Commentary

Advancing Women's Heart Health through Policy and Science: Highlights from the First National Policy and Science Summit on Women's Cardiovascular Health

Susan F. Wood, PhD, Jennifer H. Mieres, MD, Susan M. Campbell, MPH, Nanette K. Wenger, MD, Sharonne N. Hayes, MD, for the Scientific Advisory Council of WomenHeart: The National Coalition for Women with Heart Disease

*Department of Health Policy and Management, Milken Institute School of Public Health, George Washington University, Washington, District of Columbia
†Department of Cardiology, Hofstra North Shore-LIJ School of Medicine, Hempstead, New York
‡WomenHeart: The National Coalition for Women with Heart Disease, Washington, District of Columbia
¶Division of Cardiology, Emory University School of Medicine, Emory Heart and Vascular Center, Atlanta, Georgia
¶‡Department of Cardiovascular Diseases, Mayo Clinic, Rochester, Minnesota

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There are persistent and substantial gaps in knowledge and barriers to implementing strategies to improve outcomes for the 42 million women at risk for or living with heart disease, the number 1 killer of women (Gupta & Wenger, 2012; Institute of Medicine, 2010; Mosca, Hammond, Mochari-Greenberger, Toffighi, & Albert, 2013; Mozaffarian et al., 2015; Wenger, 2012). On October 26, 2015, the National Policy and Science Summit on Women's Cardiovascular Disease was convened by WomenHeart: The National Coalition for Women with Heart Disease (WomenHeart, 2016) and partner organizations to identify approaches to improve women's heart health. The Summit Steering Committee invited a diverse group of participants that included women living with heart disease, experts in women's heart health, and representatives from hospital systems, advocacy organizations, industry, and key federal agencies. Cross-disciplinary work groups were formed to identify issues, obstacles, and gaps in knowledge, practice, implementation, and translation; develop policy recommendations for solutions; and advance sex- and gender-based cardiovascular disease (CVD) research (Hayes, Wood, Mieres, Campbell, & Wenger, 2015).

The focus on both sex and gender effects related to heart disease was deliberate (Regitz-Zagrosek et al., 2016). Biologic sex contributes to and impacts many of the observed sex differences in CVD presentation, natural history, and outcomes. The effect of gender, defined as a woman's socially constructed roles, behaviors, and culture, has been shown to substantially contribute to cardiovascular outcomes, often being inextricably linked to biology (Dreyer et al., 2016; Khan et al., 2013; Leung Yinko et al., 2014; Pelletier et al., 2016; Schiebinger & Stefanick, 2016; Spatz et al., 2015; Villablanca et al., 2010).

The focal point was three unanswered research questions previously identified in the 2011 WomenHeart and the Society for Women's Health Research publication: “10Q Report: Advancing Women’s Heart Health Through Improved Research, Diagnosis and Treatment” (Friedewald, Hayes, Pepine, Roberts, & Wenger, 2013; Hayes, Wenger, Greenberger, & Tate, 2011):

1. 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?
2. What are the best strategies to assess, modify, and prevent a woman's risk of heart disease?
3. What factors influence and explain disparities in CVD epidemiology and outcomes between men and women?

Participants explored successes and failures of prior policies, scientific advances and breakthroughs, and real and perceived barriers to progress. A unique aspect of this process was the integral role that women living with heart disease played in...
planning the Summit and providing their perspectives and expertise throughout.

There was consensus that action is urgently needed. Some of the recommendations that emerged from the Summit simply require that federal agencies and scientists follow existing regulations and best practices for research; others require innovative efforts and investments to translate findings into better heart health. Research gaps are substantial and include a lack of understanding of the impacts of social determinants on heart health and the need to address the incorporation of quality, effectiveness, equity, access, incentives, and cultural appropriateness to enhance health care delivery to women.

**Summit Recommendations**

**Strengthen and Enforce Existing Guidelines and Recommendations**

Although numerous recommendations, guidelines, and legislation aimed at addressing gaps in scientific knowledge and reducing sex- and gender-based health disparities in CVD have been crafted over the last 20 years (Hamburg, 2014; Institute of Medicine, 2001, 2010; Mastroianni, Faden, & Federman, 1994; National Institutes of Health, 2001) most have not been fully implemented, nor has the benefit been fully realized (Blauwet, Hayes, McManus, Redberg, & Walsh, 2007; Dhruva, Bero, & Redberg, 2011; Dolor et al., 2012; US Food and Drug Administration [FDA] Office of Women’s Health, 2015; Geller, Adams, & Carnes, 2006; Mazure & Jones, 2015). The U.S. General Accountability Office released its report, “National Institutes of Health: Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research” (US Government Accountability Office, 2015) just days before the Summit was convened. This timely publication outlines substantial gaps in compliance and reporting, and recommends “that [the National Institutes of Health (NIH)] examine and report more detailed data on women’s enrollment in NIH-funded studies, and collect, examine, and report data on the extent to which these studies include analyses of potential differences between women and men.”

