

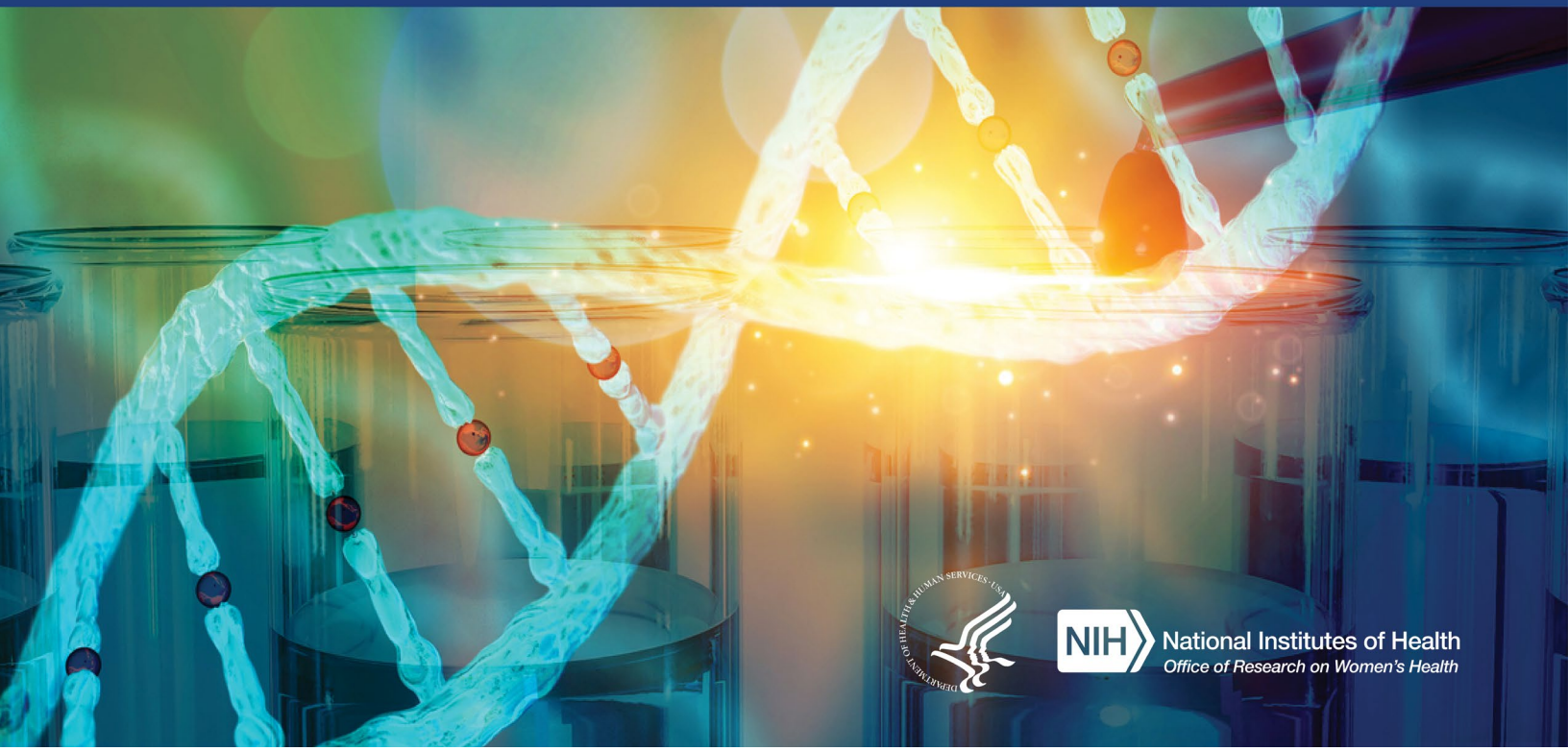
# PERSPECTIVES ON ADVANCING NIH RESEARCH TO INFORM AND IMPROVE THE HEALTH OF WOMEN

