WOMEN'S HEALTH *In Focus* AT NIH
A QUARTERLY PUBLICATION OF THE NIH OFFICE OF RESEARCH ON WOMEN'S HEALTH
National Institutes of Health • Office of the Director | Volume 3, Issue 4, 2020

Enhancing Diversity in NIH-Funded Clinical Studies

OFFICE OF RESEARCH ON WOMEN'S HEALTH
30 Years
Advancing the Health of Women Through Science

IN THIS ISSUE

Visit the subscription page to sign up to receive future issues of ***Women's Health in Focus at NIH***.

TABLE OF CONTENTS

Director's Corner

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

NIH and its extramural partners recently launched Phase III clinical trials of the mRNA-1273 candidate vaccine for COVID-19. (See p. 15 for more information.) Even with the daunting challenge of recruiting 30,000 participants for the trial, the researchers have taken steps to gather a diverse, representative study population in keeping with the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research and the Inclusion Across the Lifespan Policy. Pandemic data indicate that COVID-19 has had varying effects on different groups, with people of color, older adults, and other populations experiencing a disproportionate number of cases. Including all groups in the clinical trial helps ensure that everyone can benefit from its findings.

This issue of In Focus *explores the history, application, benefits, and challenges of NIH's inclusion policies. Our cover story discusses the policies, their history, and their application in several NIH programs. Other articles discuss areas of scientific endeavor where additional inclusion efforts are needed, such as the study of HIV/AIDS and cardiovascular disease and the reporting of disaggregated data in peer-reviewed journals; recruiting hard-to-reach populations; and analyzing results of clinical trials by sex, gender, race, ethnicity, and age.*

Please visit https://www.nih.gov/coronavirus and https://www.coronavirus.gov for up-to-date information on the coronavirus pandemic and https://www.coronaviruspreventionnetwork.org for information on participating in the mRNA-1273 clinical trial. Please share this publication with your colleagues and encourage them to subscribe.

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

Enhancing Diversity in NIH-Funded Clinical Studies

In this, the final issue of *In Focus* in ORWH's 30th anniversary year, we discuss two key NIH policies: the Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research and the Inclusion Across the Lifespan Policy. The NIH policy on inclusion of women and minorities in clinical research dates back to the mid-1980s and remains central to the mission of ORWH and NIH. Both policies were enacted to ensure that everyone benefits from biomedical research by including all scientifically relevant populations in NIH-supported clinical trials.

The History of the Policy on the Inclusion of Women and Minorities

As detailed in issue 3.1 of *In Focus*, NIH established ORWH in 1990 in response to an increasing awareness that health research had largely excluded women from clinical trials. Much of the historic medical literature evinces an incorrect assumption that, apart from their reproductive organs, men and women are physiologically similar. Two further factors contributing to the exclusion of women were misconceptions about their fluctuating hormone levels, which led researchers to believe they were inappropriate research subjects, and the desire to protect women of childbearing age and their unborn children. However, as postmenopausal women, racial and ethnic minorities, children, and older adults were also excluded, societal sexism, racism, and ageism almost certainly influenced biomedical research recruiting practices, resulting in young and middle-aged White men being treated as the medical norm.

In the 1980s, prompted by a number of advocacy groups, task forces, legislators, and scientists, both NIH and the U.S. Congress took steps to address the exclusion of women from clinical studies. In 1986, NIH enacted its original policy for the inclusion of women in clinical research, articulating the expectation that women should be included in NIH-supported clinical studies. Subsequent research[1] showed that this policy did not realize significant change in research practices, and NIH founded ORWH in 1990 as a result. The new office was tasked with monitoring and promoting trans-NIH efforts to ensure that women were included in clinical trials. NIH later expanded the policy to include racial and ethnic minorities and gave the inclusion policy the force of law as part of the NIH Revitalization Act of 1993. NIH updated the policy again in 2001 to incorporate a more precise definition of clinical research, delineate 15 racial and ethnic categories for reporting population data, and provide guidance on reporting analyses of sex/gender, racial, and ethnic differences in intervention effects for NIH-defined Phase III clinical trials.

Lending further weight to the inclusion policy, Congress passed the 21st Century Cures Act in 2016, mandating that NIH convene a workshop on the inclusion of individuals of all ages in clinical research; post workshop findings on an NIH website; publish guidelines addressing consideration of age in clinical research; report the sex/gender, race, ethnicity, and age of participants; and ensure that researchers conducting applicable Phase III clinical trials report results of analyses by sex at ClinicalTrials.gov.

The History of the NIH Inclusion Across the Lifespan Policy

As Federal laws and NIH policies enhanced the inclusion of women and minorities in biomedical research, recently, NIH adopted policies addressing the need to include older populations in clinical studies. Marie A. Bernard, M.D.,* serves as the Deputy Director of the National Institute on Aging (NIA) and Co-Chair of the NIH Inclusion Governance Committee (IGC), which monitors inclusion in clinical research by sex, gender, race, ethnicity, and age. Dr. Bernard explains that several years ago, "The question arose whether NIH was doing a good job including older adult populations in the studies it supports. Based on a trans-NIH portfolio analysis of common causes of hospitalization and disability in the older population,[2] we found that NIH was not including older Americans adequately." In 2017, in response to a component of the 21st Century Cures Act that mandated a scientific workshop to examine NIH inclusion policy by age and a potential revision of policy, NIH hosted the first Inclusion Across the Lifespan (IAL) workshop, which identified research opportunities to enhance consideration of children and older adults. NIH later published a summary of the workshop and the opportunities and challenges identified. "The workshop, the summary, and other input contributed to the development of the NIH Inclusion Across the Lifespan Policy," says Dr. Bernard.

In 2018, IGC Co-Chairs Dr. Bernard and ORWH Director Janine A. Clayton, M.D., along with NIH Deputy Director for Extramural Research Michael S. Lauer, M.D., published a seminal article in *JAMA: The Journal of the American Medical Association*, announcing the forthcoming IAL policy.[3] The new policy took effect in January 2019 and required that clinical trials include study participants of all ages, including children and older adults. Dr. Bernard says, "With this new policy, researchers have to submit progress reports that include anonymized data on age, gender, sex, race, and ethnicity for all participants. This is a real advancement for NIH and the clinical research community. Prior to this policy, we did not require such granular information and dealt mostly with aggregate data."

NIA Deputy Director Marie A. Bernard, M.D.

The IAL policy has been in effect for less than 2 years, and NIH is actively collecting data on compliance and the demographics of study participants. As part of this effort, NIH hosted a second workshop on the topic, Inclusion Across the Lifespan-II, on September 2, 2020. Dr. Bernard says, "The follow-up workshop gave scientists evidence-based tools to implement the policy fully, including guidelines for crafting study criteria so that they don't exclude the majority of older adults as well as children, women, and minorities. I expect a number of papers will be published from the data presented at the workshop." (See *NIH Inclusion Across the Lifespan-II Workshop* on p. 6 for more information.)

