



WOMENHEART

THE NATIONAL COALITION FOR
WOMEN WITH HEART DISEASE

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WomenHeart: the National Coalition for Women with Heart Disease, is pleased to provide comments to the Office of Research on Women's Health regarding the Women's Health Consensus Conference being held in October 2021.

WomenHeart is a national organization that represents the millions of women in the United States living with or at risk for heart disease, the number one killer of women. Through programs that train women living with heart disease to be support group leaders and community educators, through public education and prevention campaigns, through engagement with hospitals and health care providers, and through legislative and policy advocacy, WomenHeart strives to improve the lives and health of diverse communities of women throughout the country.

Since its founding in 1999, WomenHeart has advocated for research that recognizes and examines biological differences between men and women and the impact of sex and gender, among other critical factors, on health and disease. For decades, heart disease was considered a "man's disease," and while we have made great progress in recent decades, women often remain under-represented in clinical trials, continue to experience missed and delayed diagnosis and, even when women are well represented in the research, too often the researchers fail to report outcomes based on sex and gender.

The Office of Research on Women's Health has been a leader and critical partner in the work to make advancements in women's health and to champion our understanding of sex and gender differences relevant to the health of women. This Women's Health Consensus Conference represents a great opportunity to examine where we are and to set research priorities going forward. As such, WomenHeart recommends that Conference attendees and other stakeholders consider the following as they work to identify gaps and opportunities for NIH.

- (1) Women too often experience missed and delayed diagnosis for conditions that are under-studied, impact women more than men, or for which there's a perception that women are less likely to have them, such as heart disease. We recommend prioritizing research that informs solutions and leads to more timely and accurate diagnoses for women.**

Heart disease is commonly assumed to be "a man's disease," yet it is the leading cause of death for women in the United States, with more than 400,000 deaths each year.¹ That misconception is a blind spot for many patients, providers, policymakers, researchers and others; it also

contributes to increased likelihood of missed and delayed diagnosis of heart disease in women. Furthermore, the risk factors and symptoms of heart disease for women can differ from those for men.ⁱⁱ The challenges of heart disease combined with bias related to gender, sex, age, race and ethnicity, as well as systemic barriers to high quality care, result in diagnostic error and unequal care for women.

Research shows that women with symptoms of heart disease are less likely than men to have non-invasive diagnostic testing at the initial point of care.ⁱⁱⁱ Women of color, specifically Black women, tend to experience additional bias, such as trivialization of complaints and lack of respect from health care professionals, which further contributes to diagnostic error.^{iv} For many women, those situations result in delayed diagnosis, delayed therapeutic interventions and ultimately poorer outcomes. As just one example, research found that women and Black patients are more likely to be diagnosed with heart failure in acute care settings, even after having previously presented with symptoms in non-acute care visits, potentially delaying timely high-value interventions and exacerbating disparities.^v

Delayed and missed diagnosis of heart disease, as well as other conditions, in women may also be due to inadequate clinical training of health care providers. In a national study, only 43% of medical students reported that their educational curriculum improved their understanding of sex and gender medicine and only 35% felt prepared to manage sex and gender differences in health care.^{vi}

A scan of published literature, social media, websites and other sources of information used by clinicians and patients unveiled a preponderance of available information and evidence focused on understanding problems related to disparities in diagnosis and treatment of heart disease in women.^{vii} Substantial work has been done regarding the incidence of diagnostic errors; gender, hormones and pregnancy; comorbidities; special populations; and the experience of women with specific conditions, such as heart failure and spontaneous coronary artery dissection. However, there is a gap in research focused on how to fix those problems going forward.

WomenHeart and the Society to Improve Diagnosis in Medicine hosted a convening in January 2021 to develop research recommendations focused on solutions. While the convening focused on heart disease in women, many of the proposed areas of research, such as educating clinicians about biological sex differences, addressing bias and ensuring patients have access to support, would apply to a broad range of disease states and would contribute to better health care and diagnostic journeys for women. We recommend the NIH Office of Research on Women's Health look to prioritize areas of research identified in [the final report](#) of the convening that would lead to better outcomes.^{viii}

- (2) Pregnancy impacts a woman's health – during the time she is pregnant and often for years to come. In particular, heart health plays a major role in maternal health. Many women first experience cardiac symptoms during pregnancy, and heart disease and stroke account for one in three (34%) pregnancy related deaths.^{ix} We recommend NIH prioritize research that leads to better understanding of how to diagnose and treat conditions that may present during or soon after pregnancy but often go unrecognized, un-diagnosed and/or un-treated for too long.**

Pregnancy is a stress test for the heart, and yet diagnosing and/or treating heart disease or other conditions during pregnancy can be complicated. For example, some signs and symptoms of cardiovascular disease — shortness of breath, increased heart rate and palpitations, for example — are common in normal pregnancy. Pregnancy may also affect the results of diagnostic testing. Using mortality data from California, a timeline demonstrated when pregnant or postpartum women who died from cardiovascular disease had been diagnosed. Nearly half (48%) were diagnosed postmortem, despite having displayed concerning signs and symptoms.