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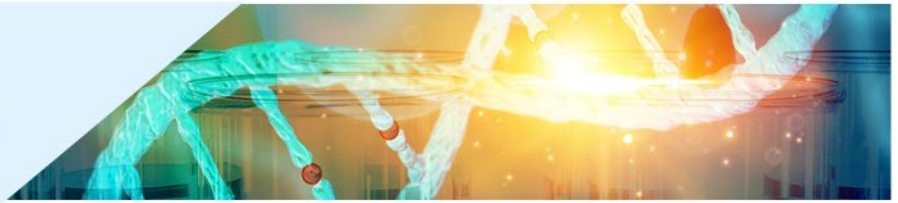
National Institutes of Health  
Office of the Director  
Division of Program Coordination, Planning, and Strategic Initiatives  
Office of Research on Women's Health

## **Executive Summary**

(last updated 3/1/2022)



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# Perspectives on Advancing NIH Research to Inform and Improve the Health of Women: Executive Summary

## Background

In their fiscal year (FY) 2021 reports, the [House](#) and [Senate](#) appropriations committees requested that the National Institutes of Health (NIH) convene a conference to evaluate research currently underway related to women's health, specifically regarding the following three topics:

- (1) maternal morbidity and mortality (MMM)
- (2) rising rates of chronic debilitating conditions in women (CDCW)
- (3) stagnant cervical cancer survival

In response to Congress, the NIH Office of Research on Women's Health (ORWH) developed a strategy to obtain input on the three priority areas from experts in women's health; members of the public; representatives from NIH Institutes, Centers, and Offices (ICOs); and members of the NIH Advisory Committee on Research on Women's Health (ACRWH). An ACRWH Women's Health Conference (WHC) Working Group was formed to review and discuss data on current NIH activities, plan the WHC, and prepare a report. Additionally, on October 20, 2021, ORWH and the ACRWH co-hosted a WHC entitled [Advancing NIH Research on the Health of Women: A 2021 Conference](#) in conjunction with the ACRWH meeting held the following day. On October 21, 2021, the ACRWH reviewed summaries from the WHC, held a robust discussion, and voted on opportunities for future NIH research on women's health, MMM, CDCW, and cervical cancer survival.

## Review of Current NIH Activities

As a first step in responding to the request from Congress, ORWH and the NIH Coordinating Committee on Research on Women's Health (CCRWH) formed a planning subcommittee and established three "clusters" corresponding to the requested topics and a fourth cluster to harmonize the data. Co-led by a subject-matter expert from ORWH and an NIH scientist, each cluster was composed of subject-matter experts from NIH ICOs, other U.S. Department of Health and Human Services (HHS) agencies—including the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), and Health Resources and Services Administration (HRSA), and the U.S. Department of Veterans Affairs (VA). Each cluster completed focused assessments and reviews of the relevant NIH research portfolios, held discussions on its respective topic area, and presented analyses, findings, and recommendations to the ACRWH WHC Working Group. Wherever possible, as the official system of record for annual NIH funding on specific research topics, the NIH's [Research, Condition, and Disease Categorization](#) system (RCDC) was used as a metric of funding.

## Research on Women's Health

As measured by the Manual Categorization System—Women's Health (MCS-WH) reporting module, in FY 2020 NIH spent 10.8 percent of its budget on [women's health research](#) (\$4,466 million). The identified grants processed by the MCS-WH reporting module include both female-specific conditions (e.g., gynecologic cancers and endometriosis) and diseases that affect both women and men but predominately affect women (e.g., fibromyalgia and rheumatoid arthritis). The ICOs with the largest absolute funding directed toward women's health research included those with the largest overall budgets: the National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). When the budgets are evaluated by percentage, NICHD, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and National Institute on Minority Health and Health Disparities (NIMHD) allocated the largest fraction of their budgets to women's health (29%, 28%, and 25%, respectively).

