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Technological Innovations in Breast Cancer Screening and Treatment

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Office of Research on Women's Health

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

This issue of In Focus *highlights a sampling of new technologies and innovative treatments—both those used in current clinical practice and those still in development by NIH-supported investigators. These new technologies may contribute to better health for women worldwide.*

Our cover story reviews recent developments in the fight against breast cancer—from sophisticated digital breast tomosynthesis scanners that produce complex digital 3D mammograms to disposable devices that can be produced on inkjet or 3D printers for less than a dollar's worth of materials. These technologies can be implemented in a variety of settings, including low-resource areas.

Other articles and commentaries discuss the fast-tracking of new technologies and vaccines in development to address testing, prevention, and treatment of COVID-19; medical interventions using ubiquitous technologies, such as smartphones; and the Nobel Prize–winning CRISPR gene-editing technology. All of these innovations will help us realize a principal goal of the Trans-NIH Strategic Plan for Women's Health Research*—for every woman to receive evidence-based disease prevention and treatment tailored to her own needs, circumstances, and goals.*

I hope you enjoy this issue of In Focus *and find it informative. Please share it with your colleagues and encourage others to subscribe.*

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

NIH Supports the Development of Innovative Technologies in the Fight Against Breast Cancer

NIH, the world's largest biomedical research funding organization, invests heavily in research on breast cancer as well as its prevention, screening, and treatment. In the 2020 fiscal year, NIH supported an estimated $768 million in research on breast cancer through grants, contracts, and other funding mechanisms.[1] A large percentage of NIH's breast cancer grant portfolio supports engineers, bioengineers, and *physicianeers*—professionals with backgrounds in both medicine and engineering—researching and developing new detection and treatment technologies. The National Institute of Biomedical Imaging and Bioengineering (NIBIB) administers over 80 funding mechanisms related to women's health, and over half of these address breast cancer.[2] NIBIB aims to integrate the efforts of engineers and biomedical researchers in the fight against breast cancer and many other diseases.

Approximately 1 in 8 women in the United States will develop breast cancer, and estimates indicate that over 42,000 U.S. women died from the disease in 2020.[3] Breast cancer is the second-most common form of cancer and the second-leading cause of death by cancer in U.S. women.[3] Breast cancer represents a substantial public health problem that imposes a large societal burden in terms of direct medical costs, resources used by the health care system, and loss of productivity. This burden warrants NIH's substantial investment in research on the disease.

In this article, we review several of the technological innovations for breast cancer screening and treatment that have emerged over the past decade from research supported by NIBIB, the National Cancer Institute (NCI), and other NIH Institutes, Centers, and Offices. Some of these technologies are used in clinical practice today, and others are still in development or preclinical testing. These technologies represent just a few of the dividends from our national investment in breast cancer research.

Digital Breast Tomosynthesis

Digital breast tomosynthesis (DBT), an alternative to traditional mammography, received Food and Drug Administration (FDA) approval in 2011.[4] DBT follows a procedure similar to that of a conventional mammogram. The breast is placed on a detector surface, compressed to reduce the amount of radiation required to penetrate the tissue, and x-rayed. Unlike 2D mammography, DBT captures several 2D images of the breast at different angles and produces a 3D-like rendering consisting of distinct angles or "slices" of the breast.

DBT scanner and workstation (image courtesy of Hologic, Inc.)

Research by Xiaochuan Pan, Ph.D., Professor of Radiology at the University of Chicago, and colleagues strives to improve the resolution and cancer-detecting capacity of DBT.[5–8] Dr. Pan explains, "DBT emphasizes breast tissue characteristics in these individual slices. Suspicious structures,

Xiaochuan Pan, Ph.D.

such as the spiculations radiating from a tumor, stand out more prominently. Clinicians can scroll through individual slice images at different depths with less obstructive tissue overlap than we see in 2D mammography." He adds, "It's like looking for a wolf in a forest. The trees might obscure the wolf from one angle, but it can be revealed by looking from multiple angles."

Dr. Pan explains that DBT offers advantages over standard mammography for imaging the complex structure of the breast, which consists of connective tissue, glandular tissue, ducts, and fat. "DBT helps distinguish true tumors from structures that have the appearance of tumors but are simply superimposed breast tissue." As a result, DBT results in fewer follow-up visits to clarify suspicious findings than 2D mammography. Dr. Pan adds, "DBT can detect cancer that might be missed in traditional mammography, particularly in women with high breast density. Several clinical studies demonstrate the superiority of DBT, with increased cancer detection rates, fewer false positives, and lower recall rates. Evidence in the scientific literature overwhelmingly suggests that DBT is superior to 2D mammography in both sensitivity and specificity for cancer detection." (Research on DBT by Dr. Pan's group was supported by NIBIB and NCI.)

The TMIST Clinical Trial Evaluates DBT

DBT measurably improves upon conventional 2D mammography in many respects, but will widespread use of this technology improve women's health outcomes overall? Worta McCaskill-Stevens, M.D., M.S., Director of the NCI Community Oncology Research Program (NCORP), has indicated that from a public health perspective, a primary goal of breast cancer screening is to reduce the incidence of late-stage, hard-to-treat cancers and not simply to increase detection of early-stage disease.[9] In pursuit of this goal, NCORP, in partnership with the ECOG-ACRIN Cancer Research Group, initiated the Tomosynthesis Mammographic Imaging Screening Trial (TMIST).

Worta McCaskill-Stevens, M.D., M.S.

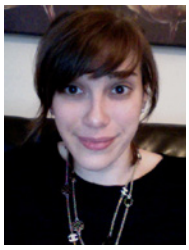
TMIST will help to determine whether DBT is a better clinical tool than conventional 2D mammography and whether regular screening with DBT would decrease the incidence of late-stage breast cancers over time as TMIST researchers hypothesize.[9] If, contrary to expectations, TMIST findings show no decrease in the incidence of advanced cancers, then the additional expense of DBT scanners might not be warranted.[9] While many radiologists currently use DBT in regular clinical practice, not all imaging facilities have access to these costly machines. (By the end of 2020, 40% of the 21,671 facilities accredited by and 68% of the 8,695 facilities certified by FDA's Mammography Quality Standards Act and Program [MQSA] had at least one DBT unit.[10])

About 33,000 women are currently participating in the TMIST clinical trial, and researchers plan to recruit nearly 165,000 more women, over a 5-year period, to receive either 2D or 3D mammography. Researchers determine the frequency of mammograms for each participant based on her menopausal status, use of hormonal replacement therapy, breast density, and other factors. TMIST will also evaluate the rates of false positives, recall visits, biopsies, and overdiagnoses for both types of mammography. "Trial results will inform the decision-making process for clinicians and patients pertaining to breast cancer treatment and the appropriate interval for screening," says Dr. McCaskill-Stevens, who has also volunteered as a TMIST participant.

