



FEMALE-SPECIFIC CHRONIC CONDITIONS

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

61st ACRWH Meeting: October 8, 2024



CONCEPT CLEARANCE

Concept Clearance: New Funding Opportunity

Title: Advancing Our Understanding of Female-Specific and Gynecologic Chronic Conditions

Objective/Purpose: To invite research projects that improve prevention, diagnosis, early detection and treatment interventions for female-specific and gynecologic chronic conditions

Funds Available and Anticipated Number of Awards: Contingent upon NIH appropriations for meritorious awards

Award Project Period: 5 years

Committee Action: Vote for approval of “Advancing Our Understanding of Female-Specific and Gynecologic Chronic Conditions”

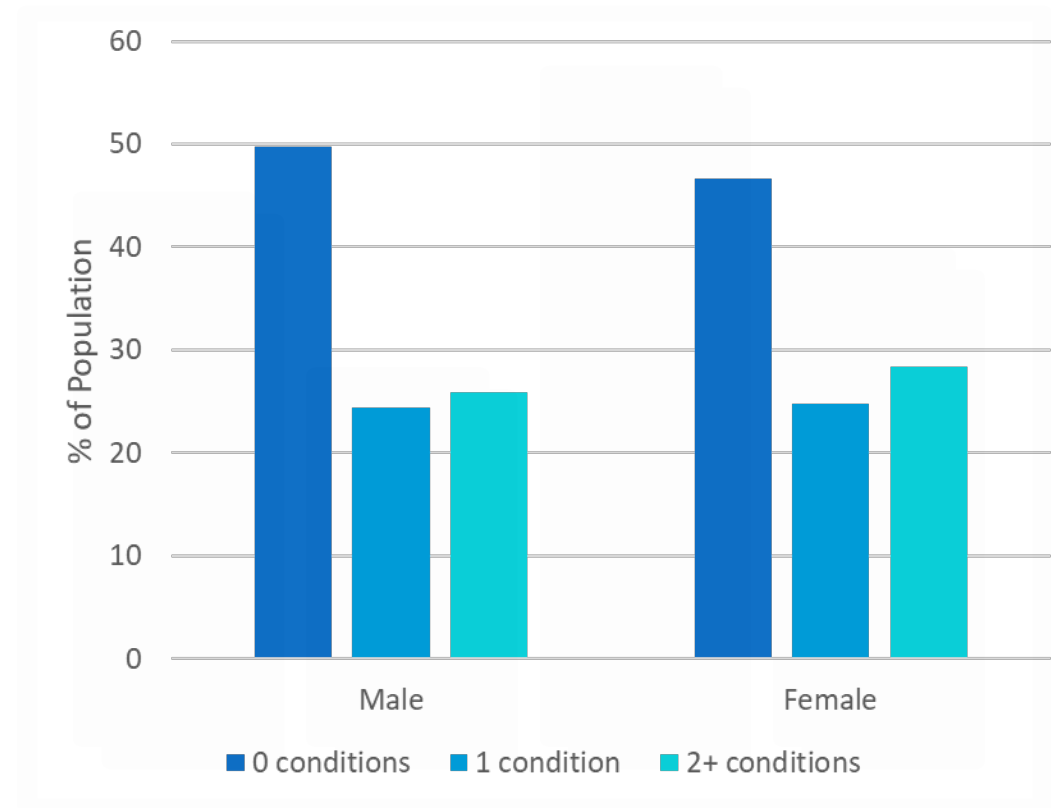
PUBLIC INTEREST IN CHRONIC DEBILITATING CONDITIONS IN WOMEN

FY21 House and Senate “Significant Items”

ORWH held the **Advancing NIH Research on the Health of Women: A 2021 Conference** on October 20, 2021, as part of the ACRWH Meeting to evaluate research and identify priorities to advance the study of women’s health

House: <https://www.congress.gov/116/crpt/hrpt450/CRPT-116hrpt450.pdf> (page 149)
Senate: <https://www.appropriations.senate.gov/imo/media/doc/LHHSRept.pdf> (page 123)

Rising Rates of Chronic Debilitating Conditions in Women



Condition Type	Condition (FY 2020 spending/2019 DALY) <i>*Per MCS-WH reporting guidance, the following RCDC disease categories are particularly relevant to women’s health</i>							
Female specific	Cancers of the female reproductive tract* (\$372)	Dys-menorrhea/ Abnormal menses	Fibroids* (\$281)	Endometriosis* and Adenomyosis (\$260)	Infertility*/ Early Pregnancy Loss (\$6108)	Polycystic Ovarian Syndrome	Pelvic floor disorders, Organ prolapse	Menopausal symptoms Pelvic Inflammatory Disease* Vulvodynia/Chronic gynecologic pain disorders – pelvic and vulvar
More common in women and/or morbidity is greater for women	Depressive Disorders (\$353)	Migraine/ Headache (\$27)	Breast cancer* (\$568)	Autoimmune diseases (*including RA) •SLE* •Sjögren’s Syndrome* Scleroderma*	Rheumatoid Arthritis* (\$463)	Multiple Sclerosis (\$866)	Sexually transmitted infections	Temporomandibular Muscle/Joint Disorder (TMJD)* Chronic Fatigue Syndrome* Fibromyalgia* Candidiasis Post-traumatic stress Irritable Bowel syndrome Interstitial Cystitis* HPV infection* Osteoporosis* Eating Disorders
Occur in both sexes/ Potentially understudied in women	Unintentional Injuries (including violence against women*)	Alzheimer’s /Dementia (\$2156)	Osteoarthritis (\$85)	Endocrine, metabolic, blood, and immune disorders	Recurrent UTI/ Interstitial Nephritis	HIV (\$25,936)	Exogenous hormone use Neuropathy Overactive bladder/Incontinence Chronic pain including chronic pelvic pain	
High morbidity for women	Heart Disease (\$472)	Lower back pain (\$17)	COPD (\$449)	Drug Use Disorders (\$967)	Stroke (\$210)	Diabetes (\$574)	Obesity/metabolic disease Influenza and pneumonia	

