# WOMEN'S HEALTH IN FOCUS AT NIH

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### NIH Office of Research on Women's Health (ORWH)

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### NIH Publishes Advancing Science for the Health of Women: The Trans-NIH Strategic Plan for Women's Health Research

ADVANCING SCIENCE FOR THE HEALTH OF WOMEN

The Trans-NIH Strategic Plan for Women's Health Research

The fact that biological sex influences human health may seem self-evident, but historically, biomedical research and clinical practice have often overlooked this

axiom. A simple examination of population health data on the diseases that place the greatest burden on our society—cardiovascular disease (CVD), diabetes, cancer, and obesity—reveals that these diseases affect men and women differently in presentation, diagnosis, progression, and treatment.<sup>1-5</sup> These differences indicate that the biological distinctiveness of men and women deserves thorough attention from biomedical researchers. Moreover, the health concerns of women, who have been historically excluded from biomedical research, warrant additional special consideration. Good health results from many factors that affect an individual. In additional to biological sex, considerations such as age, race, and ethnicity also influence health (Figure 1).<sup>1</sup> Research that accounts for these factors and differentiates them in the process of experimental design, data collection and analysis, and reporting can better inform clinical practice to improve the health of all populations.

In response to such considerations, NIH Institutes, Centers, and Offices (ICOs), including the Office of Research on Women's Health (ORWH), published a new, comprehensive plan titled Advancing Science for the Health of Women: The Trans-NIH Strategic Plan for Women's Health Research. The strategic plan provides a framework for coordinating NIH efforts to advance science for the health of women by integrating sex and gender influences into the biomedical research enterprise and by ensuring that every woman receives evidence-based disease prevention and treatment tailored to her own needs, circumstances, and goals. The strategic plan also proposes steps to help ensure that women in science careers reach their full potential.



Figure 1. By accounting for the influences of sex, gender, race, and ethnicity across the life course, biomedical research can better inform clinical practice and thereby improve the health of all populations. The graphic illustrates the intersectional relationships between these essential domains (reprinted from ref. 1).

### **A Biomedical Workshop Provides Impetus**

The Trans-NIH Strategic Plan for Women's Health Research promotes use of the term "the health of women" as opposed to just "women's health." The hope is to move past phrasing that was once taken to be synonymous with reproductive health ("women's health") and transition to thinking about the totality of a woman's health, including disease prevention ("health of women"). This change in terminology resulted, in part, from a 2015 workshop sponsored by the National Academies of Sciences, Engineering, and Medicine (NASEM) and ORWH titled *Improving the Health of Women in the United States.*<sup>6</sup> The workshop addressed how the environment for the health of women had

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**DIRECTOR'S CORNER** 

### Interdisciplinary Biomedical Research Improves the Health of All

Interdisciplinary biomedical research, at its best, involves a group of researchers with a broad set of skills from multiple fields of scientific inquiry interacting to reconceptualize health-related research questions; develop inventive studies, treatments, and prevention strategies; and identify health concerns and related topics that might be overlooked or understudied because they fall outside the boundaries of conventional scientific disciplines. NIH prioritizes interdisciplinary research to foster this innovative and holistic approach to biomedical research because it has the potential to accelerate the process of turning discovery into health.

A report from an NIH-funded study at the Montefiore-Einstein Center for CardioGenetics in New York City demonstrates the value of an interdisciplinary approach.<sup>1</sup> In developing a new model of care for patients with cardiac arrhythmia, the researchers found that treatment outcomes improved when cardiologists, epigeneticists, psychologists, medical ethicists, nurses, and other experts collaborated to determine holistic treatment plans. Other teams of researchers and clinicians have developed similar, effective interdisciplinary treatment models for diabetes, breast cancer, and kidney disease.

Interdisciplinary research also provides opportunities for diverse career paths in the sciences. Two career-oriented programs sponsored by the Office of Research on Women's Health (ORWH) and other NIH Institutes, Centers, and Offices (ICOs) are the

<sup>&</sup>lt;sup>1</sup> Erskine et al. 2013. *Per Med.* 10: 73-80.

changed in the preceding 25 years, with decreased physical activity overall, national changes in diet habits, and greater numbers of women serving as heads of households. The workshop also showed how gaps in our knowledge of diseases and conditions in women stemmed from continued overreliance on male models (e.g., animals, cells) and the historical exclusion of women as participants in clinical research.

Workshop participants concluded that interdisciplinary approaches, routine sexdisaggregation of data, refined measurement tools, and integrative approaches should become vital parts of addressing the multidimensional framework of the health of women. In this vein, *The Trans-NIH Strategic Plan for Women's Health Research* encourages scientists to incorporate the multidimensional framework illustrated in Figure 2 into their experimental design, data analysis, and reporting to ensure that all populations of women—and men—can benefit from NIH-supported biomedical advances.



Figure 2. The multidimensional framework represents the intersection of multiple biological factors over the entire course of a woman's life.

### Health Differences Across Sexes, Races, Ethnicities, and Ages

The concept that sex as well as other factors such as gender, race, ethnicity, and age fundamentally influence human health is central to NIH's mission and is one of the primary organizing principles of *The Trans-NIH Strategic Plan for Women's Health Research*.

Population health data from some of the most common health problems in the United States suggest that disease burden, treatment course, and disease progression differ between men and women. For instance, the leading cause of death in the United States, CVD, affects men and women differently. Older women have a greater incidence of CVD than men, including heart attack, heart failure, coronary heart disease, stroke, and hypertension.<sup>2</sup> Women are also more likely to die of a heart attack than men.<sup>2</sup> Additionally, many other diseases and conditions put women at risk for CVD, such as obesity and diabetes.<sup>5</sup> Among men and women with diabetes, there is a higher prevalence of obesity and poorer blood pressure control in women, both of which can cause cardiovascular complications. Diabetes is also a stronger risk factor for stroke in women than in men.<sup>3,4</sup>

Analyses of biomedical studies that incorporate racial and ethnic differences find health disparities, even after controlling for other demographic variables. As an example, breast cancer is the most common type of cancer in women ages 35-64.<sup>7</sup> Although the incidence of breast cancer is highest in white women, black women are more likely to die of the disease, and the mortality gap by race is widening.<sup>7</sup> In fact, the disparity in breast cancer mortality between black and white women is one of the most striking racial differences in oncology.

