

# OFFICE OF RESEARCH ON WOMEN'S HEALTH

## 44<sup>TH</sup> MEETING OF THE NIH ADVISORY COMMITTEE ON RESEARCH ON WOMEN'S HEALTH

BETHESDA, MD  
SEPTEMBER 13, 2017

### IN ATTENDANCE

#### ACRWH MEMBERS

Janine A. Clayton, M.D. (Chair)  
Elizabeth Spencer, R.N. (Executive Secretary)  
C. Noel Bairey Merz, M.D.  
Jill Becker, Ph.D. (via telephone)  
Geert de Vries, Ph.D.  
Carmen Green, M.D.  
Rachel Jones, Ph.D., R.N. (via telephone)  
Ana Maria Lopez, M.D., M.P.H.  
Carolyn Mazure, Ph.D.  
Mary Palmer, Ph.D., R.N.C. (via telephone)  
Connie Weaver, Ph.D. (via telephone)

#### GUESTS

Christine Bachrach, Ph.D.  
Mark Hayward, Ph.D. (via telephone)  
Ann Langer, M.D.  
Judith Regensteiner, Ph.D.

#### ORWH ASSOCIATE DIRECTORS

Monica Basco, Ph.D.  
Capt. Margaret F. Bevans, Ph.D., R.N.  
Victoria Cargill, M.D., M.S.C.E.  
Chyren Hunter, Ph.D.

#### PRESENTERS

Chloe Bird, Ph.D.  
Dawn Corbett, M.P.H.  
Joshua Gordon, M.D., Ph.D.

### CALL TO ORDER, INTRODUCTIONS, AND APPROVAL OF MINUTES

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Janine A. Clayton, M.D.  
Director, Office of Research on Women's Health (ORWH)  
and Associate Director for Research on Women's Health

Dr. Janine Clayton opened the meeting at 9:02 a.m. EDT. Committee members, presenters, and guests introduced themselves.

She welcomed four new Committee members: Rachel Jones, Ph.D., R.N., Susan Wood, Ph.D., Wendy Brewster, M.D., Ph.D., and Kimberly Gregory, M.D., M.P.H.

Dr. Clayton congratulated Committee member Dr. Ana Maria Lopez, for being named president-elect of the American College of Physicians as well as former Committee member Teresa Woodruff, Ph.D., for being awarded a Guggenheim Fellowship for research on reproductive health and fertility preservation.

It was moved and seconded to accept the ACRWH report (FY 2015-2016) as written. The motion was passed. It was also moved and seconded to accept the minutes of the April 4, 2017 meeting as provided. The motion passed.

## DIRECTOR'S REPORT

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Janine A. Clayton, M.D.  
Director, Office of Research on Women's Health (ORWH)  
and Associate Director for Research on Women's Health

Dr. Clayton provided an update on ORWH efforts and activities. More specifically, her presentation focused on four key areas: 1) Efforts to support NIH's Sex as a Biological Variable policy; 2) Outreach efforts; 3) ORWH funding; and 4) ORWH programs and funding opportunities.

Support of NIH's Sex as a Biological Variable (SABV) policy remains a foremost priority for ORWH. In January 2016, NIH adopted the SABV policy. Through this policy, NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.

Many journals now require authors to report the sex of animals used in research, including *PLOS Medicine*, *Science Immunology*, *Stroke*, *Endocrinology*, *Blood*, *Nature Medicine*, *PLOS Biology*, *Cell*, and others. Several guidelines have also assisted in the reporting of sex including the 2010 [Arrive Guidelines](#), the National Academies Press publication [Sex-Specific Reporting of Scientific Research](#), the 2016 [SAGER guidelines](#), and recommendations by the [International Committee of Medical Journal Editors](#).

Adoption of sex reporting by notable journals and the release of supporting guidelines by various key organizations have helped to incorporate sex into research and reporting. ORWH has contributed additional efforts by publishing articles on sex/gender influences on health and disease in various publications including [Gender and the Genome](#), [Physiology and Behavior](#), and [The Ocular Surface](#). These articles, authored by ORWH leadership and other researchers, help to both inform scientists and support the NIH SABV policy. Similar efforts to inform the public on SABV have taken place in media geared towards a general audience.