Condition Type	<h1>Spending/2019 DALY</h1> <p>of RCD C disease categories are particularly relevant to women's health</p>							
Female specific	Cancers of the Female Reproductive tract \$372			Endometriosis* and Adenomyosis (\$260)	Infertility*/ Early Pregnancy Loss (\$6108)	Polycystic Ovarian Syndrome	Sexually transmitted infections \$10,558	
More common in women and/or morbidity is greater for women	Depressive Disorders (\$353)	Migraine/ Headache (\$27)	Breast cancer* (\$568)	Autoimmune diseases (*including RA) •SLE* •Sjögren's Syndrome* Scleroderma*	Rheumatoid Arthritis* (\$463)	Multiple Sclerosis	Sexually transmitted infections	Temporomandibular Muscle/Joint Disorder (TMJD)* Chronic Fatigue Syndrome* Fibromyalgia* Candidiasis Post-traumatic stress Irritable Bowel syndrome Interstitial Cystitis* HPV infection* Borositis* Disorders
Occur in both sexes/ Potentially understudied in women	Heart Disease \$472			Endocrine, metabolic, blood, and immune disorders	Recurrent UTI/ Interstitial Nephritis	HIV \$25,936		use Overactive bladder/Incontinence Chronic pain including chronic pelvic pain
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CHRONIC CONDITIONS IN WOMEN ARE UNDERSTUDIED

Chronic conditions in women: the development of a National Institutes of health framework

[Sarah M. Temkin](#) , [Elizabeth Barr](#), [Holly Moore](#), [Juliane P. Caviston](#), [Judith G. Regensteiner](#) & [Janine A. Clayton](#)

BMC Women's Health 23, Article number: 162 (2023) | [Cite this article](#)

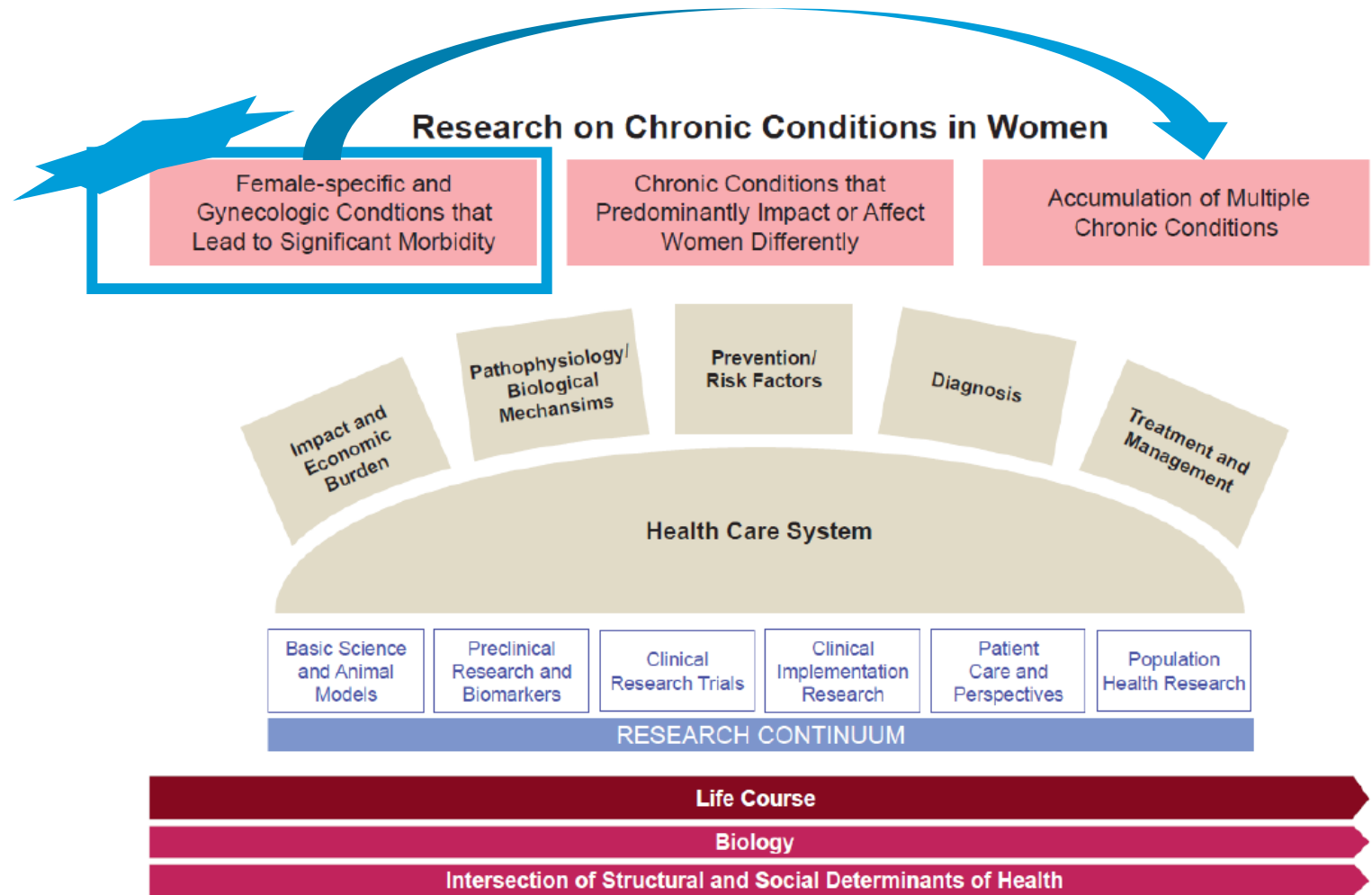
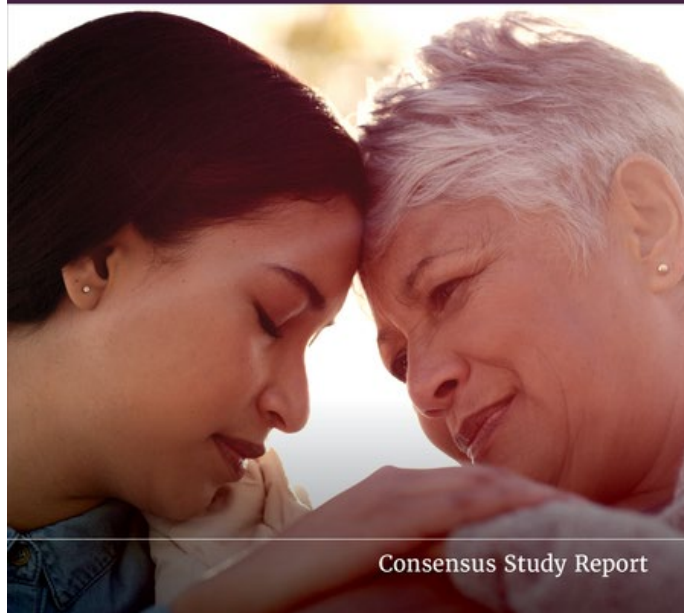
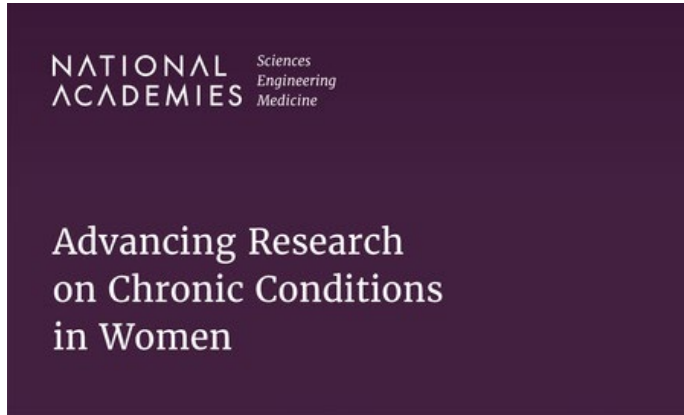
6244 Accesses | 7 Citations | 184 Altmetric | [Metrics](#)

