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Commentary

Taking a Giant Step Toward Women's Heart Health: Finding Policy Solutions to Unanswered Research Questions

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History of Women's Heart Health

In January 1986, heart disease in women emerged from the shadows when the National Institutes of Health's (NIH's) National Heart, Lung, and Blood Institute (NHLBI) convened a workshop of researchers and clinicians to describe the current state of knowledge about coronary heart disease in women and to provide direction for future research. The purpose of the meeting was to allow this diverse group of professionals to interact across disciplines and to lay the groundwork for future endeavors. The workshop's organizing committee had the vision to recognize the long-term implications of this issue and the possibilities for facilitating significant change in women's heart health. The proceedings from the workshop, "Coronary Heart Disease in Women: Reviewing the Evidence, Identifying the Needs" (Eaker et al., 1987), were released in 1987 and were used to initiate the 1992 NHLBI conference on Cardiovascular Health and Disease in Women. The landmark 1986 meeting and report sparked interest in the topic of women and heart disease. Before the late 1990s, knowledge and awareness of heart disease as the major killer of women was exceedingly low among both women and health care providers (Mosca et al., 2013). Even among

cardiologists, heart disease in women was not discussed frequently because of the widely held belief that cardiovascular disease was a "man's disease" that did not affect women.

Concurrently, efforts were being made to address the lack of research on women's health and the widespread exclusion of women from clinical trials. In 1990, the U.S. Government Accountability Office conducted a landmark study highlighting that the lack of inclusion of women in clinical studies negatively affects women's health knowledge and identifying cardiovascular disease as a field in which major studies had excluded women (NIH, 1990). Poorly understood and unacknowledged, the role of sex and gender differences in heart disease—its pathophysiology, risk factors, outcomes, and treatment—was unexplored because of inaccurate assumptions and the lack of research including women.

With the establishment of the NIH's Office of Research in Women in 1990, the reversal of the U.S. Food and Drug Administration's (FDA's) guidelines barring women of childbearing age from participating in clinical research in 1993, and the 1993 legislation mandating that the NIH include women in all human subject research, a clear path to improving the safety and efficacy of research, diagnosis, and treatment for women was set forth. The American Heart Association's 1993 scientific statement on cardiovascular disease in women continued the drumbeat for change (Eaker et al., 1993).

The end of the twentieth century was marked by several important events for women's heart health. In 1999, the American Heart Association published "A Guide to Preventive Cardiology in Women," the first sex-specific clinical recommendations for prevention of cardiovascular disease (Mosca et al., 1999), with its most recent update in 2011 (Mosca et al., 2011). The Institute of Medicine's 2001 report, "Exploring the

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Biological Contributions to Human Health: Does Sex Matter,” discussed basic biochemical and molecular differences in the cells of males and females, health variability between the sexes, and the health effects of sex and gender from conception throughout life, literally “from womb to tomb.” In this environment, WomenHeart: The National Coalition for Women with Heart Disease was founded.

Three women who were heart attack survivors and faced many obstacles, including misdiagnosis, inadequate treatment, and social isolation, were brought together by a reporter for *MORE* magazine. Each woman had experienced the lack of information and services for women with heart disease and found that women were largely invisible in the cardiovascular health care community. Together, they formed the first support network for women with heart disease; their commitment to increase the availability of support for the millions of women living with heart disease inspired them to create WomenHeart, the first national patient-centered organization focused exclusively on women’s heart disease (www.womenheart.org). Putting women patients at the center of the conversation, in the forefront of research, and in the midst of the policy debates changed the national dialogue about heart disease.

In addition to taking telephone calls from distressed women with newly diagnosed heart disease, WomenHeart was determined to put women’s heart health on NHLBI’s national agenda. The presentation of compelling data to NHLBI leadership outlining the public’s lack of awareness, disparities in care and outcomes, and most importantly, the dearth of heart-related research in women, led to the 2001 NHLBI [Women’s Heart Health Education Strategy Development Workshop \(2001\)](#); [WomenHeart the National Coalition for Women with Heart Disease, 2015](#).

