

54<sup>th</sup> Meeting of the National Institutes of Health (NIH)  
Advisory Committee on Research on Women's Health (ACRWH)  
Office of Research on Women's Health (ORWH)  
Bethesda, MD  
September 1, 2021

**Members Present**

Roger B. Fillingim, Ph.D.  
Stacie Geller, Ph.D.  
Scott Hultgren, Ph.D.  
Reshma Jagsi, M.D., D.Phil.  
Sabra Klein, Ph.D.  
Margaret M. McCarthy, Ph.D.  
Michelle Robinson, D.M.D.  
Yoel Sadovsky, M.D.  
Neel Shah, M.D.  
Melissa Simon, M.D.  
Kimberly J. Templeton, M.D.

**Other Attendees**

Haywood Brown, M.D.  
Linda Griffith, Ph.D.

**ORWH Leadership Present**

Janine Clayton, M.D., FARVO, Director  
Samia Noursi, Ph.D., Associate Director for  
Science Policy, Planning, and Analysis  
Sarah Temkin, M.D., Associate Director for  
Clinical Research

**Call to Order and Introductions**

Samia Noursi, Ph.D., ACRWH Executive Secretary and ORWH Associate Director, Science Policy, Planning, and Analysis, called the online meeting to order at 1:05 p.m. Committee members introduced themselves.

**Advancing NIH Research on the Health of Women: A 2021 Conference Overview**

Dr. Noursi introduced Sarah Temkin, M.D., Associate Director for Clinical Research, ORWH, and the Co-Chair of "Advancing NIH Research on the Health of Women: A 2021 Conference," scheduled for October 20, 2021. As background information, Dr. Temkin noted that Congress believes that more focus on research related to obstetrics and gynecology is required to address rising maternal morbidity and mortality (MMM) rates, rising rates of chronic debilitating conditions in women (CDCW), and stagnant cervical cancer (CC) survival rates. Therefore, Congress encouraged NIH to convene a consensus conference to evaluate research currently underway related to women's health and directed it to prepare a consensus report outlining the discussions and recommendations from the conference. In response, NIH has been reviewing public health needs in MMM, CDC, and CC. ORWH formed clusters made up of experts from across NIH and the U.S. Department of Health and Human Services (HHS) to review NIH portfolios related to each topic.

Dr. Temkin reviewed data on MMM which remains a public health crisis in the United States, noting the particularly high rates among Black women and women from American Indian communities. She also reviewed the steep rise in CDCW since 1990, as measured in Disability Adjusted Life Years (DALYs), i.e., the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability (World Health Organization [WHO]). She identified the female-specific causes of morbidity in women, such as gynecological diseases, as well as conditions that result in high mortality

among women, e.g., ischemic heart disease. She also reviewed stagnant CC mortality rates despite widespread screening, again noting the higher incidence among Black and American Indian women compared to other races/ethnicities.

Dr. Temkin concluded by reviewing the Women's Health Conference goals: To assess the current state of NIH-supported research on women's health, including research gaps and opportunities; set priorities for research on the health of women; and address rising maternal morbidity and mortality rates, increasing rates of chronic debilitating conditions in women, and stagnant cervical cancer survival rates. A Request for Information (RFI) related to the Conference is open for comments until September 15, 2021.

## **Chronic Debilitating Conditions in Women (CDCW): Characterizing NIH Research**

Dr. Noursi introduced Elizabeth Barr, Ph.D., Social and Behavioral Scientist Administrator, ORWH, and Co-Chair of the CDCW Cluster, who reported on a portfolio analysis of NIH research on CDCW. The analysis addressed four categories of conditions: female-specific; more common in women and/or morbidity is greater for women; potentially understudied in women; and high mortality for women. Across diagnoses, comorbidities are more common in women, especially those from communities who are underserved based on race or ethnicity.

Institutes/Centers/Offices (ICOs) were asked to submit their three highest-funded projects by CDCW category from FY 2018-2020. Eleven ICOs submitted 184 projects, which provided a limited, non-exhaustive snapshot of NIH funding within the CDCW arena. Dr. Barr summarized the findings of the portfolio analysis by the Cluster's three guiding questions as follows:

### **1. HOW to define and report on chronic debilitating conditions in women?**

- There is no standard definition of chronic debilitating conditions, nor standard way of reporting at NIH.

### **2. WHAT is known about chronic debilitating conditions that impact women? WHO is disproportionately impacted?**

- Women have higher rates of multimorbidity than men; identifying studies that include multimorbidity as an aim is difficult.
- Women of color, older women have higher rates of chronic conditions than white women, younger women; few health disparity-focused studies relevant to diverse populations of women across the life course are available.

### **3. WHAT is the distribution of CDCW research at the NIH?**

- CDCW research occurs in many Institutes/Centers (ICs); few NIH-wide CDCW efforts exist.
- Each IC considers different diseases as chronic and debilitating conditions, making it difficult to analyze the portfolio of chronic debilitating conditions **AND** women's health.