Promoting and Monitoring Current Inclusion Policies

Together, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research and the Inclusion Across the Lifespan Policy function to guide NIH and its grantees in successfully recruiting scientifically appropriate, diverse populations for all NIH-conducted or -supported research involving human subjects, as well as to encourage researchers to analyze data and present findings as they pertain to sex, gender, race, ethnicity, and age. The policies allow for certain subpopulations to be excluded from clinical research if a strong scientific or ethical justification exists. (For example, research on ovarian cancer would be limited to women participants.) Overall, the current NIH inclusion policies should lead to more robust and generalizable scientific findings. Representative, inclusive study populations are more likely to capture individuals at greater risk for certain diseases; to provide a more complete picture of the risks and the benefits of an intervention; to address differences in clinical outcomes because of biological, cultural, social, or economic factors; and to test the safety and efficacy of treatments in people who would use them. COVID-19 provides a timely and urgent example of how the same illness can have different effects on different populations, warranting diverse study participants in health research. (See *COVID-19 and the NIH Inclusion Policies* on p. 7.)

Many NIH organizations collaborate to monitor inclusion and promote greater diversity in clinical research. In addition to ORWH and the IGC, the NIH Office of Extramural Research (OER) also ensures compliance with the policies. Dawn Corbett, M.P.H., is the NIH Inclusion Policy Officer. She says, "I provide oversight of trans-NIH efforts to ensure the inclusion of women, minorities, and individuals across the lifespan in NIH-defined clinical research. OER provides the corporate framework for NIH research administration, from developing application forms and designing electronic systems to analyzing data and producing reports. I make sure the inclusion policies are appropriately implemented in each step of the process." NIH remains dedicated to the study of diverse, scientifically appropriate study populations and improving scientific rigor.

---

* See also Dr. Bernard's "Pearls of Wisdom" video on the ORWH website.

NIH Inclusion Policy Officer Dawn Corbett, M.P.H.

NIH and External Programs Promoting Inclusion in Biomedical Research

Below, we will explore some of the Federal organizations and initiatives striving for greater inclusivity in clinical research, data analysis, and reporting. The programs described here are only a sampling of those dedicated to increasing diversity. However, these programs demonstrate the types of recruitment practices, advocacy efforts, strategic planning, resource development, and public outreach that contribute to improved inclusion.

The ORWH U3 Administrative Supplement Program

ORWH supports interdisciplinary research on understudied, underrepresented, and underreported (U3) populations through the U3 Administrative Supplement Program. Studies funded through this program focus on the health effects of sex influences as they intersect with social determinants of health, such as race, ethnicity, socioeconomic status, education, gender identity, and urban or rural residence. This program supports preclinical, clinical, behavioral, and translational studies of women from NIH-designated health disparity populations. ORWH also hosts the U3 Women's Health Lecture Series, featuring principal investigators who lecture on their U3 research to inform and increase interest in pursuing biomedical and behavioral science investigations with these populations. The most recent webinar, "Improving Chronic Disease Outcomes Through Approaches that Address Social Determinants of Health," is described in more detail on p. 16.

NIH Inclusion Outreach Toolkit

In 2019, ORWH updated and released a new version of the NIH Inclusion Outreach Toolkit. Ms. Corbett describes the online toolkit as "an outstanding resource for helping investigators understand NIH inclusion policies and design studies to include scientifically appropriate populations." A new section titled "Case Studies" provides examples of evidence-based recruiting strategies to help investigators connect with hard-to-reach populations, including:

- Adapting recruitment strategies to the cultural and linguistic background of the intended study population
- Translating materials into the appropriate language
- Enlisting culturally and linguistically competent research staff
- Including families and communities in a dialogue
- Partnering with community organizations
- Engaging and retaining investigators and staff from the targeted communities to facilitate acceptance and ensure continuity

One case study describes how a clinical trial on HIV prevention used Facebook to recruit young urban women. Another explains how the Center to Address Disparities in Oral Health recruited preschool-age children, mainly from Latinx and Chinese backgrounds, by engaging in community outreach, forming local partnerships, and adopting culturally relevant approaches to recruit and retain study participants. Many of these strategies described in the toolkit were employed by Joycelyn Cudjoe, Ph.D., and colleagues from Johns Hopkins University in recruiting African immigrant women into the AfroPap study on cervical cancer screening behavior. (See p. 11 for more information.)

The toolkit also outlines how researchers can improve their cultural competence skills by learning about the values and practices of populations to be studied; reviews the scientific literature describing barriers to the recruitment of women, particularly minority women, in clinical research (e.g., distrust, lack of knowledge, logistics, fear of risk); and explains relevant Federal laws and regulations in detail. (For more information on participating in clinical trials, see *Should I Participate in a Clinical Trial?* on p. 7.)

According to Dr. Bernard, NIH officials, inspired by the example of the NIH Inclusion Outreach Toolkit, are interested in developing a similar toolkit for including individuals of all ages in clinical research. "I'd like to disseminate strategies for recruiting much older adults in clinical studies," she says. "It's not enough to recruit 60- or 70-year-olds. Our aging population includes many individuals in their 80s and 90s. We also need effective recruitment tools for children and adolescents, their parents, and younger adults."

Diabetes Prevention Program (DPP)

A program of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), DPP did an exemplary job of recruiting a diverse study population of men, women, racial and ethnic minorities, and individuals of all ages to test whether the DPP Lifestyle Change Program or taking metformin would delay or prevent type 2 diabetes.[4] DPP researchers collected, analyzed, and reported disaggregated data according to these demographic categories. DPP findings demonstrated that some outcomes differed by age and sex. For instance, while the Lifestyle Change Program was effective for men, women, and all racial and ethnic groups studied, the program worked particularly well for adults 60 or older and lowered their risk of type 2 diabetes by 71%.[4] Similarly, metformin was effective for

men, women, and all racial and ethnic groups studied but was most effective in women with histories of gestational diabetes, people ages 25–44, and individuals with obesity.[4] These findings have revolutionized how clinicians prevent and treat type 2 diabetes and demonstrate the importance of inclusivity in clinical research. The transformative results of the DPP would not have been possible with a less inclusive study population.

The Diverse Women in Clinical Trials Initiative

The Diverse Women in Clinical Trials Initiative emerged from a partnership between ORWH and the Food and Drug Administration (FDA) Office of Women's Health (OWH) "to raise awareness about diverse women of different ages, races, ethnic backgrounds, and health conditions participating in clinical trials." The initiative launched a consumer awareness campaign aimed at women who might be interested in volunteering for a clinical trial and provided them with information on the individual and social benefits of participation as well as safety and where to volunteer. Through this initiative, ORWH and OWH have also developed resources for health professionals and researchers, including a Partner Social Media Toolkit for academic and clinical organizations, complete with fact sheets, sample messaging, articles, and other materials for informing the women in their networks about clinical trials.

