

Department of Health and Human Services
National Institutes of Health
National Institute of Nursing Research
Minutes of the National Advisory Council for Nursing Research

September 12, 2023

The 111th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, September 12, 2023, at 9:00 a.m. The open session was held in person and by National Institutes of Health (NIH) videocast, and all observers, including members of the public, attended virtually. The open session adjourned at 2:38 p.m. The closed session of the meeting, which included consideration of grant applications, was convened on Tuesday, September 12, 2023, at 2:52 p.m. and continued until adjournment at 3:02 p.m. Dr. Shannon N. Zenk, Chair, NACNR, presided over both meeting sessions.

OPEN SESSION

I. CALL TO ORDER, OPENING REMARKS, AND COUNCIL PROCEDURES

Dr. Shannon N. Zenk, Director, National Institute of Nursing Research (NINR)

Dr. Zenk called the 111th meeting of the NACNR to order and welcomed all Council members, visitors, staff, and the scientific community. She noted that the open session of the meeting was being videocast live and will be archived on the NIH videocast website.

Dr. Zenk acknowledged the addition of an *ex officio* representative from the Department of Defense, Dr. Cubby L. Gardner. Dr. Gardner is a Lieutenant Colonel in the United States Air Force, Senior Service Advisor to the Dean and Assistant Professor in the Daniel K. Inouye Graduate School of Nursing at the Uniformed Services University of the Health Sciences. Lieutenant Colonel Gardner also serves as Consultant to the Surgeon General of the Air Force and is the Career Field Manager for Nursing Research.

Dr. Elizabeth Tarlov, Director, NINR Division of Extramural Science Programs (DESP), and Executive Secretary of NACNR, conducted a roll call of NACNR members and noted for the record that a quorum had been achieved. She noted that Drs. Bekemeier, Johnson, and Provencio-Vasquez were unable to attend the meeting.

Dates of Future Council Meetings

Dates for future Council meetings were included in the NIH Electronic Council Book. The next Council meeting will be held on January 25, 2024; this will be a virtual meeting. Additional meetings are scheduled for May 23, and September 12, 2024.

Minutes of the Previous NACNR Meeting

Minutes of the May 23, 2023, NACNR meeting were distributed to Council members through the Electronic Council Book. A motion to accept these minutes was made, seconded, and unanimously approved. The approved minutes of each NACNR meeting become part of the Institute's official record and are posted on the NINR website (www.ninr.nih.gov).

Conflict of Interest and Confidentiality Statement

Dr. Tarlov noted that conflict of interest and confidentiality statements were included in the Electronic Council Book. She reminded Council members that as special government employees they may not engage in lobbying activities. Dr. Tarlov also noted that she would provide specific instructions about conflict of interest and confidentiality at the beginning of the closed session.

II. REPORT OF THE NINR DIRECTOR

Dr. Shannon N. Zenk, Director, NINR

The Director's report focused on activities and news from NIH and NINR since the May 23 Council meeting. Highlights of Dr. Zenk's report included:

Firearm Injury Prevention Strategic Imperative—In January 2023, NINR announced Firearm Injury Prevention as the Institute's first strategic imperative under the 2022–2026 NINR strategic plan. An ongoing investment in a specific area of research that aligns with NINR's mission, a strategic imperative can be viewed through most, if not all, of the lenses in the strategic plan and has the potential to make a difference in addressing our nation's most pressing health challenges. This research area aligns with NINR's updated mission—to lead nursing research to solve pressing health challenges and inform practice and policy—optimizing health and advancing health equity into the future. Nursing research offers an important perspective, given that work to prevent firearm injuries and their related health sequelae are situated within the settings where nurses practice, including homes, schools, workplaces, clinics, justice settings, and the community.

NINR is taking important steps forward in addressing firearm injury prevention. In November 2022, NINR hosted a workshop that identified two critical themes. First, firearm violence prevention is a pressing public health challenge and a major health equity issue, deeply influenced by the social determinants of health (SDOH), with structural and historical roots. The second critical theme is the high potential return on investment for research in this area by nurse scientists and for research related to nursing practice.

NINR staff identified three key areas for immediate action: (1) use existing research infrastructure to expand into firearm injury prevention; (2) invest in the development of a cadre of researchers prepared to

do this work; and (3) address the gap in research in community healthcare. During the January 2023 NACNR meeting, NINR staff presented two firearm injury prevention concepts aimed at addressing some of the priorities shared by workshop participants: building capacity for firearm injury prevention research and firearm injury prevention in community healthcare settings. In March, NINR issued a Notice of Special Interest (NOSI, [NOT-NR-23-009](#)) for administrative supplements to NINR Institutional Research Training Grants (T32) to Increase Capacity for Research to Prevent Firearm Injury and Related Health Disparities. NINR is funding a supplement at Columbia University School of Nursing to mentor students in firearm injury prevention, health sequelae of firearm injury, and health disparities in firearm injury. NINR issued a notice of intent to publish a funding opportunity ([NOT-NR-23-016](#)) to establish short courses in firearms injury prevention to prepare nurse scientists and scientists in aligned fields to conduct firearm prevention research, with a goal of making awards next summer. On September 1, NINR posted a funding opportunity, Firearm Injury Prevention Research in Community Healthcare Settings ([RFA-NR-24-001](#)), to encourage novel, creative approaches to firearm injury prevention in community healthcare settings to identify risk factors; reduce exposure risk at the individual, family, and population levels; prevent injury or recurrence of injury; and mitigate disparities.

Dr. Zenk highlighted an NINR-supported mixed-method study ([1RF1NR020753-01](#)) focused on firearm injury prevention among Asian Americans. A multidisciplinary research team is examining links between multilevel risk and protective factors of firearm injury risk and neighborhood structural-level racism and discrimination to determine mechanisms connecting these factors to firearm outcomes.

Funding Updates—Since the May 2023 NACNR meeting, NINR has published the following: a NOSI ([NOT-NR-23-012](#)) focused on addressing organizational factors to prevent or mitigate nurse burnout and a Notice of Funding Opportunity (NOFO) for short courses in SDOH for research education in nursing research ([NOT-NR-23-015](#)). Dr. Zenk highlighted two examples of other NOFOs onto which NINR has also signed: Native American Research Centers for Health (NARCH, [PAR-23-166](#)) and Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science ([NOT-OD-23-165](#)).

Partnerships and Collaborations—In 2022, NINR helped launch the NIH-Wide SDOH Research Coordinating Committee (RCC) to meet the urgent need for a coordinated strategy to propel discovery toward improving individual and population health, reduce health disparities, and advance health equity. RCC objectives include sharing information about SDOH research; developing SDOH expertise, capacity, and a learning system at NIH; building a community and collaborations in SDOH research; and identifying gaps and promising SDOH research directions. Led by co-chairs Dr. Zenk and Dr. Eliseo Pérez-Stable, Director of the National Institute on Minority Health and Health Disparities (NIMHD), the Committee now includes representatives from 20 NIH Institutes, Centers, and Offices (ICOs). In a July 2023 [blog post](#), Drs.

Zenk and Pérez-Stable shared a new conceptualization of SDOH applicable to any area of NIH science and beyond, defining SDOH as conditions in which people are born, work, play, live, and age and the wider set of structural factors shaping conditions of daily life. Structural factors include social, economic, and legal forces, systems, and policies that determine opportunities and access to high-quality jobs, education, housing, transportation, built environment, information and communication infrastructure, food, and healthcare as well as the social environment and other conditions of daily life. SDOH may interact with other determinants of health (e.g., biological, psychological, behavioral, and chemical and other environmental factors) to further compromise or promote health. This SDOH concept recognizes that structural factors rooted in racism, sexism, homophobia, classism, and other discriminatory systems shape the extent to which conditions of daily life are equitably distributed in society or unfairly distributed.