Although biological, genetic, and epigenetic factors associated with race and ethnicity may factor into these disparities, inequalities in the health care system might also be an *Continued on page 4* 

**Building Interdisciplinary Research Careers** in Women's Health (BIRCWH) program and the Specialized Centers of Research (SCORE) on Sex Differences program. BIRCWH connects junior investigators interested in interdisciplinary research on the health of women with senior faculty mentors with shared interests and provides salary and other financial support. SCORE supports established scientists conducting interdisciplinary research on sex differences and major medical conditions affecting women. Through these and other initiatives and funding opportunities, NIH fosters the interdisciplinary research vital to improving the health of women-and of all.

The feature story of this issue of Women's Health in Focus at NIH highlights Advancing Science for the Health of Women: The Trans-NIH Strategic Plan for Women's Health Research, a 5-year plan developed in extensive collaboration with other NIH ICOs as well as external stakeholders. The strategic plan provides guidance and direction to all of NIH on research that affects the health of women and the professional development of women in biomedical careers. As the feature article explains, the plan promotes interdisciplinary research directly and also advocates practices and strategies complementary to it. We hope you enjoy this issue and look forward to your feedback.



Janine Austin Clayton, M.D. Director, NIH Office of Research on Women's Health NIH Associate Director for Research on Women's Health

issue. Rates of cervical cancer are higher for Asian-American women than for U.S. women of other races, and limited access to effective screening tools and gaps in health literacy may contribute to this disparity.<sup>8,9</sup> A recent study showed that Vietnamese-American women accessed cervical cancer screening services less frequently than white American women and that few Vietnamese-American women could distinguish fact from fiction about screening practices and cervical cancer causes.<sup>8</sup>

Sex-based differences in disease presentation, diagnosis, progression, and treatment manifest across the life course, and children and adults of all ages can benefit from research and clinical practices that account for these differences.<sup>10,11</sup> For example, autism spectrum disorder (ASD) is a developmental disorder that is subject to age differences and that is diagnosed five times more often in boys than girls. Although there is some evidence for a "female protective effect" to explain this dramatic difference,<sup>12</sup> the pattern could also reflect a sex bias at diagnosis. Even when boys and girls show similar ASD-like trait severity, researchers have found that girls are less likely than boys to meet the current diagnostic criteria for ASD.<sup>13</sup> Additionally, in cases of high-functioning ASD, girls are generally diagnosed later in life than boys. Data show that "gaze disturbance" is more common among boys with ASD than among girls with ASD. (See "Gaze Following..." in this issue's "In the Journals" section.) The studies referenced here suggest the clinical desirability of sex- and gender-specific diagnostic criteria for ASD.

To improve the health of women and girls, the trans-NIH strategic plan aims to raise awareness of sex and other variables and ensure that they are considered in NIHsupported research, data collection, and reporting and, in particular, that sex-based health differences become integral to all biomedical efforts, from bench to bedside.

**Strategic Goals of The Trans-NIH Strategic Plan for Women's Health Research** *The Trans-NIH Strategic Plan for Women's Health Research* includes five inter-related goals essential to support rigorous research and improve the health of women (Figure 3).





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**Goal 1 is to advance rigorous research that is relevant to the health of women.** This goal encourages research that will foster innovation, expand emerging areas of science, and address issues of public health importance. Research is necessary to improve the fundamental understanding of how sex and gender, among other critical factors, influence health and disease, and to extend this knowledge to translational and clinical studies. Adhering to high standards of scientific rigor is necessary for generating reproducible results. Research that is rigorously designed, including consideration of the influences of sex and gender, will contribute to the NIH agenda for research to improve the health of women. This first goal represents the foundation of the strategic plan, and the remaining four goals elaborate upon and bolster this foundation.

**Goal 2 is to develop methods and leverage data sources relevant to the health of women.** The plan encourages methods that consider the influences of sex and gender, that leverage relevant data sources, and that include underrepresented women. Research

### Prioritizing Recruitment of Underrepresented Women

Susan Carlson, Ph.D., and colleagues study the effects of docosahexaenoic acid on reducing preterm birth. This research team prioritizes recruiting and retaining underrepresented minorities as research participantsespecially pregnant Hispanic women. The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the Understudied, Underrepresented, and Underreported (U3) Populations program, an NIH program that co-funds biomedical research on minority and marginalized groups, supported this research, in part, because the investigators developed community-based participation strategies to improve inclusion of historically understudied populations. NIH supports research efforts dedicated to a more inclusive approach to participant recruitment and disaggregated data analysis. (Carlson et al. 2017 BMC Pregnancy Childbirth <u>17: 62.</u>)

to improve the health of women depends on creative and rigorous approaches to study design, participant recruitment and retention, measurement, and analytic techniques that identify findings of relevance to women. (See sidebar.) Intentional application of such methodologies, along with enhanced data sharing and harmonization, will increase the speed with which research can inform health care for women.

For the advances from research to have an impact, they must be shared and integrated into practice and subsequent research. Goal 3 of the strategic plan concerns enhancing dissemination and implementation of research evidence to bring in partnerships between researchers, providers, advocates, and the broader community. These partnerships are essential to communicate evidence-based health information and to understand existing real-world challenges. NIH will address this goal through a variety of means, including publications, online courses, outreach efforts, and events, such as the Annual NIH Vivian W. Pinn Symposium, which brings together leaders from multiple sectors to converge on a compelling issue or problem.

Goal 4 promotes training and careers to develop a well-trained, diverse, and robust workforce to advance science for the health of women. Building interdisciplinary research careers that are focused on the health of women and training scientists, clinicians, and other health professionals on sex and gender influences in health and disease will accelerate the translation of knowledge into improved health care for women. Programs such as

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(BIRCWH) provide funding and support toward that end. NIH also promotes the recruitment, retention, and advancement of women in biomedical careers to increase diversity in this workforce, including in leadership positions. Multiple NIH funding programs, initiatives, and committees, such as the NIH Working Group on Women in Biomedical Careers, Women of Color Research Network (WoCRN), and <u>Re-Entry into</u> <u>Biomedical Research Careers program</u>, support these goals and address barriers to progress.