In addition to supporting SABV and research on women's health through publications, ORWH conducted various outreach efforts including presentations at scientific meetings to reach key audiences. In 2017, ORWH presented at the following meetings:

- American University Sex Differences Conference: From Neuroscience to the Clinic and Beyond
- 25<sup>th</sup> Anniversary Congress on Women's Health pre-conference symposium
- Association for Research in Vision and Ophthalmology

- Annual Meeting of the Organization for the Study of Sex Differences
- NIH Inclusion Across the Lifespan Workshop
- NIH AIDS Executive Committee meeting
- Congressional Brief on Dry Eye Disease and Implications for Women
- National Medical Association: Annual Convention and Scientific Assembly
- Second Annual NIH Vivian W. Pinn Symposium

With respect to funding, ORWH support has increased since its inception, but funding levels have not seen a substantive increase in recent years. A significant budgetary increase took place in 2002 as the result of adding the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program to ORWH.

Dr. Clayton discussed various ORWH programs and funding opportunities, starting with BIRCWH. BIRCWH is a mentored career-development program to promote the recruitment, retention, and advancement of careers in women's health. A total of 20 active BIRCWH programs were funded in FY 2017 covering a wide variety of research topics including reproductive biology, cancer, depression, addiction, neuro-immune interactions, cardiometabolic risk burden, and other topics.

ORWH also funds Administrative Supplements for Research on Sex/Gender differences. The goal of these supplements is to catalyze exploratory research on sex and gender differences by providing support to ongoing NIH-funded research. Dr. Clayton provided examples of some of the research funded.

ORWH also funds the Research on the Health of Women of Understudied, Underreported, or Underrepresented Populations Administrative Supplement. These one-year supplements support research highlighting the impact of sex/gender influences at the intersection of race/ethnicity and other social determinants in human health and illness, including preclinical, clinical and behavioral studies. ORWH expects to fund 15 applications totaling \$1.7 million this year.

ORWH is accepting applicants for the Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers. These supplements can be used to support individuals with high potential to re-enter an active research career after a career interruption or other qualifying circumstances. Thus far 14 awards have been made to eight ICs: NIGMS, NCI, NCATS, NIBIB, NIDA, NIMH, NIEHS, and NHLBI.

Also highlighted were some of the efforts by the NIH Working Group on Women in Biomedical Careers. The Working Group is a trans-NIH effort that considers barriers for women in science and develops innovative strategies to promote entry, recruitment, retention, and sustained advancement of women in biomedical and research careers. The Working Group is co-chaired by both Francis Collins, M.D., Ph.D., and Dr. Clayton.

Dr. Clayton noted that all the work described above is conducted by a small staff. She recognized ORWH staff for their hard work and support to make these efforts a reality.

## CONCEPTUAL MODEL OF SEX AND GENDER INFLUENCES IN HEALTH AND DISEASE

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Chloe Bird, Ph.D.

Special Advisor to the Director, ORWH

Dr. Bird explained that in humans gender differences also must be considered in addition to biological differences. Humans do present sex differences, but social and environmental contexts can also influence health. Exposures to both external and internal factors across the life course can influence an individual's health.

It is important to understand how social environment and behavior can affect biology. Dr. Bird cited multiple examples of biosocial interactions with sex influences including lung cancer, cardiovascular disease, and Alzheimer's disease.

The influences of sex and gender on health are not only additive, but can also interact in ways that amplify or confound health effects. Understanding women's health, and the influence of sex and gender on health, requires both a clear conceptual model encompassing types of exposures and impacts as well as rigorous methodology and research. Drawing on this type of model can help investigators ask the right questions as they move from bench to bedside and bedside to community.

### Discussants

Judy Regensteiner, Ph.D.

Founder and Director, Center for Women's Health Research, University of Colorado

Mark Hayward, Ph.D.

Professor of Sociology, The University of Texas at Austin

Dr. Regensteiner cited studies showing that both women and men with type 2 diabetes have a higher rate of cardiovascular disease (CVD) than those without diabetes, but women die more rapidly after the first heart attack. She explained that research shows disparities in medication use among women and men and questioned if this played a role in death following a heart attack. Also, studies show that women with CVD are not prescribed the same number of efficacious procedures as men and women have a greater prevalence of comorbidities, such as depression. Dr. Regensteiner expressed the need to address the influence of sex and gender.