NIH has awarded \$24 million in first-year funding to establish [Maternal Health Research Centers of Excellence](#) aimed at reducing maternal morbidity and mortality rates and promoting maternal health equity. The centers are part of the IMPROVE Initiative (Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone) co-led by NINR, the NIH Office of Research on Women’s Health (ORWH), and the National Institute of Child Health and Human Development (NICHD).

In late August, [RFA-RM-23-012](#) was published to invite applications from eligible organizations to serve as Health Equity Research Hubs for awarded community-led health equity structural intervention projects within the Community Partnerships to Advance Science for Society (ComPASS) Program.

Dr. Zenk summarized NINR activities related to the NIH-wide Climate Change and Health Initiative. NINR is supporting two current funding opportunities: [NOT-ES-22-006](#) encourages applications that address the impact of climate change on health and well-being over the lifespan, and [RFA-ES-23-007](#) solicits P20 planning applications for Climate Change and Health Research Centers. NINR hosted Climate and Health Scholar Dr. Patrice Nicholas, who led an NIH-wide seminar and presented three staff seminars.

NACNR has formed a working group on this topic—led by NINR’s Dr. John Grason and Council member Dr. Betty Bekemeier—charged with considering the current state of the science and assessing pressing research questions. The goal is to present recommendations in January 2024, with a focus on research where nursing science could have the greatest impact on addressing the health effects of climate change. NINR will publish a Request for Information (RFI) to obtain comments and testimonies from the extramural scientific community, professional societies, and the public regarding health impacts of climate-associated events to assist with identification of research gaps where nursing research can provide a unique perspective. The working group recommendations and responses to the RFI will inform potential NINR research initiatives to be started in 2024.

NINR is participating in the NIH Helping to End Addiction Long-term® (HEAL) Initiative, which aims to speed scientific solutions to stem the national opioid public health crisis. Over the next 7 years, the Native Collective Research Effort to Enhance Wellness (N CREW) Program, which works in Native communities disproportionately affected by the crisis, will build partnerships with Tribes and supporting organizations to conduct research. Current N CREW funding opportunities include one for addressing overdose, substance use, mental health, and pain and creating a Native Research Resource Network. The initiative’s Prevention and Management of Chronic Pain in Rural Populations (a concept that Council approved last year) has funded three applications—two of which NINR is administering. NINR is participating in the HEAL Initiative Partnerships to Advance INterdisciplinary (PAIN) Training in Clinical Pain Research, which aims to bolster the dwindling clinical pain research workforce by supporting interdisciplinary postdoctoral training to promote the next generation of independent clinical pain researchers.

Although the Palliative Care Research Cooperative (PCRC) Group ended in June, capacity and resources live on from this initiative. Founded in 2010, NINR was one of six organizations that funded the Cooperative Group and is proud to have been on the PCRC executive committee and to have been a part of its accomplishments, like supporting research, promoting mentorships, and creating nine special interest groups. Dr. Zenk encouraged meeting attendees to visit the [website](#) for the group’s mission, history, and successes.

NINR News and Announcements—Dr. Zenk summarized findings of note from recently published studies. An NINR-supported study found [racial disparities in cesarean births](#) in healthy, first-time mothers, with Black and Hispanic individuals having nearly double the odds, compared with White mothers, of ending labor with an unplanned cesarean. A second study found that [unmet basic needs](#), as predicted by food insecurity, history of homelessness, and past incarceration led to significantly lower odds of HIV antiretroviral therapy (ART) medication adherence among Black people living with HIV, providing evidence linking SDOH and social disenfranchisement to medication adherence. Lastly, NINR-supported scientists developed a [natural language processing \(NLP\) system to detect eviction status](#) from 5,000 electronic health record (EHR) notes from the Veterans Health Administration (VHA). The system substantially improved classification and will be deployed as an eviction surveillance system for the VHA.

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) and VentureWell hosted an annual “Design by Biomedical Undergraduate Teams” (DEBUT) challenge for undergraduate student teams to develop technology solutions for unmet healthcare needs. The NIH Office of AIDS Research, National Cancer Institute (NCI), NICHD, NIMHD, and NINR each awarded a prize to the team with the most innovative technology in the IC’s respective fields. NINR awarded the 2023 DEBUT challenge prize in the *Technologies to Empower Nurses in Community Settings* category to RAAM Inc., a four-woman

team from Clemson University, for its U-Sert design, a diaper urinalysis-like insert containing reagents that indicate the presence of a urinary tract infection (UTI) in pediatric populations. This cost-effective diagnostic test can be used in clinics or at home, saves nurses' time, and increases UTI testing in low-resource settings.

Dr. Taichi Goto, a research fellow in Dr. Leo Saligan's intramural research group, presented at the 2023 NIH Pain Consortium Symposium on Advances in Pain Research. His study provides new insight into associations between brain-derived neurotrophic factor, a specific polymorphism, and neuropathic pain among cancer survivors.

Six NINR intramural fellows presented during the NIH Summer Poster Days in August. Topics included a virtual reality grocery store, quantitative analysis of RyR1, pain prediction, disparities in patients with chronic obstructive pulmonary disease, and the role of sleep diaries.

In July, Dr. Sarah Stoddard, University of Michigan, and Dr. Paul Kuehnert, Public Health Accreditation Board, delivered the [final lectures](#) in the NINR Director's series on the Institute's strategic lenses, with a focus on the population and community health lens. More than 300 individuals participated in the webinar.

In June, NINR, NIMHD, and the NIH Office of Behavioral and Social Sciences Research (OBSSR) co-hosted the [Health Equity Distinguished Lecture](#). NINR council member Professor Daniel E. Dawes shared his expertise on health equity, health reform, health systems transformation, and social and political determinants of health.

Following a national search, Dr. Courtney Aklin was selected as Deputy Director of NINR. Dr. Aklin has over 15 years of research administration and leadership experience at NIH, including as Acting Associate Deputy Director, NIH; NIMHD Chief of Staff; and positions at the National Institute of Mental Health (NIMH) and the National Institute of Neurological Disorders and Stroke (NINDS). She has led several recent NIH-wide high-impact activities, including the IMPROVE initiative, the Mental Health and Well-being Action Team, and the Resilience Through Well-being Campaign. A licensed clinical psychologist, Dr. Aklin has a background and interest in community-engaged work and behavioral and social sciences research relating to health disparities and pediatric mental health. She will join NINR on October 2.

Dr. Zenk welcomed new staff and fellows, including Presidential Management Fellow Lauren Hashiguchi, Scientific Review Officer Josh Wolff, Grants Management Specialist Susan Toy, Deputy Chief Information Officer Don Seymour, Nova Kong providing helpdesk support, and three new program officers: Julia Seay, Sylvia Long, and Karen McNamara. Dr. Zenk announced the departure of two NINR staff members: Dr. Louise Rosenbaum, a science policy analyst/writer, and Dr. Sabrina Wong, NINR Division of Intramural Research Scientific Director.