The Helping to End Addiction Long-Term℠ (HEAL) Initiative

The HEAL Initiative is a trans-NIH effort to stem the national opioid public health crisis. The initiative funds hundreds of projects nationwide to understand, manage, and treat pain more effectively as well as to improve treatment for opioid misuse and addiction. With the extent of the opioid crisis, HEAL researchers must study a diverse population, including infants and children exposed to opioids in utero; older adults struggling with pain from conditions such as arthritis and bursitis; women, who are more likely to have pain conditions such as fibromyalgia, migraine, and interstitial cystitis (see *In Focus* 2.2); both men and women who experience pain nociception via different biological mechanisms (see *In Focus* 2.2); and different racial and ethnic groups that have different patterns of opioid use and misuse, experience different rates of opioid overdose, and have different levels of access to opioid addiction treatment.[5,6]

The Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

PRGLAC was established by the 21st Century Cures Act to advise the Secretary of the U.S. Department of Health & Human Services (HHS) on safe and effective therapies for pregnant women and lactating women. The task force is chaired by members of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and includes members of NIH, the Centers for Disease Control and Prevention, the HHS Office on Women's Health, and other Federal agencies as well as representatives from medical societies, nonprofit organizations, and industry. Although PRGLAC focuses on women of childbearing age generally, the recruiting strategies of the task force also ensure racial and ethnic diversity in PRGLAC's study populations. A PRGLAC implementation plan is due to be released early in 2021 (more information is available here).

All of Us

This Federal program (see https://www.joinallofus.org and https://allofus.nih.gov) is charged with creating an enormous database of health information from over 1 million diverse participants. This database will provide researchers with data on a variety of health conditions, help investigators understand the risk factors for particular diseases, and inform the assessment of the most effective treatments for people of different backgrounds. All of Us participants confidentially share information about their health, habits, and environment by responding to surveys or by providing DNA samples and electronic health records. All of Us was established by a framework described in a 2015 report by the NIH Precision Medicine Initiative Working Group of the Advisory Committee to the Director, which articulated the inclusive impulse behind the All of Us program: "Without broad inclusion, the [program] will not fulfill its most important goal, to increase the health of all Americans through new understanding of the development and progression of disease, optimal treatment, and prevention strategies."

Inclusion Today

Thirty years after the establishment of ORWH, data show that about half of the participants in NIH-supported clinical trials are women.[7] Promoting and monitoring compliance with the NIH inclusion policies remain relevant. Women, particularly those from

NIH Inclusion Across the Lifespan-II Workshop

On September 2, NIH hosted the Inclusion Across the Lifespan-II workshop. The workshop convened individuals from a wide range of backgrounds in clinical study development, execution, and inclusion of pediatric, older adult, and special populations, such as racial and ethnic minorities, pregnant women, lactating women, and sexual and gender minorities. Researchers shared lessons learned on the recruitment and inclusion of these populations in clinical studies and presented evidence-based advice. Additional information on the workshop is available here, and a video recording of the event is available here.

COVID-19 and the NIH Inclusion Policies

News coverage of the COVID-19 pandemic provides almost daily reminders of the importance of the NIH inclusion policies and the need for biomedical research to study diverse populations to understand disease risk, progression, treatment, and outcomes more completely.

Ms. Corbett says, "Racial and ethnic minority groups are disproportionately affected by COVID-19, with current data suggesting a high burden of illness and death. Ensuring the research NIH funds reflects scientifically appropriate populations can help us better understand and address such disparities."

Early data suggest that women, who hold more positions in health care, may face more disease exposure but that more men die from the disease. Older Americans, particularly those in assisted living facilities and nursing homes, have high rates of COVID-19 infection and mortality, as do members of the Navajo Nation and other populations. These disproportionate effects necessitate an intentional, inclusive approach to descriptive studies of the disease, the development of diagnostic tests, the evaluation of vaccines, and the testing of new therapies. Including populations such as African Americans, Latinx, American Indians, Alaska Natives, older adults, people experiencing homelessness, and patients with comorbidities—vital to the study of any disease—is essential to the integrity of scientific inquiries into COVID-19 and to addressing the pandemic.

According to Dr. Clayton, "the biomedical community's response to COVID-19 requires inclusive outreach strategies, community-tailored approaches, and diverse investigators and research teams to develop and lead studies." She adds, "Just as COVID-19 researchers need to recruit diverse participants, so too must investigators disaggregate study results by sex, gender, race, ethnicity, and age and consider the effects of intersectionality on outcomes."

NIH's COVID-19 efforts include:

- Publication of the NIH-Wide Strategic Plan for COVID-19 Research
- Funding opportunities specific to COVID-19
- The Rapid Acceleration of Diagnostics (RADx) initiative for COVID-19, including the RADx-UP program targeting underserved populations
- A partnership with Moderna, Inc., to conduct a Phase III clinical trial for mRNA-1273, a candidate vaccine for COVID-19 (see "NIH Leadership, Moderna Executive, and Study Volunteer Discuss COVID-19 Vaccine Clinical Trial" on p. 15 and https://www.coronavirusprevention network.org for more information)
- Launch of the NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities to help reach underserved communities that might not be located near clinical research recruitment sites
- A forthcoming ORWH webpage dedicated to COVID-19

minority and vulnerable populations, are still underrepresented in studies of some diseases.

Compared with the policy on the inclusion of women and minorities, the IAL policy is still in its infancy, and the assessment of the impact of this policy is in the nascent stages. "We're still early in the process, and the initial lifespan inclusion data are only now coming in," Dr. Bernard says. She adds that these initial data and anecdotal evidence suggest some positive results. "I have read summary statements from NIH review panels that criticize applicants for insufficiently addressing Inclusion Across the Lifespan in their proposals. However, it's going to take a little while for a more coordinated assessment of policy compliance," she says.

Should I Participate in a Clinical Trial?

Anyone, regardless of health status, can contribute to the effort to improve public health by participating in clinical research. "You don't have to be sick to participate in a clinical trial. We also need to know what healthy looks like," says Dr. Clayton. Investigators are particularly interested in individuals from populations underrepresented in biomedical research. Below, you will find a list of websites and other resources guiding you to information about clinical trials. Before joining any clinical study, patients should consult with their doctor, ask questions, and make sure they are comfortable with the terms of confidentiality, informed consent, and risks.

- FDA's Women in Clinical Trials webpage
- These websites dedicated to the All of Us program: https://www.joinallofus.org and https://allofus.nih.gov
- ClinicalTrials.gov
- "15 Things to Know Before I Join a Clinical Trial" on the Diverse Women in Clinical Trials Initiative webpage

NIH now requires its grantees to report selected inclusion data on sex, gender, race, ethnicity, and age disaggregated for various research, condition, and disease areas through the Research, Condition, and Disease Categorization (RCDC) system. "We hope these data will help us better understand how individuals of all ages are included in the NIH research portfolio," Ms. Corbett says. "I have seen significant progress over my 17-year career at NIH. Applications proposing a study of all-White adult males used to be much more common. We have spread the word that inclusion is important and that NIH will not fund an application that excludes groups of people without a strong scientific rationale. We are doing better science as a result."