Abstract

Rising rates of chronic conditions were cited as one of the key public health concerns in the Fiscal Year (FY) 2021 U.S. Senate and House of Representatives appropriations bills, where a review of current National Institutes of Health (NIH) portfolios relevant to research on women's health was requested. Chronic conditions were last defined by the US Department of Health and Human Services (HHS) in 2010. However, existing definitions of chronic conditions do not incorporate sex or gender considerations. Sex and gender influence health, yet significant knowledge gaps exist in the evidence-base for prevention, diagnosis, and treatment of chronic diseases amongst women. The presentation, prevalence, and long-term effects of chronic conditions and multimorbidity differs in women from men. A clinical framework was developed to adequately assess the NIH investment in research related to chronic conditions in women. The public health needs and NIH investment related to conditions included in the framework were measured. By available measures, research within the NIH has not mapped to the burden of chronic conditions among women. Clinical research questions and endpoints centered around women can be developed and implemented; clinical trials networks with expanded or extended eligibility criteria can be created; and data science could be used to extrapolate the effects of overlapping or multiple morbidities on the health of women. Aligning NIH research priorities to address the specific needs of women with chronic diseases is critical to addressing women's health needs from a life course perspective.

- Multiple opportunities to align the NIH research agenda with the health needs of women.
- Integration of sex as a biological variable across the life course, including during key hormonal transitions.
- Understand how social determinants of health influence the health of women differently.