NINR and NIH is also saying goodbye to Dr. Patricia Flatley Brennan who is retiring as Director of the NINR Advanced Visualization Lab and Director of the National Library of Medicine (NLM), the first nurse, industrial engineer, and female to lead there. During her 7 years in this position at NLM, she modernized PubMed and clinicaltrials.gov. At NINR, she developed interactive virtual reality simulations to enable patients with a variety of health conditions to rehearse problem-solving behaviors to improve their health outcomes. Dr. Stephen Surry will serve as acting NLM Director.

NIH News and Announcements—NINR-supported investigator Dr. Debra Moser was selected to present in April 2024 as part of the high-profile NIH Director’s Wednesday Afternoon Lecture Series (WALS). More details are forthcoming.

NIH is accepting submissions for the [Institutional Excellence in Diversity, Equity, Inclusion, and Accessibility in Biomedical and Behavioral Research Prize Competition](#), a new initiative that seeks to recognize inclusive excellence at academic institutions. NIH will award up to 10 prizes of \$100,000 each through the competition.

The NIH [Build UP Trust Challenge](#) seeks to increase research participation by building trust and increasing engagement with historically underserved communities. The new initiative will award up to \$45,000 to up to 10 finalists and the opportunity to win one of four \$200,000 prizes for promising strategies that increase research participation and improve trust in medical care in underserved communities.

NIH has released [NOT-OD-23-163](#), an RFI inviting comments and suggestions on updating the NIH mission statement to remove the phrase, “reduce disability,” which could be interpreted as perpetuating ableist beliefs that disabled people are flawed and need to be fixed. The proposed mission statement is as follows: *To seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to optimize health and prevent or reduce illness for all people.*

Dr. Zenk welcomed Dr. Jane Simoni, NIH Associate Director for Behavioral and Social Sciences Research and Director of OBSSR. Dr. Simoni is a clinical psychologist with over 25 years of experience in research focused on health disparities and resilience among socially marginalized populations, including persons with HIV and other chronic illnesses, and Latinx, LGBT, and indigenous peoples. Dr. Karina Walters of the Choctaw Nation of Oklahoma has been named Director of the NIH Tribal Health Research Office (THRO). A social epidemiology and health prevention scholar, Dr. Walters was formerly a tenured professor and Katherine Hall Chambers Scholar at the University of Washington (UW) School of Social Work and an adjunct professor in the UW Department of Global Health and School of Public Health.

Dr. Jeanne M. Marrazzo has been named Director of the National Institute of Allergy and Infectious Diseases (NIAID), which conducts and supports basic and applied research to better understand, treat, and

ultimately prevent infectious, immunologic, and allergic diseases. Dr. Marrazzo is an infectious disease specialist joining NIH from the University of Alabama at Birmingham, where she served as Director of the Division of Infectious Diseases. She is internationally recognized for her research and educational efforts in sexually transmitted infections, especially as they affect women's health.

Budget Update—Dr. Zenk summarized the NINR and NIH appropriations history. In March, President Biden submitted his Fiscal Year (FY) 2024 budget to Congress, which retains \$10 million enacted for health disparities research that NINR received in FY 2023. Congress will make the final funding level decision. House and Senate drafts suggest a flat budget for NINR in FY 2024 and retention of the \$10 million for health disparities research.

Discussion

Dr. Zenk opened the floor for discussion, noting that NINR must recognize potential budgetary challenges on the horizon and plan accordingly for multiple scenarios—budget cuts, flat budgets, and budget increases. She requested advice on planning for FY 2024 and beyond, including strategies for extramural programs (e.g., funding fewer awards, prioritizing new and early-stage investigators [ESIs], cutting all awards by a certain percentage, funding short-term projects to reduce outyear commitments) and training.

The importance of training ESIs for the future generation of nurse scientists was emphasized. Council members suggested funding partnerships between resource-intensive, research-focused institutions and institutions that lack research infrastructure—such as minority-serving institutions (MSIs) and historically black colleges and universities (HBCUs)—to train PhD candidates. This is a way to make the most effective use of NINR investments and broaden the diversity of voices at the table.

Another Council member pointed out that such efforts should include support for senior investigators who would support ESI development and serve as mentors.

Council members supported bold approaches to address climate change, SDOH, and health inequities. NINR should consider funding fewer awards to ensure that gains in these critical areas will not be lost.

Dr. Zenk thanked Council members for sharing their ideas.

III. NCATS UPDATES, PRIORITIES, AND OPPORTUNITIES FOR COLLABORATION

Dr. Joni Rutter, Director, National Center for Advancing Translational Sciences (NCATS)

Dr. Rutter outlined the major public health challenge of developing and delivering therapies for human disease. Currently, only 5% of 10,000 diseases have treatments or cures. Moving a drug from target discovery and early development to clinical use takes an average of 10–15 years at a budget of about \$2.6 billion. The failure rate of promising therapeutic candidates that enter clinical trials is high (9 out of 10).

The NCATS mission is to turn research observations into health solutions through translational science. The Center is advancing translational science by addressing longstanding bottlenecks in the pipeline so that new treatments reach people faster. NCATS is using translational science research to tackle operational, scientific, administrative, and workforce bottlenecks.

Operational bottlenecks such as one-size-fits-all approaches can be replaced with adaptive clinical trial design and master protocols, increasing the number of small clinical trials and Rare Diseases Clinical Research Network (RDCRN) basket or umbrella trials. Low enrollment and limited diversity in clinical trials can be addressed via patient advisory groups and enhanced community engagement efforts.

Scientific bottlenecks include insufficient tools and technologies to predict toxicity and efficacy of new drugs as well as incompatible databases for advancing data science. Toxicity and efficacy prediction tools include platform-based tissue or organs on chips, three-dimensional biofabrication, gene-targeted therapies, and artificial intelligences and machine learning (AI/ML) drug development approaches such as the NCATS ASPIRE initiative (A Specialized Platform for Innovative Research Exploration). Barriers to database compatibility are being addressed through data, interoperability, and integration programs such as the NCATS Biomedical Data Translator, N3C (National COVID Cohort Collaborative), GARD (Genetic and Rare Diseases) Information Center, and RARE-Source, an Integrated Bioinformatics Resource for Rare Diseases.

Administrative and workforce development bottlenecks include administrative burden of study startup and the shortage of qualified translational investigators. NCATS is addressing these barriers through streamlined business and regulatory processes (SMART IRB) and training and career development best practices.

The NCATS vision is built on three audacious goals: bring more treatments (increase the number of diseases with treatments from 5% to 25%) to all people (dramatically increase inclusivity across every area NCATS supports) more quickly (enable diagnostics and therapeutics to reach people twice as fast). Key approaches include understanding similarities across diseases to spur multiple treatments at a time; developing models that better predict a person's reaction to a treatment; enhancing clinical trials so that results more accurately reflect the patient population; and leveraging real-world data and data science approaches to address public health needs.

The NCATS budget (\$923.3 million in FY 2023) allocates 68% of funding to Clinical and Translational Science Awards (CTSA), an NIH flagship program that funds a nationwide network of 63 research institutions with consortium-wide resource centers and collaborative initiatives. The remaining 32% of the Center's budget supports intramural and extramural programs such as drug repurposing, tissue chips, diagnostics, ethics, training, and Small Business Innovation Research (SBIR) and Small Business

Technology Transfer (STTR) grants.

Dr. Rutter presented preclinical, clinical, and data science approaches in translational science that intersect well with NINR interests. For example, NCATS is revolutionizing drug development approaches, moving beyond mouse models and two-dimensional cell lines that are not reflective of the physiological conditions to complex, multicell organoids that maximize the recapitulation of relevant conditions. For example, the Tissue Chips in Space program uses chips that can detect physiological changes in a microgravity environment that mimics the aging process.