"The history of these NIH inclusion policies shows that encouragement is not enough," Dr. Bernard says. "In the 1980s, NIH encouraged scientists to include women and minorities in their studies. It was only when the policy created a mandate that we started to see widespread inclusion of women and underrepresented minority populations in studies. Even with that mandate, we need to continue monitoring to ensure inclusion and to make sure the data are analyzed related to those populations."

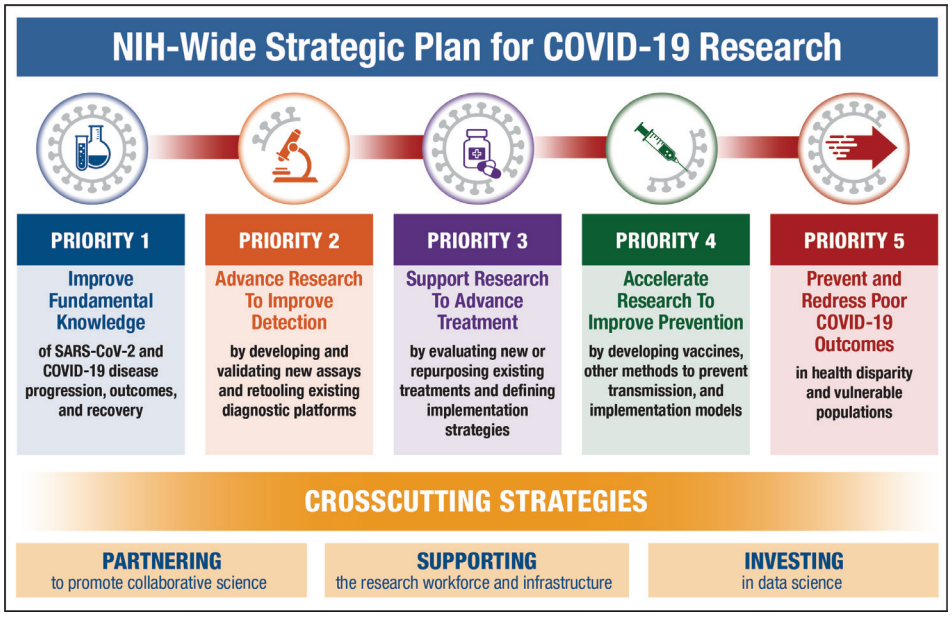
References

1. Nadel. 1990. *Problems in Implementing the National Institutes of Health Policy on Women in Study Populations.* Washington: U.S. GAO.
2. Lockett et al. 2019. *J. Am. Geriatr. Soc.* 67: 218-222.
3. Bernard et al. 2018. *JAMA* 320: 1535-1536.
4. Aroda et al. 2017. *Diabetologia* 60: 1601-1611.
5. Lippold et al. 2019. *MMWR Morb. Mortal. Wkly. Rep.* 68: 967-973.
6. Goedel et al. 2020. *JAMA Netw. Open* 3: e203711.
7. Feldman et al. 2019. *JAMA Netw. Open* 2: e196700.

NIH's Pandemic Response: A New Strategic Plan and Principles for Considering Sex, Gender, and Women's Health in COVID-19 Research

This summer, NIH released its NIH-Wide Strategic Plan for COVID-19 Research, detailing five priorities for accelerating the development of therapeutic interventions, vaccines, and diagnostics:

- Investing in NIH and NIH-funded researchers to increase fundamental and foundational knowledge of SARS-CoV-2 and COVID-19
- Speeding innovation in COVID-19 testing technologies through NIH's recently launched Rapid Acceleration of Diagnostics (RADx) initiative, which aims to deliver rapid, widely accessible testing strategies to the public
- Participating in public-private partnerships, such as NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership and Federal partnerships such as Operation Warp Speed, to forge groundbreaking approaches that speed identification, development, evaluation, and manufacturing of promising candidate therapeutics and vaccines



- Supporting studies on preventive treatments and behavioral and community prevention practices to identify and implement effective approaches for promoting individual and community safety
- Ensuring that diagnosis, treatment, and prevention options are accessible and available for underserved and vulnerable populations that have been at greatest risk for the most severe threats of the disease

ORWH, the NIH Coordinating Committee on Research on Women's Health (CCRWH), and other NIH organizations are working in concert to ensure that NIH-supported COVID-19 research will incorporate, as appropriate, a thorough

consideration of sex and gender in compliance with Federal mandates and will yield robust, generalizable scientific findings. NIH's inclusion policies (i.e., Inclusion Across the Lifespan and Inclusion of Women and Minorities as Subjects in Clinical Research) and Policy on Sex as a Biological Variable informed the creation of the strategic plan to guide NIH efforts and ensure that NIH-funded research will benefit all populations. The COVID-19 pandemic underscores the need to consider sex and social determinants of health, including gender; to respond equitably to COVID-19, as well as to any threats related to future outbreaks and pandemics; and to enhance development and deployment of effective, equitable diagnostics, treatments, and interventions. Incorporating a sex-and-gender lens into NIH's response to COVID-19 offers several unique opportunities to promote rigorous research and advance health equity, including strengthening vaccine efficacy and dosing for all sexes; enhancing investigations of new therapeutics; exploring sex differences in medication risk profiles; elucidating gender-related factors affecting treatment adherence, access to health care, and health-seeking behaviors; and understanding the long-term mental and physical health consequences of COVID-19.

In addition, NIH and the researchers it supports are considering the effects of the pandemic on women's physical and mental well-being, including the impact on:

- Older women, particularly those in nursing homes, where women represent approximately two-thirds of the population
- Pregnant women, who experience higher rates of COVID-19-related hospitalizations and may be at higher risk for the disease than nonpregnant women
- Health care workers and nursing home staff, the majority of whom are women
- Women who provide child care and other family care in their homes, particularly those who have essential jobs outside of the home
- Women who have experienced physical and/or sexual abuse with the pandemic-associated increase in domestic and intimate partner violence

You can read the *NIH-Wide Strategic Plan for COVID-19 Research* and learn more about how the framework aims to mobilize the biomedical research response to the pandemic here.