Goal 5 is to improve evaluation of research that is relevant to the health of women. Advancing Science for the Health of Women depends on identifying gaps in knowledge about the health of women and delineating opportunities for scientific advancement. Employing innovative strategies to address these gaps and opportunities makes research more relevant to the health of women.

The health of women is best understood as a dynamic, multidimensional construct resulting from both internal and external factors that are subject to change over the life course. By applying the multidimensional framework depicted in Figure 2, the NIH strategic plan promotes consideration of the intersection of sex, gender, race, ethnicity, and age,

SCIENCE POLICY, PLANNING, AND ANALYSIS

ORWH Begins Implementation and Evaluation of The Trans-NIH Strategic Plan for Women's Health Research and the Manual Categorization System

ORWH has started planning the implementation and evaluation of Advancing Science for the Health of Women: The Trans-NIH Strategic Plan for Women's Health Research. Under the leadership of ORWH's evaluation lead, Associate Director for Science Policy, Planning, and Analysis Samia Noursi, Ph.D., the implementation team has developed a communication and dissemination plan to ensure maximum exposure and to accomplish the plan's goals and objectives.

Evaluation efforts will involve engaging stakeholders to identify evaluation questions to be answered; defining outcomes to be achieved; and determining metrics, methods, and the timing of various data collection efforts to measure how well the strategic plan contributes to the achievement of ORWH's mission and NIH's vision over time. The implementation and evaluation planning process has been designed to be collaborative and to involve members of the NIH Coordinating Committee on Research on Women's Health, which includes senior members from all NIH Institutes, Centers, and Offices. The process will also involve members from the NIH Advisory Committee on Research on Women's Health, among others.

Also, under the leadership of Dr. Noursi, ORWH launched the pilot phase of the automated Manual Categorization

which allows investigators to garner insights into the health experiences of different populations of women. Application of this framework to all phases of research and to all aspects of the health of women ensures that researchers and scientists as well as clinicians gain insights into health and disease that are relevant, up to date, and inclusive of all.

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### Samia Noursi, Ph.D., ORWH Associate Director for Science Policy, Planning, and Analysis

System-Women's Health (MCS-WH) reporting module. MCS-WH will provide many benefits, including an automated Research, Condition, and Disease Categorization (RCDC) text mining process of women's healthrelated projects; data rollover from year to year; and the ability to manually prorate (divide proportionately) costs of projects in a category. MCS-WH will replace the current cumbersome manual coding efforts and streamline the trans-NIH women's health budget reporting process. Installation of the MCS-WH also aligns with Goal 5 of *The Trans-NIH* 

### Gaze Following May Not Be a Characteristic to Consider When Diagnosing Autism in Girls and Women

### (Original article by <u>Elisabeth M. Whyte and</u> <u>K. Suzanne Scherf. 2017. Clin. Psychol. Sci.</u> <u>6: 280-287.</u>)

Autism is a developmental disorder that presents as difficulty with social communication and social interaction. The disorder is diagnosed four times more often in boys than girls. Studies of boys with autism largely informed the traditionally defined symptomology of the disorder, a fact that contributes to a deficiency of defined symptoms in presenting girls.

Elisabeth Whyte, Ph.D., and Suzanne Scherf, Ph.D., recently published study results examining potential sex differences in what is traditionally considered a central characteristic of autism—difficulty with eye-gaze processing. The investigators' results suggest that eye gaze-following behavior is part of the broader autism phenotype for boys and men but may not be a part of the female autism phenotype.

In the study, 120 undergraduate students (60 women and 60 men) ages 18 to 23 were asked to view images of actors looking at one of many possible objects and asked to identify the target object.

### Implementation...

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Strategic Plan for Women's Health Research:

Improve evaluation of research that is relevant to the health of women. Using a standardized definition to classify women's health-related projects, output generated from the MCS-WH will provide NIH and taxpayers with clarity on the return on research investment related to the health of women and facilitate portfolio analysis and program evaluation. MCS-WH was developed in collaboration with the NIH Office of Budget and the NIH Office of Extramural Research/ Office of Research Information Systems. Male youths with high autistic-like traits (ALTs) had worse gaze following than did those with low ALTs. However, among female youths, gaze following did not vary with ALTs. The results suggest that deficiencies in gaze processing, currently considered a core diagnostic feature of autism, may be part of a male-specific autism phenotype.

Research suggests that women and girls with autism have a greater capacity for traditional friendships, fewer externalizing and more internalizing behaviors, less restricted interests, and fewer repetitive behaviors than do men and boys with autism. When combined with the evidence from other studies that eye gaze following is not an effective predictor of autism for high-risk female infants, the results of Drs. Whyte and Scherf suggest that abnormal eye-gaze processing is not a reliable feature of autism in women and girls.

### Study Evaluates NIH's Inclusion Policy on Clinical Trial Reporting

(Original article by <u>Geller et al. 2018.</u> Academic Medicine 93: 630-635.)

For over 10 years, a team of researchers led by Stacie Geller, Ph.D., at the University of Illinois at Chicago has been conducting periodic analyses of scientific journals to ascertain how well study authors and journal editors have complied with NIH guidelines on the collection and analysis of sex-, race-, and ethnicity-specific data in clinical trials. The investigators examined a broad sampling of articles on NIHfunded clinical trials conducted in the United States and published in leading medical journals in 2004, 2009, and 2015 to determine how well these reports complied with the NIH policy on Inclusion of Women and Minorities as Subjects in Clinical Research.

The analysis of 2015 publications found that, of the articles meeting criteria for inclusion in the study



(n = 142 articles overall, n = 107 articles on studies enrolling both sexes), a little over one quarter (26%) published data disaggregated by sex, and only 13.4% published data disaggregated by race or ethnicity. In the 107 studies recruiting both men and women, the median enrollment of women was 46%, though 16 studies enrolled less than 30%. Further, the gender of the lead author had no significant impact in the proportion of studies that published data disaggregated by sex. Comparing the 2015 results with the findings on 2004 and 2009 publications revealed no statistically significant changes, suggesting no improvement in the analysis and reporting of sex-, race-, and ethnicity-specific data over this period.