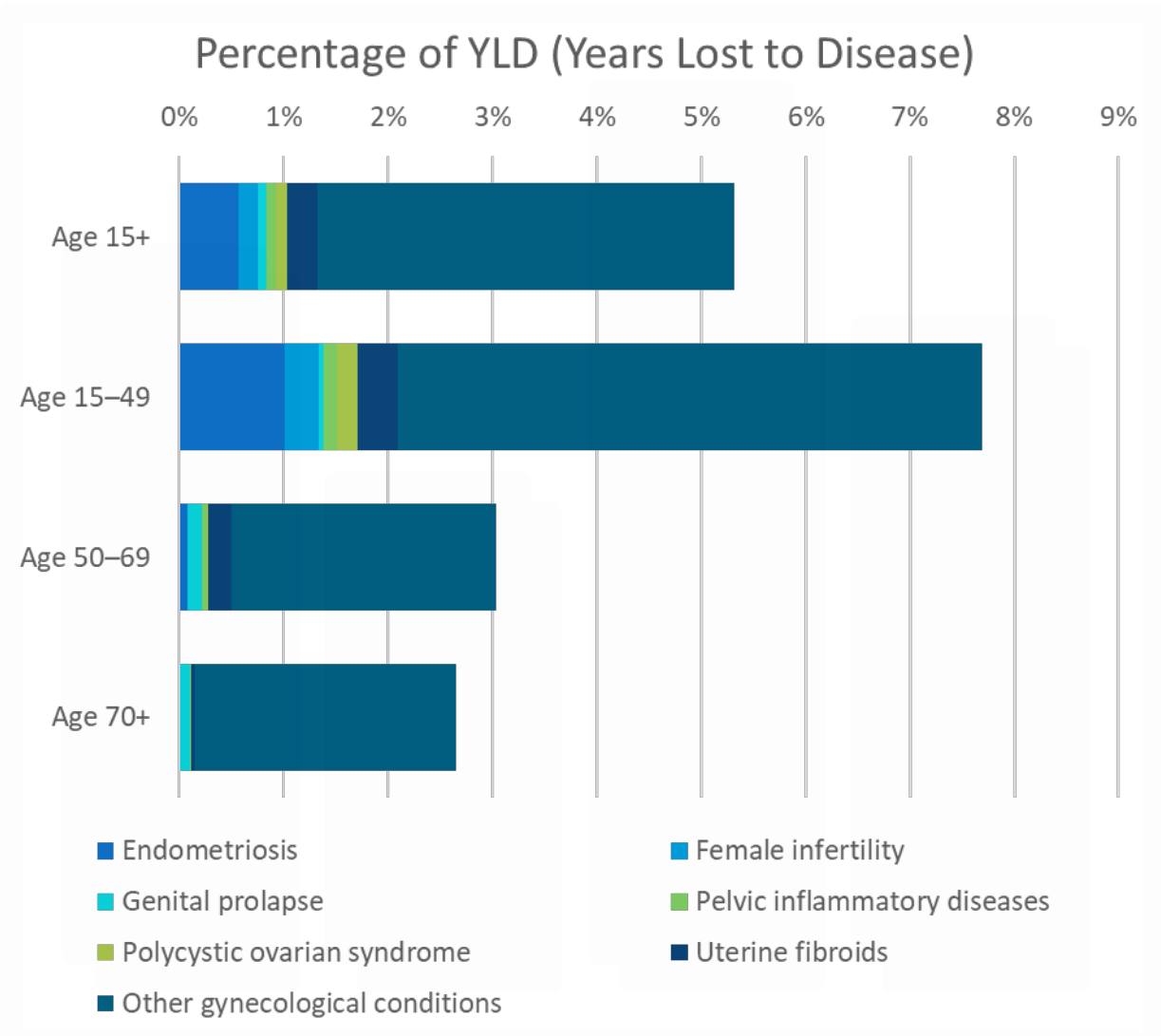
THE NASEM'S CONCEPTUAL FRAMEWORK FOR RESEARCH ON CHRONIC CONDITIONS IN WOMEN



Partner ICOs: NIA, NIAID, NIAMS, NCI, NICHD, NHLBI, OAR

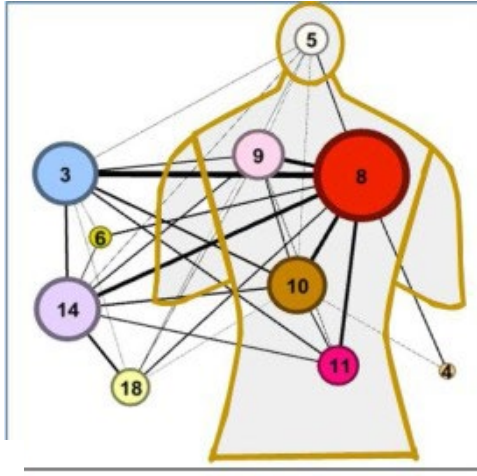
FEMALE-SPECIFIC AND GYNECOLOGIC CHRONIC CONDITIONS

- Female-specific and gynecologic conditions cause significant morbidity
- Patients are often reluctant to discuss symptoms related to the female reproductive tract
- Delays to diagnosis are common
- Significant health disparities
- Contribution to multimorbidity is rarely measured

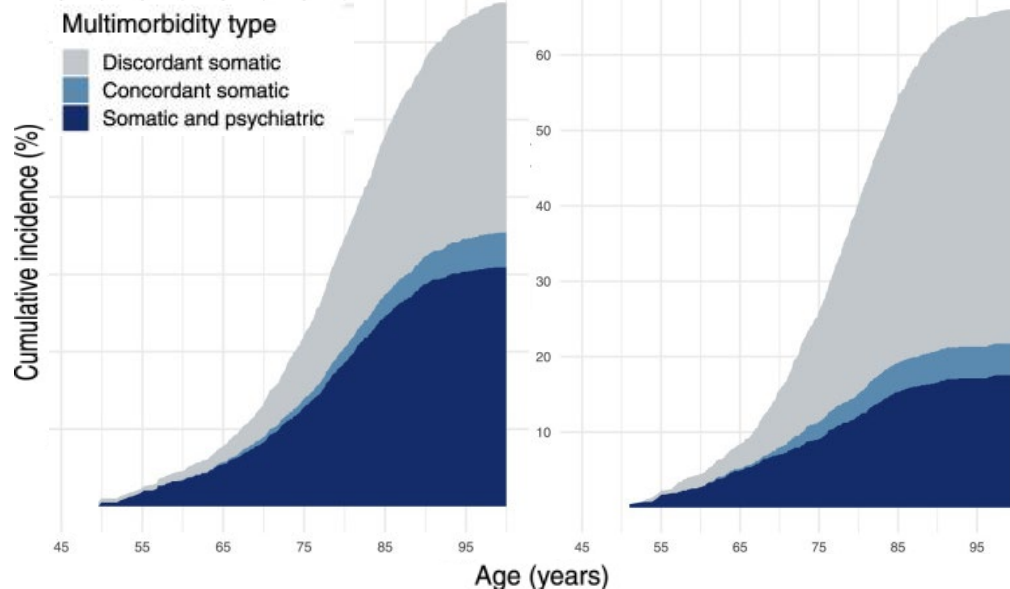
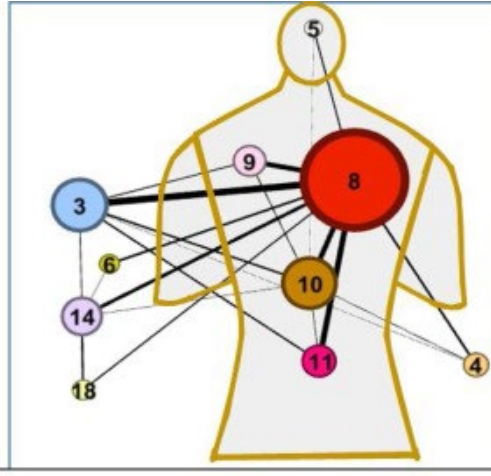