NIH Strives for Greater Inclusion of Women in HIV Research

Elizabeth Barr, Ph.D.
Social and Behavioral Scientist Administrator
ORWH Clinical Research Section

Miya Whitaker, Psy.D., M.A.
Health Scientist Administrator
Program Officer
ORWH Clinical Research Section

Women remain underrepresented and understudied in HIV research[1] despite known sex differences in HIV risk, progression, and outcomes.[2] This underrepresentation is chronic and has been well documented across funder categories[3,4] and research types.[5–7] Women's underrepresentation in HIV research constitutes a global public health issue, as women, particularly young women, account for over half of HIV diagnoses.[8] Prevention and therapeutic intervention efforts—as well as any future HIV curative strategies—must prioritize the inclusion of diverse women. Doing so is the only way to ensure that approaches are acceptable, safe, and effective across populations.[9]

In the United States, a disproportionate number of women diagnosed with HIV are members of ORWH-defined understudied, underrepresented, and underreported (U3) populations, including rural women;[10] transgender women;[11] women living at, near, or below the poverty line;[12] and Black and Latina women.[13] In 2016, Black women accounted for 6 in 10 new HIV infections among women, despite overall declines in new diagnoses.[14] Women of color are more severely burdened by HIV/AIDS globally.[15] Multiple complex determinants influence women's risk for HIV exposure[16] and health outcomes.[17,18] For example, HIV risk relates to economic opportunities, experiences of violence, and the ability to negotiate safer sexual encounters or injection practices.[19] For women of color, minority status intersects with other issues of marginalization, such as poverty. Stigma, structural racism, and other factors affect the ability of individuals with multiple devalued social identities to practice HIV risk reduction behaviors.[15,20]

Inclusive language offers one avenue for reaching U3 women. Members of the National Institute of Allergy and Infectious Diseases (NIAID) Office of Communications and Government Relations worked with community stakeholders to develop a language guide to "help scientists and administrators use fair, accurate, and respectful language" when communicating to and about people living with HIV and affected communities. Rigorous and sustained engagement with affected communities is another avenue to ensure that both HIV prevention efforts[21,22] and therapeutic interventions[23,24] are responsive to their target audience.

Recognizing the need to attend to social determinants in prevention and intervention strategies and to the contextual complexity of the lived experience of women, ORWH developed an administrative supplement program to facilitate the inclusion of U3 women and rigorous research on questions relevant to the health of women, including populations of women that experience health disparities or are otherwise socially or medically vulnerable.

In this issue of *In Focus* highlighting inclusion in research, ORWH challenges the HIV clinical research community—researchers, funders, reviewers, publishers, and others—to consider the inclusion of U3 women as a matter of scientific rigor, health equity, and policy planning. Ongoing studies and initiatives by NIH and other organizations seek to elucidate the role of self-efficacy in HIV prevention for refugee Hispanic women[25] and the effects on health outcomes of women living with HIV while incarcerated[26] or residing in impoverished or segregated neighborhoods.[27]

The end of 2020 marks the conclusion of ORWH's 30th anniversary year, and 2021 will be the 40th anniversary of the first description of HIV in the medical literature. It is our hope that, in 2021, we will advance ever further toward realizing ORWH's bold vision of every woman receiving "evidence-based disease prevention and treatment tailored to her own needs, circumstances, and goals."[28]

References

1. Curno et al. 2016. *J. Acquir. Immune Defic. Syndr.* 71: 181-188.
2. Scully. 2018. *Curr. HIV/AIDS Rep.* 15: 136-146.
3. Pepperrell et al. 2020. *J. Virus Erad.* 6: 70-73.
4. Smeaton et al. 2020. *Clin. Infect. Dis.* doi: 10.1093/cid/ciz959.
5. Goldstein and Walensky. 2019. *N. Engl. J. Med.* 381: 2491-2493.
6. Escudero et al. 2015. *AIDS Care* 27: 637-641.
7. Gianella et al. 2016. *J. Int. AIDS Soc.* 19: 20706.
8. Geretti et al. 2017. *HIV Med.* 18(S2): 3-17.
9. Ndung'u et al. 2019. *Nature* 576: 397-405.
10. Reif et al. 2017. *J. Community Health* 42: 844-853.
11. Kalichman et al. 2017. *Sex Health* 14: 469-476.
12. Breskin et al. 2017. *PLoS One* 12: e0172367.
13. Adimora et al. 2017. *Clin. Infect. Dis.* 65: 324-327.
14. Bradley et al. 2019. *MMWR Morb. Mortal. Wkly. Rep.* 68: 416-418.
15. Edwards and Collins. 2014. *J. Health Dispar. Res. Pract.* 7(SI2): 141-155.
16. Bartz et al. 2020. *JAMA Intern. Med.* doi: 10.1001/jamainternmed.2019.7194.
17. Geter et al. 2018. *PLoS One* 13: e0189973.
18. Nwangwu-Ike et al. 2018. *J. Acquir. Immune Defic. Syndr.* 79: e56-e68.
19. Li et al. 2014. *J. Int. AIDS Soc.* 17: 18845.
20. Rao et al. 2018. *Am. J. Public Health* 108: 446-448.
21. Poteat et al. 2019. *J. Acquir. Immune Defic. Syndr.* 82: 131-140.
22. DeShields et al. 2020. *Prog. Community Health Partnersh.* 14: 29-42.
23. Dubé et al. 2020. *AIDS Res. Hum. Retroviruses* 36: 324-348.
24. Njie-Carr et al. 2018. *J. Obstet. Gynecol. Neonatal Nurs.* 47: 833-843.
25. Cianelli et al. 2017. *J. Immigr. Minor. Health* 19: 905-912.
26. Cohen et al. 2019. *J. Womens Health (Larchmt.)* 28: 1083-1093.
27. Burke-Miller et al. 2016. *AIDS Care* 28: 1274-1279.
28. ORWH. 2019. *Advancing Science for the Health of Women: The Trans-NIH Strategic Plan for Women's Health Research*. Washington: HHS.

SCIENCE POLICY, PLANNING, AND ANALYSIS

The Next Steps for the NIH Inclusion Policies: Building on Three Decades of Increasing Diversity in Clinical Trials

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

Today, just over half the participants in NIH-funded clinical trials are women. This statistic is cited often in publications, public presentations, and other communications from NIH, and the scientific community can take pride in achieving this milestone. However, we have not yet fully accomplished the goals of the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research and the Inclusion Across the Lifespan Policy. NIH, researchers, publishers, and the entire biomedical and biobehavioral community still have work to do to realize truly equitable, diverse representation in clinical studies.

Women remain underrepresented in studies of some diseases, such as cardiovascular disease, hepatitis, digestive diseases, HIV/AIDS, and chronic kidney disease.[1,2] Older women, pregnant women, lactating women, women with comorbidities, women from some racial and ethnic minority groups, and women in other populations are also underrepresented in NIH clinical trials. Biomedical researchers can have difficulty recruiting study participants from racial and ethnic minority communities and other hard-to-reach populations. The recently updated NIH Inclusion Outreach Toolkit can help researchers successfully recruit underrepresented groups, and the evidence-based strategies therein

could help to enhance study population diversity. In addition, investigators must take care in crafting experimental inclusion criteria not to exclude women with comorbidities arbitrarily or to pattern the criteria solely on male manifestations of disease.

Although inclusion numbers have improved overall, reporting of data disaggregated by sex, gender, race, ethnicity, and age has lagged behind. In an analysis of 782 NIH-funded randomized controlled trials reported in peer-reviewed journals, Stacie E. Geller, Ph.D., and colleagues found that investigators do not routinely publish results by sex/gender, race, or ethnicity.[3] NIH strongly encourages its grantees to report inclusion data in print and, since 1994, has required them to do so in the progress reports they submit to NIH. However, U.S. Government agencies cannot require researchers to do so in journal articles or other publications. Many publishers, editors, and peer reviewers of scientific journals encourage or require investigators to report inclusion data and demographic-specific results, and NIH endorses this practice and challenges all academic publishers to adopt it.

