

**49th 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
October 23, 2019**

Members Present

Wendy R. Brewster, M.D., Ph.D.
Roger B. Fillingim, Ph.D.
Stacie Geller, Ph.D.
Kimberly D. Gregory, M.D., M.P.H.
Ana Langer, M.D.
Carolyn M. Mazure, Ph.D.
Margaret M. McCarthy, Ph.D.
Louise D. McCullough, M.D., Ph.D.
Amy Paller, M.D.
Elena Rios, M.D.
Marcia L. Stefanick, Ph.D.
Susan F. Wood, Ph.D.

Other Attendees

Scott Hultgren, Ph.D.
Sabra Klein, Ph.D.
Alyson McGregor, M.D. (via telephone)
Michelle Robinson, D.M.D.
Neel Shah, M.D., M.P.P.

ORWH Leadership Present

Janine Clayton, M.D., Director
Elizabeth Spencer, B.S.N., Deputy Director

HHS and NIH Leadership Present

Diana Bianchi, M.D., Director, Eunice Kennedy
Shriver National Institute of Child Health and
Human Development (NICHD)

Dorothy Fink, M.D., Deputy Assistant Secretary
for Women's Health/Director, Office on
Women's Health

Tara Schwetz, Ph.D., Associate Deputy Director,
Office of the Director

Bruce Tromberg, Ph.D., Director, National
Institute of Biomedical Imaging and
Bioengineering (NIBIB)

Call to Order and Introductions

Janine Clayton, M.D., ORWH Director and NIH Associate Director for Research on Women's Health, called the meeting to order at 9:07 a.m. Elizabeth Spencer, B.S.N., Executive Secretary and ORWH Deputy Director, announced that the meeting was being recorded and videocast. Staff and Committee members introduced themselves. The minutes of the April 10, 2019 meeting were unanimously approved.

ORWH Director's Report

Dr. Clayton recognized retiring Council member Rachel Jones, Ph.D., RN, and welcomed new Council members Sabra Klein, Ph.D.; Scott Hultgren, Ph.D.; Alyson McGregor, M.D.; Judy Regensteiner, Ph.D.; Michelle Robinson, D.M.D.; and Neel Shah, M.D. She reported on transitions among women leaders at NIH; there are now nine women Institute/Center/Office (ICO) Directors and 13 Assistant Directors across the 27 ICs. Dr. Clayton reviewed ORWH's mission and the 2019-2023 Trans- NIH Strategic Plan for Women's Health Research. She played a clip about bias in medicine against women from John Oliver's *Last Week Tonight* television program, noting the importance of such visibility.

Scientific Collaborations: ORWH has contributed \$1 million to planning grants to study the effects of pre/postnatal opioid exposure on brain development under the Helping to End Addiction Long-Term (HEAL) initiative. Dr. Clayton also highlighted ORWH's research collaborations, such as its partnership with the Department of Veterans Affairs to build the evidence base about sex and gender differences in veterans. She shared an example of an ORWH-funded Sex/Gender Administrative Supplement Grant to

an investigator funded by the National Institute on Minority Health and Health Disparities to explore the role of fetal sex in cardiometabolic complications.

Dr. Clayton also updated Council on the 21st Century Cure Act, including a new requirement that NIH-defined Phase III clinical trials report results disaggregated by sex and gender, race and ethnicity. It also reconstituted the Coordinating Committee on Research on Women's Health (CCRWH), the nexus for driving synergy across ICOs via the Trans-NIH Strategic Plan. For example, the Women's Collaborative Health Study with Apple and Harvard is led by the National Institute of Environmental Health Sciences (NIEHS) and an upcoming meeting on Pregnancy and Maternal Conditions that Increase Risk of Morbidity and Mortality is co-sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), ORWH, and multiple ICOs. Dr. Clayton highlighted how multiple ICOs have incorporated bold ideas about women's health into their strategic plans. Finally, Dr. Clayton described how ORWH coordinates resources on maternal morbidity and mortality (MMM), such as the 4th annual Vivian W. Pinn Symposium on maternal health, the ORWH web portal, and the Office's MMM booklet, a trans-NIH resource.

