Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Advisory Child Health and Human Development (NACHHD) Council

Meeting Summary

6710B Rockledge Drive, Rooms 1425 and 1427

Bethesda, MD

June 3–4, 2024

U.S. Department of Health and Human Services (HHS)

National Institutes of Health (NIH)

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

The NACHHD Council convened its 185th meeting at 10:00 a.m. ET on Monday, June 3, 2024, at 6710B Rockledge Drive, Rooms 1425 and 1427, in Bethesda, Maryland. It was a hybrid meeting that was open to the public from 10:00 a.m. to 5:00 p.m. ET. The Council reconvened on Tuesday, June 4, 2024, for another session open to the public from 8:30 a.m. to 9:15 a.m. ET. The Council then met in a session that was closed to the public from 9:30 a.m. to 12:30 p.m. ET. As provided in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of Public Law 92-463, sessions for the review, discussion, and evaluation of grant applications and related information are closed to the public. NICHD Director Diana W. Bianchi, M.D., presided.

Council Members Present[1]

Diana W. Bianchi, M.D. (Chair)
Anna Aizer, Ph.D., M.S.
Shari L. Barkin, M.D., MSHS
Susan L. Brooks, J.D.
Christina M. Bucci-Rechtweg, M.D. (virtual)
Marcelle Ivonne Cedars, M.D.
Damien Fair, Ph.D.
Cynthia Gyamfi-Bannerman, M.D.
Ethylin Wang Jabs, M.D.
Catherine E. Lang, Ph.D.
Yvonne A. Maldonado, M.D.
Genevieve S. Neal-Perry, M.D., Ph.D. (virtual)
David H. Rowitch, M.D., Ph.D.
Ignatia Barbara Van den Veyver, M.D.

Council Members Absent

None

Ex Officio Members

Patricia Dorn, Ph.D.

Department of Defense

Gayle Vaday, Ph.D.

Health Resources and Services Administration

Rui Li, Ph.D.

Executive Secretary

Rebekah Rasooly, Ph.D.

National Advisory Board on Medical Rehabilitation Research Council Liaison

José L. Contreras-Vidal, Ph.D.

In each section of this meeting summary, the number in parentheses following each heading refers to the time stamp on either the Day 1 NIH VideoCast or the Day 2 NIH VideoCast; please go to that point in the recording to listen to the full presentation.

[1] Council members absent themselves from the meeting when the Council discusses applications from their own institutions or when a conflict of interest might occur. The procedure applies only to individual applications discussed, not to en bloc actions.

I. Call to Order and Introductory Remarks (0:04)

Dr. Bianchi opened the meeting and welcomed the members of the NACHHD Council and all in-person and online attendees. She asked two new Council members, Cynthia Gyamfi-Bannerman, M.D., and Gayle Vaday, Ph.D., to briefly introduce themselves.

Dr. Gyamfi-Bannerman is a maternal-fetal medicine specialist and professor and chair of the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of California San Diego School of Medicine. Her primary research focus is on preterm birth.

Dr. Vaday is the civilian deputy director of the Congressionally Directed Medical Research Programs (CDMRP), a part of the Department of Defense. CDMRP offers funding opportunities for a wide range of congressionally directed research topics.

Review of Confidentiality and Conflicts of Interest (2:17)

Rebekah Rasooly, Ph.D., the Council's executive secretary, reminded NACHHD Council members that they are required to read, agree to, and sign the confidentiality and nondisclosure rules for special government employees on the Council member website before evaluating any NIH grant applications. Before the meeting, Council members received and signed the required conflict-of-interest certification forms. Dr. Rasooly also reminded Council members that they are required to recuse themselves and leave the meeting before any discussion that involves organizations or universities for which they are in conflict, in addition to those listed in the Council action document. Council members are not allowed to serve on any NIH peer review panel while serving as Council members, because NIH policy indicates that individuals may not serve on both the first and second levels of peer review. Furthermore, during closed sessions, Council members must turn off cloud-based voice services (e.g., Alexa) that are capable of capturing confidential information.

Council Minutes (3:34)

Shari L. Barkin, M.D., made a motion to approve the January 22–23, 2024, NACHHD Council meeting minutes as written. Catherine E. Lang, Ph.D., seconded the motion. Council members voted to approve the minutes.

Future Meeting Dates (4:48)

Dr. Rasooly announced that the future Council meetings are scheduled for September 4–5, 2024 (NIH Bethesda Campus, Building 35A on September 4 and 6710B Rockledge Drive on September 5); January 13–14, 2025 (virtual); June 9–10, 2025 (6710B Rockledge Drive); September 8–9, 2025 (NIH Bethesda Campus, Building 45); January 26–27, 2026 (virtual); June 8–9, 2026 (6710B Rockledge Drive); and September 1–2, 2026 (NIH Bethesda Campus, Building 45).

II. NICHD Director's Report (5:41)

In her report, Dr. Bianchi described the president's fiscal year (FY) 2025 budget and recent NICHD congressional interactions, announced NICHD's strategic planning goals, discussed ongoing women's health research initiatives, reviewed the latest pediatric research, provided updates on key NIH programs and policies, and gave several kudos and staff updates.

President's FY 2025 Budget and Congressional Interactions (7:10)

President Biden's proposed budget for FY 2025 includes $50.1 billion for NIH and $1.77 billion for NICHD. In women's health research, the President is proposing to develop a new nationwide network of centers of excellence and innovation in women's health and to double the amount of funding for the NIH Office of Research on Women's Health. Several topics of interest to NICHD were raised at the May 23 U.S. Senate Appropriations Labor, Health and Human Services, Education, and Related Agencies Subcommittee hearing, and it was a positive hearing.

Dr. Bianchi recently interacted with several members of Congress about NICHD initiatives. She met with U.S. Rep. Lauren Underwood (D-IL) to discuss menopause and maternal health research and U.S. Rep. Julia Letlow (R-LA) to discuss maternal health and women's health research. U.S. Rep. Robin Kelly (D-IL) and U.S. Rep. Jan Schakowsky (D-IL) both attended Dr. Bianchi's presentation on the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative and maternal mortality at the Women's Congressional Policy Institute. Additionally, ACT for NIH: Advancing Cures Today held a 10th-anniversary event that was attended by about 25 members of Congress and provided ample networking opportunities, including time with U.S. Rep. Rosa DeLauro (D-CT), the ranking member of the U.S. House Appropriations Committee and its Labor, Health and Human Services, Education, and Related Agencies Subcommittee. On May 23, 2024, U.S. Rep. Nikema Williams (D-GA) led the introduction of the Endometriosis CARE Act, which would deliver $50 million annually to advance endometriosis research and expand access to treatment.

Furthermore, NICHD staff met with congressional staff from the offices of U.S. Rep. Juan Ciscomani (R-AZ) (to discuss gynecologic health and disease research, NICHD's major clinical trial networks, and the use of pharmaceuticals during pregnancy); U.S. Rep. Katherine Clark (D-MA) (to discuss women's health research); U.S. Rep. Anna Eshoo (D-CA) (to discuss challenges in pediatric drug development); and U.S. Sen. Tim Scott (R-SC) (to discuss neonatal opioid withdrawal, maternal health, the IMPROVE initiative, and the Rapid Acceleration of Diagnostics Technology [RADx® Tech] for Maternal Health Challenge).

NICHD Strategic Planning (12:00)

NICHD's research portfolio is currently divided among pediatrics (55%), reproductive health (30%), and intellectual and developmental disabilities and rehabiltation (15%). NICHD has begun working on its 2025 Strategic Plan, which was last published in 2020 and

spans 5 years. The five scientific research themes and objectives in the 2020 Strategic Plan are as follows:

- 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
- Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities

Over the past several years, NICHD has made tremendous progress toward linking its funding opportunities to these themes. The 2025 Strategic Plan will continue to address NICHD's research, stewardship, management, and accountability goals. The institute has been documenting and tracking activities and achievements toward its current objectives and will begin refreshing the Strategic Plan over the next year. A Request for Information (RFI) to solicit feedback from the public should be issued in August 2024; the updated Strategic Plan is expected to be released in spring 2025.