The research team concludes that the NIH inclusion policy, despite having the power of law according to the NIH Revitalization Act of 1993, has not appreciably improved the publication of analysis of demographically disaggregated data. As such, Dr. Geller and colleagues call for principal investigators to strive for broad representation in study enrollment, for research teams to discuss and mitigate biases affecting recruitment and analysis, and for publishers to create strong author guidelines for reporting results by sex, race, and ethnicity.

### Survey Reveals Varying Opinions on Impact of Sex as a Biological Variable Policy in NIH Peer Review and Beyond

(Original article by <u>Nicole C. Woitowich</u> and Teresa K. Woodruff. 2019. J. Women's Health 28: doi.org/10.1089/ jwh.2018.7396.)

(Correspondence: <u>Nicole C. Woitowich and</u> <u>Teresa K. Woodruff. 2019 Nature 565: 25.</u>)

Nicole Woitowich, Ph.D., and Teresa Woodruff, Ph.D., of Northwestern University have conducted a first-of-itskind survey of reviewers of NIH grant applications. The researchers found varying opinions and attitudes among grant reviewers toward the impact the NIH Sex as a Biological Variable (SABV) policy has and should have on biomedical research and the scoring of research grant applications. As of January 25, 2016, NIH has expected SABV to be factored into experimental designs, analyses, and reporting in vertebrate animal and human studies (or that strong scientific reasons justify a single-sex study). Critical to the implementation of this policy is the NIH peer review system and the NIH grant reviewers, also called study-section members, who review NIH applications. An online survey was administered to study-section members in 2016 and 2017 following the May/ June/July meetings.

In both survey years, the majority (over 90%) reported discussing the SABV policy in their study-section meetings and an increasing number of grant applicants incorporating SABV. Reviewers generally supported the SABV policy, with 68% of study-section members surveyed agreeing that SABV is an important consideration for experimental design and 58% believing that implementing the SABV policy would improve the rigor and reproducibility of scientific results. Interestingly, as a group, researchers whose work involved the study of sex differences were significantly more likely to view SABV as important and likely to improve the rigor and reproducibility of

research. The survey also revealed that female reviewers were significantly more likely to think that consideration of SABV is important than male reviewers in 2017 (p < 0.0051) and more likely to think that consideration of SABV improves rigor and reproducibility (p < 0.0018).

Surveyed study-section members also took the opportunity to provide open-ended comments that revealed a wide range of attitudes toward the SABV policy and its effect on scoring, budgets, use of animals, and scientific impact. Some study-section members did not consider SABV to be a scoredriving factor, and others expressed concerns that the policy could increase research costs or lead to an overuse of experimental animals. Drs. Woitowich and Woodruff emphasize the continued need for training and guidance of reviewers. However, they observed increasing acceptance of the policy and anticipate new discoveries stemming from the consideration of SABV by the biomedical research community.



Retrieved from https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable.

### Sex, Gender, Race, and Ethnicity Data Promote Equity and Good Science

Commentary by Chyren Hunter, Ph.D., Associate Director, Basic and Translational Research Program, ORWH

Two studies summarized in this issue's "In the Journals" section (Geller et al.; Woitowich and Woodruff) provide snapshots of the biomedical research community's general level of acceptance and implementation of two key NIH policies: NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (NOT-94-100) and Consideration of Sex as a Biological Variable in NIH-Funded Research (NOT-OD-15-102). While the authors recognize the importance of both polices, they note that the adoption of the policies by journal editors, grant review boards, and some individual scientists has been slow.

The studies used two different approaches to shed light on the issue of sex/gender bias limiting policy uptake and implementation. Drs. Woitowich and Woodruff analyzed NIH study-section members' attitudes and opinions on the SABV policy regarding preclinical investigations, while Dr. Geller and colleagues analyzed research publications to determine how well study authors and journal editors have complied with NIH guidelines on the collection and analysis of sexspecific data in clinical trials, as well as information on race and ethnicity.

The good news is that with the identification of the issue of bias, we can move forward with time-honored and time-tested tools that can help to mitigate this problem: training, education (e.g., distinguishing sex and gender, clarifying what the policy is and is not, and providing enhanced, field-specific resources for reviewers and scientific review officers), monitoring, and evaluation. Where to start? Scientific publications are the currency of the biomedical research enterprise. Perhaps it is time to revisit the definition of "high impact" when it comes to the health of women and men. Dr. Geller's team identifies the names of the high impact journals that collectively allow 72% of NIHfunded randomized, controlled trials to publish studies without mention of sex in either their analysis or outcomes. This statistic is staggering. Publications in these journals drive current research thought and medical practice. They also drive the future of the biomedical research enterprise by influencing doctoral dissertations and by being cited in fellowship applications. Publication in these journals also helps to facilitate entry into professional career ranks.

Some scientific publishers have begun to take note. Last year, in the first issue of this newsletter, I commended several journals for adopting sex-specific reporting guidelines: Stroke, the Journal of Neuroscience Research, and the many journals published by the American Society of Microbiology. Further, Londa Schiebinger, M.D., and a team of Lancet panelists (Schiebinger et al. 2016. Lancet 388: 2841-2842) call for publishers to provide editors and authors detailed guidance on reporting disaggregated data from clinical trials. As these individuals argue, failure to do so obscures differences in outcomes between men and women, limits the reproducibility of findings, and in the end, results in poorer patient care. To their list, I add that failure to disaggregate data diminishes the return on the important investment by NIH into the biomedical research enterprise.

While reviewers and publishers can do much to promote NIH's inclusion and SABV policies, both the privilege and the onus of doing so falls largely on the shoulders of our NIH-supported scientists. NIH-funded investigators are accustomed to the NIH Public Access



Policy, which requires that "anyone submitting an application, proposal, or report to the NIH must include the PMC reference number (PMCID) when citing applicable papers that they author or that arise from their NIH-funded research." In this vein, principal investigators can include information in their papers on whether female animal models, women, and minorities were included and whether the results were reported by sex/gender and race/ethnicity. Doing so would provide metrics to assess policy uptake and implementation and develop informed strategies for improvement. As scientists, our training reminds us that data, education, and evaluation-not opinions-pave the path to pioneering research that will take us to a future of better health for everyone.