Dr. Hayward said one of the challenges is to establish a framework that articulates multileveled interactions, which are not always easy to parse apart. He added that women's health research has been almost completely biologically uninformed for decades—and it is not organized in ways that facilitates interdisciplinary conceptual frameworks and tools. Nonetheless, while investigators might not move as fast as they would like, the field is progressing and moving forward.

## Respondent

Christine Bachrach, Ph.D.

Research Professor, Department of Sociology, University of Maryland

Dr. Bachrach pointed out that the framework presented by Dr. Bird is a positive step for both moving science forward and positively serving the NIH mission. NIH has promoted interdisciplinary science for some time, but the current discussion might involve a trans-disciplinary approach. There also is a need to change the culture of science by having individuals from broadly different disciplines begin a constructive discussion about what makes good science.

Dr. Bachrach added that setting up a particular toolkit can limit the types of questions asked. The framework must find a set of methodological approaches and disciplinary tools that can be assembled to provide the best answers. Dr. Bachrach reiterated Dr. Hayward's suggestion about developing interdisciplinary training programs. She discussed training programs that were recently reviewed, noting that while approximately 100 were interdisciplinary, only a handful integrated social sciences.

## Discussion

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- Dr. Lopez said that today's discussion is important because it can lead to a new way of thinking, not just about women's health but also about population health. She added that one group that was not mentioned were communities.
- Dr. Palmer said the complexity of forces influencing health can change over time. Support is needed to work across disciplines. Data management should also be discussed as researchers develop more advanced and complex modeling.
- Dr. Green said researchers do conduct interdisciplinary research, but because the academic paradigm does not always value it, they go back to their silos after completing their work. The conversation should begin with undergraduates, who are vectors moving back and forth among disciplines and synthesize information from different sources. How could they become involved in the conversation?
- Dr. deVries commented on the importance of highlighting trans-disciplinary interactions. Success stories are needed as examples of interactions among sociologists and clinicians.
- Dr. Bairey Merz said one should consider health services research, also referred to as population health, which is a new discipline in medicine. Health services are interdisciplinary and also good at measuring things. This discipline is different from epidemiology.
- Dr. Jones observed that nurses could have more experience than other clinicians with inclusive holistic models. She added that technology and the Internet have transformed how people understand health as well as how it is communicated. The role of social media must be included in conceptual modeling and thinking.
- Dr. Clayton thanked Dr. Jones for her comments, noting that her first mentor was a nurse. She agreed that nursing has a different perspective that is needed. She urged those in the room to share this discussion within their professional communities.

## UPDATES AND INSIGHTS FROM “RAISING THE BAR” DATA ANALYSIS

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Ching-Yi Shieh, Ph.D.  
Statistician, ORWH

Dr. Shieh acknowledged her collaborator, Katrina Serrano, Ph.D., and explained the background for the “Raising the Bar” project. The report *Shorter Lives, Poorer Health* published by the Institute of Medicine in 2013 found that the health of women in the U.S. was significantly worse than their counterparts in comparable countries. In 2015, the Raising the Bar Workshop organized by ORWH and National Academy of Sciences expressed the need for high-quality, sex-disaggregated data to better understand women’s health.

To address this, ORWH examined mortality and disease prevalence trends in the U.S. from 2000 to 2015. Data were sourced from “Multiple Causes of Deaths” by the Centers of Disease Control and Prevention as well as U.S. Census data. For disease prevalence trends, data were sourced from the Integrated Public Use Microdata Series (IPUMS) Health Survey. Mortality and disease prevalence trends were calculated by sex, age group, race, and ethnicity.

Dr. Shieh presented selected results from the analyses, emphasizing that results are completely descriptive and are meant to offer a general picture of disease trends—they have not yet been tested for statistical significance. Data were presented for heart disease, stroke, diabetes, obesity, and Alzheimer’s disease (AD).

In 2000, women’s heart disease mortality was slightly higher than men’s, but in 2015 the rate was 183.1 for women compared with 211.7 for men (per 100,000 population). With respect to stroke, women’s stroke death rates have been higher than men since 2000. In 2015, the death rate from stroke was 50.3 per 100,000 for women compared with 36.8 for men.

Diabetes death rates were then presented by sex, race, and ethnicity. Overall, racial and ethnic group death rates demonstrate a similar pattern for men and women, with the lowest rates found in Asian and Pacific Islanders, followed by increasingly higher rates for Hispanics, American Indians/Alaska Natives, whites, and African Americans.