NIH and FDA policies must be strengthened and enforced to ensure that analyses include findings on sex differences and consider biological sex as a fundamental variable of health and disease.

1. Hold the NIH, the FDA, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, and private funders accountable for enforcing current policies regarding participation of women and minorities in CVD research and include these priorities in the NIH-wide strategic plan.
2. Require inclusion and disclosure of number of females in studies using animal models, cells and isolated tissue; fully implement the NIH requirement to do so.
3. Strengthen NIH and FDA policies to ensure that analyses of study results are transparent, publically available, and include reporting of results by sex and/or gender.
4. Enforce FDA regulations to insure that CVD sex-specific data and information on sex differences are required as a condition of approval for all prescription drug and device applications.
5. Require that scientific journal publications include data on the sex of subjects, animal models, and cells. Journals should not publish studies involving both sexes that lack appropriate analyses by sex.
6. Support measures to increase scientific literacy in the United States regarding the importance of research, and in particular, sex- and gender-based research.

**Research Processes, Priorities, and Participation**

Many Summit recommendations focused on improving the quality and scope of CVD research on and for women. Barriers to connecting CVD researchers and eligible women research participants include limited awareness regarding the value of clinical trials, ineffective and inadvertently discriminatory trial design, and lack of coordinated systems (Wenger, 2015). Trial design must consider appropriate inclusion of women, female tissue, or animals so that results provide meaningful data. The enrollment process in clinical trials must be streamlined, patient centered, conducted where patients receive care, and incorporate the use of telemedicine and technology.

Grassroots engagement, aggressive advocacy, and provocative social media messages communicating the effect of medical research on future generations would augment successful recruitment of women. Although stakeholders can collaborate to connect women with medical research, trusted providers of care must also assume responsibility for informing and encouraging women to participate.

1. Use a sex- and gender-specific lens to develop effective procedures for recruiting and retaining women and optimizing study design to address exclusion criteria, cost, provider concerns, and logistical barriers, with a methodology to calculate appropriate representation of women.
2. Prioritize research funding that addresses women’s heart health and sex and gender differences in CVD, especially those that are cross-disciplinary and will meaningfully engage women.
3. Require researchers to include sex and gender analyses in all proposals or to justify the rationale for not doing so.
4. Provide training to grant reviewers on the effects of unconscious bias on both study design and the review process.
5. Work with institutional review boards to encourage consideration of inclusion/exclusion criteria by sex and age in the review process.
6. Create and promote user-friendly websites and social media networks with trusted community sources linking women with clinical studies.
7. Develop, fund, and launch a public awareness campaign highlighting stories from women living with heart disease who have participated in and benefitted from medical research.

**Address Unmet Research Needs**

There is growing acceptance of the effect of sex and gender differences on prevention, diagnosis, treatment, and clinical outcomes of heart disease, but compelling evidence to individualize care of women is often lacking. The effect of women’s life transitions on heart health and CVD risks has been inadequately studied and the impact of age, mental health, reproductive status, menarche, the menstrual cycle, pregnancy, menopause, and endogenous and exogenous hormones requires further
investigation. Sex-based research, from the basic biology of heart disease to greater understanding about optimal delivery of CVD preventive services, will benefit quality of care.

There is growing evidence that pregnancy complications can influence and predict future CVD risk. Screening and early detection of these risk factors during pregnancy, with appropriate referral, treatment, and long-term follow-up, could provide women with guidance for attaining and maintaining lifelong heart health.

1. Conduct large-scale studies/national registries to collect data from pregnancy diagnosis through the postpartum period, and target factors that can predict and prevent gestational diabetes, hypertension, preeclampsia, and placental insufficiency.
3. Evaluate sex-specific epigenetic effects of environmental exposures.
4. Focus research addressing sex- and gender-specific causes, associations, and effective management strategies for depression, anxiety, and other psychosocial stresses.
5. Explore the role of assistive technology, social media, health coaching, and self-monitoring wearable devices for behavioral modification and cardiovascular risk reduction and establish their effectiveness.

Explore Health Care Delivery and Payment Models

The provision of preventive, primary, and specialty care according to evidence-based guidelines is essential for improvements in cardiovascular health for women. Disparities between women and men in receipt of guideline-based care, secondary prevention therapies, and cardiac rehabilitation result in poorer outcomes for women (Mehta et al., 2016). In addition, even though women and girls engage health care providers more often than men, they are less likely to receive CVD prevention messages.