While diagnosing conditions during pregnancy can be improved through the use of screening algorithms, decision aids and consultation with appropriate specialists, more work is needed to develop those effective tools. In addition, more research is needed to understand the safety and efficacy of prescription drugs, therapeutics and vaccines used during pregnancy and breastfeeding so that women receive evidence-based treatment for underlying conditions throughout their pregnancy and post-partem. (This speaks to the importance of the ongoing work of the Task Force on Research Specific to Pregnancy Women and Lactating Women, or PRGLAC). Finally, all clinicians caring for pregnant women, including physicians not trained as obstetric gynecology, must be trained to understand the impact on pregnancy on health and to recognize conditions unrelated to the pregnancy that may present during that time.

(3) Women and people of color are underrepresented in clinical trials and medical research. NIH should prioritize research that helps us understand why groups may be less inclined to fully participate and informs solutions to address barriers to participation.

It is well documented that women are generally underrepresented in clinical trials and medical research. Without full representation of women, our knowledge of what is safe and effective for women is limited. Because we know sex differences impact prevention, diagnosis, treatment, and outcomes of many different conditions and diseases, the lack of participation of women in clinical trials puts their health at risk.

Fortunately, policies and guidelines in recent years have improved women's representation and many researchers are at least aware that diversity based on sex and gender, race, ethnicity, age, and more are important. Yet it takes intentionality and an openness to new ideas about trial design, recruitment strategies, etc. to achieve participation rates that reflect the patient population most burdened by the disease being studied. Furthermore, once included in the research, women are more likely than men to leave the trial early and discontinue their participation in the research.

NIH should support research that allows us to understand better why women are less likely to fully participate in research and solutions to address that. Too often, the data collected that asks participants why they left the research – if it's asked at all – is insufficient to be used for publication, inhibiting our ability to create solutions.

(4) Lesbian, Gay, Bisexual, Transgender, and Queer or Questioning (LGBTQ+) adults experience health disparities, including increased risk factors for heart disease.^x We

recommend prioritizing research that helps us to understand better the causes of these disparities and interventions that can help reduce them.

There is a gap in research focused on health equity of sexual and gender diverse populations, and this gap is even wider for LGBTQ+ people of color. For example, we know little about the cardiovascular risks and disease particularly among racial minorities who are also sexual and gender diverse. There is a need to research the impact of multiple stressors that affect the health of these populations.

(5) Consider ways to incorporate patient stories into the research

Narratives are compelling and stories can often provide a more complete picture of a woman's health than a single data point. The Office of Research on Women's Health is uniquely positioned to consider research that is not limited to one organ system or disease state, but rather considers myriad factors that impact health and well-being and multiple diagnoses. As a patient-centered advocacy organization, WomenHeart encourages ORWH to incorporate women's lived experiences and stories into your work, whether that be through more qualitative research studies and other unique study designs, as well as through how you communicate the results and impact of the research you lead.

Thank you for your attention to these recommendations.

ⁱ Virani SS, Alonso A, Aparicio HJ, et al. Heart disease and stroke statistics—2021 update. A report from the American Heart Association. *Circulation*. 2021;143:e254–e743. doi:10.1161/CIR.0000000000000950

ⁱⁱ Brush JE, Krumholz HM, Greene EJ, Dreyer RP. Sex differences in symptom phenotypes among patients with acute myocardial infarction. *Circulation: Cardiovascular Quality and Outcomes*. 2020;13(2):e005948. doi:10.1161/CIRCOUTCOMES.119.005948

ⁱⁱⁱ Banks AD. Women and heart disease: missed opportunities. *J Midwifery Womens Health*. 2008;53(5):430-439. doi:10.1016/j.jmwh.2008.04.008

^{iv} Banks AD, Malone RE. Accustomed to enduring: experiences of African-American women seeking care for cardiac symptoms. *Heart Lung*. 2005;34(1):13-21. doi:10.1016/j.hrtlng.2004.08.001

^v Sandhu AT, Tisdale RL, Rodriguez, F, et al. Disparity in the setting of incident heart failure diagnosis. *Circulation: Heart Failure*. 2021; 14:e008538 doi: [10.1161/CIRCHEARTFAILURE.121.008538](https://doi.org/10.1161/CIRCHEARTFAILURE.121.008538)

^{vi} Jenkins MR, Herrmann A, Tashjian A, et al. Sex and gender in medical education: a national student survey. *Biol Sex Differ*. 2016;7(Suppl 1):45. doi: 10.1186/s13293-016-0094-6

^{vii} From errors to solutions: Building a research agenda to improve diagnosis of heart disease in women. WomenHeart and Society to Improve Diagnosis in Medicine. 2021. Accessed on September 14, 2021: <https://www.womenheart.org/from-errors-to-solutions/>

^{viii} Ibid

^{ix} Centers for Disease Control and Prevention. Pregnancy-related deaths. CDC Vital Signs Web site. <https://www.cdc.gov/vitalsigns/maternal-deaths/>. Published 2019. Updated May 2019. Accessed April 5, 2021.

^x Caceres, BA, Streed, CG, Corliss, HL, et al. Assessing and addressing cardiovascular health in L=GBTQ adults. *Circulation*. 2020;142:e321–e332. DOI: 10.1161/CIR.0000000000000914