### *Nature Cell Biology* Celebrates Women in Science

Bridging the gender gap in science, technology, engineering, and mathematics (STEM) requires that we listen to the experiences of women and seriously consider the structural and institutional concerns of women who have become leaders within their scientific fields. To this end. Nature Cell Biology (volume 20, issue 993, 2018) published a collection of 13 vignettes written by female scientists describing turning points in their scientific careers where the personal became professional and vice versa. Many of the struggles faced by this diverse group of researchers are familiar to scientists of all genders, such as finding supportive lab environments and identifying mentors at each step of their career. Other themes were more gendered, such as the explicit sexism that still pervades research environments, lab pressures with differential effects on men and women, and unwelcoming lab environments. All the authors provide advice, inspiration, and narratives that challenge the "traditional" path of science and scientists. Contributions to this issue include:

### Finding Your Way Through the Science Maze.

Asifa Akhta, Max Planck Institute of Immunobiology and Epigenetics

Having It All, A Scientific Career and a Family. Sandrine Etienne-Manneville, Institut Pasteur Paris

### Seeking and Embracing Change.

Maho Hamasaki, Osaka University

Finding Success by Following Your Heart.

Nancy Y. Ip, Hong Kong University of Science and Technology

<u>Serendipity, Luck, and Hard Work.</u> Kum Kum Khanna, QIMR Berghofer Medical Research Institute

<u>Choosing an Easier Path or Following Your Passion.</u> Melissa Little, Murdoch Children's Research Institute, University of Melbourne

<u>The Duty to Speak up.</u> Serena Nik-Zainal, The University of Cambridge

Taking a Confident Leap into Uncertainty. Melina Schuh, Max Planck Institute for Biophysical Chemistry

Perseverance When the Going Gets Tough. M. Celeste Simon, University of Pennsylvania

<u>Confidence to Go the Way that Science Takes You.</u> Anne Simonsen, University of Oslo

<u>Mentorship Comes from Many Sources.</u> Shubha Tole, Tata Institute of Fundamental Research

The Reward of Great Collaborations. Fiona Watt, King's College London Centre for Stem Cells and Regenerative Medicine

#### Helping Our Country as Women Scientists. Mayana Zatz, University of São Paulo



**Maria Constanza Camargo, Ph.D.**, is currently an Earl Stadtman Tenure-Track Investigator in the Division of Cancer Epidemiology and Genetics (DCEG) at the National Cancer Institute (NCI). In September 2018, she was a guest presenter at a meeting of the Women of Color Committee of the NIH Working Group on Women in Biomedical Careers, where she shared her current research on gastric cancer at NCI's Metabolic Epidemiology Branch. Dr. Camargo's research focuses on identifying the role of Epstein-Barr virus infection in gastric carcinogenesis; applying advanced molecular epidemiology techniques to the study of *Helicobacter pylori* infection and premalignant and malignant gastric lesions; launching the *Helicobacter pylori* Genome Project, a large, international biobank of *Helicobacter pylori* strains for studies on the role of bacterial diversity in gastric cancer; and studying esophageal squamous cell carcinoma in Asian and African populations. Dr. Camargo received her M.S. in epidemiology from the School of Public Health in Mexico, her M.H.A. from the Pontificia Universidad Javeriana in Colombia, and her Ph.D. in public health with a concentration in epidemiology from the <u>University of Illinois at Chicago (UIC)</u>.

### Q. Who were your scientific role models?

I have had great scientific role models, some of them close mentors. Firstly. Nubia Muñoz, M.D., who is a former unit chief at the International Agency for Research on Cancer in France. Over a long career, Dr. Muñoz conducted epidemiological research on cancers associated with infectious agents. Her studies on human papillomavirus were instrumental in demonstrating the role of this virus as the central and necessary cause of cervical cancer. Through her, I met Pelayo Correa, M.D. He defined a model of histologic stages in gastric carcinogenesis years prior to the recognition of the etiologic role of Helicobacter pylori infection in this neoplasia. Through Dr. Correa, I met Elizabeth Fontham, Ph.D., who has been a great inspiration to me. She is the founding dean of the Louisiana State University School of Public Health, and the first non-physician ever elected as president of the American Cancer Society. Dr. Fontham conducted epidemiologic studies of lung cancer among nonsmokers that provided key evidence for the classification of secondhand smoke as a carcinogen. Through Dr. Correa, I also met Joseph Fraumeni, M.D. He is the founding

director of the NCI's DCEG. I admire his vision, persistence, and leadership. With my research work, I do my best to honor all of them.

### Q. How has mentorship (either as a mentor or mentee) shaped your career?

I have not walked this journey alone. The support and encouragement of great mentors throughout my career and their invaluable advice have made the difference in my success professionally and personally. My first career mentor was Dr. Muñoz. My interactions with her opened my eyes to the world of research, captivating me with epidemiology and its implications for public health. My second mentor, Dr. Correa, showed me a challenging and fascinating research field in gastric cancer. During my graduate studies at UIC, I received generous support, advice, and motivation from Ronald Hershow, M.D., Leslie Stayner, Ph.D., and Garth Rauscher, Ph.D. They helped me to materialize my dream of getting a doctoral degree in epidemiology. More recently, I have benefited from continued support, nurturing, and guidance from my NCI colleagues, including Charles Rabkin, M.D., Allan Hildesheim, Ph.D., Sandy Dawsey, M.D., and Christian Abnet, Ph.D.



Maria Constanza Camargo, Ph.D., Earl Stadtman Tenure-Track Investigator, Division of Cancer Epidemiology and Genetics (DCEG), National Cancer Institute (NCI)

### Q. Do you have advice for young women scientists?

Research is not easy, but it is rewarding and fun. So, for those young women scientists considering this exciting career, I have some pieces of advice: (1) have passion for it, (2) know the knowledge gaps in your field, (3) do not be afraid of null results, (4) expose yourself to topics and people outside of your field so you can think outside of the box (a conversation can change everything), and (5) enjoy the long-term journey!