1. Enhance and incentivize coordination of CVD prevention strategies and screening practices with women’s primary care providers to reduce missed educational and interventional opportunities.
2. Develop and incorporate sex-specific CVD risk factor screening for well-women visits and incentivize primary care providers to document gender-specific risk assessment and evidence-based protocol implementation.
3. Create a comprehensive reproductive history for women’s permanent medical record.
5. Encourage coordination of CVD care among rheumatologists, oncologists, obstetricians/gynecologists, and cardiologists regarding the disproportionate burden of autoimmune, inflammatory, vasospastic, and thrombotic conditions women sustain, as well as sex-specific effects related to cancer and its treatments.
6. Develop evidence to support expansion of women’s CVD specialty and gender-based heart care clinics.
7. Promote appropriate use of cardiac rehabilitation services among women by developing evidence driven gender-specific cardiac rehabilitation options to include home and community based programs and telemedicine and designing strategies for universal access, referral, and reduction/elimination of co-pays and other barriers to participation.

Enhance Education, Training, and Dissemination

Investments in educational interventions are needed to address lack of awareness among health care providers and women regarding CVD (Lambert-Kerzner et al., 2015; Miller et al., 2013; Mosca et al., 2013).

1. Incorporate information about sex and gender on health, heart disease, and research into curricula for undergraduate and graduate medical schools, nursing, public health, pharmacy, and continuing medical education.
2. Target education to provider groups that have the most influence and frequent contact with women: primary care, specialists in women’s health, emergency medicine, obstetrics and gynecology, and first responders.
3. Partner with faith-based organizations, schools, and communities to implement culturally appropriate heart health education for women and families and focus on children for whom heart-healthy behaviors can create lifelong habits and serve to change parental behavior.
4. Engage women living with heart disease to tell their heart stories and promote heart health messages with hospitals, health systems, physicians, and employers.

Address Social Determinants and the Environment to Improve Women’s Heart Health

Conditions where people live, learn, work, play, and worship affect health risks and outcomes and are often influenced by gender. By applying what is known about social determinants of health (e.g., socioeconomic status, educational attainment), health equity can be advanced and health can be improved (Havranek et al., 2015). Social determinants of health, barriers to care, and the built environment (e.g., access to safe spaces to exercise) contribute to disparities and challenges facing women, particularly racial and ethnic minorities, immigrants, and those living in rural areas (Centers for Disease Control and Prevention, 2011). Addressing these issues is critical and will require policy changes, investments, cooperation, and collaboration among an array of stakeholders (Havranek et al., 2015).

1. Launch a cross-disciplinary advocacy effort including scientists, researchers, providers, and patients to develop programs and policies which use public health campaigns to reach U.S. women who are unaware of heart disease risks.
2. Reach new audiences via creative partnerships with sports franchises, grassroots organizations, and social media platforms.
3. Align financial and behavioral incentives and penalties, an improved built environment, and access to healthy food to support the heart health of women and their families and make the easiest choice the healthiest one.

Implications for Practice and/or Policy

The Summit focused on identifying, prioritizing, and strategically addressing both research and policy solutions aimed at improving the health of women and the health outcomes among women with and at risk for heart disease. To overcome the many
barriers to optimal women’s heart health, we must keep the pressure on, urged the Honorable Patricia Schroeder, the Summit closing speaker. Former Representative Schroeder spent her legislative career advancing women’s health research and shared her legislative and personal experience with heart disease. Having policies in place without enforcing them is unacceptable, and participants were challenged to hold officials responsible for enforcing current policies. “It’s just very frustrating,” said Schroeder, “It reminds me of when you ask your children to move the clothes from the washer to the dryer. Then you go back, and the clothes are still wet, and they say, ‘Well, you didn’t tell me to turn the dryer on’” (Rovner, 2015).

Investments must be made in research most likely to impact the heart health of women and expanded beyond traditional biomedical models to incorporate social determinants that affect health. Policies supporting the health of women must be created, which include access to high quality care, and address aspects of financing and payment models. These recommendations will result in healthier women, families, and communities only if federal agencies, researchers, clinicians, patients, women, advocates, and policy makers commit to fully implement existing policies and working together to move forward.

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References


**Author Descriptions**

Susan F. Wood, PhD, is Associate Professor of Health Policy and Management and Director of the Jacobs Institute of Women’s Health at the George Washington University, Milken Institute School of Public Health.

Jennifer H. Mieres, MD, is Professor of Cardiology, Occupational Medicine, Epidemiology & Prevention at NorthWell Health System, where she directs women’s health, community health, diversity, and cultural competency programs. Her research focuses on cardiovascular disease in women and elimination of health disparities.

Susan M. Campbell, MPH, is Vice President, Public Policy for WomenHeart: The National Coalition for Women With Heart Disease. She develops the organization’s policy, legislative, and research agenda, and works at the federal level on issues affecting women with heart disease.

Nanette K. Wenger, MD, is Professor of Medicine (Cardiology) at the Emory University School of Medicine and a Consultant to the Emory Heart and Vascular Center, Atlanta, Georgia. Heart disease in women is Dr. Wenger’s major clinical, research, and advocacy interest.

Sharonne N. Hayes, MD, is Professor of Internal Medicine and Cardiovascular Diseases and founder of the Women’s Heart Clinic at Mayo Clinic, Rochester, Minnesota. Her practice, research, and advocacy efforts focus on improving cardiovascular care for women and addressing health disparities.