TMIST researchers are also creating a tissue bank of blood and buccal (i.e., cheek swab) specimens from study participants and performing molecular characterizations of benign, premalignant, and invasive biopsy specimens. This first-of-its-kind biorepository will provide a clinically annotated data set for future research. Dr. McCaskill-Stevens believes that "these biospecimens will move us further toward personalized medicine for each patient and enable more personal decision-making and personal choices."

As is the case with many ongoing clinical trials, recruitment and data collection for TMIST have slowed as a result of the COVID-19 pandemic.[11] In August 2020, NCI leadership asked the National Cancer Advisory Board (NCAB) to create an ad hoc advisory working group to make recommendations for the future of TMIST. Dr. McCaskill-Stevens reports that since then, recruitment numbers have been bouncing back to pre-pandemic levels. However, slow recruitment caused by the pandemic may result in delays and other challenges for TMIST researchers.[11] Even in light of the pandemic, TMIST recruitment, screening, and data collection are progressing, and NIH encourages women to participate in the trial to help fill knowledge gaps about 2D and 3D breast cancer screening modalities. Those interested in participating in TMIST can find participating clinics in the United States, as well as a few locations in Canada and Argentina, here.

Lihong Wang, Ph.D.



Colleen Krause, Ph.D.

James Rusling, Ph.D.

Photoacoustic Computed Tomography of the Breast

Photoacoustic computed tomography (PACT) is an alternative breast imaging technique developed by Lihong Wang, Ph.D., Director of the Caltech Optical Imaging Laboratory (COIL), and colleagues. PACT involves applying harmless laser light to the breast. The light is absorbed by the breast tissue, blood vessels, and any tumors.[12] Energy from the laser pulse produces internal sound waves, which are received by a ring of ultrasonic detectors. These data are then transmitted to a computer and rendered into a detailed picture of the breast's blood vessel network. Areas of dense, disorganized vascularization may indicate tumor development.[12] PACT is similar to ultrasound scanners currently in clinical use. However, instead of using a transducer outside the body to project sound waves, PACT lasers generate sound waves within the breast tissue itself. In an initial test, PACT correctly detected eight of nine breast tumors present in the eight study participants (seven participants with one or more tumors, one with none).[12] PACT researchers also developed a computer algorithm that highlights potential tumors in the images to assist physicians in their interpretation of the scans.[12]

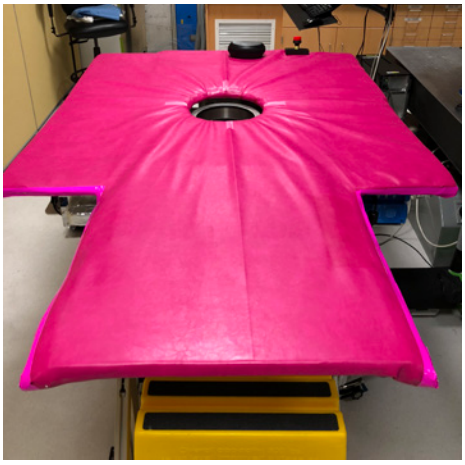


Table used for PACT imaging of the breast (image courtesy of Dr. Lihong Wang)

PACT offers several advantages over other breast imaging techniques. It provides a high-resolution image in about 15 seconds and does not require compression of the breast, which can cause discomfort in patients and discourages some women from receiving regular mammograms.[13] During a PACT procedure, the patient lies face down on a table and inserts her breast through a hole, which leads to a suspended chamber that contains the ultrasonic detectors. (See image, lower left.) Unlike conventional mammography, PACT does not use x-rays or other potentially harmful radiation and can readily detect tumors even in dense breast tissue. PACT also offers advantages over magnetic resonance imaging (MRI), which is sometimes used to screen women at high risk for breast cancer. PACT is less expensive and does not require the contrast agents sometimes used in MRI. These agents may have long-term health effects and are contraindicated in patients with kidney disease.

Dr. Wang and colleagues plan to test PACT breast imaging with a larger study population and to consider other applications of the technology, such as assessing blood vessel damage associated with diabetes. (Research on PACT was funded by an NIH Director's Pioneer Award, NIBIB, and NCI.)

Breast Cancer Screening with Low-Cost Printable Technologies

Research on 2D and 3D printable technologies for detection of breast cancer and other cancers by Colleen Krause, Ph.D., of the University of Hartford, James Rusling, Ph.D., of the University of Connecticut, and colleagues has opened the possibility for accurate and extremely low-cost alternatives to expensive imaging equipment and to invasive diagnostic practices such as needle biopsies.

In a proof-of-concept study, the researchers used an inkjet printer to layer gold nanoparticle inks onto a plastic sheet to create an array of electrochemical biosensors.[14] Investigators coated the biosensors with antibodies and connected the electrode array to a device to direct the flow of biological samples. This assembly then assayed blood samples for the HER2 protein, a biomarker for a specific type of breast cancer. Dr. Krause says, "The bioassays for HER2 demonstrated high sensitivity over a wide dynamic range, capturing clinically relevant levels of HER2 in blood serum." This assay takes about 15 minutes to perform and has the potential for use in clinical settings. The disposable inkjet-printed test chips cost about 25 cents each to make.