The NIH Research, Condition, and Disease Categorization (RCDC) system now lists publicly available inclusion data on sex, gender, race, ethnicity, and age that are disaggregated for various research, condition, and disease areas. This public reporting ensures the transparency of inclusion practices in NIH-supported research. (See https://report.nih.gov and ClinicalTrials.gov for more information.) This type of transparency is essential in all reporting of clinical studies.

Biomedical research cannot realize its full value without representative inclusion in its study populations as well as properly analyzed and reported disaggregated inclusion data. As such, the inclusion policies—as well as the mission of ORWH and other NIH organizations to promote them and monitor compliance—remain relevant to the rigor and generalizability of scientific findings and to the best interests of public health. However, the promise of the inclusion policies can be fulfilled only with the committed endorsement and cooperation of all members of the biomedical research enterprise—investigators, reviewers, publishers, editors, policymakers, funding agency leaders, and other stakeholders.

References

1. Feldman et al. 2019. *JAMA Netw. Open* 2: e196700.
2. Jin et al. 2020. *Circulation* 141: 540–548.
3. Geller et al. 2018. *Acad. Med.* 93: 630-635.

IN THE JOURNALS

Biomedical Research Improves Inclusion of Male and Female Subjects in Study Populations, but Gaps in Sex-Based Analysis Persist

(Original article by Woitowich et al. 2020. eLife 9: e56344.)

An analysis of 721 recent articles published in 34 journals indicates that the proportion of biological studies that include both male and female subjects has increased significantly over the past decade (i.e., 49% of 2019 articles surveyed reported on studies that included both sexes—up from 28% in 2009). However, the proportion of studies that analyzed data by sex did not change in eight of nine biological disciplines considered in the analysis. Pharmacology was the one discipline that realized an increase in sex-based analysis (i.e., of pharmacological articles reporting on studies that included both sexes, 48% of 2019 articles analyzed data by sex—up from 19% in 2009). Few journal articles provided a rationale for performing single-sex studies or for omitting sex-based analysis, and the few that did so relied on misconceptions about female hormonal variability.

Nicole C. Woitowich, Ph.D., and colleagues performed their bibliometric analysis to assess compliance with and the impact of the 2016 NIH Policy on Sex as a Biological Variable (SABV). The investigators compared their results with those from a similar study of 841 articles published in the same journals in 2009 (Beery and Zucker. 2011. *Neurosci. Biobehav. Rev.* 35: 565-572). Dr. Woitowich and colleagues conclude that the finding that biological research has become more sex-inclusive seems encouraging at first. However, the fact that consideration of SABV in analyses and reporting lags behind in most disciplines—in spite of numerous appeals, guidelines, and policies encouraging researchers to disaggregate and analyze data by sex—indicates room for improvement.

AfroPap Investigators Share Community-Specific Research Recruiting Strategies for African Immigrant Women

(Original article by Cudjoe et al. 2019. J. Community Health 44: 1019-1026.)

Joycelyn Cudjoe, Ph.D., and colleagues from Johns Hopkins University developed and evaluated several techniques for recruiting African immigrant women to participate in the AfroPap study, a community-based survey research project on cervical cancer screening behavior. In their report, the investigators acknowledge the challenges associated with recruitment in research, particularly for populations of immigrants and racial and ethnic minorities. Time constraints,

mistrust, language barriers, confidentiality concerns, social stigmas associated with disease, the current political climate, and other factors create challenges for researchers recruiting study participants from these populations. However, the researchers emphasize the importance of including all populations in health research to understand public health problems and develop effective interventions.

Drawing ideas from both community stakeholders and the scientific literature, the researchers employed several strategies to recruit African immigrant women, including partnering with community churches, encouraging word-of-mouth recruitment through family and friends, improving the researchers' cultural competence, fostering a sense of comfort in participants by prioritizing interactions with same-sex researchers, using health education to promote altruism, ensuring confidentiality, leveraging social media platforms, and providing participants with options for in-person or online data collection. The researchers conclude that these strategies were effective in recruiting individuals from a hard-to-reach population, consistent with recommendations from the NIH Inclusion Outreach Toolkit, which suggests similar strategies.

The researchers make particular note of the efficacy of disseminating information, recruiting, and collecting data via the internet. Leaders from community and religious organizations suggested the use of WhatsApp, a smartphone application for messaging and calling, as it is popular in the African immigrant community. The investigators posit that their use of this familiar platform helped to establish social bonds, enhancing the recruitment effort. The researchers also used Qualtrics, a web-based survey tool, to distribute and administer surveys to almost half of the 167 participants (46%).

This research was supported by a predoctoral training grant to Dr. Cudjoe from the National Cancer Institute (NCI).

WOMEN IN SCIENCE

NIH Responds to Pandemic-Era Career Challenges for Biomedical Researchers

NIH, along with many other research institutions and universities, has taken action to mitigate the career effects of the pandemic on researchers by providing timely information, establishing expedited grant application and peer review processes, extending some deadlines for grantees, and making other accommodations.

The Office of Extramural Research (OER) has developed and regularly updates the Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding webpage. This webpage should be the first stop for NIH grant applicants and NIH-supported investigators, fellows, and trainees looking for additional guidance and up-to-date information on the effect of the public health emergency on NIH-supported research. The OER webpage includes information to help investigators continue their research, including instructions for submitting proposals, guidance for animal welfare, instructions for human subjects in clinical trials, and descriptions of flexibilities available to applicants for and recipients of Federal financial assistance who have been affected by COVID-19.

OER's COVID-19 webpage includes FAQs pertaining to delays in research progress and how to request grant extensions (e.g., ESI extensions, Ruth L. Kirschstein National Research Service Award payback extensions, K99-to-R00 transition extensions, fellowship extensions, and K99 eligibility extensions). An "Open Mike" article, "Accepting Preliminary Data as Post-Submission Material and Other COVID-19-Related Application Flexibilities," provides more information on pandemic-era flexibilities and concessions to NIH-supported researchers.

NIH now offers emergency competitive revision and urgent competitive revision funding to current grantees intending to shift focus to the novel coronavirus. In other cases, current NIH funding opportunities have been revised or expanded to encompass COVID-19 research.

For instance, through notices of change NOT-OD-20-168 and NOT-OD-20-156, ORWH expanded the scope of two existing funding opportunities to include research on COVID-19 in alignment with the original grants [i.e., The Intersection of Sex and Gender Influences on Health and Disease (RFA-OD-19-029) and Research on the Health of Women of Understudied, Underrepresented, and Underreported Populations (NOT-OD-20-048), respectively]. This approach enables NIH to provide additional funds to researchers who are seeking to study factors associated with COVID-19 disease prevalence, treatment, and prevention, including the influence of comorbid conditions. More information is available here.

In addition, some NIH grantees providing caregiving for a family member afflicted by COVID-19 may be eligible to apply for a funding supplement (e.g., NOT-OD-20-054 or NOT-OD-20-055) designed to support

research continuity and investigator retention during critical life events.