MULTIMORBIDITY IN WOMEN

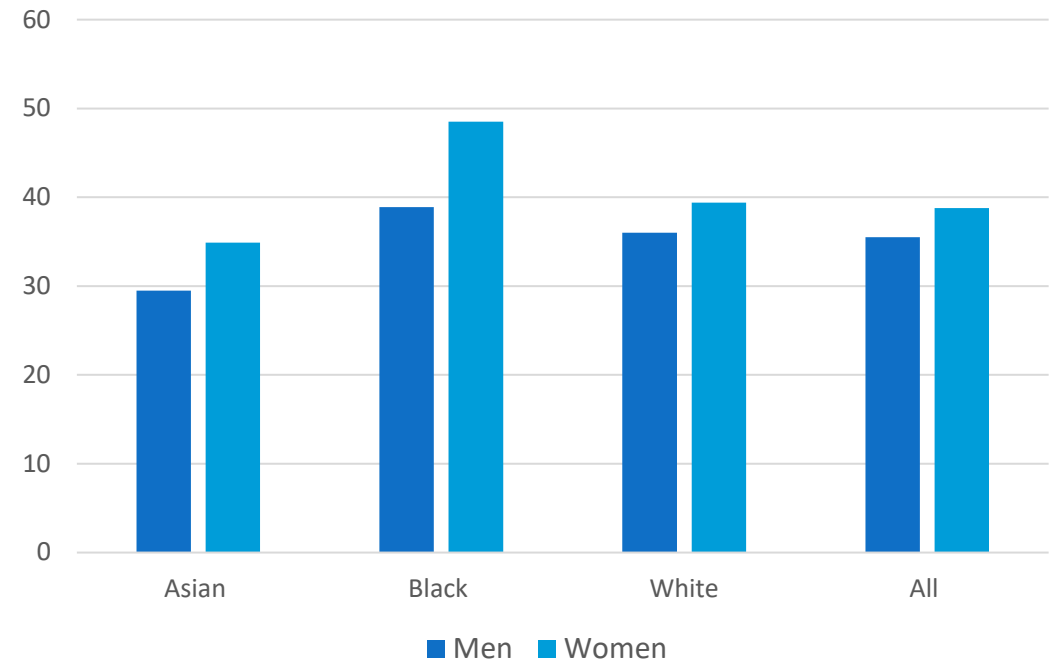
WOMEN



MEN



Age-standardized incidence rates of 2+ chronic conditions



St Sauver JL, et al. *BMJ Open* 2015;5:e006413 <http://dx.doi.org/10.1136/bmjopen-2014-006413>
 Velek P, et al. *BMC Med.* 2022 Sep 8;20(1):304. doi: 10.1186/s12916-022-02487-x
 Kalgotra P, et al. *International journal of medical informatics* 108 (2017): 22-28.

RFA-OD-23-013 AND RFA-OD-23-014: UNDERSTANDING CHRONIC CONDITIONS UNDERSTUDIED AMONG WOMEN (R01/R21)

ADVANCING SCIENCE FOR
THE HEALTH OF WOMEN
*The Trans-NIH Strategic Plan for
Women's Health Research*