African Americans had the highest diabetes mortality rate compared to other races and ethnicities, but patterns of diabetes mortality differed for African-American women and men. The mortality rate from diabetes for African-American women decreased from approximately 37.8 in 2000 to 29.8 in 2015 (per 100,000 population). Conversely, the rate increased for African-American men from 27.4 to 32.1 in 2015.

Diabetes and obesity in mid-aged African-American women were also assessed. Among African-American women 45 to 54 years old, mortality declined by about 9 deaths per 100,000 population from 2000 to 2009, but slightly increased between 2009 and 2015. In women 55 to 64 years old, there was a noticeable mortality decline from 2000 to 2008, with about 24 deaths per 100,000 population. Rates continued to diminish thereafter.

With respect to Alzheimer’s disease, the population studied was men and women 65 and older. Prior to age 74, men and women’s mortality rates for AD were similar. However, with advancing age, many more women than men die from this condition. The disease burden is also different

for women and men. Analysis of years of potential life lost before age 75 due to AD indicates that women are losing more years than men, and the disparities between sexes have increased from 0.5 years of potential life lost in 2000 to 2.4 years in 2015 per 100,000 population. In addition, women 80 years old and above with AD tend to live more years with functional impairments, indicating a higher level of caregiving needs for women in later life.

Dr. Shieh explained that the analysis of data has two phases. Phase 1 analyses are completely descriptive. Phase 2 will continue data-driven efforts and perform a series of hypothesis-testing analyses. Specifically, Phase 2 will use longitudinal panel data and a life course framework to examine women's health trajectories. It will use both sex and gender perspectives by taking biological, socioeconomic, and environmental factors into consideration.

The epidemiological assessment will solicit biomedical and clinical inputs from scientists of various disciplines. Dr. Shieh and her colleagues have identified several longitudinal panel datasets suitable for multivariate and trajectory modeling, and hope to identify sensitive time periods as windows of opportunity for disease prevention, early diagnosis, and effective treatment.

## Discussion

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- Dr. Regensteiner said the findings were interesting and echoed the earlier discussion, especially the fact that sex and gender cannot be separated from the larger context. She added that while analyzing women's health across the life course the childbearing ages are a critical time and should be separated out.
- Dr. Lopez noted that psychosocial factors and trauma were missing. Dr. Shieh replied they will look at covariate factors and key determinants. The challenge is to find the most essential predictors to use in the model.
- Dr. Green said race and ethnicity must be separated. Long-term discrimination, bias, and racism are interesting factors. It might be worthwhile to pull in these elements from another dataset. Also, there are significant challenges for the Arab-American population but not much helpful information in the literature. Dr. Shieh answered that she has been looking at data with information about as many ethnic groups as possible, including immigrant groups.
- Dr. Bairey Merz said diabetes statistics are static and shake the foundation of the diabetes/obesity hypothesis. Dr. Shieh replied she is interested in examining the interaction among diabetes and obesity mortality and morbidity. She is working with other groups to find clinical input and develop ideas.
- Dr. Mazure made a comment about diabetes death rates by sex, race, and ethnicity. Results from 2015 did not show much difference between men and women but the changing rates showed a very different picture. This illustrates the need to look at things contextually and the need for an interdisciplinary perspective.



## TRANS-NIH STRATEGIC PLAN DEVELOPMENT: ENGAGEMENT, DATA, ADVICE

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Monica Basco, Ph.D.

Associate Director, Science Policy, Planning, and Analysis, ORWH

Dr. Basco's presentation focused on the Trans-NIH Strategic Plan for Women's Health. ORWH released a Request for Information (RFI) on September 12, 2017 to obtain input on the plan from a wide variety of stakeholders. Input will be received until November 10, 2017.

Dr. Basco explained that in order to develop the RFI, ORWH used data mining from IC biennial reports; ACRWH meeting summaries; Women's Health Congress survey responses about priority areas in women's health; trans-NIH meetings; and SABV and Raising the Bar working group minutes.

Recommendations were also obtained from advisors, which include Dr. Judith Regensteiner, Dr. Carmen Green, Dr. Teresa Woodruff, Dr. Amy Paller, and Dr. Marcia L. Stefanick. These advisors were derived from the ACRWH Strategic Planning Working Group, the NIH Coordinating Committee for Research on Women's Health, women's health research leads at NIH ICs, NIH colleagues, and NIH Director Brown Bag events.