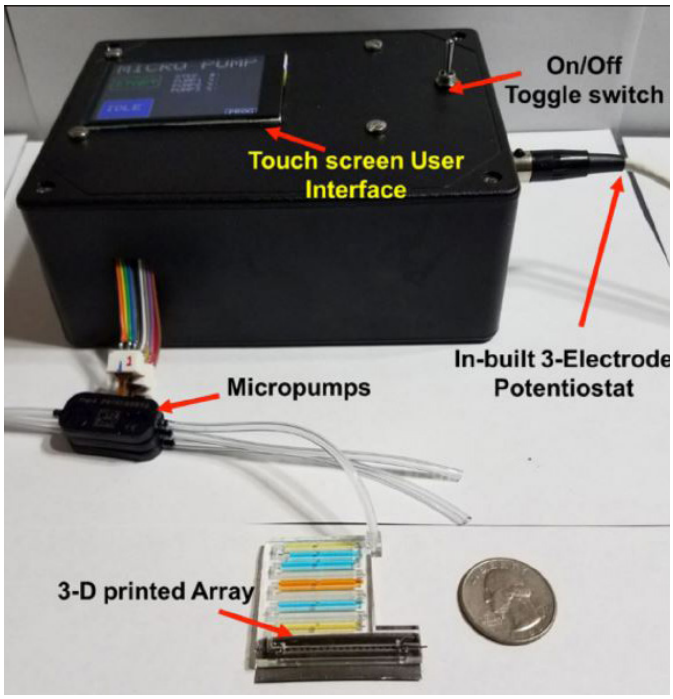
The researchers have also developed inexpensive 3D-printed technologies for detecting breast cancer and other cancers.[15] (See photo on page 6.) A microfluidic system delivers the necessary reagents and biological samples into a 3D-printed array that houses electrochemical sensors or test chips. Dr. Krause says, "These chips feature multiple working electrodes capable of detecting the multiple breast

cancer proteins or biomarkers that are known to be elevated at the onset of cancer and throughout the progression of the disease." She explains that tests that screen for a single biomarker have limited predictive power and that "simultaneously screening for multiple cancer-associated proteins increases the test's predictive ability and decreases the chances of overdiagnosis and overtreatment."

Dr. Rusling adds, "Testing for three or four biomarkers at once increases the usefulness of the test. An assay that detects only one biomarker for a tumor-specific antigen can result in a lot of false positives and negatives."

Like the 2D-printed biosensors, the 3D-printed arrays are inexpensive. "We can 3D print a device that can measure four to eight proteins for about 50 cents," says Dr. Rusling. "Of course, you need to connect these devices to pumps and detection manifolds, but none of them is very expensive." Despite their low cost and the ease of manufacturing them, these assay systems are highly accurate and sensitive. Dr. Rusling's team recently developed a microfluidic sensor array to detect proteins associated with aggressive prostate cancers. He believes this array sets a record for sensitivity for a device that detects multiple proteins.[16] "The sensitivities for all our systems are at least 1,000 times better than those of most commercial systems," says Dr. Rusling. "Sometimes you need that sensitivity. Sometimes you don't. That gives you a lot of leeway in how you design a practical assay. If you reduce the sensitivity of the assay, you can increase its speed and/or use a high dilution of samples, which decreases interference." In addition to those advantages, these 3D-printed detection systems require only noninvasive or minimally invasive methods, accommodate small sample volumes, and can be easily redesigned and reprinted throughout the development process.

"There's a serious lag in translating research in multi-biomarker detection to widespread use. Measuring biomarkers for breast and other cancers has not entered the clinical mainstream as rapidly as we expected," says Dr. Rusling. "For the most part, cancer screening today still involves looking for tumors. After tumors form, many patients are already in trouble. Our dream is to have an assay that can test for 100 proteins at a time and screen for all the major cancers before tumors begin to form. It's a big project. It may not happen in my lifetime, but I want to get this translated to the clinic." (This research was supported by NIBIB.)



A prototype automated blood test with low-cost 3D-printed array for cancer detection (image courtesy of Dr. James Rusling; quarter for scale)

Bioengineering Team Develops Low-Cost Solutions for Breast Cancer Imaging and Treatment

Nirmala Ramanujam, Ph.D.

For over a decade, bioengineering teams led by Nirmala Ramanujam, Ph.D.—the Robert W. Carr, Jr., Distinguished Professor of Biomedical Engineering at Duke University—have developed technologies and procedures for detecting and treating breast cancer and other cancers. Dr. Ramanujam and colleagues have prioritized medical innovations that can help patients in multiple settings, particularly low- and middle-income nations. These areas typically have high breast cancer burdens[17] and limited treatment options.

Dr. Ramanujam's lab focuses on leveraging imaging technologies better to understand and predict recurrence, a common cause of breast cancer mortality. One of the Ramanujam lab's innovations—breast margin–assisted mapping (BMAP)—enables health care providers to use optical imaging to check the margins of surgically removed breast tumors to ensure total removal of diseased tissue.[18] Dr. Ramanujam explains, "There are two goals with most breast cancer surgery: to remove all of the diseased tissue and to conserve as much healthy tissue as possible."

Unfortunately, cancer recurrence often follows breast-conserving surgeries or lumpectomies. "In BMAP, we image the circumference of an excised specimen and look for diseased tissue on the margin," says Dr. Ramanujam. "This technology is not a microscope and cannot detect individual cancer cells. Rather, this spectral imaging technology creates a breast density map similar to a mammogram. Areas of high density are associated with recurrence," she says. Dr. Ramanujam and other researchers have shown that BMAP is accurate, results in few false positives, and helps both to preserve breast tissue and to ensure "clean margins" around the excised tissue, which prevents recurrence and later metastases.[18]

Additional innovations from Dr. Ramanujam's team leverage information on breast density to predict the risk of recurrence in a manner similar to that of the Oncotype DX test, a commercially available test that estimates the likelihood of recurrence in women with estrogen receptor–positive breast cancer. Breast density imaging data—coupled with information on patient pathology, age, body mass index, and other features—serve as inputs into a computer algorithm that determines the risk of recurrence. Unlike the Oncotype DX test, which requires samples to be shipped to a facility for genetic assessment, the algorithm can rapidly report on recurrence shortly after surgery and pathology diagnosis. Dr. Ramanujam says, "In some cases, this technique could serve as an alternative to the costly Oncotype DX test, which may not be available to underinsured patients."

Complementing her work on predicting recurrence, Dr. Ramanujam also examines breast cancer metabolism. She has developed a versatile optical imaging platform that enables researchers to assess the metabolic effects of local and systemic cancer therapies as well as the metabolic underpinnings of cancer recurrence. This technology could assist pharmacological researchers in the development of drugs that inhibit tumor metabolism.

