 2020;17:200130

Dana E. King, Jun Xiang, Courtney S. Pilkerton. *JABFM* 2018, 31 (4) 503-513

# Race and multimorbidity

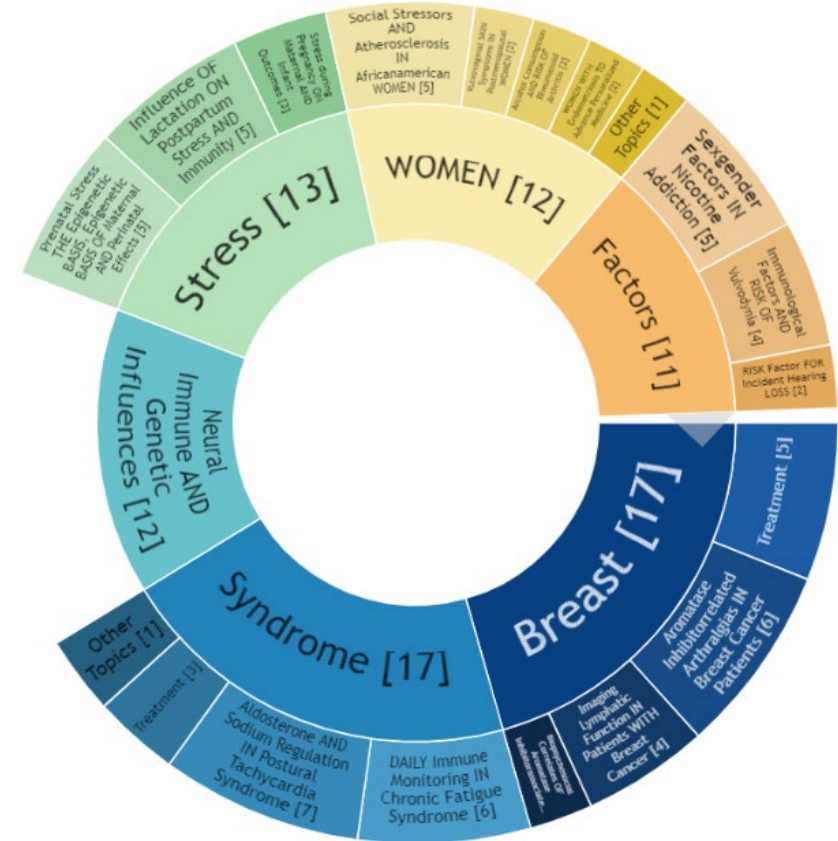
- Data disaggregated by race, ethnicity and gender is infrequently reported
- Incidence of multimorbidity varies by race
- Influence of additional social factors (e.g., income, rurality, education) is understudied





# Chronic Debilitating Conditions in Women: Current NIH Activities

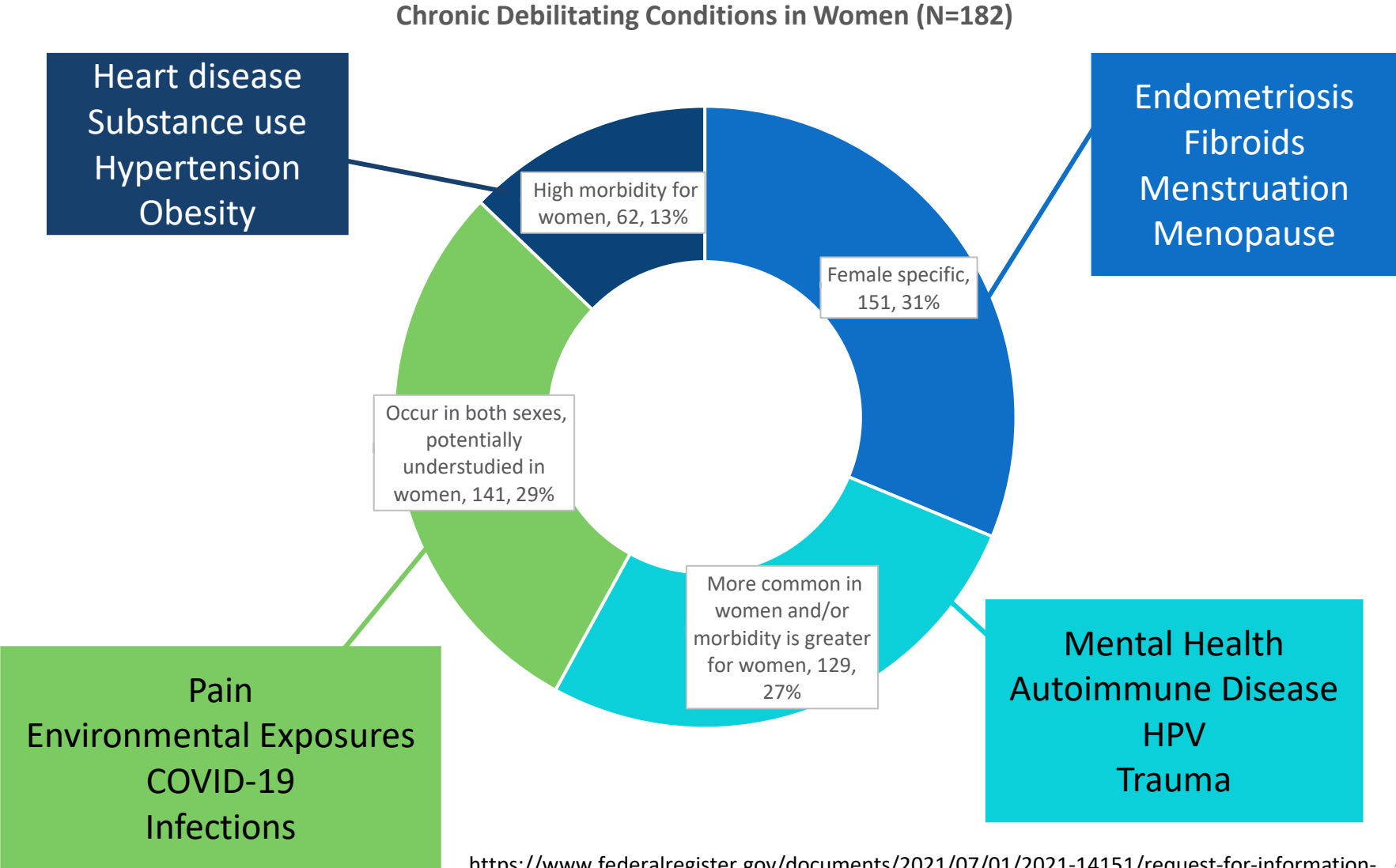
- Many ICs support research on chronic conditions in women
- Support for conditions varies markedly across conditions
- Assessment of projects centered around the needs of women was limited
- Few projects on multimorbidity specific to women were identified