Research Programs: ORWH funding has remained relatively static in recent years, and extramural funding supports the Building Interdisciplinary Research Careers in Women's Health (BIRCWH), other IC co-funding, Specialized Centers of Research Excellence (SCORE), Sex and Gender Administrative Supplements), U3 Administrative Supplements, and the R56 grants. ORWH has also invested \$1 million in its first R01 on the Intersection of Sex and Gender Influences on Health and Disease in a landmark move on the eve of its 30th anniversary.

SABV Update: To disseminate the importance of Sex as a Biological Variable (SABV), ORWH has developed online educational materials and a new SABV Primer (in development). ORWH is also developing comprehensive evaluation tools to assess SABV in grant applications and to identify relevant reviewer comments in summary statements.

Women in Biomedical Careers: Dr. Clayton reported that the new ORWH-sponsored report on women in science from the National Academies of Science, Engineering and Medicine (NAEM) will be published in March 2020. She also noted that she has been part of the Advisory Committee to the Director (ACD) Working Group on Changing the Culture to End Sexual Harassment, which has issued interim recommendations. NIH Director Francis Collins, M.D., Ph.D., garnered significant media attention with his announcement on June 12, 2019 that he would no longer participate in "manels," conference panels in which women are not included.

Building Connections: Dr. Clayton reviewed recent media coverage making the case for women's health research, publications by ORWH staff, and upcoming meetings relevant to ORWH and women's health.

Discussion: In response to a question about whether the new R01 opportunity only addresses research with humans, Dr. Clayton responded that ORWH has been extremely broad in how it defined sex and gender. She challenged applicants to this Funding Opportunity Announcement (FOA) to identify the most interesting research question that they cannot address under a different NIH mechanism.

NIH Institute/Center Update: Bioimaging and Bioengineering in Women's Health

Bruce Tromberg, Ph.D., Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), provided an overview of the Institute's history, mission, and the centrality of biomedical imaging and bioengineering to the future of medicine and to women's health. For example, he noted the growth

in undergraduate enrollment in biomedical engineering and the increasing representation of women among graduate students and faculty in this field.

At the center of all bioimaging and bioengineering technologies is modeling, computation and machine intelligence, i.e., the symbolic/mathematical representation of all life processes. Currently, healthcare is conducted via static snapshots, but digital technologies allow for complex, multi-parametric dynamic data that can help predict the future.

Approximately 8 percent of NIBIB's portfolio—80 projects representing \$22 million of funding—address women's health issues. Breast cancer and reproductive health represent the largest categories of this funding. Examples of technologies being explored include advanced image reconstruction for digital breast tomosynthesis as an improvement on traditional mammography and longitudinal imaging of fetal development during pregnancy. The ultimate goal is to personalize diagnosis and treatment, as well to integrate prevention into health care to expand lifespan.

To stimulate undergraduate training, NIBIB sponsors a competition titled Design by Biomedical Undergraduate Teams (DEBUT) in which it awards \$80,000 in prize monies. To promote women in bioimaging and bioengineering, NIBIB created the Women in Science and Engineering (WISE) program to recognize its outstanding women grantees; four are featured on the NIBIB website.

NIBIB represents only 1 percent of the total NIH budget but influences the work of all the ICs by leveraging its funds. Dr. Tromberg expressed interest in partnering with ORWH on women's health.

Discussion: Council questions addressed how NIBIB approaches the ethical issues that arise with new technologies; opportunities to leverage monies derived from patents back into the system; development of new technologies to study the gut biome; opportunities within the NIBIB portfolio where sex differences could be explored; regionalization of opportunities to connect hospitals and community health; types of funding mechanisms within the NIBIB portfolio; and diversity among biomedical engineering students beyond the undergraduate level.