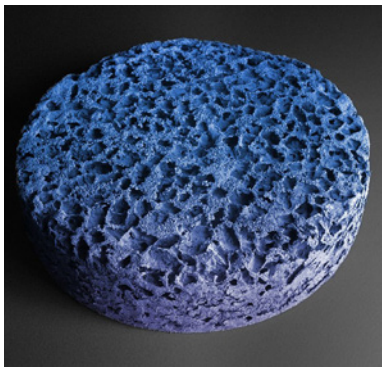
Dr. Ramanujam's most recent research revisits an older, largely obsolete treatment called ethanol-based tumor ablation, which involves injecting ethanol directly into tumor tissue.[19] "Ethanol ablation has been used in the past to treat inoperable liver and thyroid cancers," says Dr. Ramanujam. "It can destroy tumors, but it's leaky and damages surrounding tissues. It's fallen out of use in favor of more sophisticated energy-based ablation technologies. However, these are expensive and require specialists to operate." To create a low-cost alternative to these technologies and address the limitations of traditional ethanol treatment, the researchers added ethyl cellulose, a polymer used in pharmaceuticals and food as a thickening agent, to the ethanol injection. "When ethyl cellulose hits an aqueous medium like human tissue, it becomes a gel that looks like cotton and functions to keep the ethanol in place," she says.

The efficacy of the ablation technique using ethanol and ethyl cellulose has been confirmed in animal models[19] and may someday enter clinical practice in the treatment of breast cancer and other cancers. Dr. Ramanujam reports that her team is currently working to refine that ablation technique in ways that may increase its efficacy by initiating an anti-tumor immune response and decreasing the number of pro-tumor cells in the body. Although it is unlikely that ethanol ablation will replace more sophisticated treatments—such as immunotherapy and radiation treatment—in high-income nations, it may provide low-resource settings with alternatives to surgery. (Dr. Ramanujam's research has been supported by NIBIB and NCI.)

Implantable Biomaterial Vaccine for Breast Cancer

David Mooney, Ph.D.

David Mooney, Ph.D., the Robert P. Pinkas Family Professor of Bioengineering at Harvard University, and colleagues develop materials that can manipulate immune cells in a patient's body to generate protective and therapeutic responses. As part of this work, Dr. Mooney's lab developed an implantable cancer vaccine, which can be injected into body tissue to activate an anti-tumor response by using the body's immune system to destroy cancer cells and prevent their recurrence.[20] He explains,



Two images of the Mooney lab's implantable vaccine, a cryogel scaffold infused with tumor antigens (images courtesy of Dr. David Mooney and Mr. Seth Kroll, Wyss Institute)

"The integration of bioengineering tools and approaches with immunotherapy promises to yield highly effective and practical approaches to treat breast cancer. Support from NIH is absolutely essential for this new approach."

The vaccine consists of a small, flexible cryogel scaffold structure about the size of an aspirin tablet, which is infused with tumor antigens. After a minimally invasive injection, the scaffold attracts dendritic immune cells to the area with a protein called granulocyte-macrophage colony-stimulating factor (GM-CSF). The vaccine then activates the dendritic cells' anti-tumor immune response with an infused adjuvant called CpG oligonucleotide and tumor antigens. Similar vaccines have demonstrated efficacy in mouse models[20] and preclinical studies, and a vaccine using a different type of scaffold has been studied in a Phase I trial for treating melanoma.[21]

Other biomaterial-based cancer vaccines developed to date require removal of immune cells from the patient's body, activation of the cells' immune function, and transplantation back into the patient.[20] Although such vaccines have shown anti-tumor effects, their success has been limited by the short lifespan of the transplanted cells or by immunosuppressive factors from the tumor. The vaccine from the Mooney lab activates the body's immune cells and requires neither cell manipulation in the lab nor transplantation. (This research was supported by NIBIB, the National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], and the National Institute on Aging [NIA].)

The Future of Technology in Preventing and Treating Invasive Breast Cancer

NIH and its grantees continue to develop, test, and refine these and other technologies to improve breast cancer screening and treatment. NIH will continue the fight against breast cancer by supporting research to improve the safety and effectiveness of the diagnostic tools and treatments discussed here, as well as other innovative technologies in development. These studies will help investigators and clinicians better understand, prevent, screen for, and diagnose breast cancer; personalize treatment plans; reduce costs and other obstacles to health care; and improve outcomes for women with the disease.

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COVID-19 Highlights the Importance of ORWH's Mission

Rajeev K. Agarwal, Ph.D.
Senior Research Program Officer, ORWH

It has been over a year since the first cases of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection were reported in Wuhan, China, and almost a year since the World Health Organization declared COVID-19, the disease caused by SARS-CoV-2, a pandemic. NIH, other health organizations, and biomedical corporations have fast-tracked research on the disease, treatments, and vaccines. ORWH has supported these efforts through supplemental funding programs and with initiatives related to its key mission areas, including promoting the study of sex as a biological variable (SABV) in scientific research, ensuring the inclusion of women and vulnerable populations in NIH-funded clinical studies, and supporting women in the STEMM workforce. Research on the pandemic demonstrates the relevance of these mission areas to COVID-19 mitigation efforts as well as to the biomedical research enterprise as a whole.

COVID-19 Underscores the Value of SABV in Biomedical Research. In accordance with the NIH SABV policy, the consideration of sex differences should inform the scientific evaluation of the risk, progression, and outcomes for COVID-19 as well as the development of treatments and vaccines. Prior to the pandemic, researchers had identified sex differences in susceptibility to and outcomes from pathogenic human coronaviruses, such as the virus responsible for the SARS pandemic in 2002 and 2003.[1] More recent research on SARS-CoV-2 has shown that COVID-19 outcomes are worse in men than in women.[2] Contributors to these outcomes include differences in host cell vulnerability caused by ACE2—an enzyme associated with the coronavirus—and its interactions with estrogens and androgens; the male predominance of comorbidities such as cardiovascular disease, hypertension, and diabetes; sex differences in immune function; and other factors.[2] Other research has demonstrated possible SARS-CoV-2 transmission from mother to fetus in some cell types and fetal organs,[3] and at least one case of in utero coronavirus infection has been reported.[4] Additional research indicates that consideration of sex differences, which influence adaptive immune responses, should inform vaccine development.[5] These findings highlight the importance of the SABV policy and suggest that incorporating consideration of sex differences into research on SARS-CoV-2 is essential to understanding the virus and to developing effective interventions for COVID-19.

Diagnostic and Other Public Health Efforts Must Incorporate Diverse Populations. Data show disproportionate rates of COVID-19 infection, hospitalization, and mortality among Black, Latinx, and American Indian/Alaska Native populations in the United States.[6] These high rates may be attributable, in part, to decreased access to COVID-19 testing among these and other communities. NIH's Rapid Acceleration of Diagnostics (RADx) programs strive to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing, and RADx Underserved Populations (RADx-UP) aims to improve access to testing and to examine factors contributing to disproportionate disease burden in underserved communities. (More information on RADx-UP and ORWH's support of the program is available here.) RADx-UP complements other NIH practices, such as the inclusion policies, that help to ensure that women, underrepresented racial and ethnic groups, and individuals of all ages are included in clinical research when scientifically appropriate.