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

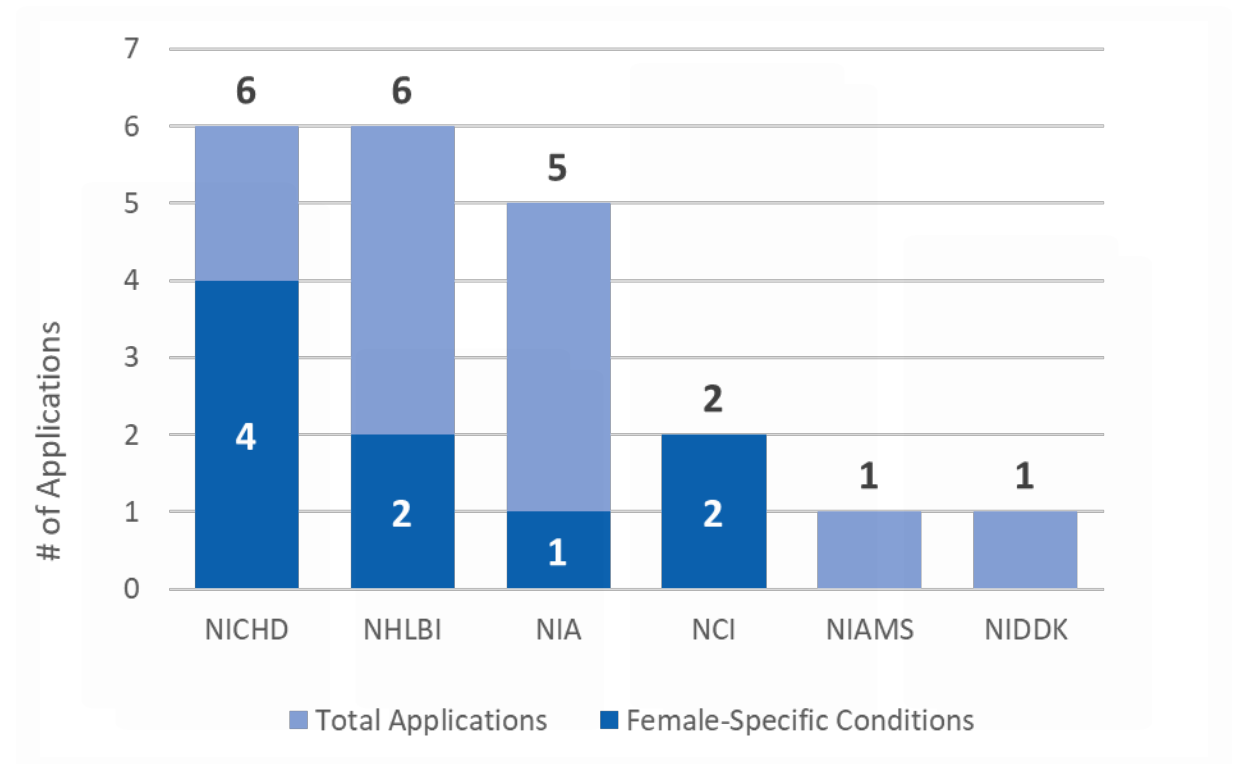
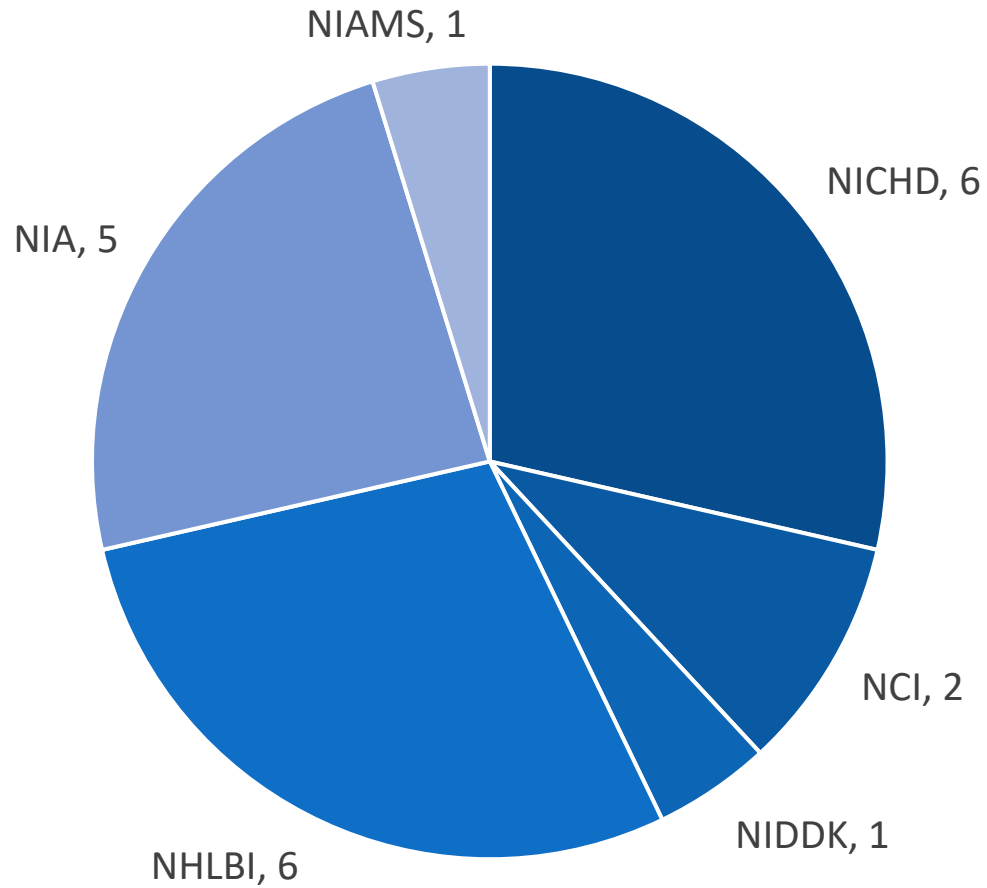
Purpose: Invite applications on chronic conditions understudied among women and/or that disproportionately affect populations of women who are understudied, underrepresented, and underreported in biomedical Research should align with Goal 1 of the 2019-2023 Trans-NIH Strategic Plan for Women's Health Research "Advancing Science for the Health of Women."

Application due dates: June 20, 2023 and 2024

Partner ICOs: NIA, NIAMS, NCI, NICHD, NHLBI, OAR

<https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-23-013.html>
<https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-23-014.html>

RFA-OD-23-013 AND RFA-OD-23-014 FY24 FUNDED APPLICATIONS



FY24 FUNDED APPLICATIONS (9/21 ON FEMALE-SPECIFIC CONDITIONS)