Women's Health Research (16:44)

NICHD conducts women's health research in each of the following "below the belt" areas:

- Gynecologic health and disease
- Contraception research
- Fertility and infertility
- Pregnancy and perinatology
- Maternal and pediatric infectious disease
- Obstetric and pediatric pharmacology and therapeutics
- Population dynamics

Dr. Bianchi provided updates on the White House Initiative on Women's Health Research, an endometriosis research RADx® Tech challenge, and the IMPROVE initiative. Each of these programs addresses women's health research in some way. She later noted that NICHD communications staff have created a new series of one-page summaries on women's health topics. These summaries have been particularly helpful in congressional meetings.

White House Initiative on Women's Health Research (17:55)

On March 18, 2024, President Biden issued an Executive Order on Advancing Women's Health Research and Innovation. This cross-government initiative is being championed by the first lady, Dr. Jill Biden. It was designed to promote collaborative, interdisciplinary research; to assess unmet needs in women's health research; and to develop a research agenda and common data elements (CDEs) related to menopause. To date, NIH actions related to the executive order have included the following:

- Issuing a Notice of Special Interest on Women's Health Research

- Developing a list of all NIH grant opportunities related to women's health research

Whether Congress will appropriate the funding that is proposed in the White House Initiative on Women's Health Research is not known.

Endometriosis (20:16)

One of NICHD's 10 Aspirational Goals in its 2020 Strategic Plan is to "Accelerate efforts to definitively diagnose, prevent, and treat endometriosis, a disease that affects an estimated 10% of women in the United States and results in chronic pain, infertility, and a higher risk of some cancers."

Affecting nearly 1 in 10 women from all races and backgrounds, endometriosis is difficult to diagnose, in part because of wide-ranging symptomatology that overlaps with other conditions. No reliable blood test or other noninvasive diagnostic tool for endometriosis currently exists. Because gold-standard diagnosis currently depends on laparoscopic visualization, clinicians instead rely on medical history, physical examination, and imaging studies that cannot detect most forms of endometriosis. Despite the prevalence and severe impact of this disorder on quality of life, a diagnosis of endometriosis can be delayed up to 10 years.

To address this major innovation gap, NICHD is proposing a RADx® Tech challenge to develop reliable noninvasive tests that (1) enable early and accurate diagnosis of endometriosis and (2) facilitate the treatment of endometriosis. The RADx® Tech challenge will be called the Advancing Cures and Therapies and ending ENDOmetriosis diagnostic delays (ACT ENDO) challenge.

To be launched in late summer 2024, ACT ENDO will be a partnership between NICHD and the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to leverage the RADx® Tech innovation funnel program. Its goals will be to accelerate the time to diagnosis, eliminate the invasiveness of current techniques, and/or improve accessibility, safety, convenience, and cost of diagnosis. Example approaches might include the following:

- The use of new or existing biomarkers from serum, saliva, or menstrual effluent
- Distinguishing between benign and malignant endometriosis
- The analysis of epigenetic or genomic data with machine learning (ML) to diagnose early disease states

IMPROVE Initiative (24:21)

The IMPROVE initiative has now set up 10 Maternal Health Research Centers of Excellence, a data hub, and an implementation science hub. The initiative's two current challenges are both expecting to have final winners announced this fall.

- The RADx® Tech for Maternal Health Challenge is a competition to develop diagnostics for postpartum monitoring in maternity care deserts. Final winners will be announced in October 2024.
- The Connecting the Community for Maternal Health Challenge is designed to build research infrastructure in communities and teach community-based advocacy groups how to be competitive when applying for funding opportunities. Final winners will be announced in September 2024.

The IMPROVE Community Implementation Program (IMPROVE-CIP) is supporting research to increase intervention uptake in community settings. IMPROVE-CIP was designed to support community-engaged implementation research to address factors that contribute to maternal death and severe illness, including mental health issues, substance use, psychosocial influences, and social and structural determinants of health. IMPROVE is also developing electronic health record (EHR) standards for pregnancy to enable real-world research.

Pediatric Research (26:22)

NICHD conducts pediatric research in each of the following areas:

- Developmental biology and congenital anomalies
- Child development and behavior
- Intellectual and developmental disabilities
- Pediatric growth and nutrition
- Pediatric trauma and critical illness
- Maternal and pediatric infectious disease
- Obstetric and pediatric pharmacology and therapeutics
- Population dynamics

Dr. Bianchi provided updates on the April 2024 Impact of Technology and Digital Media on Child and Adolescent Development and Mental Health workshop, the *All of Us* Research Program's pediatric enrollment plan, a pediatric medical devices public-private partnership (PMD-PPP), and the NIH Pediatric Research Consortium (N-PeRC). Each of these programs addresses pediatric research.

Effects of Technology and Digital Media Use on Children (26:53)

On April 4 and 5, 2024, NICHD and the National Institute of Mental Health (NIMH) co-sponsored a workshop titled the Impact of Technology and Digital Media on Child and Adolescent Development and Mental Health. Attendees discussed the current state of and future directions for research, and the positive and negative effects of technology and digital media on developmental and mental health outcomes. The VideoCast recordings and the agenda, which is annotated with VideoCast time stamp locations for each session, are now available. A white paper identifying new research opportunities for this topic will be forthcoming.

All of Us Research Program (27:46)

The *All of Us* Research Program identified the enabling of pediatric participation as its number one program priority for 2023–2024. Thus far, the program has recruited a pediatric team, completed its pediatric protocol, and garnered Institutional Review Board approval for enrolling babies of currently enrolled pregnant people. It is further developing pediatric surveys, identifying its pediatric enrollment sites, training staff, and testing its systems for pediatric enrollment. Unfortunately, an FY 2024 $184 million budget cut has now slowed progress. NICHD is working with *All of Us* to offer as much support as possible, and Dr. Bianchi serves on the *All of Us* Research Program's Executive Committee.

N-PeRC (30:22)

The NIH Pediatric Research Consortium (N-PeRC) was established in 2018 to increase collaboration and coordination of pediatric research across NIH. Its accomplishments thus far have included the following:

- Holding a recent workshop and issuing a Notice of Special Interest on the transition from adolescent to adult health care
- Identifying issues, developing CDEs, and securing funding for pediatric research on COVID-19
- Establishing a collaboration with the Helping to End Addiction Long-term® Initiative, or HEAL Initiative®, for pediatric pain research
- Promoting a standardized approach for conducting pediatric clinical trials
- Helping address the crisis in the pediatric research workforce
- Forming the PMD-PPP

PMD-PPP (31:42)

A new PMD-PPP is now in the design phase. Information about the program's many government and private sector partners can be found on the PMD-PPP website. The PMD-PPP seeks to address the problem of PMD approval lagging behind approval for adult devices. It aims to do the following:

- Consolidate a national ecosystem to accelerate advancements in medical devices designed, evaluated, and approved for pediatric populations.
- Derisk and streamline processes enabling translation of medical advances from bench to bedside for medical devices for children.
- Ultimately address the lack of access to medical device options designed and approved for the pediatric population.

Together with the Foundation for NIH (FNIH), NICHD's Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB) is taking a leadership role in this critical program.

NIH Program and Policy Updates (32:53)

Dr. Bianchi shared updates on a new NIH program to support clinical research in primary care settings, the increases in pre- and postdoctoral research fellow stipends, and the newly simplified review framework for research project grants.

Clinical Research in Primary Care Settings (33:20)

Conducting clinical research in primary care settings is one of the priorities of new NIH Director Monica M. Bertagnolli, M.D. The NIH Common Fund is therefore seeking to establish a disease-agnostic primary care–focused clinical research network to facilitate clinical research in mission areas across all 27 NIH Institutes and Centers and NIH Offices (ICOs). The goals are to (1) integrate innovative research with routine clinical care in real-world settings and (2) create a foundation for sustained engagement with communities underrepresented in clinical research. The program will initially receive funding from the Office of the Director (OD) (i.e., $5 million in FY 2024, $25 million in FY 2025); after feasability and budget requirements are assessed, it will receive $50 million to $100 million per year. The program will be launched in 2024, with an initial research opportunity announcement due date of June 14.

Pre- and Postdoctoral Research Fellow Stipends (35:15)

In FY 2024, stipends for extramural trainees will be raised. Predoctoral trainees stipends will increase by approximately 4% compared with last year; stipends for postdoctoral sholars will go up by about 8%. This is the most substantial year-over-year increase since FY 2017. NIH selected the current plan to allow for an immediate pay increase without drastically cutting the number of available National Research Service Awards, although a small reduction in the number of positions is expected. As appropriations and budget realities allow, the NIH goal is to reach the NIH Advisory Committee to the Director's recommended stipend levels in the coming years (around $70,000 per year for postdoctoral scholars). Additionally, the child care subsidy will be increased by $500 (from $2,500 to $3,000 per scholar) in FY 2024.