Gender Inequities in the Workplace and Public Health Management. COVID-19 has profoundly affected the global economy, and women, particularly women of color, are more likely to have been laid off or furloughed since the pandemic began.[7] Women in STEMM fields are no exception. Numerous articles in leading journals (e.g., references 8 and 9) describe disproportionate decreases in productivity and publication from academic women as well as possible increased disparities in hiring, tenure, and promotion. Other studies find gender inequities in public health governance and decision-making related to the pandemic. Of 115 COVID-19 expert task forces, 85.2% have more men than women, and only 3.5% have gender parity.[10] Numerous studies demonstrate that diversity benefits science and innovation.[11] Research efforts and health policy development—both those related and those unrelated to COVID-19—lack equitable gender representation and thus the multiple perspectives that inclusivity affords. NIH supports women in STEMM through funding opportunities, programs for career development and interprofessional education, the Women of Color Research Network (WOCRN), and other programs. However, the pandemic has revealed persistent inequities throughout the biomedical research enterprise and the need for additional improvement.

The COVID-19 pandemic has resulted in great upheavals in nearly all aspects of life, and biomedical research is no exception. The disruptions associated with the health crisis emphasize the continuing importance of ORWH's mission, of NIH's SABV and inclusion policies, and of supporting equitable representation in STEMM fields and health policy management.

See reference list on page 10.

NIH Welcomes New Leadership—Women Will Direct 10 of 27 NIH Institutes and Centers




NIH Institute Directors Dr. Tucci, Dr. Zenk, Dr. D'Souza, and Dr. Criswell (left to right)

Since September 2019, NIH has welcomed four women as new directors of NIH Institutes. On September 3, 2019, Debara L. Tucci, M.D., M.S., M.B.A., became the Director of the National Institute on Deafness and Other Communication Disorders (NIDCD). Dr. Tucci, formerly of Duke University Medical Center, where she co-founded the Duke Hearing Center and directed Duke's Cochlear Implant Program, is the first woman to direct NIDCD. Shannon N. Zenk, Ph.D., M.P.H., RN, FAAN, a leading nurse researcher and former Professor at the University of Illinois at Chicago College of Nursing, began as the Director of the National Institute of Nursing Research (NINR) on September, 14, 2020. Rena N. D'Souza, D.D.S., M.S., Ph.D., assumed her position as Director of the National Institute of Dental and Craniofacial Research (NIDCR) late last year, after serving as an administrator and educator at the University of Utah. Finally, Lindsey A. Criswell, M.D., M.P.H., D.Sc.—currently a Professor of Rheumatology at the University of California, San Francisco Department of Medicine and a Professor of Orofacial Sciences in its School of Dentistry—has accepted the position of Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and is expected to begin this role early this year.

These remarkable clinicians and researchers join six other women currently serving as directors of NIH Institutes and Centers (ICs): Diana W. Bianchi, M.D., Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD); Patricia Flatley Brennan, RN, Ph.D., Director of the National Library of Medicine (NLM); Noni Byrnes, Ph.D., Director of the Center for Scientific Review (CSR); Helene Langevin, M.D., Director of the National Center for Complementary and Integrative Health (NCCIH); Andrea Norris, M.B.A., Director of the Center for Information Technology (CIT); and Nora Volkow, M.D., Director of the National Institute on Drug Abuse (NIDA). ORWH congratulates these new appointees and welcomes them to the NIH family.

References for "COVID-19 Highlights the Importance of ORWH's Mission"

(From previous page)

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Researchers Develop Smartphone Intervention to Increase Exercise, Reduce Cardiometabolic Disease Risk in African American Women

(Original article by Joseph et al. MIR Mhealth Uhealth. PMID: 32130198.)

Recent research demonstrates that interventions for increasing physical activity are more effective when delivered via technological means, such as smartphones, email, and social media. In a recent article, Rodney P. Joseph, Ph.D., and colleagues describe the development, testing, and refinement of "Smart Walk," a smartphone-delivered intervention designed to encourage physical activity and thereby reduce cardiometabolic disease risk in African American women.

The researchers designed the application with input from focus groups of African American women. Intervention development was also informed by social cognitive theory, which posits that learning and behavior relate directly to social interactions, media influences, and other experiences. The Smart Walk app targets outcome expectations, self-efficacy, and social support and addresses characteristics such as body appearance and racial pride. The application also features personal profile pages, promotional videos and messages, discussion boards, and a tool linked to a Fitbit, with which users can monitor their physical activity.

Researchers tested the usability of the Smart Walk phone application with 12 African American women over the course of 1 month. Overall, user feedback was positive, and most critical comments focused on technical issues related to functionality. After making improvements based on user feedback, the developers are now testing a new version of Smart Walk in an 8-month randomized controlled pilot trial. The researchers are tracking several of the participants' cardiometabolic measures and hope that the app will help users achieve better health.

Smart Walk represents another way that NIH-supported researchers are leveraging technology—in this case, readily available technology—to improve human health. This research was funded by the National Heart, Lung, and Blood Institute (NHLBI).

Death Rates Associated with Drugs, Alcohol, and Suicide Increase, Show Trends Related to Sex and Other Demographic Factors

(Original article by Shiels et al. 2020. JAMA Netw Open. PMID: 32915234.)

U.S. life expectancy has decreased in recent years, a trend driven in large part by "deaths of despair"—suicides as well as fatalities related to alcohol and other drugs. NIH researchers, including Meredith Shiels, Ph.D., of the National Cancer Institute (NCI) and ORWH Special Advisor David A. Thomas, Ph.D., recently published findings on such deaths of despair. The researchers analyzed death certificate statistics from the Centers for Disease Control and Prevention (CDC) on premature deaths (i.e., deaths of individuals ages 20–64) and compared data by geography, age, sex, and race/ethnicity.

The researchers identified several troubling trends. (1) Overall, death rates for all three causes were higher among men than women from 2013 to 2017, but from 2000 to 2017, these death rates increased more rapidly among women. (2) Geographical analysis identified clusters of premature mortality associated with drug poisoning in the Northeast through Appalachia, with suicide and alcohol in the Western U.S. region, and with suicide in rural areas in general. (3) Death rates from drug poisoning were highest among 35-to-49-year-olds. Death rates from suicide and alcohol were highest among 50-to-64-year-olds. (4) Complex patterns associated with race and ethnicity varied over time and among the three causes of death. (5) Drug poisoning and alcohol-induced deaths increased dramatically in recent years (2013–2017 and 2012–2017, respectively). Suicide rates were more constant from 2000 to 2017.