Legislative Update: NIH and Congress

Ms. Spencer introduced Adrienne Hallett, Associate Director for Legislative Policy and Analysis at NIH. Ms. Hallett explained that 21 percent of Congress is new this year. NIH is educating these freshmen legislators about key issues in order to develop advocates for biomedical research and women's health. To date, NIH has experienced steady predictable growth in funding. Currently the House of Representatives has included a \$2 billion increase for NIH in the new budget; the Senate has included a \$3 billion increase. Currently, there are 12 appropriation bills that need to be negotiated before a bipartisan budget can be completed and delivered to the White House for approval. The "hot topic" questions that Congress most often asks of Ms. Hallett's office are largely about foreign influences and sexual harassment and, to a lesser extent, health disparities and maternal mortality.

Discussion: Council questions focused on Congressional interest in foreign influences and NIH's funding if the current Continuing Resolution (CR) is extended to a full year; possible NIH concerns about scientists from other countries who are choosing not to come to the United States to work; the need for greater knowledge to turn the tide on MMM; the extent of Congressional concerns about the inclusion of underrepresented groups in the biomedical workforce; whether Ms. Hallett's office communicates with political candidates and campaigns; NIH policies on sexual harassment; how Ms. Hallett's office works with the media to bring attention to key issues; if NIH invites comments from legislators on issues

such as family-friendly training grants; motivations of Members of Congress to support NIH; and how NIH quantifies return on investment of its funding.

The meeting broke for lunch at 11:51 a.m. and reconvened at 1:05 p.m.

2019-2023 Trans-NIH Strategic Plan for Women’s Health Research: Implementation and Evaluation

Laura Sharon represented Samia Noursi, Ph.D., Associate Director, Science Policy, Planning, and Analysis, ORWH, who was unable to attend. Her report addressed the development of ORWH’s efforts to implement and evaluate the Trans-NIH Strategic Plan for Women’s Health Research. The process began with the development of a concept model to guide implementation and a logic model to guide evaluation. The concept model was reviewed by 80 stakeholders who proposed implementation activities to ensure achievement of the Plan’s goals and objectives and related process metrics, as well as evaluation questions, outcomes, and related metrics. The next step is to complete drafting of “*A Guide for Implementing and Evaluating the 2019–2023 Trans-NIH Strategic Plan for Women’s Health Research Across NIH ICOs.*” Council members will be asked to review and comment on the draft guide.

Discussion: Council discussion included the appropriate metrics to track gender; the nature of process metrics, such as for collaboration; selection of metrics by ICs; and sources of bias (e.g., absence of gender identification) in genomic databases that result in incomplete or biased analyses.

Concept Clearance for Challenge Prize and Other Concepts of the NIH Working Group on Women in Biomedical Careers

Dr. Clayton reviewed statistics about diversity in academic careers in science, technology, engineering, and medicine (STEM). To accelerate progress in creating a diverse biomedical research workforce, ORWH presented four concepts for which it was seeking Council approval.

- **Supplements to Promote Research Continuity and Retention of NIH Mentored Career Development (K) Award Recipients.** P. Kay Lund, Ph.D., Director of the Division of Biomedical Research Workforce, shared data showing that since 2005, women have represented only a third or less of the Research Project Grants (RPG)-funded workforce. The K to R transition represents a particularly vulnerable career stage. Surveys of postdoctoral scientists indicate that family responsibilities are a major driver for women opting out of academic research. To support the transition and retention of investigators from mentored career development to research independence and to minimize departures from the biomedical research workforce at critical junctures, ORWH proposes supplements that provide temporary supplemental research support to help sustain the investigator’s research during critical life events, such as childbirth and primary caregiving of young children or ailing relatives. The supplement may be used to hire additional personnel to promote the continuity of the career development research project during a period when the investigator experiences an issue that impacts progress or potential productivity. Eligible applicants would be K awardees who are late-stage post doctorates, instructors, early stage-tenure-track or non-tenure-track faculty and recipients of individual mentored K awards are encouraged to apply. There is ICO support for such supplements.
 - **Discussion:** Council discussion included comments about issues related to the K grant program; its failure to stem the decline of physician-scientists; why the proposed concept was limited to K awardees when family issues are more likely to affect women at the graduate and post-doctoral levels; and clarification that the proposed award does not affect those funded under BIRWCH.