Simplified Review Framework for Research Project Grants (36:51)

In the NIH's newly simplified review framework for evaluating research project grants, investigators and environments will now be evaluated as "sufficient" or "gaps identified." This part of the evaluation will be considered in the overall impact score but not in the individual score. Additional review criteria related to human subjects (e.g., inclusions, study timeline) will now be evaluated within Factor 2, for more rigorous review. Most additional review considerations will be shifted from reviewers to NIH staff. These changes will apply to applications submitted for January 25, 2025, due dates and beyond. These changes to the grant review process were made to facilitate the overarching goal of peer review: identification of the strongest, potentially highest-impact research.

Kudos (38:05)

Gisela "Gigi" Storz, Ph.D., an NIH Distinguished Investigator at NICHD, has been elected as a fellow of the American Association for the Advancement of Science. Dr. Storz, who leads NICHD's intramural Section on Environmental Gene Regulation, was honored for "distinguished contributions to the field of microbiology, particularly on the role of noncoding RNAs in gene regulation and on mechanisms of the oxidative stress response in bacteria and yeast."

NIH and NICHD Staff Updates (38:51)

Sean Mooney, Ph.D., has been selected as the new Director of the NIH Center for Information Technology. Kathryn Neuzil, M.D., M.P.H., is the new Director of the Fogarty International Center. The vacancy for the directorship of the National Library of Medicine position has been posted, and the Director of NIMH, Joshua A. Gordon, M.D., Ph.D., recently announced his resignation and plans to return to Columbia University as the chair of the Department of Psychiatry.

NICHD currently has job openings for extramural branch chiefs, program officers, and policy officers and for intramural laboratory postdoctoral fellows and trainees.

Discussion (41:22)

Dr. Barkin thanked Dr. Bianchi for her leadership and asked how NICHD can become more involved in the *All of Us* Research Program, noting that it provides so much opportunity for pediatric research, which currently represents just under 25% of the U.S. population. Dr. Bianchi said that *All of Us* has already made great progress in setting up pediatric enrollment, so the congressional budget cuts have been devastating. She encouraged Council members to contact their congressional representatives and senators to discuss funding this important program. NIH Institutes and Centers (ICs) will contribute to the program if possible, but they will be unable to make up the $184 million that was cut. Dr. Barkin asked if N-PeRC could help with *All of Us.* Dr. Bianchi said that the director of pediatrics for *All of Us,* Sara Van Driest, M.D., Ph.D., was a member of N-PeRC. In a later comment (at 1:07:28), José L. Contreras-Vidal, Ph.D., said that it might be possible for *All of Us* to form partnerships with industry or foundations, or to take public donations. Dr. Bianchi said that industry partners have been included in the PMD-PPP and other NICHD projects, and that FNIH is committed to creating such partnerships. Alison Cernich, Ph.D., added that NICHD cannot solicit charitable donations for its gift fund, but it can receive them.

Marcelle Ivonne Cedars, M.D., said that she was pleased to see the increase in salaries for postdoctoral research fellows. She asked for clarification on whether fewer physician-scientists would be funded because of the change. Dr. Bianchi said that fewer *positions* would be funded.

Beyond the possible future funding of the White House Initiative on Women's Health Research, Ethylin Wang Jabs, M.D., asked how much of the current NIH budget was allocated to funding women's health research. Dr. Bianchi said that although $4 billion to $5 billion has been allocated solely for women's health research, the total amount has been difficult to measure accurately because many studies enroll all genders. New analytics are being implemented to more accurately break down the numbers and monitor trends. Furthermore, discussions are underway about which topics should be included in women's health research (e.g., conditions such as Alzheimer's disease are more common in women). Patricia Dorn, Ph.D., asked for clarification on how women's participation in studies that affect all genders could be quantified. Dr. Bianchi said that government-wide discussions are taking place. Dr. Cernich added that various programs and policies are tracked and coordinated separately, so different issues are being approached in different ways. There are opportunities to improve the way that women's health research is funded, tracked, and considered.

Regarding Dr. Bianchi's comment that NICHD's research portfolio is currently divided among pediatrics (55%), reproductive health (30%), and intellectual and developmental disabilities and rehabiltation (15%), Dr. Gyamfi-Bannerman asked whether those percentages had evolved over time. Dr. Bianchi said they had: The percentages have evolved based on the priorities of each NICHD director and the evolution of knowledge on each of these topics. Most recently, the percentage of research on reproductive health has increased. In a later question (at 58:21), Dr. Cedars asked how much of the reproductive health portfolio was dedicated to non-pregnancy–related women's health. Dr. Bianchi said that it was a considerable amount, because the Gynecologic Health and Disease Branch has been growing (e.g., it oversees the ACT ENDO initiative, pelvic floor disorders, uterine fibroids, polycystic ovarian syndrome) and building interdisciplinary collaborations with other ICs. The Fertility and Infertility Branch (FIB), the Contraception Research Branch, and a few other branches also study non-pregnancy–related topics.

Anna Aizer, Ph.D., asked how social determinants of health (SDOH) were incorporated into the NICHD research portfolio for women's health and pediatric research. Dr. Bianchi said that SDOH were included in each of NICHD's research themes and that health disparities were included as a cross-cutting theme in the previous Strategic Plan. These will continue to be included in the subtopic areas of the Strategic Plan. Dr. Aizer asked a follow-up question about how social outcomes of research are considered to be outcomes of health research and health interventions. Dr. Bianchi said that later in the day, Jane Simoni, Ph.D., would present the work of the NIH Office of Behavioral and Social Sciences Research (OBSSR).

Genevieve S. Neal-Perry, M.D., Ph.D., asked whether NICHD would include or expand on the study of menopause and perimenopause in its women's health research portfolio. Dr. Bianchi said that there is tremendous congressional interest in studying menopause and that Dr. Bertagnolli has noted this interest. NICHD has also had preliminary discussions with the National Institute on Aging (NIA), the institute that currently funds most of the research on menopause. NICHD is currently funding a study on early menopause, but the hope is that more interest will translate to increased funding and further opportunities. Dr.

Neal-Perry said that menopause has sometimes seemed like a topic that does not have a research home at NIH because it does not fall under the category of maternal health or into an age range of particular interest to NIA.

Dr. Gyamfi-Bannerman described difficulties in securing funding for obstetric studies that have a well-defined phenotype but no long-term tracking, or no phenotype but a large amount of long-term data. She noted that researchers in Sweden have access to these types of studies. Dr. Bianchi said that a big-data approach was needed with CDEs and refined phenotyping. She added that those studies are possible in Sweden (which is not as diverse a country as the United States) because patients are given health identification numbers at birth and then keep them for life. This allows researchers to take a cohort of women in their 50s and 60s and look back at pregnancy and other data from earlier in life. The United States did not adopt EHRs until several years ago, and some paper medical records cannot be read because of illegible handwriting. Partnerships with other countries might help. David H. Rowitch, M.D., Ph.D., said that having a well-phenotyped longitudinal cohort was a challenge in countries that do not have national health or education records. He agreed that partnering with other countries would be a good strategy. The insights gained could then be validated in the United States and be used to develop "smart cohorts" that use artificial intelligence (AI) and big-data approaches to gain new insights. Dr. Bianchi said that more OB-GYN researchers need to promote the concept that pregnancy is not a discrete life experience but rather a part of the life continuum. Dr. Neal-Perry said that she shared Dr. Bianchi's concerns about data from Sweden being from too homogenous of a population; it would be a mistake to use AI to make translational assumptions from such data.

Ignatia Barbara Van den Veyver, M.D., asked whether NICHD had provided input into the *All of Us* Research Program on women's health research. Dr. Bianchi said that it had, and that *All of Us* has enrolled more than 10,000 diverse participants who were pregnant at the time of enrollment. The program has also collected EHR data on each participant. Dr. Bianchi said that she was able to search the *All of Us* Data Browser for a specific genetic variant, query its association with postpartum cardiomyopathy, and then review the results by racial background. *All of Us* also has stillbirth as a keyword category. Dr. Van den Veyver said that she has had difficulty using *All of Us* data to research infertility. Dr. Bianchi said that she would convey that issue to Josh Denny, M.D., M.S., the chief executive officer of *All of Us.* Other NICHD staff commented that there are multiple levels of access to *All of Us* data beyond the Public Data Browser, including the ability to interrogate EHR data.