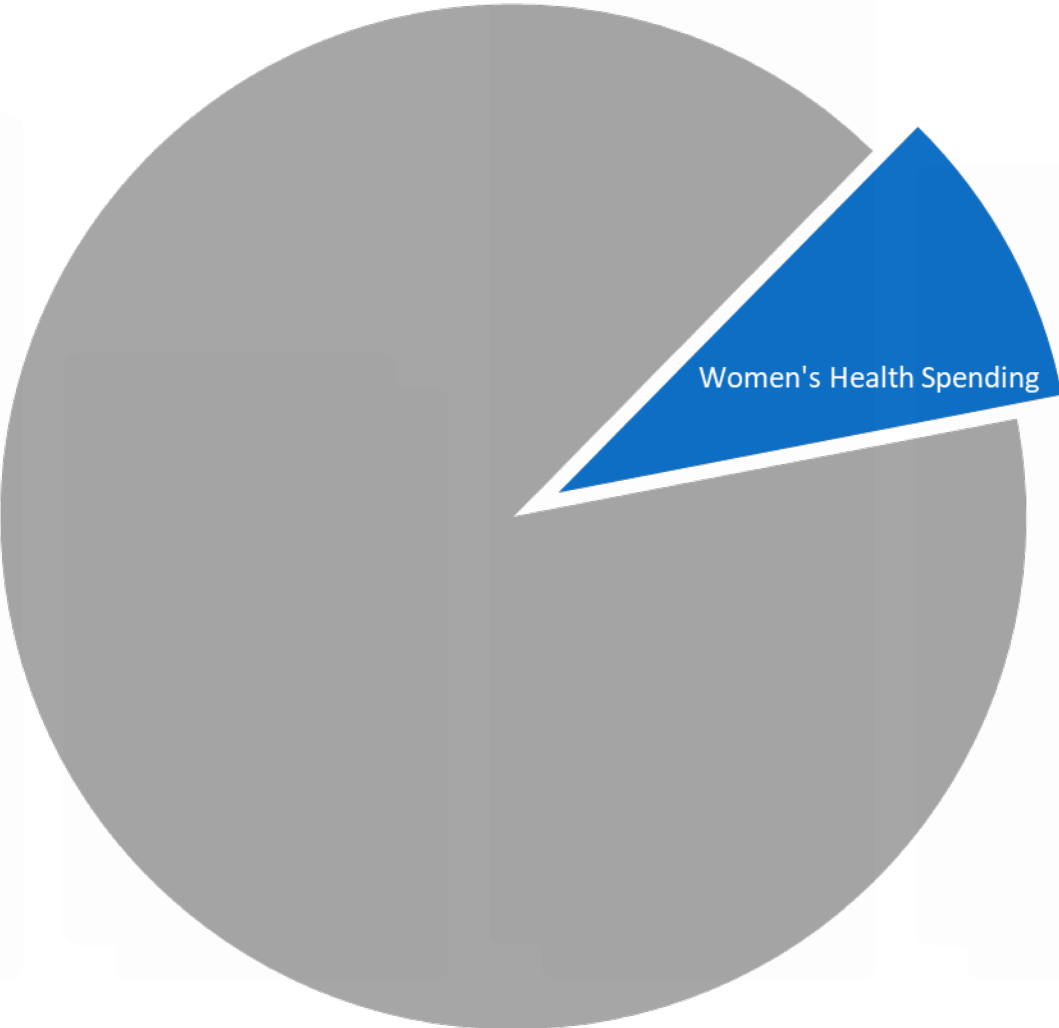
Title		PI	Institution
Regenerative biomaterial for combating genitourinary syndrome of menopause	R01	ALPERIN, MARIANNA	UNIVERSITY OF CALIFORNIA, SAN DIEGO
Heavy Menstrual Bleeding Progestin Treatment in Bleeding Disorders Study	R01	BALDWIN, MAUREEN	OREGON HEALTH & SCIENCE UNIVERSITY
Clinical assessment of radiotherapy-induced vaginal toxicity with multiparametric ultrasound imaging	R21	BURGESS, MARK THOMAS	SLOAN-KETTERING INST CAN RESEARCH
State Policy and Intimate Partner Violence	R01	DALTON, VANESSA K	UNIVERSITY OF MICHIGAN AT ANN ARBOR
Resistant starch treatment of polycystic ovary syndrome: impact on cardiometabolic dysfunction and the gut microbiome	R01	DOKRAS, ANUJA	UNIVERSITY OF PENNSYLVANIA
Noninvasive and early detection of endometriosis using a biological neural circuit-based novel gas sensor	R21	FAZLEABAS, ASGERALLY T	HENRY FORD HEALTH + MICHIGAN STATE UNIVERSITY HEALTH SCIENCES
Single cell analytics and drug discovery at the endometrial-myometrial junction in symptomatic adenomyosis	R21	GIUDICE, LINDA C	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
Risk factors for and consequences of endometriosis among Black women	R21	HARRIS, HOLLY RUTH	FRED HUTCHINSON CANCER CENTER
Heat therapy to improve functional performance in Heart Failure with Preserved Ejection Fraction	R21	HIRAI, DANIEL M	PURDUE UNIVERSITY
The impact of structural racism during pregnancy on future cardiopulmonary health	R01	JANEVIC, TERESA	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI
Sex-based study of chronic hypoxia-related vulnerability to depression: age effects	R21	KANEKAR, SHAMI	UNIVERSITY OF UTAH
Prospective Health Impacts of Chronic Binge Eating Disorder in Hispanic Older Women Living with Food Insecurity (PROSPERA)	R01	KILPELA, LISA	UNIVERSITY OF TEXAS HLTH SCIENCE CENTER
Targeting Estrogen-Sensitive Hypothalamic Neurons to Reverse Frailty in Aging Females	R21	KRAUSE, WILLIAM CHARLES	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
Antibody bound bacteria during HPV infection and cervical dysplasia	R21	LANGEL, STEPHANIE N	CASE WESTERN RESERVE UNIVERSITY
Multi-omic Characterization of COPD in Females	R01	LIU, DAJIANG	PENNSYLVANIA STATE UNIV HERSHEY MED CTR
CD38 intensifies immune activation in women living with HIV (the SIGNAL study)	R21	MATHUR, POONAM	UNIVERSITY OF MARYLAND BALTIMORE
Pubovisceral muscle enthesis injury: A bioinspired approach to repair	R01	MOALLI, PAMELA A	MAGEE-WOMEN'S RES INST AND FOUNDATION
A sex-biased obesity gene on the X chromosome	R01	REUE, KAREN	UNIVERSITY OF CALIFORNIA LOS ANGELES
Leveraging Sexual Dimorphism to Predict Cardiac Remodeling and Enhance Treatment in Women with Severe Aortic Stenosis	R21	RIKHTEGAR NEZAMI, FARHAD	BRIGHAM AND WOMEN'S HOSPITAL
Concurrent eradication of pathogenic plasma cells and their precursors in systemic lupus erythematosus	R21	SWAMINATHAN, SRIVIDYA	BECKMAN RESEARCH INSTITUTE/CITY OF HOPE
Changes in cardiometabolic tissue gene regulation and omics profiles with menopause	R21	THEUSCH, ELIZABETH	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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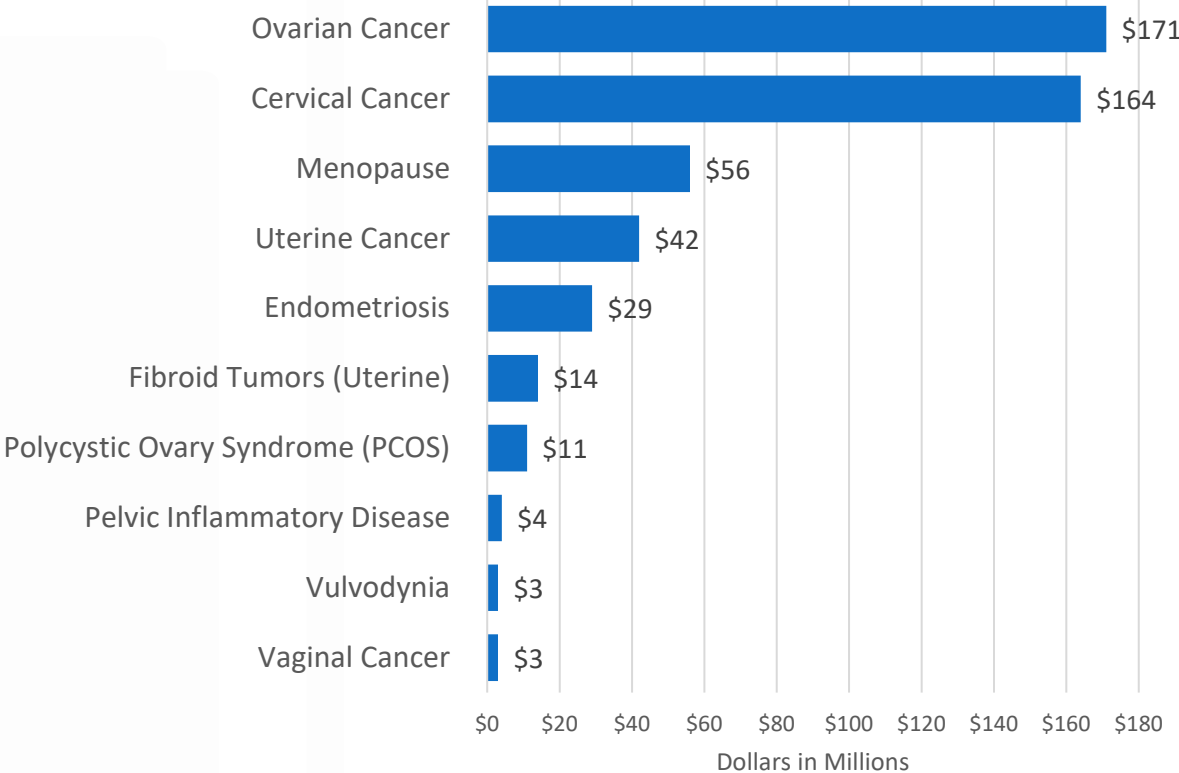
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FEMALE-SPECIFIC WOMEN'S HEALTH AND CONDITIONS FY23