NIH has also temporarily amended its Guidance for NIH Peer Reviewers to accommodate the needs of the research community better during the pandemic, expedite the peer review process, and help turn discovery into health benefits that can mitigate the effects of COVID-19. NIH will also distribute a survey to the research community to provide input about the impact of the pandemic on research that will provide important insights and inform future efforts.

NIH is deeply concerned for the health and safety of people involved in NIH research and about the pandemic's effects on the biomedical enterprise. NIH will continue to serve the scientific community and will help to mitigate interruptions to ongoing research.

FEATURED RESEARCH AND PERSPECTIVES

Black Scientists Respond to Racism and Advise Colleagues and Institutions

(Original article by Gewin. 2020. Nature *583: 319-322.)*

Science journalist Virginia Gewin, Ph.D., reports on interviews with six Black academic researchers who provide thoughtful advice to institutions and the scientific community as a whole. These scientists respond to institutional racism within the scientific community, describe its impact on their careers, and offer advice to research institutions and White colleagues on how to take positive action. The investigators share their experiences with microaggressions as well as with more overt racist acts and statements. The scientists outline steps for creating inclusive environments and increasing diversity:

- Forming committees and other programs to foster diversity and inclusion
- Committing to ambitious diversity goals and new strategic practices for recruiting students and hiring staff, particularly leadership
- Collecting and publishing data on equity, diversity, and inclusion to ensure accountability
- Creating opportunities for difficult conversations
- Fostering a welcoming environment in which all voices are heard
- Making hiring for leadership posts more transparent

Several of the scientists emphasize that everyone has biases. Working in a discipline that prioritizes objectivity, scientists may be unaware of the institutional racism pervading their places of work or personal networks and may even be unaware of their own attitudes. Interventions that draw attention to institutional and personal biases can mitigate the inequities in the scientific community.

SCIENTIST SPOTLIGHT

Paule Joseph, Ph.D., M.S.

Paule Joseph, Ph.D., M.S., is a tenure-track Principal Investigator in the Sensory Science and Metabolism Unit of the Biobehavioral Branch of the National Institute of Nursing Research (NINR) with a joint appointment at the National Institute on Alcohol Abuse and Alcoholism (NIAAA). She is an NIH Lasker Clinical Research Scholar, an NIH Distinguished Scholar, and a Fellow of the New York Academy of Medicine. She investigates the complex interplay of biological and behavioral components that influence chemosensory symptoms in the context of diseases such as metabolic and substance use disorders. Some of her most recent research involves the sensory symptoms of COVID-19.

Could you highlight a recent research development you're particularly excited about?

My lab studies taste and smell, an area of inquiry that has become extremely relevant during the COVID-19 pandemic. Normally, my lab studies these senses as they relate to obesity and other health conditions, but over the past few months, we're working to understand biological mechanisms by which the coronavirus affects taste and olfaction. An early symptom of the disease can be the loss of taste or smell. We've been very busy during the pandemic and have published a number of papers on the sensory effects of COVID-19 (e.g., Hannum et al. 2020. *medRxiv.* doi: 10.1101/2020.07.04.20145870 and Cooper et al. 2020. *Neuron* 107: 219-233).

How has the trajectory of your career changed over time?

I came to the United States from Venezuela 20 years ago and went to nursing school at a community college, where I obtained an associate degree to become a registered nurse. My early college training focused on practical clinical skills. I then earned my B.S.N. and M.S. and became a nurse practitioner. Later, I earned my Ph.D. and became a scientist. It was a long trajectory. Sometimes, students working toward associate degrees or in other certificate programs may think they cannot achieve a Ph.D., but they can. It is important not to lose focus on the goal and the passion they have.

What have been the most rewarding aspects of your career?

As both a scientist and a nurse, the most rewarding parts of my career have been mentoring. I love teaching students in my lab and seeing them blossom. Years ago, working as a nurse and helping junior members of the staff become independent clinicians was similarly rewarding. I like to help people reach their goals—whether they want to become clinicians, technicians, or independent investigators. There are many ways scientists can make an impact, and mentoring is one of them.

Did you benefit from good mentoring?

I had good mentors throughout my formal education and continue to have amazing mentors now. Early on, I learned to develop a circle of mentors and find people from different walks of life and different "walks of science" to mentor me. Mentors taught me to achieve a good work–life balance and pushed me to pursue my goals. The encouragement of Marilyn Jaffe-Ruiz, Ed.D., and Sandra Lewenson, Ed.D., two of my professors at Pace University, led me to apply for Ph.D. programs when I did. I knew I wanted to pursue a Ph.D., but I wasn't sure whether the timing was right and whether I had what I needed to succeed. I am glad they saw in me something I didn't see in myself. That is what mentors do! During my doctoral studies, I met Charles Rotimi, Ph.D., and Adebowale A. Adeyemo, M.D., from the National Human Genome Research Institute at a conference and asked them point-blank, "Would you mentor me?" They were happy to help someone starting out in genomics, and I continue to consult them today. Don't be afraid to ask people you respect for help.

What are some career barriers you have faced?

I'm Black, Latina, and a woman. Some people see my name, assume I'm a man, and then are surprised to find that I'm a woman doing genomics research. Also, I have a nursing background, and some people wonder why I decided to study genomics.

I have experienced microaggressions. However, I try to use micro- and macroaggressions as fuel to motivate me by thinking, "Okay, let me focus. One more paper. Let's work." They still hurt. I'm human, but I work to turn them into motivation. My goal is to create an environment in my lab where people feel like they belong.

Many barriers are structural. We need more women in leadership roles breaking the glass ceiling and encouraging other women to take on leadership positions. Many of us who will be or are in leadership positions have a duty to support each other, as mentors and sponsors, by providing knowledge or by simply lending a hand and opening a door.

How do you contend with professional adversity and times of crisis like the current pandemic?

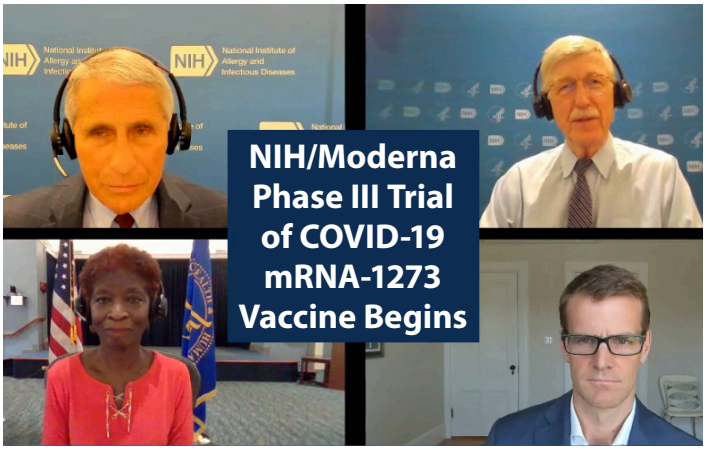
I'm a longtime practitioner of yoga and meditation, and my daily practice has helped me develop skills that help me avoid stressing over things I can't control. I have no control over the pandemic or the response of leadership. I try to focus on the things I can change: maintaining a positive attitude, spending time with my family, and creating a sense of community in my lab, particularly for the young people—students and postdocs—who may be far from home. The pandemic has been hard, but we can remain positive and take advantage of the opportunities that arise.