III. NICHD Extramural Training and Career Development (TCD) Implementation Working Group (WG) Progress Update (1:09:35)

After the recommendations of the NICHD Extramural TCD WG were presented at the January 2024 NACHHD Council meeting, the TCD Implementation WG was formed to begin implementing those recommendations. Joseph Gindhart, Ph.D., deputy director of the NICHD Division of Extramural Activities (DEA), and Lesly Samedy Bates, Pharm.D., Ph.D., a Clinical Pharmacology Training Network (CPTN) program officer in NICHD's Obstetric and

Pediatric Pharmacology and Therapeutics Branch (OPPTB), presented an update from the TCD Implementation WG.

Background Information (1:11:42)

The NICHD Extramural TCD WG was created in January 2023 to help NICHD staff identify opportunities for its extramural TCD programs to prepare the future research workforce to address NICHD's mission. From January 2023 to December 2023, the WG developed six recommendations and 32 associated action items across three key areas: career development (K) programs, pre- and postdoctoral (F, T, Supplement) training programs, and the alignment of TCD goals with NICHD's strategic priorities.

The WG's six recommendations were to:

- Rethink How We Talk About Outcomes
- Reinvigorate Institutional TCD Programs (T32 and K12)
- Create Community Among Trainees
- Use TCD to Diversify NICHD's Reach
- Reinvigorate the Loan Repayment Programs (LRPs)
- Use Training Programs to Support Strategic Research Priorities

Formation of the TCD Implementation WG and Subgroups (1:14:14)

To support implementation of the TCD WG's recommendations and action items, the TCD Implementation WG was formed in February 2024 with 20 members and 3 co-chairs from both NICHD extramural divisions: the Division of Extramural Research (DER) and the DEA. The TCD Implementation WG was also tasked with releasing an RFI to solicit comments on the recommendations and action items that were presented to the Council. The TCD Implementation WG has been organized into three subgroups:

- Subgroup A: Strategic Priorities, Outcomes, and Loan Repayment (chaired by Tessie October, M.D., M.P.H., a medical officer in the Pediatric Trauma and Critical Illness Branch (PTCIB))
- Subgroup B: Community and Diversity (chaired by Dr. Gindhart)
- Subgroup C: Institutional (T32 and K12) TCD Programs (chaired by Susan Taymans, Ph.D., deputy branch chief, Fertility and Infertility Branch (FIB))

TCD Implementation WG Progress Report (1:16:32)

Each subgroup has prioritized and made progress on its assigned action items.

Subgroup A: Strategic Priorities, Outcomes, and LRPs (1:16:50)

This group is addressing three of the TCD WG's recommendations:

- Rethink How We Talk About Outcomes

- Reinvigorate the LRPs
- Use Training Programs to Support Strategic Research Priorities

Two of the subgroup's 11 action items have been accomplished:

- Expand LRPs to include the L32 funding mechanism (Clinical Research for Individuals from Disadvantaged Backgrounds). As mandated by the NIH Division of Loan Repayment, NICHD joined this program in September 2023.
- Diversify the team involved in the LRP selection process to include representation from the NICHD Office of Health Equity (OHE) and the training committee team.

One additional action item is currently in progress:

- Develop approaches and algorithms to track and encourage important career trajectories in the future and to describe them all as valid and successful outcomes.

Subgroup B: Community and Diversity (1:18:13)

This group is addressing two of the TCD WG's recommendations:

- Create community among trainees.
- Use TCD to diversify NICHD's reach.

One of the subgroup's 11 action items has been accomplished:

- Recommend that OHE develop a systematic process for evaluating and signing on to diversity-focused training notices of funding opportunity (NOFOs).

Three additional action items are currently in progress:

- Host an annual or biennial workshop with fellowship trainees at NICHD.
- Create a distribution list of scholars and fellows to advertise NICHD-wide events. Initiate equitable outreach across institutions to increase the number of fellowship applications from institutions without a history of significant NIH/NICHD funding.

Subgroup C: Institutional TCD Programs (1:20:02)

This group is addressing the TCD WG's recommendation to reinvigorate institutional TCD programs (T32 and K12).

One of the subgroup's 10 action items has been accomplished:

- Establish a differential payline for new versus renewal programs.

Two additional action items are currently in progress:

- Cluster Type 1 and Type 2 T32 applications separately in peer review.

- Create evaluation metrics to determine when a K12 program has achieved its goal or to indicate that another tactic for growing a workforce should be used.

RFI Results (1:21:40)

In February 2024, the TCD Implementation WG released an RFI inviting comments on NICHD's strategic recommendations for the future of extramural research TCD. The WG received 13 responses from both individuals (7) and groups (6). The groups represented health care provider institutions (3), academic or research institutions (6), and special interest groups (4).

Notable findings included the following:

- The training and career development recommendation, "Reinvigorate Institutional Training and Career Development Programs (T32 and K12)," was referenced in all but one RFI response.
- All training and career development recommendations were referenced in three or more RFI responses.

Additional findings that WG co-chairs deemed to be potentially actionable included these:

- Consider a broader spectrum of metrics when determining a successful research career (e.g., continued funding from any external source, careers in research-related positions, involvement in team science as a co-investigator, leadership positions outside of academics, mentoring success).
- Capitalize on the benefits of partnership and collaboration (e.g., expand on partnership models already in place at NICHD; create partnerships with T32/K12 institutions and smaller or less resourced institutions to get broader involvement; pair new or emerging programs with successful longstanding programs; and leverage the wealth of existing expertise across physician-scientist training programs).
- Provide extra support for the transition period from K to R.
- Use formal, funded opportunities to bring the trainee community together (e.g., funded retreats for networking and career development can be powerful for creating community).
- Increase transparency in the LRP review and selection process.
- Link K12/T32 training programs to existing research networks.
- Incentivize training programs to emphasize multidisciplinary and team science components.

Voice of the Trainee (1:25:43)

Dr. Samedy Bates provided background information on the CPTN, presented results from a survey of trainees in the program, and shared actionable items for future development of the training program.

CPTN Background Information (1:27:11)

The T32 fellowship program was funded through the Best Pharmaceuticals for Children Act (BPCA). BPCA mandates the training of experts in pediatric pharmacology research, and the CPTN's T32 Institutional Research Training Grant program is designed to ensure that a diverse and highly trained workforce is available in an area that currently has a limited number of researchers. Current CPTN sites include T32, K12, and NICHD-affiliated locations, and the network offers collaboration, career development, mentorship, a lecture series, a virtual network, and research training experiences. Beyond these core components, the network also offers an annual meeting for showcasing work; NICHD orientation insights and navigation tips; an enhanced lecture series schedule that incorporates fellow-centric workshops; a new K12 extension; inclusion of K23, K99, F31 and F32 awardees; an alumni network; fellowship networking and collaboration opportunities; and partnerships with other networks and with industry.

Survey Design (1:31:36)

In 2022–2023, an anonymous trainee survey was designed by the chief fellows in the program; it was originally created as a "needs assessment" and was sent only to a group of 13 current fellows. With a goal to inform short- and long-term programmatic development, the CPTN expanded the survey to 17 questions in an electronic format and sent it via email to 155 current and alumni fellows from May 18 through June 23, 2023. The CPTN now plans to send the survey annually while keeping the survey topics and questions consistent to allow for longitudinal analyses.

Survey Results (1:33:24)

A total of 85 responses (55%) to the 2023 survey were received. Demographically, the 74 respondents who answered the questions identified as female (61%), male (38%), and other (1%) and were in the White (75%), Asian (17%), and Black (8%) racial/ethnic categories. Only one respondent identified as Hispanic/Latino. When asked whether they had a disability as defined by the National Science Foundation or the Americans with Disabilities Act, 4% said yes. Respondents held M.D. (67%), Ph.D. (33%), and Pharm.D. (13%) degrees (responses included those with dual degrees). Response rates varied for each question.