Overall, the data show that from 2000 to 2017, drug poisoning, suicide, and alcohol caused 1.45 million premature deaths—450,000 more deaths than would be expected from 2000 rates. Though economic factors may have played a role in these unexpected increases, the researchers conclude that no single cause, demographic group, or region explains these trends, suggesting the need for numerous specifically targeted interventions. This research was supported by NCI, the National Health, Lung, and Blood Institute (NHLBI), and the National Institute on Minority Health and Health Disparities (NIMHD).

Researchers Develop and Evaluate Intervention on Culturally Aware Mentoring

(Original article by Womack et al. 2020. PLoS One. PMID: 32764768.)

A team of researchers led by Veronica Y. Womack, Ph.D., developed an 8-hour intervention on culturally aware mentoring for university faculty and administrators serving as advisors for STEMM students from historically underrepresented populations. Culturally Aware Mentorship (CAM), a program of the National Research Mentoring Network (NRMN), focuses on intra- and interpersonal awareness; cultural, racial, and ethnic identity; and skill building. The researchers conducted three sessions of CAM and analyzed its efficacy by interviewing 24 participants 18–24 months after the intervention.

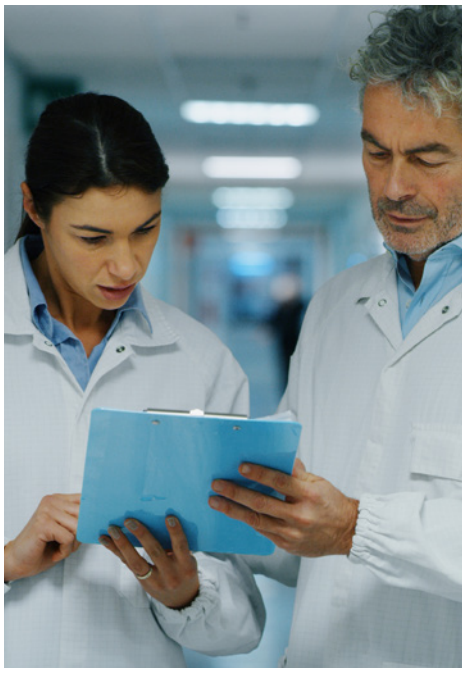
Thematic analysis of the qualitative interviews demonstrated that CAM had a lasting effect on participants, who reported improved awareness of cultural differences, more open interactions with students and colleagues, and more inclusive teaching and mentoring practices. CAM improved the participants' awareness of their own identities through role-playing, a cultural sharing exercise, and a video dramatizing the experience of being the only visible member of a group in a professional setting. One interviewee shared how CAM had helped her to realize that striving for a "colorblind" racial perspective had resulted in a lack of awareness of some of the cultural differences in her interpersonal relationships. Another interviewee explained that he had grown more adept at communicating and intervening in a constructive way when insensitive comments came up in students' discussions.

The researchers conclude that the 1-day CAM intervention can be an effective addition to mentor training programs, can improve mentors' awareness of cultural factors and diversity concerns, and can thereby facilitate the training and future professional success of emerging scientists from historically underrepresented populations.

Collecting and Disseminating Career Advice from Women Medical Leaders

(Original article by Farrugia et al. 2020. JAMA Netw Open. PMID: 32697324.)

A group of researchers at the Mayo Clinic in Rochester, Minnesota, led by Gianrico Farrugia, M.D., recently surveyed 40 women leaders, both physicians and administrators, at that institution about the professional advice they had received over the course of their careers. A qualitative analysis of survey responses found that most of the advice fell into one of four categories. (1) Leadership styles tend to be perceived as either masculine or feminine. However, advice varied as to which style is preferrable for women leaders in academic medicine.

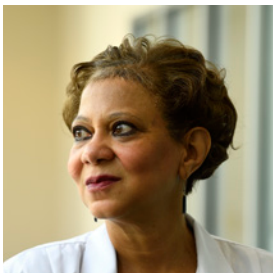


(2) Learning leadership skills involves a strategic process as well as conscious efforts to modify one's behavior. (3) Achieving a good work–life balance is a challenge, but this difficulty should not deter women from pursuing leadership roles in academic medicine. (4) Barriers exist, and women in this discipline require the courage to believe in themselves and to decide for themselves whether to follow the advice they receive. The article includes numerous quotations from the individuals surveyed and collects a wide range of advice for women seeking senior positions in biomedical research.

Dr. Farrugia and colleagues chose to initiate this study, in part, because of the underrepresentation of women in medical leadership throughout the United States. Although there has been increasing support for women in undergraduate STEMM programs and women have represented more than half of the matriculants at U.S. medical schools in recent years, commensurate increases have not occurred in leadership positions. Academic medicine also continues to suffer from systemic gender inequities and associated issues related to promotion, publication, grant awards, salary, sexual harassment, and discrimination. These inequities contribute to professional dissatisfaction, physician burnout, and problems with retention, particularly among women of color.

Systemic change is, by nature, a lengthy process. While many institution-level initiatives and programs have been implemented to address these problems from the top down, Dr. Farrugia and colleagues suggest a more bottom-up effort. Collecting and disseminating career advice to encourage future women leaders in biomedical research may help to realize a needed cultural shift.

SCIENTIST SPOTLIGHT



Lisa A. Cooper, M.D., M.P.H.

Lisa A. Cooper, M.D., M.P.H., is a Liberian-born general internist, social epidemiologist, and health services researcher. She is a Bloomberg Distinguished Professor and James F. Fries Professor of Medicine at the Johns Hopkins University School of Medicine, Director of the Johns Hopkins Center for Health Equity, and Director of the Johns Hopkins Urban Health Institute. She was one of the first scientists to document disparities in the quality of relationships between physicians and patients from socially at-risk groups. She designed innovative interventions targeting physicians' communication skills, patients' self-management skills, and health care organizations' ability to address needs of populations experiencing health disparities. She is the author of over 200 publications and has been the principal investigator of more than 15 Federal and private foundation grants. Currently, Dr. Cooper and her transdisciplinary team work with stakeholders from health care and the community to implement rigorous clinical trials, identifying interventions that alleviate racial and income disparities in health outcomes. Dr. Cooper spoke on health equity as part of the NIH Director's Wednesday Afternoon Lecture Series (WALS) on October 28, 2020.