Rare diseases affect nearly every system, organ, and disease studied by NIH. NCATS partners with 10 NIH ICs to address issues around rare diseases. An NCATS study found that healthcare for people who have rare diseases costs three to five times more than for those who do not have a rare disease. Collectively, rare diseases affect an estimated 25 to 30 million people in the U.S. at an annual total direct medical cost of approximately \$400 billion; if indirect medical costs such as home care and hospitalizations are included, the numbers rise to \$1 trillion per year for this population.

Given that 80% of the 10,000 rare diseases are caused by a single gene mutation, NCATS has developed a platform-based approach for genetically driven treatment modalities. NCATS gene therapy and gene editing programs include Somatic Cell Gene Editing ([SCGE](#)), the Bespoke Gene Therapy Consortium ([BGTC](#)), and the Platform Vector Gene Therapy ([PaVe-GT](#)) pilot project. The PaVe-GT program is about a year from its first clinical trial for a gene therapy using the same AAV virus for two different genes to test streamlined approaches using a template for regulatory development that others can use. Dr. Rutter noted that different workforce communities—nurses, pharmacists, statisticians—will be involved in translating these genetic-driven therapeutics.

Dr. Rutter described the CTSA program, with a focus on the nurses involved in the program, including 4 Principal Investigators (PIs) with nursing degrees, 43 institutions with a nursing school, 24 scholars and trainees with nursing degrees, 12 pilot project PIs with nursing degrees, and 8 projects related to nursing interests. She expressed enthusiasm about the depth and breadth of the CTSA program that open the way for potential collaborations. CTSA institutions have local strengths that, collectively, enable nimble, rapid, robust responses to national public health challenges such as the opioid crisis, the COVID-19 pandemic, community engagement needs, telehealth, genomics, and rare diseases.

NCATS efforts in community engagement include the Trial Innovation Network, which is designing a clinical trial for dissemination and outreach. Dr. Rutter shared the experience of a community advisory board member who went into a community that had been documented as a food desert; it became clear that the real barrier was broken, cracked sidewalks that hindered foot and stroller traffic. Recently, a CTSA program supplement was awarded for the ComPASS Collective for Community Engagement (C3E) to

build stronger ways to enhance community engagement.

Dr. Rutter provided examples of CTSA projects with a focus from the nursing perspective. At Case Western Reserve University, Dr. Shanina Knighton is exploring the feasibility and acceptability of a technology-based patient hygiene self-management intervention among older adults in acute care and retirement community settings. At Emory University, Dr. Alexis Dunn-Amore is highlighting the interconnection between the maternal mortality crisis, the COVID pandemic, and structural racism. Two Heilbrunn Nurse Scholars received prestigious awards. Dr. Paule Joseph received the Brilliant New Investigator Award and Inaugural American Academy of Nursing/National Academy of Medicine Fellowship; her research on taste and smell disorders proved important during the pandemic. Dr. Cassandra Godzik was selected to participate in the U.S. Postdoctoral Fellows Fulbright Israel program, where she will continue her research focused on sleep patterns of older adults.

Based on percentage of funding by IC budget, NINR is leading the way in the digital health technologies (DHT) space at NIH. Wearables and mobile technologies are key aspects of the CTSA program, with potential for monitoring disease progression. For example, Dr. Christina Calamaro and her team at the Georgia CTSA are improving a mobile nursing-patient communicator app for nurses helping patients with limited English proficiency. Researchers at the Scripps CTSA combined DHT and self-reported symptoms to improve prediction of COVID infection. Investigators at the Hershey CTSA evaluated available wearables that provide greater detail about sleep patterns.

NCATS is undergoing strategic plan development, including stakeholder roundtables and an RFI. Dr. Rutter called on Dr. Zenk and Council to offer input on potential interactions between NINR and NCATS that can be built into the NCATS strategic plan.

Discussion

Dr. Munro led the discussion, highlighting the intersection of nursing research and work NCATS is doing. With its focus on people's lives and living conditions, nursing research is well positioned to contribute to areas of more interest. Nursing interventions that target resilience can be tested more readily than pharmacologic approaches. The many CTSA with associated nursing schools provide a pathway for greater connections—for example, improving nursing school awareness of available CTSA opportunities for scholarly, infrastructure-supported research. Dr. Rutter suggested that the 24 NCATS scholars and trainees with nursing degrees might serve as ambassadors to make those connections.

Dr. Munro asked about the role of nursing science in gene therapy. Dr. Rutter noted that safety and efficacy of gene therapies have been challenging and suggested that unexpected toxicities, perhaps due to underlying conditions, will be made apparent through care itself. That points to the need to train a

workforce to handle unexpected problems, especially with new modalities.

Dr. Rutter noted that the physiologically relevant *in vitro* systems will elevate the ability to consider efficacy. More validation and experimental work must be done, but that is the wave of the future.

IV. COMMUNITY PARTNERSHIPS TO ADVANCE SCIENCE FOR SOCIETY (ComPASS)

Dr. Cheryl Boyce, Team Lead, ComPASS, Office of Strategic Coordination, NIH

Dr. Boyce provided an overview of the ComPASS program, which is supported by the NIH Common Fund and has a keen focus on health equity and community-led research that will intervene on SDOH. ComPASS also leverages structural interventions and multisectoral partnerships to achieve its goals of improving health outcomes of communities, reducing health disparities, and changing and informing systems, policies, and practices to achieve optimal health for all. Dr. Boyce noted that Dr. Zenk co-chairs ComPASS, along with Directors of ORWH, NIMH, and NIMHD.

The NIH Common Fund is under the NIH Office of the Director and managed in partnership with NIH ICOs. Common Fund programs are designed to address emerging scientific opportunities and pressing challenges important to the missions of multiple NIH ICOs but that no single NIH ICO can address on its own. Common Fund program goals are designed to be achieved within 10 years.

ComPASS aims to: 1) catalyze, deploy, and evaluate community-led health equity structural interventions that leverage partnerships across multiple sectors to reduce health disparities and 2) develop a new health equity research model for community-led, multisectoral structural intervention research across NIH and other federal agencies. These goals will be carried out in partnership with multiple sectors (e.g., community organizations, federal agencies, businesses, and local and state governments) through the formation of local and national health equity research assemblies (HERAs).

ComPASS has a budget of \$153 million over the next 5 years to fund up to 25 community-led structural interventions (CHESIs, [OTA-22-007](#)) and 1 coordination center award ([RFA-RM-23-001](#)) in FY 2023 (earliest start dates in September 2023) and up to 5 health equity research hubs ([RFA-RM-23-012](#)) in FY 2024 (earliest start dates in July 2024). This significant investment highlights NIH's commitment to addressing health disparities and advancing health equity.

CHESIs will follow a three-phase approach: planning (years 1–2), implementation (years 3–8), and dissemination (years 9–10) to develop, implement, assess, and disseminate co-created community-led health equity structural interventions in partnership with research organizations by intervening upon structural factors that produce and perpetuate health disparities. The response to CHESI outreach has been enthusiastic, with over 2,400 participants in technical assistance webinars and office hours plus more than

3,300 views of technical assistance videos on YouTube.

The coordination center will lead the consortium, including overall program management and coordination of administrative, data, capacity-building, partnership, training, and national HERA activities. Data-related planning activities will include identifying common data elements and health outcomes to be collected across all CHESI sites. HERA activities will include interdisciplinary subject matter experts, policymakers, community organizations, nonprofit foundations, public and private-sector organizations, and awardees to advise the overall initiative.