As the congressionally mandated focal point for coordinating research on the health of women at NIH (per section 486 of the Public Health Service Act, [42 U.S.C. 287d](#)), ORWH collaborates with the 27 constituent NIH Institutes and Centers and the broader scientific community to ensure that sex and gender are integrated into an interdisciplinary scientific framework at NIH and throughout the biomedical research enterprise. In FY 2020, the ORWH budget was \$45 million—largely unchanged since 2003 (\$41 million).

Since the passage of the [NIH Revitalization Act in 1993](#), the representation of women in clinical research has improved, and today, roughly half of NIH-supported clinical trial participants are women.<sup>1</sup> However, substantial underrepresentation of women into clinical trials persists in multiple disease categories, including HIV/AIDS, chronic kidney diseases, and certain cardiovascular diseases.<sup>2</sup> For diseases that afflict primarily one sex, the funding patterns favor disorders that predominantly affect males when compared to burden of the disease within the population: The funding disparity was nearly twice as large for conditions that occur predominantly in males as for those more common in females.<sup>3</sup>

As part of its mission, ORWH provides inclusion data from across NIH, in its, currently biennial, [Report of the Advisory Committee on Research on Women's Health: Fiscal Years 2019-2020](#). Recent expansion of the NIH inclusion policy to incorporate inclusion across the lifespan in addition to sex and/or gender, race, and ethnicity as a result of [21<sup>st</sup> Century Cures Act](#) requirements will lead to the addition of age at enrollment to future reports. Inclusion data are also now being reported by [RCDC categories](#). In addition, NIH inclusion data are incorporated into the NIH Directors' Report formerly biennial, now triennial. Harmonization of data reported in the NIH Women's Health Research biennial report and the NIH Director's triennial report is essential to provide a comprehensive and clear picture of inclusion data that is in compliance with NIH inclusion policy; therefore, triennial women's health research reporting aligned with the triennial NIH Director's report would promote clarity and transparency.

## Maternal Morbidity and Mortality

In response to the MMM public health crisis, NIH established a new RCDC category in 2017 for Maternal Health, which includes projects focused on pre-pregnancy through one-year postpartum. In 2020, another RCDC category for MMM was created to capture the subset of topics within the Maternal Health category specifically related to pregnancy complications and death associated with pregnancy. In FY 2020, the largest investment in MMM came

from NICHD (\$76 million), followed by the National Heart, Lung, and Blood Institute (NHLBI, \$40 million); National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK, \$19 million); and National Institute of Mental Health (NIMH, \$18 million).

Current NIH activities specific to MMM include basic and translational science investigating the underlying physiology of pregnancy, as well as the pathophysiology of pregnancy-associated disorders through such programs as the [Human Placenta Project](#). Prospective clinical trials research investigating interventions to reduce maternal and infant morbidity, deaths, and complications is performed through NICHD's [Maternal-Fetal Medicine Units \(MFMU\) Network](#). NHLBI supports projects on maternal cardiovascular health; NIDDK, on diabetes; National Institute of Environmental Health Sciences (NIEHS), on the environmental impact on maternal health; NIMH, on maternal psychiatric conditions; National Institute on Drug Abuse (NIDA) on drug abuse and National Institute on Alcohol Abuse and Alcoholism (NIAAA) on alcohol abuse disorders; and NIMHD, on structural inequities in maternal health. Additionally, the NIH Maternal Mortality Task Force (MMTF) created early in FY 2020 to generate evidence-based solutions to the MMM crisis is led by the NIH Office of the Director (OD), NICHD, and ORWH. The MMTF established the [Implementing a Maternal health and PRenancy Outcomes Vision for Everyone](#) (IMPROVE) initiative to support research to reduce preventable maternal deaths and improve health for women before, during, and after delivery. Reducing inequities related to such factors as race, age, and geographic region is prioritized. Furthermore, a [new collaboration](#) between ORWH and the National Institute of General Medical Sciences (NIGMS) focused on studying women's health through the [Institutional Development Award](#) (IDeA) Program, which supported 13 awards on MMM in FY 2020. The IDeA Program is congressionally-mandated and administered by NIGMS, with the goal of building research capacity in states that historically have had low levels of NIH funding (23 states and Puerto Rico).