Dr. Basco reviewed the three cross-cutting themes of the RFI and then proposed three questions for discussion: Is the scope of the proposed goals too broad or too narrow? Is there anything missing? Can the goals be accomplished in 5 years?

She added that Dr. Clayton will provide an update on the plan and discuss progress to date during the Council of Councils Meeting to be held on January 16, 2018.

### Discussion

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- Dr. Green encouraged bold and aspirational thinking. Her concern is the possibility of thinking too small. Dr. Basco agreed, noting that the RFI asks for big ideas (or audacious goals) that NIH should pursue to improve women's health.
- Dr. Langer said research has not been equally efficient in demonstrating how different stages of the life course are connected in women's health. It would be interesting to conduct this type of analysis around specific conditions to illustrate complex connections. Diabetes and mental health would be good examples of how a concrete approach could shed light on these complex issues.
- Dr. Regensteiner said it is critically important to think across the life course.
- Dr. Becker said she was struck by the sex differences in stroke prevalence and AD. She asked whether there was an impact from women's decreased use of hormone replacement therapy after publication of the Women's Health Initiative.
- Dr. Clayton said the question about WHI is exactly the type of clinical/contextual question that ORWH is beginning to entertain. Another example is diabetes diagnosis



and whether it has changed because of differences in diagnostic criteria or clinical practice/guidelines.

- Dr. Jones offered trauma as another example. Trauma and its effect on women's health goes far beyond domestic violence to encompass vast global weather events such as recent severe hurricanes. Another consideration is the internationalization of illness. Illnesses that were seen only overseas are now more common in the U.S.
- A suggestion in response to Dr. Jones' comments was to incorporate a scan for environmental issues in the strategic plan. For example, in 2000 no one anticipated an opioid epidemic.
- Dr. Clayton said she sees strategic planning as a strategic thinking process. There are many needs, but they must be prioritized in order to be as effective as possible in deploying ORWH's relatively small office and resources. Priorities are important in setting the research agenda.

## SEX AS A BIOLOGICAL VARIABLE UPDATE

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Chyren Hunter, Ph.D.

Associate Director, Basic and Translational Research, ORWH

Dr. Hunter said it is necessary to “cross the bridge” from SABV policy to SABV implementation and application. A trans-NIH SABV working group was established on September 2014 to inform SABV policy development. The working group's first action was to release the RFI “Consideration of Sex as a Biological Variable in Biomedical Research” to obtain input from the research community and other interested stakeholders.

Following publication of the SABV policy in June 2015, a Rigor and Reproducibility email mailbox was established under the NIH Office of Extramural Research to address applicants' questions on the NIH policy on Rigor and Reproducibility, including questions on SABV.

The next steps to support SABV implementation include further refinement of SABV language in grant applications and instructions, as well as in other tools and resources for NIH staff and the extramural community. ORWH staff will also launch a new round of “IC Roadshows” to engage NIH business practices and then disseminate the new tools and resources across the NIH community.

Dr. Hunter added that the Sex and Gender course has been redesigned to incorporate SABV into each of the following lessons: cardiology, neurology, endocrinology, pulmonology, mental health, and immunology.

### Discussion

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- Dr. Bairey Merz suggested outlining a timeline for adoption of the SABV policy.
- Dr. Clayton said ORWH recognizes this will take some time. Different disciplines are at different points in the process of incorporating SABV policy. It is challenging to develop guidelines that are appropriate for all approaches from different ICs, and the trans-NIH

working group is addressing such issues. Dr. Clayton said the Advisory Committee will be kept informed of developments.

- Dr. Bairey Merz said that study sections must include issues relating to gender, age, and ethnicity.
- Dr. Clayton replied that study sections are aware of what should be done to implement SABV policy. As far as clinical experience is concerned, despite the fact that ORWH has been in existence for 25 years, she is dismayed that fewer than one-third of NIH publications of clinical trials have sex-specific results. Dr. Bairey Merz agreed, but noted that this percentage previously was 10 percent.
- Dr. Bairey Merz asked whether a goal of the policy is to tidy up clinical gaps. Dr. Clayton replied that it is complementary to the NIH inclusion policy.

## NIH INCLUSION DATA FY 2016–2017

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Dawn Corbett, M.P.H.