FY23 NIH Women's Health \$4.6 Billion



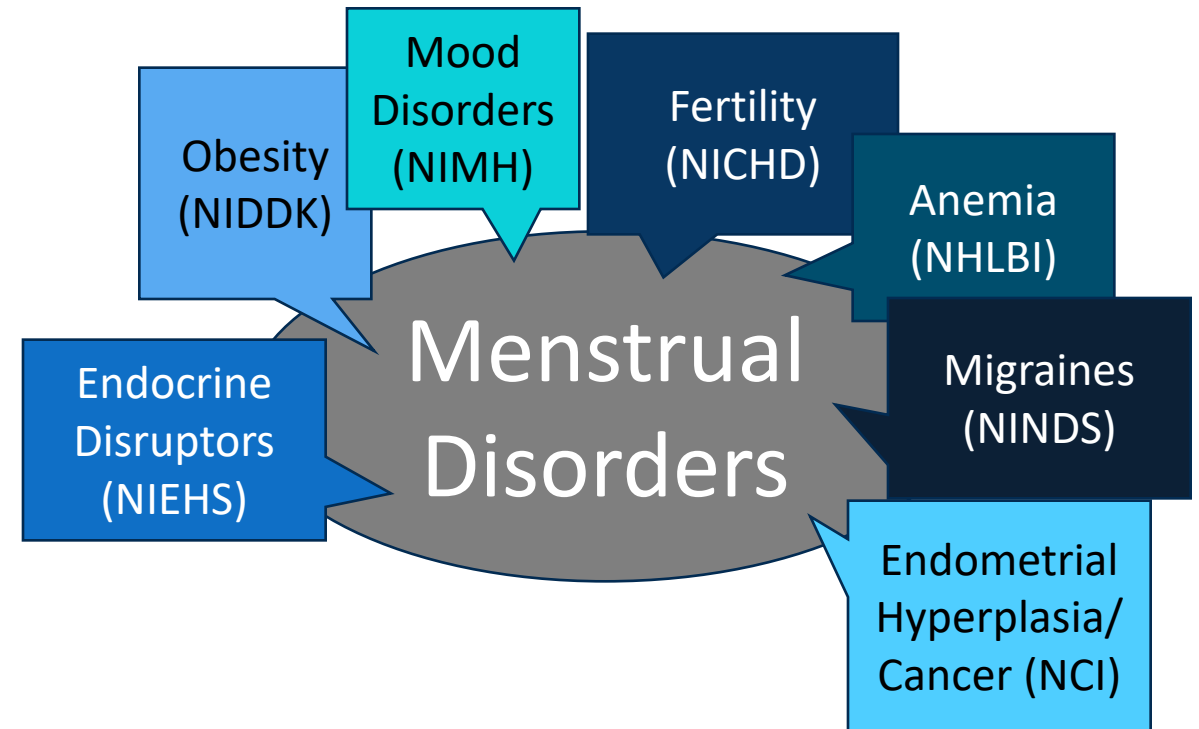
FY23 Female-Specific Conditions



FEMALE-SPECIFIC CHRONIC CONDITIONS SUMMARY

- Highly prevalent
- Understudied
- Cross multiple IC priorities
- Significant health-related disparities
- Interactions with other chronic conditions unknown
- Opportunity for NIH wide collaboration

Example condition and potential alignment with IC priorities:



Committee Action: Vote for approval of “Advancing Our Understanding of Female-Specific and Gynecologic Chronic Conditions”



COUNCIL ACTION

Council vote for Approval of the concept for Advancing Our Understanding of Female-Specific and Gynecologic Chronic Conditions