What was the topic of your WALS lecture?

The title was "Deep and Wide: The Voyage to Discover Local and Global Health Equity." The lecture described the concepts of health disparities, health equity, and social justice. I explained studies using transdisciplinary research methods to understand and overcome local and global health disparities and to identify gaps in the evidence base for disparities in health. I also described lessons learned from recent and current innovative community-engaged intervention studies in the United States and sub-Saharan Africa to address these gaps. I discussed how COVID-19 has magnified health disparities and how to address them. I concluded with implications for future research, education and training of health equity scholars, stakeholder engagement, as well as translation, dissemination, and sustainability efforts.

What are some of the barriers to equitable health care faced by patients from underrepresented groups?

Barriers to equitable care exist at individual, family and social network, community, provider/health system, political, and environmental levels. Factors related to provider care, social support systems, local and national policy environments, and individual health behaviors and beliefs all have the capacity to prevent equitable health care. Social determinants of health—such as housing, poverty, transportation, access to healthy food, and more—are significant barriers to equitable health for underserved groups as well. Furthermore, underrepresented racial and ethnic groups face inequalities that permeate society in social structures, norms, and policies, which lead to widespread discrimination and disenfranchisement for these groups.

Has your research suggested ways of overcoming these barriers through systemic change?

Our research has shown that targeted interventions with robust and sustainable community engagement can help overcome health equity barriers and that we must improve the link between health systems and the communities they serve. Investing in and creating communities where economic, educational, housing, and labor opportunities are abundant and of good quality will also be required to overcome these barriers. Additionally, we must emphasize prevention in health care while also addressing patients' social risk factors and unique needs. Ultimately, we must build trust in health systems if we hope to eliminate health disparities.

What are some short-term strategies that individuals can use to overcome these barriers and navigate the current system?

Patients who are active and effective managers of their own health have more appropriate treatment, better experiences in health care, and better outcomes, including better control of depression. In the Patient-Physician Partnership (Triple P) Study, we provided communication skills training to doctors, focusing on how to address the concerns of patients from underserved communities. We also trained community health workers to act as coaches for patients. This training led to greater patient participation in decision-making and better blood pressure control among urban and poor patients, most of whom were African American.

Here's a quick way of remembering how you can do your "**P.A.R.T.**" during your office visits or those of family members.

Prepare a list of your medications and notes about any problems or questions that have come up since your last visit.

Actively engage the physician by stating your concerns, medical history, questions, and treatment preferences and by clarifying the physician's instructions and explanations.

Review key recommendations and make sure to write down instructions and any new information.

Take recommendations home. Make a to-do list and keep it in a visible place.

IN CASE YOU MISSED IT

Nobel Laureate in Chemistry Jennifer Doudna Discusses Gene Editing with NIH Director Francis Collins

In October 2020, Jennifer A. Doudna, Ph.D., and Emmanuelle Charpentier, Ph.D., won the Nobel Prize in Chemistry for their CRISPR gene-editing technology, the first time this award went to two women. Soon after the announcement, NIH Director Francis S. Collins, M.D., Ph.D., spoke with Dr. Doudna during a Twitter and Facebook Live event, which focused on gene editing, the development of CRISPR, and other topics. A video recording of the discussion is available here.

NIH Offers Challenge Prize to Address Gender Diversity and Equity Problems Faced by Faculty in Higher Education

ORWH is now accepting applications for a Challenge Prize competition aimed at increasing gender diversity among faculty members at colleges and universities and removing barriers to the uptake of systemic institutional approaches for transformative change. The NIH Prize for Enhancing Faculty Gender Diversity in Biomedical and Behavioral Science will recognize institutions that have acted systemically to address gender diversity and equity issues among faculty members within their biomedical and behavioral science departments. The competition will highlight and promote their best practices, lessons learned, and evidence-based approaches. Applications will be accepted through 5:00 p.m. Eastern Time on April 16, 2021. You can learn more about the Challenge Prize here and in this message from ORWH Director Janine A. Clayton, M.D.

New United Nations Database Tracks Pandemic's Effects on Women

UN Women, a United Nations organization for gender equality and women's empowerment, and the United Nations Development Programme recently launched the COVID-19 Global Gender Response Tracker. This database has collected over 2,500 policy measures, enacted by 206 national and territorial governments, to tackle the COVID-19 pandemic. The tracker gauges policies pertaining to (1) women's economic insecurity, (2) the surge in violence against women and girls, and (3) child care support. The data show that only 12% of countries addressed all three areas in their pandemic policies and that one in five addressed none of them. The tracker also points out exemplar nations that are actively responding to these secondary effects of the coronavirus pandemic. Argentina, Egypt, Morocco, and Togo have implemented financial relief programs for domestic workers and women-led businesses. Sweden and Canada have dedicated many resources to protecting women, children, and LGBTQ+ individuals from violence. Poland, South Korea, Italy, the Cook Islands, Austria, and Australia have implemented programs to support parents caring for children at home or day care centers. A detailed overview of these data is available on these COVID-19 Global Gender Response Tracker fact sheets.

Smith College Engineers Invent Prize-Winning Ventilator to Treat COVID-19

A team of 30 engineering faculty members, staff, and alumnae from Smith College recently developed the SmithVent ventilator. The team designed this easily manufactured medical ventilator as part of the CoVent-19 Challenge, an engineering competition sponsored by anesthesiology residents at Massachusetts General Hospital and the Ximedica medical device company to address the shortage of ventilators during the coronavirus pandemic. The competition lasted only 8 weeks, and ventilator developers were asked to submit two designs: one for a rapidly deployable ventilator and a second design modifying existing ventilators to enable one machine to ventilate two patients simultaneously. ORWH congratulates the members of the Smith College team and thanks them for their contribution to pandemic relief efforts. More information is available here.