NIH Inclusion Policy Officer, Office of Extramural Programs, Office of Extramural Research

Ms. Corbett addressed the context for the discussion of inclusion data and the acceptability of inclusion plans for extramural research awards. She also provided an overview of inclusion data, aggregate enrollment for sex/gender, and aggregate enrollment for race/ethnicity in U.S.-based studies.

### Discussion

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- Dr. Lopez asked if there were plans for collecting gender data beyond the binary male/female identification. Ms. Corbett answered that categories are defined by the Office of Management and Budget (OMB) and used across the federal government so that databases are comparable. They must report in OMB-approved categories, which would be either male, female, or unknown.
- Dr. Regensteiner asked for further explanation of the ethnic and racial breakdowns, and why Hispanic was included as an ethnicity but not a racial category. Ms. Corbett said that OMB does not include Hispanic as one race but rather as multiple races.
- Dr. Green said that a large percentage of Arab-Americans might identify as white as there is no other option. LGBTQI identification is also problematic. This should be considered in the strategic planning process in promoting women's health. It must be addressed in a thoughtful manner that results in recommendations.
- Ms. Corbett responded that OMB has proposed adding a Middle Eastern category to the current racial categories. OMB also has also proposed collapsing the racial and ethnic categories so that individuals may choose multiple races and ethnicities to which they belong. She added that NIH encourages investigators to collect information about relevant subpopulations.
- Dr. Basco said the missing data—the large bars of “unknown” or “not reported” relating to the sex, race, or ethnicity presented—are a vexing problem. The unknown numbers appear to be much smaller for clinical trials than other research. She wondered if clinical trial researchers doing something different that allows them to collect more data.

- Dr. Lopez said that in some segments of the health system the most common race was “unknown.” They worked with the electronic health record in Epic and realized that the window for race/ethnicity came up only when people registered. They changed the program so that the window keeps coming up until it is filled or the person declines to specify race/ethnicity.
- Ms. Corbett said there were a number of changes to how data were monitored in 2015. There also are challenges related to coding, large health networks combining their data, and the large number of unknowns. Also, there is no specific format requirement for data collection. Requirements state that information should be voluntary and self-reported when possible. This applies to both race/ethnicity and sex/gender.
- Dr. Mazure asked whether it might be time to revisit that policy, in order to help people who need help.
- Dr. Jones said her team used computerized surveying. In addition to required fields, a comment box allows explanation of multiple categories. There is also a Middle East category. She advocated using a similar text box to allow people to add their comments when collecting data on surveys.
- Dr. Clayton said the information must be self-reported instead of an observation from the investigator. She added that typically the “unknown” field is used for those who choose not to respond. However, it would be more accurate to call it “unreported” than “unknown.” This is an issue that requires further discussion. The goal is to be as inclusive as possible, keep all populations in mind, and address the scientific questions appropriately.
- Ms. Corbett added that individuals who do not identify as male or female would be included in the “unknown” category.

## WOMEN'S MENTAL HEALTH: A VIEW FROM THE NATIONAL INSTITUTE OF MENTAL HEALTH

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Joshua Gordon, M.D., Ph.D.  
 Director, National Institute of Mental Health (NIMH)

Dr. Gordon presented the four objectives of the NIMH Strategic Plan for Research, which are to: 1) Define the mechanisms of complex behaviors; 2) Chart mental illness trajectories to determine when, where, and how to intervene; 3) Strive for prevention and cures; and 4) Strengthen the public health impact of NIMH-supported research.

He added that the NIMH intramural research program in the Behavioral Endocrinology Branch is examining postpartum depression, premenstrual dysphoric disorder, and perimenopausal depression. In the international arena, NIMH has set up five international hubs to bring together researchers from middle and lower income countries. Two of these—in South Asia and Africa—have specific goals for women’s health.

Dr. Gordon also discussed large cohort studies and large databases.

The large cohort studies discussed included the Precision Medicine Initiative *All of Us* (goal of 1 million participants); the Environmental Influences on Child Health Outcomes (goal of 50,000 children from diverse racial, geographic, and SES backgrounds); and the Adolescent Brain Cognitive Development Study (goal of 10,000 children).

Large database studies discussed included the National Database for Autism Research (NDAR), the National Database of Clinical Trials Related to Mental Illness (NDCT), and the Research Domain Criteria database (RDoCdb).