- **Council Action:** Ms. Spencer asked for a vote to approve the concept; Susan Wood, Ph.D., so moved and Louise McCullough, M.D., Ph.D., seconded the motion. It passed unanimously.
- **Continuity of Biomedical and Behavioral Research Among Recipients of First-Time NIH Independent Research Awards Concept (Administrative Supplement Pilot):** Melissa Ghim, Ph.D., ORWH, presented the second individual career award concept which seeks to enhance the retention of investigators who are transitioning to the first renewal of their first independent research award and to provide additional support during critical life events (e.g., childbirth) to maintain/enhance continuity of research, productivity, and competitiveness for a first renewal or second independent research award. These supplemental one-year awards would be available, contingent upon NIH appropriation and the submission of applications. Dr. Ghim reviewed NIH analyses that show that women individually hold fewer grants, submit fewer applications, and are less successful in renewing grants, making their research career trajectories less stable, especially during critical life events. The proposed supplements offer flexible use of funds within the scope of the parent project, including supporting the effort of additional scientific staff to sustain the investigator's research during a critical life event.
 - **Discussion:** Council discussion addressed the logistics of the award in terms of eligibility and timing; the need to communicate clear criteria by which applications will be judged; the fact that the supplements would not be gender-specific; the impact on applicants of academic events (such as the departure of a dean); the fact that the award would support both renewals or a second independent R01; the underlying rationale for the supplements being that not enough women apply and their success rates are too low; and the need for system changes to create meaningful opportunities for women in biomedical careers.
 - **Council Action:** Ms. Spencer asked for a vote on the concept. Stacie Geller, Ph.D., moved to approve the concept; Margaret McCarthy, Ph.D., seconded the motion. Council members voted unanimously in favor of the motion.
- **Achieving Gender Diversity (AGD): Inclusive and Sustainable Institutional Approaches:** Lynn Morin, ORWH, presented the third concept, which supports institutional development of broad sustainable strategies to achieve change toward enhanced gender equity. Multi-level approaches are required to achieve systemic and sustainable change. Thus, this award would provide support for institutions to implement a multi-pronged, trans-institutional strategy to enhance faculty gender diversity in biomedical and behavioral disciplines, including more and regular collection of data on areas where barriers exist; increasing the number and engagement of women in leadership positions; and equity in hiring, promotion, and career development opportunities. Two-phase awards for a total of five years are proposed, contingent upon NIH appropriations and the number of applications submitted.
 - **Discussion:** Questions raised during Council discussion included the need for these grants to be sufficiently significant in size that institutions will want to apply; the feasibility of merging funds with the Health Resources and Services Administration (HRSA)'s faculty development program for Title VII; the success of a National Science Foundation ADVANCE grant to promote women's careers in academic science and engineering in changing institutional culture; the importance of mentors and the need to incentivize them to work with younger

faculty; and encouragement to ORWH to disentangle the unique biological roles that women play versus gender issues to achieve a more successful policy.