Traditional medical ventilators

ORWH Hosts 30th Anniversary Virtual Meeting Series: Advancing the Health of Women Through Science

On December 14–16, 2020, ORWH hosted a series of three virtual meetings to celebrate 30 years of women's health research and sex and gender studies within and beyond the NIH scientific community. These meetings convened women's health and sex differences researchers as well as members of two signature ORWH programs: Building Interdisciplinary Research Careers in Women's Health (BIRCWH) and Specialized Centers of Research Excellence (SCORE) on Sex Differences. The meeting series also featured the ORWH 30th Anniversary Scientific Symposium, which included presentations by ORWH Director Janine A. Clayton, M.D.; NIH Director Francis Collins, M.D., Ph.D.; Pauline M. Maki, Ph.D., of the University of Illinois at Chicago; President of Research!America Mary Woolley, M.A.; Senior Advisor for Public Health at the National Institute of Environmental Health Sciences (NIEHS) John Balbus, M.D., M.P.H.; and Shaheen Lakhan, M.D., Ph.D., M.Ed., M.S., of Virginia Tech University. Video recordings of the BIRCWH meeting, 30th Anniversary Scientific Symposium, and SCORE keynote address are available on the NIH Videocast website. A virtual environment website created for the meeting series includes scholarly posters, informational videos, and other resources and will be available until December of 2021. For more information and a complete list of speakers, visit this ORWH webpage.

The virtual environment for the 30th Anniversary Meeting Series

NIH Launches IMPROVE Initiative to Prevent Maternal Morbidity and Mortality

In response to high rates of maternal morbidity and mortality in the United States, the NIH Office of the Director (OD), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), ORWH, and other NIH Institutes, Centers, and Offices have developed the NIH-wide IMPROVE initiative (Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone) to support research on reducing preventable maternal mortality; improving health for women before, during, and after delivery; and promoting health equity. The IMPROVE initiative has recently awarded

approximately $7.2 million in grants through a notice of special interest on maternal mortality. Areas of research include heart disease, hemorrhage or bleeding, and infection (the leading causes of U.S. maternal deaths); contributing conditions, such as diabetes, obesity, mental health disorders, and substance use disorders; and structural and health care system factors that may contribute to delays or disruptions in maternal care. More funding opportunities and expansions of the initiative are expected this year. More information is available on the IMPROVE webpage and the Office of the NICHD Director's blog.

NIH's COVID-19 Scientific Interest Group Hosts Lecture on Ethical Quandaries in the Pandemic

On November 19, 2020, the NIH COVID-19 Scientific Interest Group (SIG) hosted a lecture by Christine Grady, M.S.N., Ph.D., of the NIH Clinical Center, titled "Ethical Quandaries in the COVID-19 Pandemic." Dr. Grady's lecture discussed the myriad ethical dilemmas facing patients and their families, nurses, other health care providers, and researchers functioning in the wake of the COVID-19 pandemic. The COVID-19 SIG was created in March 2020 in response to the pandemic and aims to promote collaboration among NIH intramural scientists and their U.S. Department of Health and Human Services (HHS) colleagues on research on COVID-19 and SARS-CoV-2. A video recording of the lecture is available here.

NIH Panel Recommends Communication Strategies to Promote COVID-19 Vaccine

An expert panel convened by an NIH workgroup led by Office of Behavioral and Social Sciences Research (OBSSR) staff recently released a report titled COVID-19 Vaccination Communication: Applying Behavioral and Social Science to Address Vaccine Hesitancy and Foster Vaccine Confidence. This report summarizes relevant communication research and recommends actionable strategies for promoting the safe, effective, and FDA-approved vaccines and addressing concerns about getting vaccinated. A one-page fact sheet summarizing the panel's recommendations is available here.

NOTEWORTHY

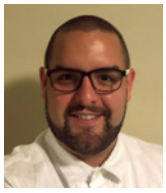
New CoEPE Website Provides Resources for Pain Management Training

Through the Centers of Excellence in Pain Education (CoEPE) program, NIH supports academic and research centers that act as hubs for the development, evaluation, and distribution of pain management curriculum resources for students in many health disciplines. Recently, CoEPE's parent organization, the NIH Pain Consortium, rebuilt the program's website to gather these resources in a single location with a streamlined user interface. CoEPEs perform valuable educational and public health services. Chronic pain affects approximately 100 million Americans, costs up to $635 billion in medical treatment and lost productivity annually, and produces immeasurable suffering. However, health education programs seldom include extensive pain management training, and clinical approaches can be inconsistent. Men and women have different neurological mechanisms for pain, pain sensitivities, risks for chronic pain conditions, and responses to treatment. As such, ORWH and other NIH Institutes, Centers, and Offices—notably, the National Institute on Drug Abuse (NIDA) and National Institute of Neurological Disorders and Stroke (NINDS)—have been regular supporters of the CoEPE program. CoEPE resources are available here.

STAFF UPDATES

Elizabeth Barr, Ph.D., recently became a Social and Behavioral Scientist Administrator at ORWH after working as a contractor analyst in the office over the past year. Dr. Barr's work focuses on community-centered research, HIV, reproductive justice, and gender-based violence, and she leads the development of ORWH's e-learning products. Dr. Barr completed her Ph.D. in communication, with training in science and technology studies, at the University of Wisconsin–Madison and her M.S. in women's and gender studies at Towson University. Her research has been published in the *Journal of Health Disparities Research and Practice, The Lancet HIV,* the *Journal of Virus Eradication*, *AIDS Research and Human Retroviruses*, and the *Journal of the International AIDS Society*. Prior to joining ORWH, Dr. Barr led interdisciplinary and cross-sector projects to increase women's engagement with clinical research and served on the faculties of Towson University and the University of Maryland, Baltimore County.

Eddie Billingslea, Ph.D., has joined ORWH's Science Policy, Planning, and Analysis team as a Health Science Policy Analyst. Prior to accepting his current position, Dr. Billingslea worked at the National Cancer Institute (NCI), where he led the development of the assessment framework for NCI's Cancer Moonshot. Dr. Billingslea has also worked in the NIH Scientific Workforce Diversity Office, where he organized the Future Research Leaders Conference and helped devise strategies to increase representation of African American students and investigators within the NIH biomedical enterprise. Dr. Billingslea began his NIH career in the Division of Neuroscience at the National Institute on Aging (NIA), where he supported cognitive and affective neuroscience research. He received his Ph.D. in neuroscience from Georgetown University and completed a postdoctoral fellowship at the University of Pennsylvania, where he studied NMDA receptor hypofunction associated with schizophrenia and autism.



Mason Scott, J.D., M.A., joined ORWH as a Communications Specialist through the Presidential Management Fellows Program in September 2020. Mr. Scott graduated with a B.A. in international studies from Baylor University in 2012. Immediately afterward, he attended Seton Hall University, where he received his M.A. in diplomacy and international relations in 2014. After managing a restaurant for almost 3 years, he returned to school and earned his J.D. at George Mason University.

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