At this meeting, patients, researchers, public health leaders, women’s health advocates, health communicators, and health care delivery experts developed a blueprint for a comprehensive health education action plan and in 2002 launched The Heart Truth “Red Dress” campaign. This first national awareness campaign was sponsored by the NHLBI and U.S. Department of Health and Human Services, in partnership with the Office on Women’s Health, American Heart Association, WomenHeart: the National Coalition for Women With Heart Disease, and other organizations committed to the health and well-being of women ([NHLBI, 2002](#); [National Heart, Lung, and Blood Institute, 2001](#)).

The centerpiece of The Heart Truth is the Red Dress, which was introduced during American Heart Month, February 2003, as the national symbol for heart disease awareness in women. The Red Dress reminds women to protect their heart health and inspires them to take action to lower their risk of heart disease. The Heart Truth’s message is: “Heart Disease Doesn’t Care What You Wear—It’s the #1 Killer of Women” ([NHLBI, 2013](#)). The stories of women living with heart disease were featured in the campaign materials and resonated with First Lady Laura Bush, who in 2004 invited WomenHeart members to the inaugural National Wear Red Day ceremony at the White House, further increasing the visibility of heart disease in women. This successful campaign continues today.

In 2006, WomenHeart collaborated with the Society for Women’s Health Research to publish the first “10Q Report: Advancing Women’s Heart Health Through Improved Research, Diagnosis and Treatment,” which was updated in 2011 ([Wenger et al., 2013](#); [WomenHeart 2011](#)). The report identified the top 10 unanswered research questions concerning the prevention, diagnosis, and treatment of heart disease in women and was a

call to action to members of Congress, administration officials, researchers, health care providers, and women. As WomenHeart marks its fifteenth anniversary, we reflect on the advances that have been made, as well as the questions that remain unanswered.

Current State of Women’s Heart Health

In the past decade, considerable progress has been made in the prevention, diagnosis, and treatment of heart disease in women, and many lessons have been learned. The number of women dying of heart disease has decreased by approximately 30% ([Mozaffarian et al., 2015](#); [Wenger, 2012](#)). In fact, since 2000, cardiovascular disease deaths among women have decreased even more sharply than for men. This striking improvement has been attributed to increased awareness, use of evidence-based guidelines, integration of preventive interventions for coronary risk factors, and sex-specific treatment strategies.

Despite these gains, for the past 3 decades women have had more cardiovascular deaths annually than men, and among American women, deaths from cardiovascular disease exceed those from all forms of cancer combined. Among women aged 35 to 54 years, death rates from coronary heart disease showed an unfavorable trend ([Ford & Capewell, 2007](#)). Further, disparities in care and outcomes continue for subgroups of women, especially among racial and ethnic minorities ([Gupta & Wenger, 2012](#)), those with lower education levels, and those who are otherwise socially disadvantaged ([Institute of Medicine, 2010](#)).

The 2010 Institute of Medicine report, “Women’s Health Research: Progress, Pitfalls, and Promise,” stated the need for significant improvement in women’s health research ([Institute of Medicine, 2010](#)). It cited the underrepresentation of women “in the design, conduct, and analysis of research studies” ([Wenger, 2012](#)). Basic science research on diseases that occur more commonly in women than men also have primarily used male animal models. Because research trials consistently reveal sex and gender differences in the presentation, symptoms, diagnosis, and treatment strategies for heart disease, attention must be paid to ensure that these differences are addressed appropriately and that inclusion criteria for trial participation do not inadvertently or inappropriately exclude women.

To address the persistent lack of appropriate participation of women in clinical trials, Congress, at the urging of WomenHeart, the American Heart Association, and the Society for Women’s Heart Research, included language in the 2012 FDA Safety and Innovation Act that required the FDA to address the extent to which clinical trial participation and safety and effectiveness data by sex, age, race, and ethnicity are included in applications for drugs, biological products, and devices submitted to the FDA ([FDA, 2012](#)). This provision also required the development of an action plan with recommendations for improving the availability of this information. The action plan, released in August 2014, included 29 recommendations for achieving the goal of increasing participation in clinical trials and making data stratified by sex, race, and ethnicity publicly available ([FDA, 2014](#)).