### Q. What do you enjoy about being a scientist?

Epidemiology is truly a team science. Research evolves out of an open exchange of ideas with others. I enjoy all the steps of the process: conceiving, proposing, executing, and publishing our results.

### Q. What are some of the challenges of being a woman scientist?

A science career is demanding and requires some sacrifices. The main challenges that women scientists face are cultural stereotypes, discouragement at

a young age, and balancing a career with motherhood. Women scientists often choose to give priority to their families. Although it seems to be changing, young women are not encouraged enough to go into science or are not exposed to positive role models.

### Q. What have been the most rewarding aspects of your career?

I feel honored to be an NCI investigator. The extensive resources, expertise, and diversity of thought in the intramural program provide unique opportunities to conduct long-term, innovative, and high-impact science. It is exciting to contribute a small part to the progress of cancer research.

### Q. Has the trajectory of your career changed over time?

Yes, it has changed. After high school, I imagined my professional career in a

clinical or research lab setting. I received a B.S. in bacteriology and worked in a clinical lab for a few years. I stumbled into the field of epidemiology by accident. To redirect my career, I joined a master's program in health administration in which a course on the principles of epidemiology was required as part of the curriculum. I became fascinated with the potential of using epidemiology to improve public health. Soon after graduation, I was offered an opportunity to become a field coordinator for a cohort study tracing the natural history of cervical human papillomavirus infections at the Colombian National Cancer Institute. Through this field experience working with real-world epidemiologists, I developed a deeper appreciation for population and public health sciences, which drove me to pursue a master's and later a doctoral degree in the area.

### Q. What are some characteristics of a successful scientist?

There are several characteristics that are common among successful scientists. These include curiosity, imagination, critical thinking, open-mindedness, persistence, hard work, and respect and value for the work and opinion of others.

### Q. Why is it important to support and encourage the next generation of female scientists?

Diversity is an essential element of highquality scientific research. People who are different from one another in sex, race/ethnicity, and other domains bring unique information and experiences to the table. The next generation of female scientists have creative minds with ideas and perspectives that have the potential to move science forward faster. If we do not support and encourage them, they unfortunately will go somewhere else.

### INSTITUTIONAL SPOTLIGHT

The Association for Women in Science (AWIS) is an organization supporting women in science, technology, engineering, and mathematics (STEM) fields, with a specific focus on increased growth and opportunities for women in STEM, greater recognition of their achievements, and support for them as leaders in STEM employment sectors. The organization calls for training, mentorship, and other support for women in STEM, and its research division provides the latest findings on how to make the workplace more equitable. AWIS provides an interactive online Career Center, linking STEM professionals with opportunities in STEM industries.

AWIS recently announced its Pinnacle Award recipient: Nobel Laureate Carol Greider, Ph.D., the Daniel Nathans Professor and Director of Molecular Biology and Genetics at The Johns Hopkins School of Medicine and winner of the 2009 Nobel Prize in Physiology. According to AWIS National Governing Board President Susan Windham-Bannister, Ph.D., the organization presented its Pinnacle Award, its highest honor, to Dr. Greider in recognition of her discovery of telomerase, a key enzyme in age-related disease and cancer.

AWIS's Next Generation Award is going to Mareena Robinson Snowden, Ph.D., who, in 2017, became the first African-



American woman to earn a Ph.D. in nuclear engineering from MIT and whose inspirational story has been featured on television, on radio, and in print media. Dr. Robinson Snowden is currently the Stanton nuclear security fellow at the Carnegie Endowment for International Peace.

Said Dr. Windham-Bannister, "Both are wonderful examples of the contributions that women in STEM fields have made and will continue to make to the greater good." Drs. Greider and Robinson Snowden will receive their respective awards at AWIS's annual premiere event—<u>The Innovation and Inclusion</u> <u>Summit and Awards Dinner</u>—on April 24, 2019.

# *Forbes* Article Explores Gender Gap in Medical Research, Features ORWH Director

On September 26, 2018, Forbes magazine published "Meet the Woman Helping to Fix the Gender Gap in Women's Health," featuring an interview with ORWH Director Janine Austin Clayton, M.D. In the article, Dr. Clayton sheds light on the importance of considering sex in the entire biomedical research spectrum to improve the health of women and men. She explains how biological differences between women and men can have profound effects on how we manifest diseases and respond to treatments. She states, "If we do not take into consideration what I feel is the most important fundamental biological variable-being male or female-we run the risk of making errors in our medical conclusions." Dr. Clayton also highlights how the NIH Inclusion Policy has improved the representation of women in NIH-funded studies but acknowledges that there is still work to be done in medical research and beyond to close the gender gap.

### **NIH Expands Inclusion Policy**

NIH has expanded an existing policy that requires children's participation in clinical trials to include people of all ages, including older Americans. The <u>NIH Inclusion</u> policy became effective on January 25, 2019, and applies to all grant applications submitted thereafter. The policy (1) ensures that individuals of all ages, including children and older adults, are included in clinical trials; (2) clarifies the potentially acceptable reasons for excluding participants based on age; and (3) requires the provision of data on participant's age on enrollment in progress reports. Applicants seeking funds for trials must develop a plan to include individuals of all ages or to justify exclusions for scientific or ethical reasons.