ComPASS hubs will provide tailored scientific, technical, and collaborative support for sustainable community engagement, research capacity building, and training for awarded CHESI projects.

Dr. Boyce described a ComPASS consultative resource to support best practices and provide customized expertise to optimize inclusive participation and improve community engagement across the research ecosystem. She expressed the hope that a community member will win a Build UP Trust Challenge award.

Discussion

Dr. Ayala opened the discussion by asking how the ComPASS HERA assembly concept is different from or similar to a coalition or advisory committee. Dr. Boyce explained that HERA is intended to bring together different groups to emphasize sustainability and policy aspects in a unique way that allows for local and national resources from other agencies. One component of the coordinating center applications is a description of how they would accomplish this.

Dr. Ayala asked whether metrics related to publications and obtaining additional funding are part of the evaluations, given that these are not typical expectations of grantee institutions. Dr. Boyce responded that the Common Fund has metrics for publications, capacity building, and dissemination; she noted that some of the ComPASS deliverables include demonstrating that the approach works, which will inform NIH on whether to continue using these mechanisms.

Dr. Ayala asked about the flexibility of the Other Transaction Agreement (OTA) and the extent to which it might apply to funding academic institutions. Dr. Boyce commented that other government agencies and NIH programs (e.g., All of Us) have employed OTAs to tackle new kinds of challenges. OTAs have a different kind of application structure, and they are milestone-driven, which requires closer scrutiny and more frequent reporting, but milestones can be changed, which is difficult to do within a grant structure.

Council members commented on the 10-year funding period and the impact of dynamic culture and environment over the years. Dr. Boyce responded that there are checks and balances during the 10 years; the OTA is nimble enough to accommodate discoveries and advances that affect the intervention, make

adjustments, or stop a site that is not doing well.

Dr. Zenk acknowledged Dr. Boyce for her dedication and commitment to this transformative program.

V. ARTIFICIAL INTELLIGENCE/MACHINE LEARNING CONSORTIUM TO ADVANCE HEALTH EQUITY AND RESEARCHER DIVERSITY (AIM-AHEAD) PROGRAM

Dr. Susan Gregurick, Director, Office of Data Science Strategy (ODSS), NIH

Dr. Gregurick discussed the promises and challenges of AI for medicine, current [AIM-AHEAD](#) research and its impact, and new opportunities arising in AI. Current trends in biomedical AI include AI and public health, large language models, and clinical models. An [evaluation of trends and future directions in AI](#) since the launch of ChatGPT highlighted a significant increase in studies focused on exploration of possible ChatGPT applications and recommended ongoing vigilance to optimize ChatGPT performance while mitigating risks of AI use in healthcare.

As leaders in using EHRs and collecting real-world data, nurse scientists and data science are “a match made in heaven.” Nurses understand the data challenges; for example, specific data elements may differ in practice and research, which has been a conundrum for NIH. Nurse scientists recognize the challenges around data quality, accuracy, and completeness that often require extensive data mapping, cleaning, and curation as well as the need for data system interoperability and expanded data science training in nursing research.

Dr. Gregurick described the promise of AI for healthcare and health research as well as challenges, solutions, and new opportunities. For example, AI combined with rapid whole-genome sequencing reduced time and effort for diagnosis of rare genetic disorders in infants in the ICU and can analyze 4.5M variants associated with 13,000 genetic disorders in 5 minutes. This pipeline may be particular for the institution and hospital, and applications elsewhere must be considered with rigor, but it points to a potential role for AI in health diagnosis. For AI, potential biases arise from unrepresentative data; bias within training data; bad design/asking the wrong question; bias in algorithm development and implementation; lack of diversity of researchers; and lack of data in lived experiences in historical/cultural contexts such as SDOH. For example, a [2019 study](#) revealed rampant racism in decision-making software used by U.S. hospitals; a [2021 publication](#) described how age disparities in an AI model trained to detect COVID-19 using adult chest x-rays reported false positives in children.

These problems are not static. A model may work well at deployment but could deteriorate over time, losing accuracy little by little over the course of months. Deterioration of an algorithm results from data

shifts—changes in data distributions over time due to external influences (e.g., SDOH) that change input and output data—and concept shifts that change input and output variables (e.g., in health-related quality-of-life surveys).

To address issues with AI and health equity, Dr. Gregurick introduced the Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) Program. The goals of AIM-AHEAD are as follows: enhance participation and representation of researchers and communities currently underrepresented in the development of AI; address health disparities and inequities using AI/ML; and improve capabilities of AI technology. The AIM-AHEAD consortium has four cores: leadership, research, training, and infrastructure. The leadership core will lead, recruit, and coordinate; the research core will use a co-design concept to develop research priorities and address needs to form an inclusive basis for AI/ML; the training core will assess, develop, and implement a data science training curriculum; and the infrastructure core will assess data, computing, and software infrastructure to facilitate AI/ML and health disparities research. In addition, the AIM-AHEAD program is a network of ‘Hubs’ (Central, Southeast, Northeast, North/Midwest, and West) that engage their communities and support research, training and mentorship.

The AIM-AHEAD vision is based on four North Stars: (1) develop a diverse, equitable, and inclusive AI/ML workforce; (2) increase knowledge, awareness, and national-scale community engagement and empowerment in AI/ML; (3) use AI/ML to address disparities and minority health in behavioral health, cardiometabolic health, and cancer; and (4) build community capacity and infrastructure in AI/ML to address community-centric health disparities and minority health. Dr. Gregurick outlined activities for each North Star.

To increase participation of underrepresented communities in AI, the Central Hub aims to make existing Papakolea community data AI/ML ready, integrate genomics and EHR data to address lung cancer for Native Hawaiian and Other Pacific Islanders (NH/PI), and train community health workers in delivering information about AI/ML. The Southeast Hub is identifying healthcare biases and determinants of high cancer death rates in rural Appalachia in collaboration with Vibrent Health Inc., AWS, and the Appalachian Clinical Translation Science Institute. The North/Midwest Hub is developing a 4-year dementia risk prediction for American Indian/Alaska Native (AI/AN) and NH/PI patients to improve diagnosis and care and using an AI chat bot to assist AI/AN patients with diabetes diagnoses, self-care, and management. The West Hub is conducting large-scale analysis to address cardiometabolic health in AI/AN and NH/PI patients in collaboration with the Los Angeles County Department of Health Services on EHR and digital health uptake among Spanish-speaking patients.

To increase diversity in the AI workforce through training and mentoring, AIM-AHEAD Connect was built

as a virtual hub to connect diverse mentors and mentees from across the country and encourage collaborations within the AIM-AHEAD Connect network. AIM-AHEAD disseminates awards for graduates, leaders, and community members to conduct research; to date, recipients include 25 graduate trainees, 22 early-career investigators, 25 leadership fellows, and 46 healthcare worker fellows.

To address health disparities and inequities using AI, Dr. Amy Waterman (Houston Methodist Research Institute) is enhancing the kidney transplant derailers index to predict transplant dropout risk for African American and Hispanic patients and exploring clinical- and community-level variables in multiethnic populations. Dr. Alexander Stokes (University of Hawaii at Manoa) is addressing intersex underdiagnosis/under recognition (UD/UR) to mitigate bias in the application of AI/ML to intersex UD/UR. Dr. Suman Niranjani (University of North Texas) is evaluating bias in predictive, explainable ML algorithms among older adults with cancer using multiple data sources for diverse groups, including rural populations. Dr. Luohua Jaing (University of California, Irvine) is working on cardiometabolic risk prediction among AI/AN adults and increasing AI/AN stakeholder engagement and collaboration in AIM-AHEAD.