## Discussion

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- Dr. deVries asked about means of death by suicide. Dr. Gordon said there has been no increase in suicide deaths by any particular means. There has been greater growth in certain age groups—for example, elderly males/females, middle-aged men, and preteens. Researchers do not completely understand why rates are increasing, but it could be associated with increased opioid use.
- Dr. Langer inquired about NIMH research on eating disorders. Dr. Gordon said eating disorders are associated with a high rate of suicide and metabolic mortality. Some of the preclinical research is trying to understand the effects of starvation on brain function, while clinical studies are examining theories about learning disruption, getting rewards from self-starvation, and other topics.
- Dr. Green asked if the same challenges are seen in Caucasian populations and minority populations with respect to suicide. Also, some communities struggle with eating disorders and others with obesity. Dr. Gordon said he was not sure about the role of disparities in eating disorders. Caucasians have a higher rate of suicide than minority groups, with the exception of Native Americans. He added that disparities are generally understudied in psychiatry.
- Dr. Becker asked whether computational approaches could be used to reach across institutions. Dr. Gordon said they could, particularly in areas where disorders overlap. There is considerable interest in the overlap of NIMH, NIDA, NINDS, and NIAAA related to the determinants of behavior that lead to substance abuse and mental illness.

## OPEN DISCUSSION

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- Dr. Clayton said Committee members should consider the strategic plan as a living document, a work in progress. The plan should recognize the environmental landscape and public health needs.
- Dr. Regensteiner emphasized that incorporating sex and gender into research is critical.
- Dr. Green said it is also necessary to understand men, especially black men, their premature deaths, and violence.
- Dr. Mazure said there are many research areas with little information, and ORWH is trying to do something that others are not. She added that approaches with big data are the future of research.

- Dr. Lopez said there are many elements (e.g., psychosocial, behavioral, biological) that influence women across the lifespan that must be taken into account. How these elements are assessed and work together leads to the ultimate form of personalized medicine.
- Dr. Becker pointed out that the topic arising out of today's meeting was the multidimensional approach, which should be considered in the context of the RFI that was just issued.
- Dr. Palmer said public health must embrace interdisciplinary approaches. Not only do phenotypes affect behavior, but so does the environment. Non-pharmaceuticals are also something important to keep in mind with respect to women's health. She also advocated including aging in strategic planning.
- Dr. Jones said that Dr. Bird's models emphasized the overarching concepts of uncertainty and vulnerability, which can be expressed and manifested in risk behavior, uncertainty, and vulnerability, leading to substance abuse and risky sex behaviors.
- Dr. Lopez said that clinicians should also think of themselves in the context of resilience. She said that for health care clinicians women as a whole are more effective at suicide compared with men. This is a serious risk and professionals must think about their own wellness.
- Dr. Clayton replied that uncertainty and vulnerability are the other side of the coin of resilience. She added that she has not seen much research exploring resilience.
- Dr. Langer said incorporating sex as a biological variable has been challenging, but trying to incorporate gender could be more complicated. It is important to start thinking about how to implement a vision of having sex and gender as important variables. She also reiterated the importance of integrating the life course.

## DIRECTOR'S CLOSING

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Janine A. Clayton, M.D.  
 Director, Office of Research on Women's Health (ORWH)  
 and Associate Director for Research on Women's Health

Dr. Clayton said she typically uses the phrase "the health of women" rather than "women's health." The latter implies reproductive and maternal health, which people do not perceive as needing increased attention whereas "the health of women" incorporates a holistic perspective.

Everything that affects the health of a woman, from head to toe, is what ORWH sees as its purview. Biologic factors such as sex as well as external, social, dynamic, and contextual factors also clearly affect the health of women.

Underlying genetic predisposition, intergenerational effects, likelihood and history of trauma, childhood experiences, and cumulative disadvantage or advantage also contribute to a person's health.

She said she looks forward to working with the Committee as well as everyone who attended or watched the videocast. Dr. Clayton adjourned the meeting at 3:22 p.m. EDT.

## CERTIFICATION

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We certify that the contents above are accurate and complete.

\_\_\_\_\_  
Janine Austin Clayton, M.D.  
Director, ORWH

Date \_\_\_\_\_

\_\_\_\_\_  
Elizabeth Spencer, R.N.  
Executive Secretary, ACRWH

Date \_\_\_\_\_