IN CASE YOU MISSED IT

A Pandemic-Era Résumé Addendum Is Available for Biomedical Professionals

Women in Medicine recently released the *COVID-19 Contribution Matrix Addendum for CV*. This document provides an added resource for researchers and clinicians updating their curricula vitae to describe professional activities and career interruptions related to the pandemic.

NIH Leadership, Moderna Executive, and Study Volunteer Discuss COVID-19 Vaccine Clinical Trial



The National Institute of Allergy and Infectious Diseases (NIAID) has partnered with Moderna, Inc., to launch a Phase III clinical trial of mRNA-1273, a candidate vaccine for COVID-19. On July 27, NIH Director Francis S. Collins, M.D., Ph.D.; NIAID Director Anthony S. Fauci, M.D.; Moderna President Stephen Hoge, M.D.; and Robyn, a volunteer from the Phase I trial, discussed the ongoing testing of mRNA-1273 and the concerns that potential volunteers may have as they decide whether to participate.

Dr. Fauci said, "We're dealing with a historic outbreak. [There's] really nothing that we've ever faced like this in the last 100 years since the 1918 pandemic." He explained that NIH and Moderna experts worked quickly to create and test this vaccine and that this effort represents the fastest development period "from the time a pathogen was identified to the time it actually goes into a Phase III trial ... in the history of vaccinology in the United States, at least, and maybe even throughout the world." He added that in spite of this unprecedented speed, "Safety has not been compromised. Scientific integrity has not been compromised."

Robyn articulated many of the questions and concerns she had before she decided to volunteer for the Phase I trial. "When I told my friends and relatives that I was going to participate, they were absolutely adamant that it was a bad idea. They tried to discourage me because they were concerned about my health and about my safety," she said. Robyn then explained that the history of the Tuskegee experiments has made many African Americans hesitant to participate in biomedical research. She said, "The Tuskegee experiments were public health experiments with hundreds of African American men who were tricked into participating … so that doctors could watch the progress of syphilis in their bodies without giving them any treatment. The experiment ran for 40 years. It only ended in 1972." Robyn said that when you ask many African Americans about participating in clinical trials, "They'll give you two words: 'Tuskegee' and 'No.' I was one of those people." She explained that she changed her mind for three reasons. One, she did not want the unethical behavior of the scientists coordinating the Tuskegee experiments to deter African Americans from participating in research that could help them. Two, COVID-19 has disproportionately affected African Americans, Latinx, and other people of color, and she felt she had to step up to help modern science determine why. Three, many people have lost their jobs, homes, health, and lives to the pandemic, and she wanted to do something to help.

Drs. Collins, Fauci, and Hoge responded to Robyn's questions and concerns and discussed NIH's outreach efforts to communities of people of color; the role of genetics in vaccinology; the safety, transparency, and informed consent protocols of the trial; the risks and benefits of volunteering; the process of participating in the trial; the anti-vaccination movement; the scientific rigor in the development of the candidate vaccine; and related topics.

A recording of the livestream discussion is available on the NIH Facebook page. Those considering volunteering for Phase III of the trial can find more information and make a no-commitment registration of their interest on the clinical trial's website: https://www.coronaviruspreventionnetwork.org. Additional information is available at ClinicalTrials.gov and a Moderna webpage explaining the development of the candidate vaccine.

NOTEWORTHY

ORWH Hosts Webinar on Social Determinants of Health and Disease Outcomes

On July 22, ORWH hosted an online panel discussion titled "Improving Chronic Disease Outcomes Through Approaches that Address Social Determinants of Health." This webinar was part of ORWH's Understudied, Underrepresented, and Underreported (U3) Women's Health Lecture Series. Marie Lynn Miranda, Ph.D., of the University of Notre Dame, and Johns Hopkins University's Leah H. Rubin, Ph.D., M.P.H., a former Scholar in the NIH Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program, gave lectures. A moderated Q&A session followed. Dr. Miranda's lecture, "Assessing Residential Segregation's Role in Shaping Health and Well-Being," characterized national and local population patterns as they pertain to race, educational attainment, health care availability, and other factors correlated with health. In particular, she detailed how areas of racial isolation correlate with factors associated with poor health outcomes. Dr. Rubin's lecture, "Social Determinants of Central Nervous System (CNS) Dysfunction in Research and Clinical Practice: A Lesson from HIV," described cognitive problems and mental health issues associated with HIV. Though effective antiretroviral therapy has reduced the higher rates of HIV-related CNS dysfunction seen in the early years of the AIDS epidemic, the problem persists for many patients. ORWH's U3 Women's Health Lecture Series has been designed to stimulate interest in the complex issues affecting the health of women, including the influences of community attributes. A video recording of this webinar is available here.

New Scoring System Compares Rates of Severe Pregnancy Complications Across U.S. Hospitals

NIH-funded researchers have developed a new system for classifying severe maternal morbidity—life-threatening complications associated with childbirth—across U.S. hospitals to aid research, surveillance, and improvement initiatives. The system relies on patient discharge data to compare rates of severe maternal morbidity among different hospitals and different groups of patients. As detailed on ORWH's Maternal Morbidity and Mortality web portal, rates of severe maternal morbidity are rising, particularly among racial and ethnic minorities. Researchers studying severe maternal morbidity lack reliable ways of comparing rates among groups with different underlying health statuses. This new tool helps to address this need. A report from the study team that developed this scoring system is available (Leonard et al. 2020. *Obstet. Gynecol.* doi: 10.1097/AOG.0000000000004022). Funding for this research was provided in part by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of Nursing Research (NINR).

UPCOMING EVENTS

51st Meeting of the NIH Advisory Committee on Research on Women's Health (ACRWH)
October 20, 2020

Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Annual Meeting (20th Anniversary of the Program)
December 14, 2020 | 10:00 a.m. – 5:00 p.m. (Eastern Time)

ORWH 30th Anniversary Scientific Symposium
December 15, 2020 | 9:30 a.m. – 5:30 p.m. (Eastern Time)

Specialized Centers of Research Excellence on Sex Differences (SCORE) Annual Meeting
December 16, 2020 (keynote address open to the public, 10:40 a.m. – 11:30 a.m. Eastern Time)

For up-to-date information, visit the ORWH events page.

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

6707 Democracy Boulevard, Suite 400
Bethesda, MD 20817
Phone: 301-402-1770

ORWHinfo@mail.nih.gov
Twitter: @NIH_ORWH
Facebook: /NIHORWH

To subscribe to future issues of Women's Health in Focus at NIH, click here or visit us on the web at nih.gov/women.
This publication was publicly funded by the NIH Office of Research on Women's Health.