### NIH Director Outlines Efforts to Reduce Sexual Harassment

For decades, efforts have focused on recruiting, retaining, and advancing women in the fields of science, technology, engineering, and math (STEM). NIH also undertook efforts to ensure more women took part in the important work of public health research and application and that fewer women would face barriers in the workplace. Unfortunately, sexual harassment remains a problem and constitutes a major barrier in the STEM workplace. Recent study results published in a report from the National Academies of Sciences, Engineering, and Medicine (NASEM) and funded by NIH and other government science agencies found no evidence that current policies, procedures, and approaches have significantly reduced sexual harassment in academic sciences, engineering, and medicine. NIH has taken several major steps to bolster efforts to address sexual harassment in science, including:

- A comprehensive anti-sexual harassment program for NIH staff, including new policies and practices to make it easier for people to report an allegation and for NIH to address it
- A guide notice to the NIH grantee community to inform them of our internal policies and procedures in the Federal Register and to urge institutions to consider similar approaches
- A survey of all NIH staff, including employees, contractors, and fellows, in early 2019 to assess workplace climate at NIH facilities
- A new <u>Anti-Sexual Harassment website</u> to increase our transparency on NIH policies and procedures for NIH staff and extramural researchers
- A working group of the Advisory Committee to the NIH Director to advise on ways to strengthen anti-sexual harassment efforts
- Support of research, including funding the NASEM study mentioned above and a study on gender equity in academic medicine resulting in a JAMA publication (Jagsi et al. 2016. JAMA. 315: 2120-2121)

NIH Director Francis Collins, M.D., Ph.D., has posted a <u>statement</u> detailing these and other NIH efforts to remedy the problem of sexual harassment and to position NIH, the largest funder of biomedical research in the world, to take the lead on overcoming this unacceptable behavior throughout the biomedical community.

## ORWH Leads NIH Scientific Interest Group (SIG) on Estrogen and Heart Disease

The NIH Sex and Gender in Health and Disease (SGHD) SIG explores the influences of sex as a biological variable and of gender as a social construct on health and disease across the lifespan. The SGHD SIG also promotes research dissemination and fosters interdisciplinary collaboration among NIH scientists who work on, or are interested in, aspects of sex-based research or in sex/gender influences relevant to health and disease. A SGHD SIG meeting on November 20, 2018, featured Elizabeth Murphy, Ph.D., Head of the Cardiac Physiology Section in the Cardiovascular Branch of the National Heart, Lung, and Blood Institute (NHLBI), who spoke on "The Role of Estrogen in Cardioprotection." Dr. Murphy's research explores how estrogen affects cardiovascular tissue; lipid profiles, including lowering LDL cholesterol; vascular remodeling; blood pressure; and cardioprotection. Although the mechanisms by which estrogen mediates these effects is not fully understood, Dr. Murphy's research suggests that estrogen regulates gene transcription in specific tissues and participates in other signaling pathways. Further study Continued on page 14

of the complex interactions of estrogen may explain why premenopausal women experience less cardiovascular disease and why older postmenopausal women do not seem to gain a cardioprotective effect from hormone replacement therapy.

### ORWH Seminar Addresses the Health of Young Transgender Women

The ORWH Women's Health Seminar Series, in collaboration with the NIH Sexual and Gender Minority Research Office (SGMRO), featured a presentation by Nadia Dowshen, M.D., on December 6, 2018. Dr. Dowshen, the cofounder and Medical Director of the Gender and Sexuality Development Clinic at the Children's Hospital of Philadelphia (CHOP), spoke on "Improving the Health and Well-Being of Young Transgender Women: Intersections of Research, Policy, and Practice." A review of her research described HIV-related and other health inequities faced by young transgender women. Dr. Dowshen also discussed how these data have informed policy and the development of a successful multidisciplinary model of clinical care for transgender children and adolescents. This seminar introduced a new series of webinars, set to launch early in 2019, that will focus on the effects of sex and gender influences among populations of women covered by the <u>Understudied</u>, Underrepresented, and Underreported (U3) Populations Program, an NIH program that co-funds biomedical research on minority and marginalized groups.



(*Left to Right*) ORWH Director Janine Clayton, M.D., Nadia Dowshen, M.D., ORWH Associate Director of Interdisciplinary Research Victoria Cargill, M.D., M.S.C.E., AAHIVS



Marsha Henderson, M.C.R.P.

### A Powerful Figure in Women's Health Research Retires

Marsha Henderson, M.C.R.P., has retired from her role as the Assistant Commissioner for Women's Health at the Office of Women's Health (OWH) at the Food and Drug Administration (FDA), following more than 30 years of service to the Federal government and 20 years at the FDA. In addition

to directing OWH, she coordinated FDA policy, research, and outreach efforts to protect and advance the health of women and advocated for the participation of women in clinical trials and for sex, gender, and subpopulation analyses. She developed the Women's Health Take Time to Care Program, which reached more than 120 million people with FDA consumer information in 18 languages. The program received awards from more than 96 national organizations.

Ms. Henderson also collaborated with ORWH on several projects, working closely with Janine Clayton, M.D., Associate Director for Research on Women's Health and Director of ORWH. "It has been a pleasure collaborating with Marsha on women's health issues," said Dr. Clayton. "Together we launched the Diverse Women in Clinical Trials initiative and collaborated on the development of the Science of Sex and Gender in Human Health course series."

Another collaboration between OWH and ORWH was an interactive panel discussion, Meet the Faces of Clinical Research: Beyond Inclusion, which took place during National Women's Health Week in May of 2015. The event celebrated and recognized the importance of women and diversity in clinical research.

Under Ms. Henderson's leadership, OWH released the first Women's Health Research Roadmap at FDA, which outlines seven priority areas for new or enhanced research, including biomarkers, clinical trials design, nanotechnology, cardiovascular disease, and post-market surveillance.

Ms. Henderson has received numerous awards from professional and consumer organizations, such as the inaugural Estelle Ramey Award for Women's Health Leadership, the "HerMANA" Award for innovative outreach to Hispanic women, and the Pinnacle Award for exceptional leadership in enhancing health care quality and medication use for patients and caregivers.

ORWH wishes Ms. Henderson the best in her welldeserved retirement.

# Sociologist Lectured on "The Social Life of DNA" in the Wednesday Afternoon Lecture Series

Alondra Nelson, Ph.D., President of the Social Science Research Council and Professor of Sociology at Columbia University, was the featured lecturer on January 16, 2019, at the Wednesday Afternoon Lecture Series (WALS), the highest-profile lecture program at NIH. She spoke on "The Social Life of DNA" and addressed the intersections of race, science, history, and contemporary social issues. This lecture was co-sponsored by ORWH, the National Institute on Aging (NIA), and the National Human Genome Research Institute (NHGRI). More information on Dr. Nelson is available at https://oir.nih.gov/wals/2018-2019/social-life-dna.



Alondra Nelson, Ph.D.