Noting that ethics are at the forefront of accelerating AI/ML, Dr. Gregurick described a [community engagement effort in Birmingham, Alabama](#) designed to increase understanding of ethical challenges and biases that can occur within the AI field, improve participant understanding of AI, help identify opportunities where AI could affect individual and community health outcomes, and enable underrepresented communities to contribute to the conversation on AI and healthcare. This effort was supported through a partnership with the Bridge the Gap Initiative.

In addition to the AIM-AHEAD initiative, the Office of Data Science Strategy, in partnership with the NIH Institutes, Centers and Offices, supplemented NIH researchers with an interest in ethical frameworks, bias, and risk mitigation in AI ([NOT-OD-22-065](#)). Supported projects include Explainable AI to Improve Trust of and Detect the Bias of AI Models (Dr. Qing Zeng, George Washington University); Genetics of Deep-Learning Derived Neuroimaging for AD (Dr. Degui Zhi, University of Texas Health Science Center); and Characterizing Patients at Risk for Sepsis Through Big Data (Dr. Andre Holder, Emory University).

Dr. Gregurick highlighted new opportunities in AI with a focus on developing sociotechnical solutions for ethical AI; creating and validating an approach for using synthetic clinical datasets for AI; leveraging new technologies and methods for AI and foundational models to accelerate biomedical and behavioral research; developing new AI technologies to enable translation of data to knowledge; and enhancing NIH capabilities in AI through partnerships across federal agencies and communities.

Discussion

Dr. Stone opened the discussion with two examples of nurse scientists applying AI in their work: a nurse scientist using NLP to study patients' refusal of palliative care and a study of stigmatizing remarks in obstetrical notes that contribute to poor maternal health outcomes in minority women. She stressed the importance of algorithms that support health equity and co-designs that are user-friendly to avoid negative impacts on workflows in clinical settings. Dr. Stone asked what nurses and other scientists need to do to ensure that the translation of AI systems works in a dynamic society.

Dr. Gregurick responded that improving current AI requires someone who understands the data and the patients and can bring those insights into assessment, validation, and integration of the human into the loop.

T32s at Columbia and Emory have data science components. This area is ripe for involvement of more nursing leaders, perhaps through CTSA's. For example, nursing researchers are developing new data and technologies to implement in healthcare settings through the National Science Foundation's interagency Smart and Connected Health program.

Council members commented on interventions that provided feedback to clinicians in a federally qualified health center to inform changes in how EHRs are used, as well as ongoing work evaluating the impact of AI on quality of care and risk of physician burnout.

VI. CSR INITIATIVES TO STRENGTHEN REVIEW PANEL DIVERSITY, ADDRESSING BIAS, AND EVALUATING PANEL QUALITY

Dr. Noni Byrnes, Director, Center for Scientific Review (CSR), NIH

Dr. Byrnes provided an overview of CSR initiatives to strengthen review panel diversity, address bias, and evaluate panel quality. The CSR mission is to ensure that NIH grant applications receive fair, independent, expert, and timely scientific reviews—free from inappropriate influences—so that NIH can fund the most promising research. During FY 2023, CSR reviewed 161 NIH-wide special initiatives and approximately 60,000 (76%) NIH applications, including 94% of R01s, 96% of SBIRs/STTRs, and 84% of Ruth L. Kirschstein National Research Service Award (NRSA) Fellowships. Since 2019, CSR has based all actions on a strategic framework for optimizing peer review built on principles of transparency, data-driven decisions, stakeholder engagement, and staff engagement, training, and development.

Dr. Byrnes' presentation focused on the Evaluating Panel Quality in Review (ENQUIRE) process, simplifying reviews, improving review of NRSA Fellowships, promoting fairness, and diversifying panels.

[ENQUIRE](#) is a systematic, data-driven, continuous process to evaluate study sections. The process includes (1) evaluation for scientific currency, optimizing identification of high-impact release and identifying

emerging and declining areas; (2) process evaluation of study section function; and (3) CSR Advisory Council approval. About 20% of CSR study sections are assessed per year so that all of them are evaluated every 5 years. CSR scientific division directors oversee the process, which involves ICO stakeholder input and program officer feedback (via surveys). Evaluations generally result in substantive changes such as elimination or merging of smaller “boutique” panels, refreshed scientific guidelines, and new study sections. Currently, 13 clusters (152 study sections) have been evaluated or are in the process.

Dr. Byrnes outlined the goal of simplifying review of NIH Research Project Grant (RPG) applications: optimize identification of the most promising scientific research by removing administrative and policy compliance items from peer review and by reducing reputational bias during evaluation of the investigator and environment by evaluating both within the context of the proposed research project. Changes to the peer review framework for RPGs will reorganize the five regulatory review criteria into three factors: importance of the research (scored), rigor and feasibility (scored), and expertise and resources (not scored). All three factors are to be considered in arriving at an overall impact score. Since January 2020, progress toward these changes has included input gathering, establishment of two CSR Advisory Council working groups, provision of legal and regulatory guardrails, establishment of NIH working groups, IC and NIH leadership approval, and public input via an RFI. Next steps toward implementation include issuing a *Guide* notice announcing changes and obtaining higher-level approvals; changes to eRA systems; and development and dissemination of training/outreach resources to socialize the change for reviewers, chairs, applicants, and staff. Implementation of the new peer review framework is scheduled for 2025 (i.e., applications received in January for funding consideration during October councils).

The goal for improving review of NRSA Fellowships is to optimize identification the most promising trainees and the individualized training programs that will help them become outstanding scientists of the next generation. This effort arose in response to concerns from the scientific community that NIH may be leaving out very promising research scientists because of a process that favors elite institutions and senior, well-known sponsors. An analysis of over 6,000 applications supported those concerns, demonstrating that many NRSA applications are submitted by a small number of institutions, applications from institutions that submit fewer NRSA applications have worse review outcomes, and review outcomes improve as academic rank of the sponsors rise. Recommended changes to NRSA Fellowship review criteria reflect a shift in focus to scientific potential, fellowship goals, and applicant preparedness; science and scientific resources; and the training plan and related resources. In addition, the fellowship application has been revised to eliminate grades and financial support from the sponsor; changes will eliminate the use of boilerplate language so often seen in letters of support and allow for an optional statement of special circumstances. Progress toward implementation of these criteria began in September 2021; implementation

is planned for 2025.

Steps to promote fairness in review have included annual chair orientation sessions in the summer, reviewer bias awareness training (introduced in August 2021) and review integrity training that will be required for all NIH reviewers beginning with February/March 2024 review meetings, and a direct bias reporting mechanism overseen by CSR Chief Diversity Officer Dr. Gabiel Fosu.

CSR strategies for diversifying review panels include emphasizing the critical need for NIH to hear diverse perspectives toward identifying the best, most disruptive, novel science; recognizing that the most effective, highest-quality review committees are broadly diverse in multiple dimensions (i.e., scientific background and perspective, demographic/geographic, career stage, and peer review experience); raising collective awareness, setting expectations, and sharing panel-level data with management and staff; providing tools for scientific review officers (SROs) to find qualified reviewers; and ensuring that the standing study section membership process is thorough, with multiple levels of oversight and approval.

Discussion

Dr. Zenk noted that all Council members will be invited to complete the CSR bias training for reviewers.