### Rising Rates of Chronic Debilitating Conditions in Women

NIH supports a wide range of research on chronic diseases—covering screening and prevention, diagnostics, treatment and therapeutics, health disparities, and other aspects (e.g., mechanisms and pathogenesis). However, no single NIH RCDC for reporting medical research funding to the public encompasses chronic debilitating conditions. In 2010, HHS defined chronic illnesses as “conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living.”<sup>4</sup> This definition was used to describe chronic debilitating conditions in women. A CDCW framework was created for the purposes of the WHC planning and NIH portfolio analyses that categorized CDCW into the following categories: (1) female-specific, (2) more common in women and/or morbidity is greater for women, (3) occur in both sexes but potentially understudied in women, and (4) high morbidity in women. Disability-adjusted life years (DALYs), [defined by the World Health Organization](#) as “the loss of the equivalent of 1 year of full health,” were used as a metric by which to measure the burden of disease in women.

Using this definition and framework, a qualitative assessment of ICO priorities related to CDCW was performed. Each ICO represented within the CCRWH was invited to submit at least three of its highest-funded projects related to chronic debilitating conditions in women from FY 2018 to 2020. One hundred and eighty-four priority projects were submitted by 11 ICOs. The associated RCDCs from these submitted projects demonstrated that all topics of chronic conditions relevant to women, as defined in the WHC CDCW framework, are included in ongoing NIH-supported research. The largest proportion of projects were focused on conditions more common in women or for



which morbidity was greater for women (49%), followed by conditions potentially understudied in women (25%), conditions with high morbidity in women (15%), and female-specific conditions (11%). This limited, descriptive summary provided a rough estimate of NIH-wide priorities related to research on CDCW.

## Cervical Cancer

The RCDC for cervical cancer includes basic research, translation and clinical studies, and premalignant and invasive cervical diseases, as well as human papillomavirus (HPV) biology, prevention, screening, vaccination, treatment, and related health services. In FY 2020, NIH invested about \$113 million in cervical cancer research, with most projects funded by NCI (\$91 million). Cervical cancer research represents about 1.4 percent of the overall NCI budget based on RCDC. NIAID, NIMHD, and NICHD also fund research on cervical cancer, primarily focused on research on HPV biology, screening and prevention of pre-invasive cervical disease, and reducing disparities in screening and prevention in historically underrepresented communities.

Comparably, more NIH-supported projects are classified as research investigating etiology, prevention, early detection, and cancer control than research focused directly on cervical cancer treatment. Almost all cases of cervical cancer are caused by infection of human papillomavirus (HPV). NIH supports a robust research program around the biology, prevention, screening of HPV infection and cervical cancer. These efforts include projects directed toward development of novel preventive and therapeutic vaccines, [self-sampling](#) to overcome barriers to screening, and [one-dose HPV vaccination](#) efficacy. The clinical trials portfolio includes secondary prevention and health care delivery research. Ongoing clinical trials researching innovative care in cervical cancer treatment include studies within NCI's clinical research networks: the [Experimental Therapeutics Clinical Trials Network](#) (ETCTN), [National Clinical Trials Network](#) (NCTN), and the [NCI Community Oncology Research Program](#) (NCORP).

## Public Comments

On July 1, 2021, ORWH published a Request for Information (RFI) in the *Federal Register* ([86 FR 35099](#)) to inform the WHC. The RFI invited comments and testimonies from the extramural scientific community, professional societies, and the general public to assist with identifying research gaps, determining pitfalls in clinical practices, and obtaining real-life testimonial experiences (direct or indirect) related to any or all of the three congressionally-specified public health issues.

Of the 247 comments received, 104 addressed MMM, 182 discussed CDCW, and 27 mentioned cervical cancer. Most comments were submitted by researchers or research groups (N = 56), followed by members of the public (N = 49), awareness and advocacy groups (N = 36), patients (N = 40), and health care providers (N = 34). The 10 most frequently identified keywords, ordered from most to least frequently mentioned, from the manual coding were as follows: (1) MMM, (2) racial disparities, (3) access to care, (4) provider training, (5) mental health, (6) Black or African American women, (7) screening, (8) quality of care, (9) time to diagnosis, and (10) social determinants of health.