When asked about future career plans, 75% of the respondents indicated that they planned to pursue a career in academia, but many of those responses were from alumni fellows already established in academia. Importantly, only one of the 14 current fellows who responded to the survey indicated an intention to pursue a career in academia. According to respondents, the most important factors for making career decisions were work-life balance, location, and personal or family considerations, closely followed by salary, work environment, and research opportunities. Debt level did not necessarily influence career plans or decisions. When questioned about the level of support they received in their career trajectory, most respondents (40%) chose selective support, which meant being supported in some (but not all) areas. The outlook on job prospects was mixed.

The top needs that respondents identified during the training process were grant writing, applying for funding, identifying funding, and preparing for jobs. They identified their top career needs as mentorship, funding, clear career paths, and networking or collaboration. The trainees identified the following barriers: insufficient training time and mentorship, insufficient funding opportunities, an unclear career path, a lack of funding or positions, poor compensation, and not enough career mentorship.

In conclusion, there is an opportunity to enhance demographic diversity within the program. In general, fellows feel supported, but their outlook on jobs is mixed. Work-life balance and personal considerations were ranked as highly important for making career decisions. There are opportunities to improve the training experience, including increased mentorship, role models, and assistance with identifying and applying for funding. Fellows could also be offered guidance in preparing for jobs. In addition, respondents provided positive and negative feedback about the CPTN program through program evaluation forms (e.g., after attending a workshop).

Future Plans (1:41:18)

The CPTN has identified the following actionable items for improving the training network:

- Continue to provide unique training-related workshops.
- Request ideas for experiences that fellows would find valuable to their training.
- Ask principal investigators (PIs) and program directors to share any deficits in training experiences to identify areas where the network could assist.
- Encourage career-level peer-to-peer mentoring.
- Enhance job preparation resources (e.g., consider a trainee/scholar toolbox).
- Encourage fellows and scholars to apply to the NIH LRP and offer guidance throughout the process.
- Help OPPTB conduct an internal survey with standardized core questions.

Discussion (1:43:10)

Dr. Barkin said that many trainees say that they cannot afford a career in research, which makes the LRP important to maintain. She said that she also strongly supported the idea of connecting trainees with existing NICHD networks and advocated for creating the infrastructure needed to make those connections. Dr. Gindhart agreed, saying that the CPTN program could be a model for making such connections. Dr. Samedy Bates also agreed with the comment and said that leveraging the networks would be a great opportunity for trainees, so she will be working toward developing the needed infrastructure. Later in the discussion (1:47:02), Dr. Lang also expressed support for the idea of connecting trainees with networks within—and outside—NICHD. Even further in the discussion (1:53:05), Dr. Neal-Perry commented that as a person of color, she would have pursued a different career if not for the LRP and expressed her continued support of the program.

Dr. Lang commended Dr. Samedy Bates for including alumni in the trainee survey. She agreed that it would be valuable to continue administering the regular survey to both current and alumni trainees to gather longitudinal data.

Dr. Lang encouraged the CPTN to provide transparency to trainees about what networks can *and cannot* provide. She added that clear information and expectation setting is important for next-generation researchers.

Dr. Cedars said that the CPTN's example in pharmacology could easily be applicable across many areas of NICHD research. She asked for clarification on how the needs assessment was designed: Did it include questions about benefits that the trainees were already receiving, or did it ask about benefits that could be offered in the future? Are different programs offering different benefits? Dr. Samedy Bates said that this was a good observation, because these types of issues were what prompted her and Dr. Gindhart to suggest creating a core survey with standardized questions. Dr. Gindhart agreed, providing as an example that as many as 75% of trainees indicated that they wanted to go into academia, but only 25% planned to do so.

Dr. Van den Veyver asked about career path differences found between current trainees and alumni trainees. Dr. Gindhart said that the former hierarchy of outcomes had diversified over the past 20 years: Trainees today have more career options available than did past trainees, and there are now fewer jobs in academia. Damien Fair, Ph.D., said that it is a large shift if 75% of trainees want to go into academia but only 25% are able to do so. Dr. Samedy Bates said that she learned from fellows-only workshops that academia is having to compete with industry to recruit trainees, so the CPTN intends to further evaluate the factors surrounding the competition to hire trainees. Further in the discussion (1:54:52), Dr. Neal-Perry said that she agreed with Dr. Fair's comment and asked whether the CPTN could determine where the trainees who were not going into academics were going. She noted that trainees may not truly understand what "work-life balance" means (e.g., industry jobs often come with late work nights).

Dr. Neal-Perry said that she was surprised and expressed disappointment that the response rate to the TCD Implementation WG's RFI was so low. She asked whether there were plans to gather more than 13 responses. Dr. Gindhart said that the RFI was posted and shared in multiple ways (e.g., in the Director's Newsletter, on LinkedIn and Facebook, in staff emails to grantees and applicants). Dr. Neal-Perry suggested working directly with program directors and PIs (in a network model), because people are becoming desensitized to emails.

IV. Invited Director: OBSSR (1:56:21)

Jane M. Simoni, Ph.D., is Associate Director for Behavioral and Social Sciences Research (BSSR) at NIH and the Director of OBSSR. She presented an overview of the importance of BSSR across all aspects of health and described OBSSR efforts to advance and coordinate BSSR at NIH by working closely with all NIH ICs, including NICHD.

After briefly sharing her academic and research background, Dr. Simoni said that history has shown that ignoring BSSR can significantly—and negatively—affect human health. Specifically, without attention to BSSR, the promises of even the greatest biomedical breakthroughs can fall short. She provided examples from HIV research on stubbornly low patient uptake, health care system resistance, and stigma surrounding the use of oral pre-exposure prophylaxis (PrEP) pills, which are antiretroviral drugs that prevent HIV infection in people who are HIV negative but at high risk of exposure.

All biomedical interventions in humans are biobehavioral interventions. BSSR shapes health policies and improves health outcomes. For example, it leads to improved health through:

- Adherence to medical treatment
- Reducing health disparities
- Smoking cessation programs
- HIV prevention strategies
- Physical activity promotion
- Dietary interventions
- Vaccination campaigns
- Mental health interventions

Congress created the NIH OBSSR in 1993. It opened in 1995 to (1) coordinate the health-relevant behavioral and social sciences at NIH and (2) identify challenges and opportunities to advance these sciences at NIH. OBSSR is located within the OD as part of the Division of Program Coordination, Planning, and Strategic Initiatives and staffed by a team of 25 creative, high-energy people. It has an annual budget of about $40.8 million, 75% to 80% of which is distributed across the NIH ICs to co-fund high-quality BSSR that is consistent with the OBSSR mission. For NICHD, for example, OBSSR spent more than $3 million to co-fund 14 grants in FY 2023.

A May 2022 NIH Council of Councils WG report, "Integration of Behavioral and Social Sciences Research at the National Institutes of Health," found significant gaps and variation in BSSR integration across NIH. To address these gaps, the WG made specific recommendations in the areas of strategic integration, expertise and representation, capacity building, data and diversity, and scientific practice. Recommendations that apply to NICHD included the following: "Ensure each IC Advisory Council has at least two members with behavioral or public health expertise" and "Ensure scientific review panels reflect BSSR knowledge and expertise."

OBSSR's five scientific priorities for FY 2024 are as follows:

- Behavior Change, Maintenance, and Mechanisms of Impact
- Social Connection and Health
- Multilevel Research
- Integration of BSSR into Biomedical Research
- Health Communication Science

For strategic planning, OBSSR is updating its 5-year Strategic Plan for release in 2025. The plan will support OBSSR's mission to enhance the impact of health-related BSSR by identifying BSSR projects that should be supported by NIH, developing and coordinating BSSR initiatives with NIH ICOs, integrating BSSR within the larger NIH research enterprise, and communicating significant BSSR findings within NIH and beyond. OBSSR envisions a world in which the synergistic integration of the behavioral and social sciences with biomedical research leads to accelerated scientific discovery, effective treatment and health-promotion interventions, and equitable implementation strategies that will improve health for all. Each of OBSSR's research, capacity, and operational strategic priorities seeks to address the cross-cutting theme of health equity.

OBSSR leads or co-leads several initiatives (e.g., the Brain Behavior Quantification and Synchronization program, Violence Research Initiatives), training programs (T32 and R25), and time-sensitive opportunities for health research (e.g., supplements with an accelerated review and award process to support research to understand health outcomes related to an unexpected or time-sensitive event such as a pandemic, national policy change, or natural disaster).

