

SEX-SPECIFIC MEDICAL RESEARCH: WHY WOMEN'S HEALTH CAN'T WAIT

Summary of the Report of the Mary Horrigan Connors Center for Women's Health & Gender Biology at Brigham and Women's Hospital

Twenty years ago, a bipartisan group of legislators worked with patients, providers, policy makers, and advocates to create and pass the 1993 National Institutes of Health (NIH) Revitalization Act, a law mandating that women and minorities be included in clinical trials funded by the NIH. In many ways the law has been a success. Women are now routinely included in clinical trials, and we have learned how certain diseases present differently in men and women. Yet, despite some progress, medical research is too often flawed by its failure to examine sex differences. It is now clear that men and women experience illness differently and the full report looks closely at four diseases where this is especially true: cardiovascular disease, lung cancer, depression and Alzheimer's disease.

Cardiovascular Disease: We now know that cardiovascular disease, the Number One killer of women in the United States, affects women and men differently at every level, including prevalence, underlying physiology, risk factors, presenting symptoms, and outcomes. Yet only one-third of cardiovascular clinical trial subjects are female and fewer than one-third (31 percent) of cardiovascular clinical trials that include women report outcomes by sex.⁸

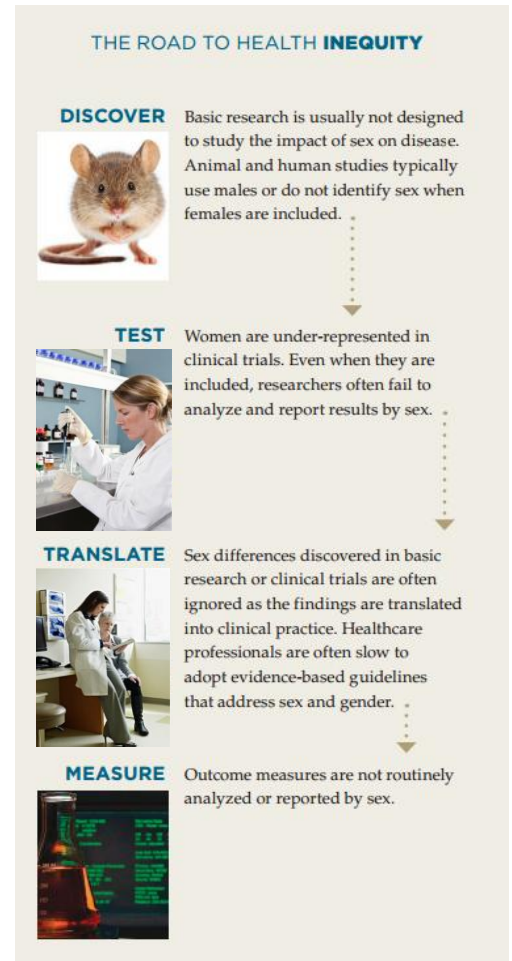
Lung Cancer: Women who have never smoked are three times more likely than nonsmoking men to get lung cancer. Although the number of women participating in lung cancer clinical trials has risen, women—particularly those from racial and ethnic minorities—are still less likely to enroll in these trials than men. Even when studies include women, researchers often fail to analyze data by sex or include hormone status or other gender-specific factors.

Depression: Depression is the leading cause of disease burden worldwide and in the U.S., twice as many women than men suffer from depression. We know that changes throughout a woman's life, including puberty, pregnancy, and menopause, have been directly linked to increased risk for depression and research has shown that women metabolize drugs differently than men. Yet fewer than 45 percent of animal studies on anxiety and depression use female lab animals.

Alzheimer's Disease: Two-thirds of the 5.1 million people currently suffering from Alzheimer's disease are women. Women are also the primary caregivers of adult loved ones with Alzheimer's disease, meaning they shoulder both the risks and the burdens of the illness. Even though a woman's overall lifetime risk of developing Alzheimer's disease is almost twice that of a man, the prevailing thinking in the field is that this is simply because women live longer. However, the impact of hormonal changes at menopause and sex differences in gene expression are emerging as potential explanations.

Equity in research is essential for quality outcomes and value

As the investment in healthcare has skyrocketed, as healthcare reform extends care to more Americans, and as the healthcare system evolves to meet shifting needs, research on sex and gender differences must become the norm, not the exception. Without gender equity in research, we are not getting the full value of our massive public investment.



A Call to Action

Don't leave women's health to chance. Research on sex and gender differences must become the norm, not the exception, for the United States to achieve health equity and, most important, to improve the health and well-being of all. Our leaders must ensure that all health agencies are actively engaged in women's health research and the evaluation of sex differences across the lifespan. And in this new era of personalized medicine, **a multi-stakeholder approach** is the best way to ensure quality, safety, value, and efficacy in the methods we use to address disease.

Hold federal agencies accountable. Government and other funding agencies, including the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) should ensure that the design of clinical studies includes a consideration of the sex of the subject, adequate participation of women, and the reporting of sex-stratified findings.

Promote transparency and disclosure regarding the absence of sex- and gender-based evidence in research, drugs and devices.



Warning Labels: Medical device and pharmaceutical labeling should carry a disclaimer or warning label if clinical testing did not include adequate numbers of female subjects.

Research Facts: Researchers should be required to disclose in a standardized format

(similar to a **nutritional label**) how their study addresses sex and whether the data are analyzed by sex. An annual review of peer-reviewed journals should be conducted to assess how well and often they present sex- and gender-based research. An online gateway should be developed to provide public access to sex-stratified data from government-sponsored research.

Expand sex-based research requirements. Institutional Review Boards can require that research plans include adequate numbers of female and male human subjects and lab animals. Journals can require authors to report the sex of lab animals and human subjects and encourage the publication of sex-specific results.

Adopt clinical care practices and training curricula that incorporate a sex- and gender-based lens in care and research. Medical education and research on all levels should include differences based on sex and gender.

Make Your Voice Heard. All women and men can play a role in making sex- and gender-based research the norm. They can demand that their policymakers ensure that women are included in all phases of medical research and that sex differences are studied and evaluated at all levels as is currently required by law. They can demand that the findings be translated from bench to bedside for the benefit of all. And when they seek care, they can ask their doctors if the recommended prevention strategies, diagnostic tests, and medical treatments are based on research that included women.

Two decades after the landmark NIH Revitalization Act was signed into law, we still have much work to do to make certain that its promise is realized. The passage of the law was a critical milestone. Now is the time to recommit to its vision and ensure that research at all levels is performed with a sex- or gender-specific lens. Women's health can't wait!

To link to our website and a full copy of the report, please visit www.brighamandwomens.org/summitreport

Research Facts	
Sex-specific breakdown for medical research	
Total number of study	Subjects 100
% Study Subjects	
50%	Women 50 participants
30%	Minorities 30 participants
10%	African American
8%	Latino/Hispanic
5%	Asian
4%	American Indian/Alaska Native
3%	Pacific Islander
✓	Stratified Analysis by sex conducted
	Stratified Analysis by minority status conducted
✓	Findings by sex/minority status presented