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

Thirty-two [speakers discussed a wide range of topics](#) related to research on women's health and the three public health needs identified in the Congressional request (MMM, CDCW, and cervical cancer survival). Below is the meeting agenda:

<b>Welcome</b>   Samia Noursi, Ph.D., Office of Research on Women’s Health (ORWH)		
<b>Introduction</b>   Janine Clayton, M.D., FARVO, ORWH		
<b>Women’s Health Matters: When, Where, &amp; Why</b>   Chloe Bird, Ph.D., RAND Corporation		
<b>How Stereotypes Underpin Inequities for Women in Academic STEM &amp; Advancements in Women’s Health</b>   Molly Carnes, M.D., University of Wisconsin–Madison		
<b>The U.S. Maternal Health Care Crisis</b>   Elizabeth Howell, M.D., M.P.P., University of Pennsylvania Health System		
<b>Impact of Chronic Disease: The Sex &amp; Gender Gap</b>   Marjorie Jenkins, M.D., M.E.H.P., University of South Carolina School of Medicine Greenville		
<b>Cervical Cancer: How Can We Overcome Our History</b>   B.J. Rimel, M.D., Cedars-Sinai Medical Center		
<b>Concurrent Sessions</b>		
<b>Maternal Morbidity &amp; Mortality</b> Moderated by Yoel Sadovsky, M.D. University of Pittsburgh	<b>Chronic Debilitating Conditions</b> Moderated by Judy Regensteiner, Ph.D. University of Colorado Anschutz Medical Campus	<b>Stagnant Cervical Cancer Mortality</b> Moderated by Wendy Brewster, M.D., Ph.D. The University of North Carolina School of Medicine
<b>Maternal Morbidity &amp; Mortality: Tip of a Lifecourse Iceberg</b> Janet Rich-Edwards, Sc.D., M.P.H. Brigham & Women’s Hospital	<b>Prevention of Chronic Conditions in Women to Advance Health &amp; Function Across the Lifespan</b> Heidi D. Nelson M.D., M.P.H., MACP, FRCP Kaiser Permanente Bernard J. Tyson School of Medicine	<b>The Future of Cervical Cancer Prevention in the United States: The Realities of Evidence Beyond Innovation</b> Cosette Wheeler, Ph.D. The University of New Mexico Health Sciences Center
<b>Harnessing the Power of Research: Optimizing Infrastructure to Optimize Maternal Outcomes</b> Uma Reddy, M.D., M.P.H., MFM Yale School of Medicine	<b>The Impact of Chronic Debilitating Conditions on Women</b> Kim Templeton, M.D. University of Kansas Medical Center	<b>A Path Forward Toward Accelerating Cervical Cancer Eradication</b> Diana S.M. Buist, Ph.D., M.P.H. Kaiser Permanente Bernard J. Tyson School of Medicine
<b>Opportunities in Clinical Research to Reduce Maternal Morbidity &amp; Mortality</b> Cynthia Gyamfi-Bannerman, M.D. University of California, San Diego, School of Medicine	<b>The Case of Fibroids as a Female-Specific Chronic Debilitating Condition</b> William Catherino, M.D., Ph.D. Uniformed Services University of the Health Sciences	<b>Improving Treatment for Cervical Cancer: What Can Tumor Biology Tell Us?</b> Julie Schwarz, M.D., Ph.D. Washington University in St. Louis School of Medicine
<b>Expanding Maternal Morbidity &amp; Mortality Research Within &amp; Beyond Our Hospital Walls</b> Mary D’Alton, M.D. Columbia University Irving Medical Center	<b>Fortifying Opportunities to Advance Female-Specific Chronic Disease Research</b> Stacey Missmer, Sc.D. Harvard T.H. Chan School of Public Health	<b>Translating Science into Improved Patient Care for Women with Cervical Cancer</b> Janet Rader, M.D. Medical College of Wisconsin
<b>How Can Research Findings Be Translated into Reduced Maternal Morbidity &amp; Mortality?</b> Elliott Main, M.D. Stanford University	<b>What We Do &amp; Do Not Know About the Leading Killer of Women &amp; What We Should Do About It!</b> C. Noel Bairey Merz, M.D. Cedars-Sinai Medical Center	<b>The Future of Clinical Research in Cervical Cancer Treatment</b> Charles Kunos, M.D., Ph.D. University of Kentucky
<b>You Are What You Love: Prioritizing Women’s Health Research for a Healthier Society</b> Maeve Wallace, Ph.D. Mary Amelia Center for Women's Health Equity Research	<b>Using Cardiovascular Disease as a Framework for Thinking About Chronic Diseases in Women</b> Judy Regensteiner, Ph.D. University of Colorado Anschutz Medical Campus	<b>NCI Clinical Trials in Gynecologic Cancer: A Changing Landscape</b> Robert Mannel, M.D. University of Oklahoma College of Medicine