With NICHD, OBSSR is involved with the IMPROVE initiative and also supports various studies on persons with disabilities.

Discussion (2:21:12)

Dr. Aizer asked whether OBSSR was interested in supporting short- and long-term studies on social outcomes associated with health and health interventions. Dr. Simoni said that it was true that NIH was more focused on individual health, and she asked Dr. Aizer for an example of such a study. Dr. Aizer said that any condition that affects someone early in life creates all kinds of social and economic impacts (e.g., education, labor market) that feed into that person's future health. For example, there are dynamic interactions between social and health conditions over the lifespan that have not been studied. Dr. Simoni said that the point was well taken and that these ideas (e.g., thinking about SDOH in a bidirectional fashion) warranted further discussion with Dr. Aizer.

Susan L. Brooks, J.D., said that she appreciated that Dr. Simoni highlighted the importance of and complexity in multilevel research. She asked what funding sources could do to support more of that type of research. Dr. Simoni said that multilevel research was expensive and difficult to do at some of the current NIH funding levels, so creativity is needed. Team science approaches can be effective. Later in the discussion (at 2:26:30), Dr. Barkin said that she appreciated the way that Dr. Simoni sought to create synergy and creativity between researchers. She asked how to design longitudinal studies that are powerful enough when it is impossible to do whole-community or whole-society interventions and whether, for example, analytic modeling could be used. Dr. Simoni said that one of OBSSR's research priorities is investigation with innovation for assessment, design, and analysis. AI has the potential to be valuable in this area, especially for ontology and definition of key terms.

Dr. Lang said that she liked the idea of using an R25 award to add BSSR components to a researcher's skill set. She suggested that OBSSR could find ways to better communicate those awards throughout the research community.

V. Scientific Presentation: The Unpredictability of Life Outcomes: Evidence from the Future of Families and Child Wellbeing Study (2:28:30)

Kathy Edin, Ph.D., the William Church Osborn Professor of Sociology and Public Affairs at Princeton University who specializes in qualitative methods and Co-Principal Investigator of the Future of Families and Child Wellbeing Study, and Matthew Salganik, Ph.D., a professor of sociology at Princeton University who specializes in computational social sciences, presented their research on the unpredictability of life outcomes evidence from the Future of Families & Child Wellbeing Survey (FFCWS), FF Challenge, and in-depth qualitative interviews with a subset of survey respondents. FFCWS is an NICHD-funded, ongoing, nationally representative longitudinal birth cohort study of 4,898 children born from 1998 through 2000 and their parents. The cohort was drawn from a stratified sample of 20 large cities in the United States and oversampled births to unmarried parents. This work highlights the use and limitations of cutting-edge data science approaches to predict social and behavioral outcomes.

Life Trajectory Prediction Task (2:31:34)

Data science techniques allow social scientists to answer questions using data from existing datasets. The FF Challenge, using data from the FFCWS is one such example. Researchers were interested in a life trajectory prediction task and launched the FF Challenge, inviting researchers from around the globe to use machine learning to create models to predict adolescent outcomes with the extensive data available through FFCWS. Shockingly, even the most accurate predictive models were remarkably unprecise, correctly predicting, at most, 20% of the respondents' outcomes. This finding led to the FF Dark Matter interviews, a set of qualtiative interviews with about 40 child-parent dyads seeking to understand whether there were key constructs shaping adolescent outcomes that had not been captured in the FFCWS surveys. Based on these interviews, the team identified some possible factors (e.g., deaths of people the young adult was close to and having an important non-parental adult involved in their lives) which were added to the Age 22 FFCWS survey. This research also spurred a paper, published in 2024, on the origins of unpredictability which questions researchers' abilities to predict life outcomes. This research has important implications for both research and policy, highlighting limitations of algorthmic systems used in domains such as child welfare and criminal justice.

The Evolution of FFCWS (2:36:49)

The FFCWS began as a two-generation study, where children and their parents were enrolled in the study at the time of the child's birth. At the time of the FF Challenge, data

had been collected at birth and ages 1, 3, 5, 9, and 15. The FF Challenge used variables from birth through age 9 as predictors of age 15 outcomes. Since the FF Challenge, the FFCWS has continued to evolve, surveying the children (now young adults) and a parent at age 22. As these young adults have begun to have children themselves, FFCWS has become a multigenerational study, enrolling the young adults' children through the FF Generation 3 study (PIs: Julien Teitler and Nancy Reichman). These valuable longitudinal data, which are collected by researchers, have already been used in more than 1,300 published papers. There are now more than 13,000 variables in the FFCWS dataset, collected from mothers, fathers, primary caregivers, the focal children, teachers, child care providers, and through in-home assessments.

Data Prediction Models (2:39:45)

Before the FFCWS data collected at age 15 became widely available, researchers decided to design the FF Challenge using the "common task method." The problem was to try to predict six different outcomes for children, parents, and families: (1) child grade point average (GPA), (2) child grit, (3) household eviction, (4) household material hardship, (5) adult job loss, and (6) adult job training. They invited hundreds of researchers around the world to use the FFCWS, a large, high-quality social science dataset including data from birth to age 9 to predict outcomes at age 15 using modern machine learning (ML) methods to determine how accurately outcomes from children, parents, and families can be predicted. When compared with a benchmarking model, hundreds of different ML models were unable to reliably predict any of the outcomes. See "Measuring the predictability of life outcomes with a scientific mass collaboration," by Matthew J. Salganik et al., published in *Proceedings of the National Academy of Sciences* in April 2020.

Finding Unmeasured Variables (2:49:09)

The researchers then wanted to understand the origins of the unpredictability in the life trajectory dataset (e.g., what factors were allowing some children to do better than expected or to struggle unexpectedly). ML techniques cannot be used to find important unmeasured variables, but sociologists have a technique for doing so: in-depth, semi-structured qualitative interviews. The FF Dark Matter team conducted such interviews with 40 parent-child pairs drawn from the FFCWS sample. The sample was evenly divided among young adults whose GPAs were as predicted, below the predicted value, and above the predicted value. The interviews focused on three specific time periods (birth to age 9, ages 9 to 15, and age 15 onward). Two interviewers, one blinded to the child's GPA at age 15 and one unblinded, conducted the interviews. Researchers found some important unmeasured variables (e.g., exposure to the death of a close friend or family member and connections to significant adults). Zooming out, "The origins of unpredictability in life outcome prediction tasks," by Ian Lundberg et al., published in *Proceedings of the National Academy of Sciences* in June 2024, developed a framework to understand why even machine learning models struggle to predict individual outcomes.

Next steps include the exploration of other shapes of datasets in collaboration with Statistics Netherlands and the Dutch population register. The intersection of social science

and data science is called computational social science; it is now evolving into an intersection of social science and AI (which has different characteristics than the intersection of social science and data science).

The Future of FFCWS (2:58:06)

The FFCWS is a longitudinal study and will continue long beyond the FF Challenge. The core study typically fields surveys every five years and the next planned surveys will be when the young adults are 27 years old. In addition to the core study, the FFCWS is the bedrock for a series of collaborative studies including following the children of the FFCWS birth cohort, examining brain development, cardiovascular health (in particular, racial disparities), criminal-legal system involvement, aging, and fatherhood. Collaborative studies provide emerging scholars with an opportunity to significantly contribute to the country's only contemporary birth cohort study and to further innovate using the FFCWS data. In addition to collaborative studies, FFCWS holds a summer data workshop to develop its pipeline of data users, with a particular focus on young scholars of color. FFCWS also supports working groups where researchers can present their findings and receive feedback from longtime data users, including FFCWS principal investigators.

VI. Voice of the Participant: A Participant from the FFCWS (3:01:00)

Mary Lou is a mother with five children, including a set of triplets. She said that she hoped her comments could do justice to 25 years of research, noting that those 25 years went by amazingly fast for her. She was invited to join a "survey of new parents" in 1999 after her triplets were delivered following a high-risk pregnancy. Eighteen weeks into the pregnancy, Mary Lou and her husband were shocked to learn that she was carrying triplets. The couple also has an older son, who at the time was already in high school.