Dr. Lee led the discussion, expressing appreciation for the training initiatives and the formal direct bias reporting mechanism. He asked whether CSR has considered random auditing or formal direct feedback to SROs or reviewers on how they use skills gained through the training. Has CSR considered using technologies to automate detection of bias? Dr. Byrnes noted that SRO evaluations are quite rigorous, and senior CSR staff attend meetings and provide feedback; indeed, most bias reports that lead to a re-review come from the SROs. The CSR Division of Data and Technology has developed and is testing ML-based methods to flag issues in critiques, which will be validated by a human.

Dr. Lee asked about the response to the decision not to score RPG factor three (expertise and resources). Dr. Byrnes noted that the distribution was normal, with the middle group agreeing that it was a good idea. Others supported fully blinding reviews, which is extremely labor-intensive and impractical, as demonstrated by an ongoing partial blinding experiment for transformative R01s. Factor three does impact the overall score. In her opinion, a 9-point score scale is not necessary to take the investigator expertise and resources into account. Another Council member commented on the importance of the environment for community-based work. Dr. Byrnes agreed that environment will be evaluated within the context of the proposed project using the drop-down (i.e., gaps identified), which will affect the overall score.

Dr. Lee asked about the status of new study sections on mobile health and SDOH. Dr. Byrnes responded that most of the 13 study-section clusters have been implemented. She noted that one of the first new study

sections implemented in 2020 on clinical care in different settings is relevant to NINR and seems to be functioning well.

A Council member commented that these changes will have an impact on the way grants are written and asked about training for the external research community relevant to changes in application structure, etc. Dr. Byrnes noted that changing application structure is a longer-term step that requires approval from the Office of Management and Budget. Over the next 18 months, a variety of webinars and other training opportunities will be offered to socialize changes across the broader community.

VII. IMPLEMENTING A MATERNAL HEALTH AND PREGNANCY OUTCOMES VISION FOR EVERYONE (IMPROVE) INITIATIVE

Dr. Diana Bianchi, Director, NICHD, NIH

Dr. Bianchi provided an overview of NICHD, including its mission: leading research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. Research themes in the NICHD 2020 strategic plan include understanding the molecular, cellular, and structural basis of development; promoting gynecologic, andrologic, and reproductive health; setting the foundation for healthy pregnancies and lifelong wellness; improving child and adolescent health and the transition to adulthood; and advancing safe and effective therapeutics and devices for pregnant and lactating women, children, and people with disabilities.

Co-chaired by NINR, NICHD, and ORWH, the [IMPROVE Initiative](#) is an NIH-wide effort designed to address the U.S. maternal morbidity and mortality crisis. According to the Centers for Disease Control and Prevention (CDC), 84% of pregnancy-related deaths are preventable; their causes vary across racial and ethnic categories; and maternal mortality increased by 29% from 2019 to 2020. More than 2.2 million women in the U.S. live in [maternity care deserts](#).

IMPROVE goals include reducing preventable causes of maternal morbidity and mortality; addressing disparities in maternal health outcomes; expanding implementation of evidence-based maternal healthcare practices before, during, and after pregnancy; building research capacity in community-based organizations; promoting access to maternal healthcare with innovative technology; and enabling real-world research with EHR standards.

During FY 2020 and 2021, more than \$20 million in IMPROVE supplements supported 58 projects. IMPROVE received a \$30 million appropriation in FY 2022. Programs conducted in FY 2022 and 2023 included a Connectathon focused on developing EHR standards for pregnancy to enable real-world research; a dissemination and implementation science NOSI ([NOT-HD-22-043](#)) to inform policy and

practice interventions across pre-pregnancy, pregnancy, and postpartum care; and RADx® Tech for Maternal Health to funnel technology toward development of home-based or point-of-care diagnostics to extend care to maternal care deserts. Additional activities included the Connecting the Community for Maternal Health Challenge program to build effective research infrastructure and capacity in communities; the Community Implementation Program to enable adoption and integration of effective interventions into community settings; and establishing Maternal Health Research Centers of Excellence (CoE) to develop, implement, and evaluate community-tailored interventions to address disparities in maternal health.

The [RADx Tech for Maternal Health Challenge](#) prioritized home-based or point-of-care diagnostic devices, wearables, and other remote sensing technologies to extend postpartum care in maternal care deserts. Up to \$8 million has been awarded through several phases. The top Challenge Innovator Teams submitted projects involving vital sign monitoring, UTI diagnostics, digital screening for maternal mental health risk, and AI determination of risk for suicide and postpartum depression.

The [Connecting the Community for Maternal Health Challenge](#) is a \$3 million competition to encourage U.S. community-based and advocacy organizations to develop the infrastructure and capabilities necessary to conduct maternal health research. Participating organizations will receive training and mentoring in writing research proposals and building maternal health research infrastructure. Proposal phase winners (announced in June) are exploring doula care, maternal morbidity risk prediction, and peer support to improve maternal mental health. Final winners will be announced in September 2024.

The IMPROVE Community Implementation Program (IMPROVE CIP, [OTA-20-014-C](#)) is looking at community-informed and -engaged implementation strategies. Awardees include Arizona State University (indigenous, Black, Latinx communities), University of Nebraska Medical Center (Winnebago Tribe), and Texas Tech University Health Sciences Center (underserved women in rural and urban counties in the Panhandle region) are looking at doulas, kinship involvement to improve outcomes, and cardiovascular complications.

The [CoEs announced last month](#) will design and implement research projects to address the biological, behavioral, environmental, sociocultural and structural factors that affect pregnancy-related complications and deaths. Ten COE institutions are supported by a data innovation and coordinating hub at Johns Hopkins University and an implementation science hub at the University of Pennsylvania. CoEs are exploring a broad range of conditions, different time points, novel approaches, SDOH, and underserved populations.

Dr. Bianchi presented highlights from the NICHD research portfolio, which covers pediatrics (55%), reproductive health (30%), and intellectual and developmental disabilities and rehabilitation (18%). She described the opioid-exposed neonates [Eat, Sleep, Console \(ESC\) study](#) that reported a reduced hospital

stay and a significant reduction in the neonates' need for medication; no adverse outcomes were observed at follow up. A follow up for developmental effects is planned at 2 years of age.

The Maternal Fetal Medicine Units (MFMU) Network includes 14 sites that conduct collaborative, multisite clinical trials and observational studies involving newborns and lactating people to inform maternal healthcare practices. This mature network has shown interest in approaches and technologies arising from IMPROVE, suggesting opportunities for cross-fertilization.

The Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) is tasked with identifying and addressing knowledge gaps regarding safe and effective therapies and vaccines for pregnant and lactating women. Established in 2016, PRGLAC issued [15 recommendations](#) in 2018 and delivered an implementation plan in 2020. Recommendations focused on changing the existing culture of protecting pregnant women *from* research to protecting pregnant people *through* research, removing pregnant women as a vulnerable population through the Common Rule, removing regulatory barriers, and expanding the workforce of clinicians and researchers with expertise in obstetric and lactation pharmacology and therapeutics.

The Maternal and Pediatric Precision in Therapeutics ([MPRINT](#)) Hub is a national resource to expand available knowledge, tools, and expertise in maternal and pediatric therapeutics to the broader research, regulatory science, and drug development communities. MPRINT provides ways to study pharmacodynamics and pharmacokinetics in pregnant and lactating people who are taking medications for their own health.