<p><b>Root Causes of Maternal Health Outcomes &amp; Research Justice</b>                  Joia Crear-Perry, M.D.                  National Birth Equity Collaborative</p>	<p><b>Integrating Biopsychosocial Determinants of Health to Develop and Implement Culturally Sensitive Care for Women</b>                  Cheryl Giscombé, Ph.D., RN                  The University of North Carolina at Chapel Hill</p>	<p><b>The Urgent Need for Crosscutting Anti-Racist Approaches to Cancer Disparities Research</b>                  Kemi Doll, M.D.                  University of Washington</p>
<p><b>Opportunities for Research to Reduce Disparities in Maternal Mortality &amp; Morbidity</b>                  Stacie Geller, Ph.D.                  University of Illinois College of Medicine</p>	<p><b>Beyond Sex as a Biological Variable: Addressing Chronic Debilitating Conditions Among All Women</b>                  Melissa Simon, M.D., M.P.H.                  Northwestern University Feinberg School of Medicine</p>	<p><b>Clinical Trials in Cervical Cancer: Can They Be All That We Want Them to Be?</b>                  Charles A. "Trey" Leath, III, M.D., M.S.P.H.                  The University of Alabama at Birmingham</p>
<p><b>Innovation Through the Lens of Women’s Health Research: A Rising Tide Lifts All Boats</b>                  Linda Griffith, Ph.D., Massachusetts Institute of Technology</p>		

## Research Gaps and Opportunities

Research to improve the health of women is embedded in the work and mission of all NIH ICOs. ORWH acts as the focal point for coordinating this research and ensures that sex and gender are integrated into an interdisciplinary scientific framework at NIH and throughout the broader scientific enterprise.

The following three crosscutting themes emerged from stakeholders participating in the WHC:

### Implementation Research

Research to understand how best practices can be applied to women’s health topics is urgently needed. The quality of care received by women varies tremendously by factors that include, but are not limited to, geographic location, insurance status, educational attainment, and other social factors. Interventions—such as safety bundles, collections of best practices that offer a framework to incorporate established guidelines into health care practice using a standard approach to pregnancy and postpartum care—have demonstrated large-scale improvements in pregnancy outcomes, yet remain unimplemented in many hospitals.<sup>5,6</sup> Vaccines that prevent cervical cancer have been approved for use in the United States since 2006, yet just over half of adolescents have completed the HPV vaccine series.<sup>7</sup>

Moreover, the paradigm of “1 patient–1 disease” no longer fits the medical necessities and needs of most patients with chronic diseases, and a more holistic, patient-centered view should be developed. Innovative trial design and outreach are needed to generate data required to develop evidence-based care for women. Research to “scale up” successful interventions that have demonstrated improvements in the health of women, such as maternal safety bundles and cervical cancer screening, should be prioritized.