- **Council Action:** Ms. Spencer asked for a vote for support for ORWH to work with ICs to implement the FOA. Dr. Geller moved to support the concept; Marcia Stefanik, Ph.D., seconded the motion. It passed unanimously.
- **RFI For Gender Diversity in the Biomedical Research Workforce Prize (NOT-OD-19-141):** Teraya Donaldson, Ph.D., ORWH, reviewed a Request for Information (RFI) published by ORWH to seek feedback on a proposed prize competition that aims to recognize institutions that have demonstrated commitment to systemically addressing faculty diversity and equity issues within the biomedical and behavioral science departments. Issues to be considered about such a strategy include: 1) By acknowledging transformative structures, systems, projects, and processes that have enhanced faculty gender equity and diversity within an institution, could this serve as an impetus for future change? 2) What are the best practices for disseminating institutional approaches that have led to an environment conducive to the retention and advancement of women faculty in biomedical and biobehavioral disciplines in academic institutions? and 3) Through an anticipated contest, the potential prize seeks to highlight practices that have created a more inclusive environment for faculty. Comments on the RFI were due by October 31, 2019.
- **Discussion:** Council members suggested that there should be a marriage of the two institutional concepts since they address related concerns; that the prizes should be made regional to enhance interest; that part of the application should address how these best practices will be disseminated so the trajectory can be sustained over the next 5-10 years; that there be an emphasis on sex and gender minorities; that one criterion might address how the institution is working across professions to promote diversity; that additional metrics, such as the number of publications and grants on women's health, the existence of a committee for the advancement of women, and an institutional climate survey addressing women's promotion to encourage institutions to apply, be included; that smaller institutions may believe they're not competitive; that the question of disadvantage across regions be investigated before adopting a regional approach; that when only men apply for an assistant professor opening, there is an opportunity to investigate why women chose not to apply; that differences between private and state schools should be taken into account; that there be an emphasis on helping African American and Hispanic women into faculty positions; that search committees need to be trained in bias; and that faculty/career development should be part of the award criteria, along with an interdisciplinary focus and regional collaboration.

Addressing a Compelling Challenge for the Health of Women: Maternal Morbidity and Mortality

Dr. Clayton introduced panel presentations on MMM by emphasizing that it is an important challenge for the health of women. NIH has invested \$324 million in maternal health in 2019. She introduced panel moderator Tara Schwetz, Ph.D., who provided a brief introduction to the topic, citing headlines that the United States is the most dangerous place in the developed world to deliver a baby. Approximately 700 women die annually from pregnancy-related causes; three in five of these deaths could have been prevented. NIH has been working to address these issues over the past four years.

- **HHS: Addressing Maternal Health, Maternal Morbidity and Maternal Mortality in the United States:** Dr. Schwetz introduced Dorothy Fink, M.D., Deputy Assistant Secretary for Women's

Health and Director of the Office on Women's Health (OWH) at U.S. Department of Health and Human Services (HHS). Dr. Fink reported on data trends related to MMM, including increasing mortality rates; those at highest risk are American Indians/Native American and African American women. She also reviewed the causes of pregnancy-related deaths, noting that the prevalence of underlying health conditions such as hypertension and obesity in the population have increased over time. The number of newborns affected by maternal opioid use increased steadily between 2000 and 2008. She also shared data on health disparities in breastfeeding patterns between non-Hispanic white and black mothers across the nation. There is a committee within the Office of the Assistant Secretary of Health (OASH) that coordinates the maternal health efforts of 12 constituent agencies. Common themes and opportunities across HHS to address MMM include an increased emphasis on cardiovascular disease among women, the leading cause of maternal mortality; more coordinated and targeted approaches to address the preventable risk factors faced by women of reproductive age; enhanced data systems to generate higher quality and more timely data on measures of maternal health outcomes and care; and improved understanding of the social determinants of health and impacts on maternal health, morbidity and mortality. Dr. Fink reviewed several upcoming OWH campaigns that address maternal health, including one that targets improved breastfeeding rates among African-American women and another that addresses post-partum depression. She also discussed OASH policy initiatives related to opioid use and maternal health. In addition, Dr. Fink reviewed promising practices such as a text-based monitoring and post-partum blood pressure follow-up program and a brief intensive weight loss intervention that improved reproductive outcomes in obese, sub-fertile women. Dr. Fink concluded her presentation with a review of research gaps related to MMM in both the basic and clinical sciences.