### TEAMING UP FOR WOMEN'S HEALTH

### Tilted: A Lean In Podcast—Why Women Get Overlooked in Health Care

Numerous studies and anecdotes characterize how doctors perceive men's and women's pain differently, generally ascribing less seriousness to the pain of women. Gender perceptions continue to affect the care patients receive. Janine Clayton, M.D., ORWH Director; Esther Choo, M.D., M.P.H., Associate Professor at Oregon Health and Science University; and tennis champion Serena Williams discuss bias in health care, including misdiagnoses and incorrect treatment, in the podcast <u>Tilted: A Lean In Podcast</u>.

### NIH Science, Health, and Public Trust Initiative Launches New Website

The NIH <u>Science, Health, and Public Trust</u> initiative recently redesigned and relaunched its website. This site was created to share strategies and best practices to help convey complex research results to the public in ways that are clear, credible, accurate, and accessible.



The new <u>Perspectives</u> section offers insights on biomedical communication from NIH experts in diverse fields. For example, Anthony S. Fauci, M.D., discussed <u>how to</u> <u>communicate about crises</u> like the Ebola and Zika outbreaks. Nora D. Volkow, M.D., described <u>how to report on the science</u> <u>behind addiction</u>. Eliseo J. Pérez-Stable, M.D., discussed <u>the</u> <u>importance of considering race and ethnicity in research</u>. New Tools and Resources sections provide additional information, guides, references, and links to helpful sites at NIH and elsewhere.



The <u>NIH Spanish Health Information Portal</u> offers a wealth of free, reliable health information in Spanish. It features monthly content from <u>NIH</u> News in Health and an Ask Carla column to help users locate NIH health resources in Spanish. Users can also sign up for the e-newsletter <u>NIH</u> Información de Salud. Each month, the newsletter contains resources on important topics, such as heart health, diabetes, and much more. 48<sup>th</sup> Meeting of the NIH Advisory Committee on Research on Women's Health (ACRWH) April 10, 2019, 9:00 a.m. - 4:00 p.m. (Eastern Time) (Event time subject to change) NIH Main Campus, Natcher Conference Center

"Advancing Science for the Health of Women: The NIH Office of Research on Women's Health" A Symposium at the Organization for the Study of Sex Differences (OSSD)/International Society for Gender Medicine (IGD) Joint Meeting 2019 ORWH Symposium: May 5, 2019 Joint Meeting: May 5-8, 2019 Washington Marriott Georgetown, Washington, DC

#### National Women's Health Week - May 13-19, 2019

### 4<sup>TH</sup> ANNUAL NIH VIVIAN W. PINN SYMPOSIUM

Improving Maternal Health: Behind the Numbers May 15, 2019 12:00 p.m.- 4:30 p.m. (Eastern Time) NIH Main Campus, Wilson Hall

### 49<sup>th</sup> Meeting of the Advisory

**Committee on Research on Women's Health** October 23, 2019, 9:00 a.m. - 4:00 p.m. (Eastern Time) NIH Main Campus, Natcher Conference Center

For more information, please visit <u>www.nih.gov/women</u>.

### FUNDING OPPORTUNITIES

### Opportunities for Collaborative Research at the NIH Clinical Center (U01 Clinical Trial Optional)

The goal of this program is to support collaborative translational research projects aligned with NIH efforts to enhance the translation of basic biological discoveries into clinical applications that improve health. It encourages high-quality science demonstrating the potential to result in understanding an important disease process or lead to new therapeutic interventions, diagnostics, or prevention strategies within the research interests and priorities of the participating NIH Institutes/Centers (ICs). Specifically, the program seeks to broaden and strengthen translational research collaborations between basic and clinical researchers both within and outside NIH to accelerate and enhance translational science by promoting partnerships between NIH intramural investigators (e.g., those conducting research within the labs and clinics of the NIH) and extramural investigators (e.g., those conducting research in labs outside the NIH), and by providing support for extramural investigators to take advantage of the unique research opportunities available at the NIH Clinical Center by conducting clinical research projects in collaboration with NIH intramural investigators. First applications are due April 15, 2019. For more information, see FOA number PAR-18-951. Contact ORWH at ORWHinfo@nih.gov if you have questions.

### Emerging Global Leader Award (K43 Independent Clinical Trial Required)

This Funding Opportunity Announcement (FOA) is designed specifically for applicants proposing to serve as the lead investigator of an independent clinical trial, a clinical trial feasibility study, or a separate ancillary study to an existing trial, as part of their research and career development. Applicants not planning an independent clinical trial or proposing to gain research experience in a clinical trial led by another investigator must apply to companion FOA PAR-17-001. The purpose of the Fogarty Emerging Global Leader Award is to provide research support and protected time (3-5 years) to an early career research scientist from a low- or middle-income country (LMIC) who holds a junior faculty position at an LMIC academic or research institution, as defined by the World Bank (including "low-income," "lower-middle-income," and "upper-middle-income" countries). This intensive, mentored research career development experience is expected to lead to an independently funded research career at the LMIC institution or in another LMIC. This FOA invites applications from LMIC scientists from any healthrelated discipline who propose career development activities and a research project that is relevant to the health priorities of their country under the mentorship of LMIC and U.S. mentors. Applications are due November 7, 2019. For more information, see FOA number PAR-19-051. Contact ORWH at ORWHinfo@nih.gov if you have questions.

### Accelerating the Pace of Child Health Research Using Existing Data from the Adolescent Brain Cognitive Development (ABCD) Study (R01-Clinical Trial Not Allowed)

The Adolescent Brain Cognitive Development (ABCD) Study is collecting data on health and mental health, cognitive function, substance use, cultural and environmental factors, and brain structure and function from youth starting when they are 9-10 years old and following them longitudinally to early adulthood. These data will be made available to the scientific community through the NIMH Data Archive. The purpose of this FOA is to encourage applications proposing the analysis of this public use dataset to increase knowledge of adolescent health and development. More information about the ABCD Study may be found on the ABCD Study web page (www.abcdstudy.org). Applications will be accepted beginning May 5, 2019. For more information, see FOA number <u>PAR-19-162</u>. Contact ORWH at <u>ORWHinfo@nih.gov</u> if you have questions.

### NIH Office of Research on Women's Health (ORWH)

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