**Discussion:** Dr. Noursi asked ACRWH members to identify research gaps and opportunities related to CDCW. Dr. Temkin facilitated the discussion. Major discussion points and comments raised by ACRWH members included:

- Rates of CDCW, including rates of infectious diseases, are on the rise, but there is a need to remove roadblocks that discourage the translation of women's health needs into effective therapeutics.
- Research tends to focus on single conditions, but co-morbidity is often the norm. Depression and other psychiatric concerns are very often co-morbid with CDCW.

- How women’s health is addressed at NIH needs to be revisited, e.g., through a new center for gynecological research. It could support more basic research on women’s health and more thoughtful use of bioinformatics and bioengineering.
- The current structure of ORWH as an OD office without grantmaking authority and with a very limited budget is not congruent with advancing the science needed for women’s health. ORWH should instead become a grant-making center with an appropriate budget. One argument in favor of doing so is that a large proportion of women’s health research funding currently is reviewed by Special Emphasis Panels (SEPs) rather than standing study sections with specific expertise in these topics, which contributes to the lack of a stable research community.
- More research in translating knowledge into physician education is needed so that healthcare providers can apply new research and the next generation of physician-scientists in the field can be cultivated.
- With long COVID being more prevalent among women, there is an opportunity to align concerns about CDCW with the momentum of the current pandemic.

### **Women’s Health Conference: Cervical Cancer (CC) Cluster**

Dr. Noursi introduced Nikeya Macioce, Ph.D., Science Management Analyst, ORWH, and Co-Chair of the CC Cluster, who identified several public health needs related to cervical cancer, i.e., prevention (poor uptake of HPV vaccine in U.S. adolescents); disparate screening rates across race/ethnicity, education, income, and other socio-economic factors; access to health services, which is highly dependent on insurance status; and the improvement of available therapeutics.

Dr. Macioce identified potential new research opportunities, including primary and secondary prevention; basic science research; treatment, including access to healthcare/ specialty care; implementation research projects that considers Social Determinants of Health (SDoH); reducing health disparities; and partnerships with other HHS agencies (e.g., the Centers for Disease Control and Prevention [CDC], the Health Resources and Services Administration [HRSA]).

**Discussion:** Dr. Noursi asked ACRWH members to identify research gaps and opportunities related to CC. Discussion points included:

- To overcome gaps related to prevention, access to care, and treatment of CC, large multi-site implementation studies are needed. These require larger budgets than ICs currently permit, even under Requests for Application. Collaboration with other HHS agencies interested in implementation may be one way to address this issue.
- There is a need for the full translational research spectrum (T0 to T4)-- from bench to bedside to community--for each of the three topics.
- There is little research on specific interventions to increase HPV vaccination, beyond education. Prevention needs new ideas, e.g., empowering women with an HPV self-swab.
- Seventy percent of oral cancers are caused by human papillomavirus (HPV); lack of knowledge about this relationship may be a gap although not one directly addressing CC. Currently, a large percentage of the \$91 million spent on CC is HPV research; however, it should be more focused on cervical cancer.
- There are strong research gaps in the treatment of CC, including the development of innovative drugs and drug-surgery combinations.
- Consider tying NIH funding to outcomes, e.g., enrollment of women in clinical trials, reducing health disparities.

## Maternal Morbidity and Mortality (MMM): Research Gaps and Opportunities

Dr. Noursi introduced Damiya Whitaker, Psy.D., Health Scientist Administrator/Program Officer, ORWH, and Co-Chair of the MMM Cluster. Each year, 700 women die from pregnancy-related complications; 3 in 5 of those deaths could be prevented. There are wide racial, ethnic, and geographic disparities related to MMM; those disparities increase with maternal age, with African American/Black and American Indian/Alaska Native women older than 30 being 4 to 5 times more likely to experience pregnancy-related death compared to their white counterparts.

There are ongoing programs, both NIH-wide and in specific ICs, which aim to improve maternal health and to address the causes of disparate outcomes. These include Implementing a Maternal Health and PRegnancy Outcomes Vision for Everyone (IMPROVE) (multiple ICs); the Maternal-Fetal Medicine Units (MFMU) Network (primarily the Eunice Kennedy Shriver National Institute of Child Health and Human Development [NICHD]); the Maternal and Infant Environmental Health Riskscape (MIEHR) Research Center (National Institute on Minority Health and Health Disparities [NIMHD], National Institute of Environmental Sciences [NIEHS]); and the Nulliparous Pregnancy Outcomes Study-Monitoring Mothers-to-Be Heart Health Study (National Heart, Lung, and Blood Institute [NHLBI]); among others. More work is needed, however. There are significant geographic barriers in NIH-funded work, especially in the West, South, and Central U.S. Further, little research has addressed sexual minority women.

Dr. Whitaker summarized her presentation by observing that MMM is a critical health issue in the United States, with different rates between women who are from racial and ethnic groups and based on their geographic location. The MMM Cluster members agreed that: All women must have access to streamlined and evidence-based and patient-centered comprehensive maternal health interventions across the life course, as well as skilled community-based birth attendants, even in remote areas. Alliances must be formed to address barriers that limit access to quality maternal health services. Women and their services providers must feel educated and empowered about maternal health issues.