Discussion

Dr. Fitzpatrick led the discussion, acknowledging that maternal morbidity rates had not been on her radar until recently despite her state (Georgia) having one of the worst maternal morbidity outcomes in the nation. She applauded the IMPROVE effort as timely, important, and particularly appropriate for community engagement. She asked about common data element (CDE) collection across the portfolio.

Dr. Bianchi noted that the NIH-wide N-PeRC (the NIH Pediatric Research Consortium) collaborated on CDEs that were collected for children and pregnant people for COVID-19 research. The IMPROVE data hub will be responsible for establishing CDEs to ensure that the 10 funded groups can collaborate and share data.

Dr. Fitzpatrick asked about research following children who survive their mothers. Dr. Bianchi noted that other NICHD programs focus on trans-generational health, including epigenetic factors, where people live, and more. She noted that the rising consciousness about maternal health is due, in part, to more women in Congress and to tragic pregnancy complications experienced by female athletes that have received a lot of

attention.

VIII. CONCEPT PRESENTATION: Understanding and Addressing the Intersection of Social Inequities to Advance Health: The Axes Initiative

Dr. Shalanda A. Bynum, Program Director, NINR

Dr. Zenk noted that Council is a source of non-government advice on NINR's direction and long-term planning. Concept clearance is the earliest planning stage of an initiative prior to release of a Request for Applications (RFA), Program Announcement, or contract. Concepts describe background objectives and potential funding mechanisms for an initiative. An approved concept may become a funding initiative, depending on several factors, including availability of funds.

Dr. Bynum introduced a concept focused on the intersection of social statuses that society has marginalized. SDOH—conditions in which people are born, work, play, live, and age and the wider set of structural factors shaping conditions of daily life—play a key role in determining trajectories of health and illness at intersections of marginalization. Closing scientific gaps in our understanding of intersectionality will require research methods suited to identifying complex pathways through which SDOH determine individual and population health.

The Axes Initiative aims to advance research to understand and address the impact of SDOH at intersections of social statuses (e.g., race, ethnicity, gender identity, socioeconomic, sexual orientation, immigration, ability) that have been marginalized. Populations of focus for this concept include those who experience health disparities and intersectional marginalization.

The Initiative may include observational, interventional, or training objectives. The proposed Initiative advances NINR's holistic approach to optimizing health for all.

Discussion

Dr. Atkins led the discussion, describing the proposed concept as innovative and thought-provoking and applauded NINR's growing interest in SDOH research. He highlighted a connection between the Axes Initiative concept and communities of greatest disinvestment (i.e., the Rust Belt, Appalachia, Tribal lands) and how opportunity is conferred through place. He asked how to bring these places or communities into the conversation about SDOH and intersectionality. Dr. Bynum responded that current intersectional research has focused on a narrow set of intersections, leaving much room to expand the scope toward understanding community needs in those places. She commented on the importance of understanding how systems, forces, and structures advantage some people and disadvantage others.

Another Council member pointed out shared community resources as assets rather than deficits. Dr. Bynum

agreed that communities do have assets that act as buffers that serve to mitigate experiences that people encounter. This will be an important consideration in this concept.

IX. COUNCIL OPEN DISCUSSION

None.

Adjournment

Dr. Zenk thanked the meeting attendees and adjourned the open session of the meeting at 2:38 p.m.

X. CLOSED SESSION

This portion of the meeting was closed to the public in accordance with the determination that this session concerned matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5, USC Appendix 2). Dr. Tarlov reminded members of the requirement to leave the room prior to discussion and voting on any application with which they are in conflict and instructed them to speak up if they are in conflict if staff have not already identified them as being in conflict, and staff will move them to a waiting room (virtual or physical). Members were asked to sign and submit a conflict-of-interest statement at the conclusion of the meeting.

Review of Applications

Dr. Tarlov provided a report on votes of early concurrence on two sets of applications that took place in August. Council members Dr. Fitzpatrick and Dr. Provencio-Vasquez provided concurrence for 40 applications to RFA-OD-23-005, NIH Research Evaluation and Commercialization Hubs (REACH) Awards (U01 Clinical Trial Optional). The REACH program is a partnership program between NIH and the qualifying research institutions to accelerate the creation of small businesses and the transition of discoveries originating from academic research into products that improve patient care and enhance health. NINR participates in REACH by contributing to the funding of one or more applications. In addition to votes indicating concurrence with the results of the peer review process registered by Dr. Fitzpatrick and Dr. Provencio-Vasquez, no advisory votes were cast by other Council members. No applications were identified by Council members for discussion at this NACNR meeting.

Council members Dr. Johnson and Professor Dawes provided concurrence for 22 applications to RFA-NR-23-004, Clinical-Community Linkages to Address Social Needs and Social Conditions to

Advance Health Equity among Populations Experiencing Health Disparities: The Bridge-to-Care Initiative (R01 Clinical Trial Required). The purpose of the Bridge-to-Care initiative is to promote research that links clinical care with community resources to address the social circumstances and conditions that limit the optimization of health. In addition to votes indicating concurrence with the results of the peer review process registered by Dr. Johnson and Professor Dawes, one advisory vote was cast by other Council members. No applications were identified by Council members for discussion at this NACNR meeting.

Council members considered 94 research and training grant applications on which NINR was the primary Institute; these applications requested a total of \$78,194,322 (direct costs year 01). The Council also considered 146 applications on which another Institute/Center was primary and NINR was secondary. The Council concurred with the Institutional Review Group recommendations on these 240 applications. All applications (including those for which early concurrence was obtained) requested a total of \$90,130,264 (direct costs year 01).

ADJOURNMENT

The 111th meeting of the NACNR was adjourned at 3:02 p.m. on Tuesday, September 12, 2023.

CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete.



Shannon N. Zenk, PhD, MPH, RN

Chair

National Advisory Council for Nursing Research



Elizabeth Tarlov, PhD, RN

Executive Secretary

National Advisory Council for Nursing Research

COUNCIL MEMBERS PRESENT

Dr. Shannon N. Zenk, Council Chair

Dr. Elizabeth Tarlov, Executive Secretary

Dr. Robert L. Atkins

Dr. Guadalupe X. Ayala

Prof. Daniel E. Dawes

Dr. Anne M. Fitzpatrick

Dr. Christopher Lee

Dr. Cindy L. Munro
Dr. Patricia W. Stone
Dr. Cubby L. Gardner, *Ex Officio*
Dr. Sheila Cox Sullivan, *Ex Officio*

NIH STAFF PRESENT at OPEN SESSION

Olga Acosta
Frances Bevington
Libbey Bowen
Cheryl Boyce
Edmond Byrnes
Noni Byrnes
Shalanda Bynum
William Duval
Dionne Godette-Greer
John Grason
Susan Gregurick
Lily Gross
Cheryl Howard
Karen Huss
Karen Kehl
Kristin Kramer
Jo-Ann Kriebel
Sylvia Long
Mia Rochelle Lowden
Tanna Nelson
Liz Perruccio
Wendy Pond
Alex Ross
Mayra Saintilus
Will Thompson
David Tilley
Pooja Varma
Sarah Yoon

The open session was held in person and via NIH videocast. All observers, including members of the public, attended virtually.

NIH STAFF PRESENT at CLOSED SESSION

Olga Acosta
Anita Ambs
Frances Bevington
Shalanda Bynum
Hristina Denic-Roberts

William Duval
John Grason
Karen Huss
Karen Kehl
Jo-Ann Kriebel
Liz Perruccio
Samantha Sanchez
David Tilley
Sarah Yoon

The closed session was held in-person.