Fiscal Years: All  
 Agencies: NIH  
 Text Search: chronic debilitating disease women [AND]  
 Project Search Results (138)  
 Date of Access 8/1/2021

<https://federalreporter.nih.gov/>

# Public Comments on Chronic Debilitating Conditions in Women



<https://www.federalregister.gov/documents/2021/07/01/2021-14151/request-for-information-inviting-comments-to-inform-the-womens-health-consensus-conference-whcc>



# ACRWH Identified Opportunities in Chronic Debilitating Conditions Research

## Opportunities

- Develop definitions and a framework specific to chronic debilitating diseases in women
- **Align clinical research with the needs of women (e.g., study objectives and endpoints)**
- **Increase research activity on female-specific diseases, menopause and aging**
- Create clinical research networks, specific to research on chronic diseases in women
- **Encourage research through the development of funding opportunities around multimorbidity in women**

# U3 Supplement Program Supports Understudied Conditions

- **Menopause**

- FY21: [Arsenic Metabolism, Menopause and Diabetes in the Strong Heart Study](#)
- FY17: [MsFLASH \(Finding Lasting Answers for Symptoms and Health\): Living a Healthy Menopause](#)
- FY17: [Study of Women's Health Across the Nation \(SWAN\) V: UCLA Site](#)

- **Trauma and Mental Health**

- FY19: [Offering Women PrEP with Education, Shared Decision-Making and Trauma-Informed Care: The OPENS Trial](#)
- FY 19: [NYU Center for the Study of Asian American Health \(CSAAH\)](#)
- FY18: [Development of Co-Morbid PTSD and Chronic Pain Among Inner-City Women](#)
- FY18: [The Role of Cultural Risk and Resiliency Factors and the Built Neighborhood Environment on Maternal Depressive Symptoms in Pregnant Mexican-American Women](#)
- FY18: [Sexual Trauma and HIV Susceptibility Among Women: The Role of Stress and Genital Immunity](#)
- FY17: [Effectiveness of a Safety Intervention for Dating Violence, or "College Safety Study"](#)
- FY17: [Ethnic Differences in Outcomes and Treatment Barriers after Sexual Assault](#)

- **Musculoskeletal disease**

- FY21: [Biobehavioral basis of knee osteoarthritis pain](#)
- FY21: [Stress, epigenetic aging and peripartum health risks among Black women](#)

- **Multimorbidity**

- FY21: [Hopkins Center to Promote resilience in persons and families living with multiple chronic conditions \(the PROMOTE Center\)](#)
- FY20: [The Role of 27-hydroxycholesterol in Breast Cancer: A Population-Based Multiethnic Study](#)

- **Female-specific conditions**

- FY20: [MD Anderson Gynecologic SPORE \(Specialized Programs of Research Excellence\) for Uterine Cancers](#)
- FY19: [Environmental Risk Factors for Uterine Fibroids: A Prospective Ultrasound Study](#)

- **Inflammation and Immunity**

- FY21: [COBRE-DIABETES](#)
- FY19: [Inflammation, Vaginal Microbiota, and STI/HIV Risk](#)

# Rationale: Emphasize Research on Understudied Conditions Relevant to the Health of Women

- Develop a new funding opportunity to support research on Understudied conditions that affect women
- Specific conditions of interest include the following:
  - Menopause
  - Musculoskeletal disease
  - Inflammation and immunity
  - Mental health and trauma
  - Female-specific conditions
- Encourage participation of diverse patients (including U3 populations)
- Supporting research in the populations with the highest burdens of Understudied conditions
- Plan to partner with interested ICs



**Thank you!**

**Questions or Comments?**