### Research That Addresses Inequities in Care

Although race, ethnicity, and sex and/or gender reporting from applicable NIH-defined Phase 3 clinical trial results is now [required](#), identifying outcomes for populations with overlapping identities (e.g., Black women) remains challenging, limiting data on the health consequences of intersectionality. The burden of chronic debilitating conditions on women from underserved and underrepresented populations is not well described in current scientific literature. The disproportionate disease burden of MMM and cervical cancer on women from historically underserved, understudied, and underrepresented populations is notable. Black, Alaska Native, and American

Indian persons die from pregnancy-related causes at a rate almost three times as high as White women.<sup>8</sup> Despite similar rates of cervical cancer screening and HPV vaccination, Black women remain 30 percent more likely to be diagnosed with cervical cancer and 75 percent more likely to die of disease than White women.<sup>9</sup> Attention to these communities through community-engaged research is an urgent need.

### Intentional Research on the Health of Women

The mission of ORWH includes strengthening and enhancing research related to diseases, disorders, and conditions that affect women; ensuring that research conducted and supported by NIH adequately addresses issues regarding women's health; and ensuring that women are appropriately represented in biomedical and bio-behavioral research studies supported by the NIH. NIH has made significant advances in research focused on the health of women, spearheaded by ORWH and in collaborations with the various ICOs and stakeholders. Today women are enrolled into NIH-supported clinical research at similar rates to men. However, more work remains to be done, as inclusion is only one component of equity. The historic overreliance on male clinical research subjects has created gaps in our current evidence-base regarding disorders and diseases that occur in women, including impacts on functioning and quality of life across the life course, which still must be addressed. Many female-specific conditions including menopause, endometriosis, and fibroids are chronic debilitating conditions that fall under the purview of multiple ICOs and currently have few standing funding opportunities. Filling the gaps in evidence pertinent to the health of women requires research that is centered on female-specific conditions as well as a better understanding of the prevention, diagnostic, and treatment needs that are unique to women. Despite the significant advances made to date, fundamental basic and translational research is needed on such topics as the initiation of labor, the root causes of preeclampsia, basic physiology of the uterus and of typical and atypical menstruation, the innate differences between male and female systems' pathogenesis of chronic conditions, and the discrepant carcinogenesis of various HPV types within the cervix.

Studies that provide detailed sex-disaggregated clinical outcomes data—tied to critical life course windows, such as menarche and menopause—from a diverse population of women are needed to support this important work. To fill evidence gaps related to women's health, clinical trials networks with the following could be created: a specific emphasis on women (including pregnant persons), tools to design trials that answer questions specific to women, and capacity to enroll women of all ages and from diverse backgrounds, into studies. Large-scale prospective cohort studies of women might likewise begin to fill some of our gaps in understanding the specific pathophysiology of CDCW.

The 2016 NIH [Sex as a Biologic Variable \(SABV\) policy](#) has led to advances in our understanding of relevant diseases that affect women. Despite the policy, gaps remain in basic and translational understanding of sex differences. Continued attention to and application and enforcement of the SABV policy will allow further understanding of how sex influences physiology and pathophysiology paving the way for improved disease prevention and treatment strategies in the multitude of conditions that present differently and require different treatment in women and men.

Intentional funding opportunities can improve NIH-wide support of research on women's health. Intentional funding of studies of women leveraging existing NIH resources—such as cohorts, biobanks, and bioinformatics—can also advance the continued growth of the NIH women's health research portfolio. The review process can be



improved through the creation of standing study sections within the NIH Center for Scientific Review on sex differences and women's health research and the inclusion of researchers with women's health expertise on additional study sections.

## Conclusion

Improving the health of women benefits all members of our society<sup>10</sup>. Increasing research on the health of women has been demonstrated to [produce significant returns on investment](#). The [2019–2023 Trans-NIH Strategic Plan for Women's Health Research](#) sets out an ambitious vision for a world in which the biomedical research enterprise thoroughly integrates sex and gender influences; every woman receives evidence-based disease prevention and treatment tailored to her own needs, circumstances, and goals; and all women in scientific careers reach their full potential.

Broad support for increased prioritization of research on women's health was expressed by members of the public, NIH stakeholders, ACRWH members, and the participants of the WHC.

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