Immediately after the discovery of the triplet pregnancy, Mary Lou was put on strict bed rest and prescribed medications to stop preterm labor. She said that she was unable to fully prepare for the birth of one child, let alone three, but was determined to delay delivery as long as possible for the growth and development of the babies. She was in and out of the hospital many times, which caused her to lose her income and time at home with her family. The telephone and television charges during those days in the hospital really added up, she said, but she needed to phone home and check in to keep her family and friends updated, and she also passed time by watching TV. She spent time worrying, too, about the pending change in her family demographic.

Not long after Mary Lou delivered the triplets, an FFCWS representative came into her hospital room and asked whether she wanted to participate in a survey. There was a small stipend, she explained. Mary Lou thought, "Great, I'll pay for the TV!" After Mary Lou explained that she had delivered triplets who were in the neonatal intensive care unit (NICU), the FFCWS representative told her to answer the questions about the firstborn triplet, who was named Luke. At that time, Mary Lou did not fully realize the scope of the

study and how it would become a shared experience for her and Luke over the next 25 years.

The survey modules asked Mary Lou and her husband a series of questions about their lives, relationships (both together and with their family), financial circumstances, educational backgrounds, and beliefs. The survey was mainly focused on the rearing of Luke, such as how home or parenting tasks were shared or divided. Many years went by. After Mary Lou and her husband had their fifth child in 2001, the survey became "the survey of parents." As Luke became more more verbal and grew, he became the focus of the study. During home visits, Luke was weighed, measured, and asked a series of questions. Sometimes he would be given pictures and asked to describe them, making Mary Lou wonder whether they were early childhood IQ tests. Although her husband was surveyed by phone early on, the study seemed to become more focused on Luke and Mary Lou, she said.

Staying in the study became important to Mary Lou, because it enabled her and Luke to have one special thing to do together, with just each other. It also allowed her to see his growth and development separately from the growth and development of the other children. This was important because although he was the largest triplet by weight at birth, he also had the most complications. He was in the NICU the longest. He had early intervention services at home and later at school. Mary Lou said, "I was fortunate to find such programs available to us." Continued participation in FFCWS also allowed Mary Lou and Luke to try to have some impact on other families and children.

As Luke grew older, he became more aware that his experiences in life were a snapshot of or a peek into the lives of other kids his age. Through the study, Mary Lou explained to Luke, programs could be developed or funding could be affected for other kids and families who were just like them. Luke enjoyed participating in FFCWS and discussed his experiences with Mary Lou after visits or calls from the researchers. Mary Lou said that she never, at any point, wanted to taint Luke's thoughts or replies to the researchers during visits. When they were asked to provide a DNA sample for the research, Mary Lou wondered what it could show or how would it be used in the future, but she and Luke filled their little spit tubes together and sent them back with the hope that they would help the study.

When Luke became a "tween," the survey became "The Survey of Parents and Teens." In those years, Mary Lou's husband became disabled, so she began homeschooling her children and working part time outside of the home. Homeschooling allowed Luke the opportunity to explore many educational interests on his own. As he got older, participating in the follow-up surveys allowed Luke to purchase camera equipment or computer components; he had shown a gift for photography at a very early age, and has built a few personal computers from the bottom up. The financial help from the study helped the family; it also taught Luke to handle his own money better. According to Mary Lou, "He outgrew his early delays very fast, and he was extremely bright." Despite college looming, Mary Lou and Luke were always happy to receive updates from FFCWS or the requests for information (by mail) that had become so familiar to them. "The letters from

[FFCWS] meant it was time to help the research teams at Princeton and Columbia," said Mary Lou. "We were like pioneers, in a sense, and it had a purpose."

Mary Lou and Luke had a special interview with Dr. Edin and Dr. Salganik, in person, at their home. The participants both signed new waivers to be taped during the visit and were asked to invent new names to remain anonymous. The tapes would be used or reviewed in the future by researchers. The interviews lasted for several hours. "We understood the importance of it all," said Mary Lou. "Although it can be said that our family is fragile, we continue to do our best and find ways to accomplish our shared or singular goals."

Luke has now graduated from college with honors and a B.S. in management information systems. He worked on his college newspaper as a photographer, a photo editor, and, finally, as the business manager. He continues to do photography and video work in his free time while he works for a major corporation in Philadelphia that has a global footprint. He moved out of the family home 2 years ago. "He amazes me," said Mary Lou. "All children do ... Truthfully, it's why I agreed to continue this [study] for 25 years with my son … I want my children and all of our children to have what they need in order to become productive citizens of this country. Our society is based upon the future success of our youth. The children in this study are now called 'Gen Z.' Let's see where they go."

Mary Lou said that she appreciated the Council allowing her time to speak. She said that she hopes the research presented earlier, as well as what can be learned from her family and all of the participants in the study, is enlightening. "We must continue to help children attain the best possible outcomes in our lives," she said. "It truly benefits us all. Thank you for your efforts on behalf of these important topics … and for continued funding of programs or research that impact the future of childhood development."

Discussion (3:11:12)

Dr. Bianchi thanked Mary Lou for her engaging story and asked her whether her five children were all boys. Mary Lou said that her first four children are boys, but her youngest is a daughter.

Dr. Bianchi said that these are the stories that everyone on the Council remembers. Dr. Bianchi said that as a researcher, she is enormously grateful to people such as Mary Lou who set aside their time and, as in Luke's case, had made a lifetime commitment to research. That time is really precious, and no one can put a price on it. She thanked Mary Lou on behalf of the entire Council and all of the researchers.

VII. NICHD Data Sharing Strategy Update (3:13:00)

Rebecca Rosen, Ph.D., director of the NICHD Office of Data Science and Sharing (ODSS), presented an update on NICHD's data strategies and activities since her last presentation to the NACHHD Council, in January 2023. She said that NICHD is committed to promoting data sharing to accelerate scientific progress in order to support its mission to understand human development, improve reproductive health, enhance the lives of children and

adolescents, and optimize abilities for all. The ODSS was established in 2021 under the NICHD Strategic Plan's 2020 scientific stewardship goal "Facilitating data sharing and access to biospecimens." The ODSS vision is to create a culture of responsible and innovative use of data and biospecimens that accelerates research and improves health for NICHD populations.

The ODSS takes a community-informed approach to enhance data sharing across the research and data lifecycles by regularly engaging with NICHD's OHE, Office of Communications, Office of Global Health, Office of Legislative, Public Policy, and Ethics (OLPPE), and Office of Science Policy, Reporting, and Analysis on data sharing strategy. At NICHD, the ODSS's strategy is informed by an Extramural Data Sharing Committee, an Intramural Data Sharing Committee, and an Ecosystem Working Group. Data sharing is also foundational to responsible and innovative development and use of Artificial Intelligence (AI) and Machine Learning (ML) technologies for NICHD research. Progress is being made across the federal government in establishing frameworks and resources for the responsible development of AI. An NIH-wide AI strategy that aligns with a forthcoming HHS AI Strategic Plan will guide the NICHD strategy.

The NIH Data Management and Sharing (DMS) Policy that became effective on January 25, 2023, applies to all NIH-supported research that generates scientific data. The policy requires researchers to prospectively plan for how scientific data and metadata will be managed and shared through submission of a DMS plan (DMSP) that considers any potential restrictions or limitations. The goal of the NIH DMS Policy is to maximize the appropriate sharing of scientific data. NICHD follows the policy as written and has not added any NICHD-specific recommendations. If data sharing is limited or delayed because of "justifiable limitations," such as laws or IRB requirements, researchers must explain why; NIH staff and the researchers can then work together to navigate any real or perceived barriers. Data sharing is defined by the DMS Policy as the act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public) by using an established repository or other means. Now that the Policy has been in effect for more than a year, ODSS worked with NICHD program officers who review the DMSPs submitted to NICHD to identify several common issues across plans:

- Some elements of the NIH-provided format page contain conflicting information.
- Some DMSPs are unclear about which data will be generated versus those to be shared. The plans also lack important data details (e.g., species/source, formats shared, amount of data, metadata).
- Some DMSPs that include human genomic data do not adhere to NIH's genomic data submission and release expectations or timelines.
- The duration of data availability in some DMSPs follows local retention cycles rather than repository retention timelines.
- Some DMSPs do not identify an established repository or do not commit to using one. Others name a data repository that is inappropriate because it is not broadly accessible or does not contain the correct data type. Some DMSPs list multiple repositories but do not indicate which data go to which repository. There is an

overreliance on "generalist repositories" when discipline-specific repositories should be prioritized.
- DMSPs that plan to share data only through publication or conferences, those that are too restrictive, or those that share only "by request" or with PI control (even if using a repository) do not meet policy requirements.
- In some DMSPs, the "justifiable limitations" are not adequately justified. Others have vague reasons for not sharing (e.g., ethical issues, privacy, sufficient quality, law) or provide no justification for not using a data repository or delaying the sharing timeline.