Government agencies and policies must ensure that appropriate research is conducted, sex-specific results are reported, and the knowledge gained is translated into high-quality health care for women. The federal and state roles extend to creating private and public insurance coverage for women’s heart health care, health promotion activities in communities and the health care system, and reducing the personal, social, and environmental risk factors for heart disease. The NIH, together with the

Agency for Healthcare Research and Quality, the FDA, and the Centers for Disease Control and Prevention, have an important responsibility in advancing our knowledge and strategies for improving the health of all. Identifying gender gaps and taking appropriate steps to address them requires commitment and vigilance from researchers, clinicians, patients, advocates, and policy makers.

Summary of the Problem

Despite many advances, heart disease remains the number one cause of death in women. There is a continued lack of specific attention to sex and gender differences in research, prevention, diagnosis, and treatment in both our public health strategies and health care systems. Disparities persist across populations of women. Change is clearly needed in our approach to addressing these high priorities if we are to effectively reduce the burden of heart disease in women.

Key Questions

Critical and unanswered research questions remain from the 10Q Report ([WomenHeart, 2011](#)). Probing these questions through policy change and investment in research is of great importance to improve the care of women living with and at risk for heart disease. These questions include:

- What factors influence or explain disparities in cardiovascular disease epidemiology and disease outcomes between men and women? For example, how do age, cardiovascular function, anatomic characteristics, hormonal status, inflammatory or coagulation processes, or comorbid conditions affect risk and disease development? How do differences in disease presentation, symptoms, and patient access to care affect the quality of care for women, including appropriate prevention, diagnosis, treatment, and rehabilitation?
- What are the best strategies to assess, modify, and prevent a woman's risk of heart disease? How do we appropriately identify women at risk early in life? What strategies work best to change both women's and health professionals' awareness of women's cardiovascular risk and to change behaviors that can reduce these risks? What performance measures for women need to be developed and implemented to improve quality of diagnostic and preventive care?
- What biological variables are most influential in the development and clinical outcomes of heart disease, and what can be done to reduce mortality rates in women? ([WomenHeart, 2011](#)). What biomarkers, including biomediators, neurohormones, and inflammatory and surrogate markers, are relevant for women, and which of them, if modified, will result in improved outcomes? How can we ensure that sex-specific research in these critical areas is a priority and adequately funded?

Next Steps

In October 2015, WomenHeart will convene the National Policy & Science Summit on Cardiovascular Health. This summit will bring together women with heart disease and key leaders in women's cardiovascular health, with the goal of improving cardiovascular health for women through the development of policy solutions to the scientific questions posed. The participants in

this summit will critically evaluate the state of women's heart health through the lens of primary and secondary prevention strategies and will identify policy steps needed to ensure the establishment of a woman-centered approach to heart health. The success of the summit will rely on a collaborative approach among multiple stakeholders who will identify priorities and develop recommendations. These recommendations will serve as a call to action for all stakeholders, to guide our efforts and to provide strategies and mileposts for progress.

The goal is to develop a patient-centered holistic approach to sex- and gender-specific heart health that is supported by research and policies addressing women's needs. The conveners of the 1986 NHLBI workshop assembled a diverse group of professionals to interact across disciplines and to lay the groundwork for future efforts in women's heart health. In response to patient advocacy, the 2001 NHLBI workshop led to the creation of the campaign to increase awareness. These landmark meetings, along with many initiatives developed over the past 3 decades, laid a solid foundation for new action. This 2015 summit will build on that foundation to initiate substantial improvements in women's heart health. By focusing on research and policy solutions with well-trained patient volunteers, experts in women's heart health, progressive hospitals, generous partners, advocacy organizations, and relevant governmental organizations, we will advance the fight against heart disease in women. Improving women's heart health can improve the health of families and the broader community. As the nation moves from a focus on sick care and disease to wellness and prevention, decreasing heart disease morbidity and mortality and ensuring that women with heart disease can thrive is critical and is within our reach ([National Prevention Council, 2011](#)).

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