NIH is committed to improving maternal health and sees health equity-focused research opportunities in the following areas: Community Engaged Research (e.g., interventions addressing SDoH-related needs; structural racism/discrimination impacts on maternal health outcomes/services utilization); Outcomes-Driven Research (e.g., interventions leveraging quality improvement tools, protocols and tracking/monitoring to ensure high-quality maternal health services across care systems for all patients); and Partnerships within HHS and public-private partnerships. Other areas of expansion include Prevention (e.g., modifiable factors linked to maternal health disparity gaps/multilevel interventions) and Clinical Research (e.g., clinical management of chronic conditions during pregnancy, establishing care protocols/standards attuned to risk, evidence-based healthcare systems interventions).

**Discussion:** Dr. Noursi led a discussion of research gaps and needs in MMM. Points raised by ACRWH members included:

- There is a need for NIH to broaden its thinking about what will work to improve research in MMM. Single clinical interventions have had limited impact, especially in reducing health disparities. A paradigm shift is needed that considers factors such as generational racism and the dynamics between the healthcare system and Black women.
- Such a paradigm shift should include addressing health policies, putting a greater emphasis on implementation research, and educating providers outside the obstetrics/gynecology field (e.g., cardiologists) about medical issues such as hypertension and how they are related to MMM.

There are opportunities for such collaboration, e.g., the American College of Cardiology Cardio - Obstetrics Work Group.

## **Closing Statement and Remarks**

Dr. Noursi presented the following framework of questions for each topic to be addressed at the Women's Health Conference. These questions reflect ACRWH feedback to a draft framework and questions developed by the Conference Working Group.

### **Maternal Morbidity and Mortality**

- What current research gaps can be filled to reduce the burden of maternal morbidity and mortality?
- What opportunities exist to improve research on prevention of maternal morbidity and mortality?
- How can clinical research on maternal morbidity and mortality be improved to reduce the burden of these events on our communities?
- What opportunities for health services research exist that can translate research findings into practice?
- What are the research opportunities that can be leveraged to reduce disparities in maternal morbidity and mortality?

### **Chronic Debilitating Diseases**

- What current research gaps can be filled to reduce the burden of chronic debilitating conditions in women?
- What opportunities exist to improve research on prevention of chronic debilitating diseases in women?
- What research is needed to reduce the burden of disease in female-specific chronic debilitating conditions?
- What research is needed to reduce the burden of disease in chronic debilitating conditions that cause high rates of morbidity among women?
- What are the research opportunities that can be leveraged to reduce disparities in chronic debilitating diseases in women?

### **Cervical Cancer**

- What current research gaps can be filled to improve survival from cervical cancer?
- What research opportunities exist to improve prevention of and screening for cervical cancer?
- How can basic and translational research on cervical cancer be improved?
- How can clinical research on cervical cancer be improved to improve survival from this disease?
- What are the research opportunities that can be leveraged to reduce disparities in cervical cancer?

**Action:** In response to a motion made by Stacie Geller, Ph.D., and seconded by Melissa Simon, M.D., Dr. Noursi called for a vote on the question: Does the ACRWH confirm that the Women's Health Conference Agenda Framework reflects the topics that correspond to the most compelling public health needs and clinical questions for increasing rates of chronic debilitating conditions in women, stagnant cervical cancer survival rates, and rising maternal morbidity and mortality rates?

**Vote:** The conference agenda framework was accepted with 8 in favor, 2 abstaining, and none opposed.

Janine A. Clayton, M.D., FARVO, Director, ORWH, thanked everyone for their contributions to the planning process. She noted that ORWH has played an integral role in carrying out the will of Congress, including convening internal and external stakeholders to collect, analyze, deliberate, and make recommendations about women’s health research; it will produce a report outlining research gaps and opportunities. She also reiterated the main takeaway messages from the day’s discussions. These included:

**CDCW:** There is no standard definition of CDCW; women have higher rates of co-morbidities; racial and age disparities exist; and, without a standard definition, identifying related research gaps and opportunities is difficult.

**CC:** Three factors contribute to stagnant rates of cervical cancer: frustrated prevention efforts, disparities in access to care, and a need for improved therapies.

**MMM:** There is a need to focus on social determinants of health, as deeply rooted racial, ethnic, and geographic disparities exist.

Dr. Clayton reviewed key dates in the Conference process, including the end of the public comment period in response to the RFI on September 15, 2021; the Women’s Health Conference on October 20, 2021, and the 55<sup>th</sup> meeting of the ACRWH on October 21, 2021. The ACRWH meeting will focus on the state of NIH-supported women’s health research and future priorities to help inform the report to Congress, due in December 2021.

Dr. Noursi adjourned the meeting at 2:21 p.m.

**Certification**

We certify that the contents above are accurate and complete.

Janine A. Clayton  
Janine Austin Clayton, M.D., Director  
Office of Research on Women’s Health

Samia D. Noursi  
Samia Noursi, Ph.D., Executive Secretary  
Advisory Committee on Research on Women’s Health

Date 9/15/21

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