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Commentary

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

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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, Towfighi, & 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

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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 insure 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 participle.

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