- **Discussion:** Council members recommended including information about depression during pregnancy to OWH's post-partum campaign and ensuring that access to care for African American women is part of HHS initiatives.
- **HRSA Efforts to Address Maternal Mortality and Morbidity:** CDR Johannie Escarne reviewed HRSA programs that address MMM, focusing primarily on efforts within the Maternal and Child Health Bureau. These include the Alliance for Innovation on Maternal Health; State Maternal Health Innovation Awards; support of clinical providers at Healthy Start sites; the Maternal, Infant, Early Childhood Home Visiting (MIECHV) Program; block grants to states that support maternal mortality activities; the Healthy State Initiative to reduce health disparities in perinatal health; focused investments in screening and treatment of maternal depression; and challenges to encourage technology-based remote monitoring of pregnancies and to increase access to quality healthcare for pregnant women and new mothers with opioid use disorders, among others.
- **CDC Efforts to Prevent Maternal Mortality:** Sarah Foster, Associate Director for Policy, Partnerships, and Communication in the Division of Reproductive Health at the U.S. Centers for Disease Control and Prevention (CDC), described her agency's efforts to prevent maternal mortality via strengthening data and improving quality of care. The primary data efforts are the Pregnancy-related Mortality Surveillance System (PMSS) based on death certificate data and the Maternal Mortality Review Committees (MMRCs), which review multiple sources to develop a deeper understanding of each death. CDC supports MMRCs in 25 states. To improve quality of care, CDC funds 13 Perinatal Quality Collaboratives, multidisciplinary teams that seek to improve measurable outcomes for maternal health by advancing evidence-informed clinical practices and

optimizing resources to improve care and outcomes. In carrying out these initiatives, CDC works closely with HRSA’s Maternal and Child Health Bureau to coordinate maternal health care.

- **Discussion:** Council discussion focused on the following issues: what Federal health agencies are doing to address the underlying causes of MMM; the need for qualitative research with families of those who died and those who survived severe morbidities; the need for training on implicit bias at all birthing hospitals as part of the systems change work needed; the need for greater effort beyond clinical bundles; a suggestion that the loss of the protective effect that Hispanic women once had be studied; the need for healthcare providers that look like their patients and the need for care that is not only evidence-based but also person-centered; an encouragement for NIH to think boldly about its role to combat MMM beyond the translation of evidence; a suggestion that the United States learn from global efforts and maintain public visibility of the issue by going beyond simply the number of maternal deaths to also include the financial and social implications that MMM has on children and communities as well as the issues surrounding how women navigate the path to good health care; and the need for research on trans-generational issues, e.g., preeclampsia increases women’s risk of stroke and that of their offspring, that could have major societal impacts.

ACRWH Meeting Wrap-up: Member Ideas Exchange

Council members shared the following concerns with ORWH: greater emphasis should be placed on the health of girls, e.g., anxiety and depression; trans-generational studies of maternal morbidities are important; both the field and study section reviewers need more education on the difference between sex differences and sex as a biological variable (SABV), e.g., the new SABV primer should be made required reading; attention should continue to be paid to preventing female faculty members from dropping out of research, as well as to alternative ways they may be contributing to the field; there is a need to look at the impact of racism on women’s health broadly, not just on access to care; a continued focus on health disparities can improve all Americans’ health; there should be greater NIH funding of implementation science; minority health conferences need leadership on women’s health, e.g., MMM and female leadership/career development.

Closing Remarks

Dr. Clayton reminded ACRWH members that the next Council meetings are April 21, 2020 and October 20, 2020. She reminded Council that October 31 will mark ORWH’s 30th anniversary. She adjourned the meeting at 4:37 p.m.

Certification

We certify that the contents above are accurate and complete.

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

Elizabeth Spencer, B.S.N., Executive Secretary
Advisory Committee on Research on Women’s Health

Date _____

Date _____