These findings have been presented internally and externally by program staff, including most recently at the May 2024 meeting of the Federal Demonstration Partnership.

To address the issues identified in the DMSPs, the NICHD ODSS website has been continually updating an expandable section called "Data Management and Sharing (DMS) Policy Resources." Some of the resources in this section are listed below:

- Tips for Writing a DMS Plan. This document describes what is expected for each DMSP element and budget. It was recently updated with "Tips for Secondary Analysis Projects."
- The NICHD Data Repository Finder. This tool lists data repositories that typically accept data from NICHD researchers. It also helps researchers write DMSPs, because it lists the information that must be included in them.
- Example DMSPs developed by NICHD staff for four different types of projects.
- A new Data Standards webpage that explains data standards and provides examples that may be relevant to NICHD research. NICHD staff created the webpage in response to issues identified during the DMSP review process. It includes expandable sections for Metadata Standards; Controlled Vocabularies, Terminologies, and Ontologies; Common Data Elements; Common Data Models; and Other Standards and Resources.

NICHD's Data and Specimen Hub (DASH) is a centralized, controlled-access repository that allows researchers to share and access deidentified data and select biospecimens from NICHD-funded clinical studies. DASH is now a key resource for the implementation of NICHD's data sharing strategy. Data annotation and standardization are crucial for the DASH platform. The DASH codebook is a variable-level data dictionary that enables researchers to annotate the meanings of elements in their datasets in a manner that is consistent and machine readable, which allows secondary users to interpret and harmonize shared datasets. The codebook ensures that data are accurately and consistently annotated, making it easier for researchers to analyze and compare different studies.

Several repositories named in the DMSPs did not align with the "Desirable Characteristics of Data Repositories for Federally Funded Research" guidance issued by the White House in May 2022 (e.g., GitHub, PubMed). NICHD created the new Data Repository Finder tool to help staff and researchers identify acceptable repositories for sharing data and to identify

DMS Policy-specific characteristics for the repositories. An NICHD-wide analysis of repository characteristics and use is being used to educate staff and researchers on this topic.

NICHD's data sharing policies and data repositories must be aligned with both the NIH Data Ecosystem and the needs of NICHD researchers. Ideally, all NICHD-relevant data repositories would be interconnected and accessible for the use of scientific analysis tools. To this end, the ODSS is working to create a human-centered data ecosystem by assessing all relevant data repositories for sustainability and interoperability, collecting and prioritizing user stories, then developing enhancements to and connections between data systems. Governance, data, and system interoperability are all being assessed. Collecting user stories in NICHD's public GitHub repository provides the foundation for the development of formal use cases, fosters collaborative solutioning, and helps create effective, broadly applicable solutions. Such user stories inspired the development of a record linkage project that is using cryptography to protect sensitive information in multiple NICHD-relevant data repositories. The result was a record linkage implementation checklist that identifies the governance and technical considerations for developing a record linkage implementation. The checklist was then sucessfully used by NICHD's investigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project Data Coordinating Center to securely link data across NIH data repositories for authorized researchers. The data repository assessment process was also what led to the creation of the Data Repository Finder tool mentioned above. NICHD's user story-driven data interoperability work led to a trans-NIH collaboration that made it possible for researchers to log in to cloud-based workspaces (e.g., CAVATICA) to access data from three NIH controlled-access data repositories (e.g., INCLUDE, the Gabriella Miller Kids First Pediatric Research Program, Sequence Read Archive) and co-analyze clinical and genomics data in a secure cloud workspace.

The ultimate goal for the development of the NICHD Data Ecosystem is the adoption of relevant standards, policies, and other best practices in data repositories (and other systems) to meet the needs of the NICHD research community. Among other future plans, the ODSS will continue learning how best to respond to the data management and sharing needs of the community.

Discussion (3:41:40)

Dr. Fair asked what the ODSS was doing to educate researchers on how to comply with complex data management and sharing practices. Dr. Rosen said that despite issues with some of the DMSPs that have been submitted, many researchers already know a lot about how to successfully use and interact with data repositories. Sometimes improving upon practices that researchers are already using is what is warranted. Dr. Cernich said that NICHD is likely further ahead of other NIH ICs in many of its data management and education strategies, but that Dr. Bertagnolli would like to see NIH become the leader in bioinformatics. Dr. Rosen agreed, saying that all ODSS work is being shared broadly throughout NIH.

VIII. Pregnant Women and Lactating Women (PRGLAC) Implementation WG Report (3:48:28)

The PRGLAC Implementation WG of Council was established in 2023 to monitor and report on the implementation of the 15 recommendations of the congressionally mandated Task Force on Research Specific to Pregnant Women and Lactating Women, a 21st Century Cures Act program. As co-chairs of the Implementation WG, NACHHD Council member Christina M. Bucci-Rechtweg, M.D., Global Head of Pediatric and Maternal Health Policy at Novartis Pharmaceuticals Corporation, and Susan Abdel-Rahman, Pharm.D., chief scientific officer at Health Data Synthesis Institute, presented a status update on the implementation plan, which was originally released in 2020.

Review Process (3:51:07)

After briefly providing background information and historical context about PRGLAC and the urgent public health need to increase scientific evidence around medication use during pregnancy and lactation, Dr. Abdel-Rahman said that the 15 PRGLAC recommendations and the congressional language appropiating funding for, and reporting requirements of, the Implementation WG are available online.

The PRGLAC Implementation WG divided the 15 recommendations into five clusters and met three times to review implemenation progress by cluster, as follows:

- On November 17, 2023, the WG virtually reviewed Cluster D: Registries and real-world data.
- On January 19, 2024, the WG virtually reviewed Cluster A: Conduct clinical research and trials, Cluster E: Novel drug discovery and development, and Cluster C: Policy, regulatory, and liability.
- On March 22, 2024, the WG met in person to review Cluster B: Education, outreach, training, and career development.

During the meetings, Implementation WG members invited speakers from relevant federal agencies (including NICHD), professional societies, and stakeholder groups to provide updates on each cluster area. In addition, the WG engaged in a sizeable amount of online activity, including some ad hoc meetings with stakeholders, between each of the three main meetings.

Findings (3:57:40)

Dr. Bucci-Rechtweg presented the Implementation WG's findings. She said that the review process identified the following overarching themes:

- There is a real need to create a distinction between research for pregnancy and research for lactation. The recommendations were progressing at different rates for each of these groups.

- Some of the recommendations were failing to show progress because of a lack of clear ownership. Ownership should therefore be assigned to facilitate progress.
- Numerous recommendations called for engaging with multiple, diverse stakeholders. Identification and assignment of neutral conveners may facilitate progressing these recommendations.
- In order to move forward, some of the recommendations require additional resources and/or congressional action (e.g., funding, granting new authority).
- Many of the recommendations require continued assessment of the implementation progress.

Specifically, the Implementation WG members categorized the status of each task force recommendation as implemented, in progress, or not implemented. They then outlined each category by cluster area. The status of each recommendation is listed below by cluster area.

Cluster A and E: Conduct Clinical Research and Trials and Novel Drug Discovery (4:00:03)

Three recommendations have been implemented:

- 2B. Utilize longer award periods by government funders (beyond the typical 5-year award), when needed, for study design and data collection.
- 8B. Develop separate prioritization processes for therapies and/or conditions in pregnant women and lactating women.
- 9A. Create separate prioritization processes for pregnant women and lactating women.

Three recommendations are in progress:

- 2A. Provide additional resources and funding for research to obtain clinically meaningful and relevant data for specific and co-occurring conditions in pregnant women and lactating women.
- 11B. Broaden focus of ongoing research networks to include research on therapeutic products in pregnant women and lactating women.
- 11A. Provide financial support and incentives to established, and develop new, multicenter infrastructures.

There are three recommendations that have not been implemented:

- 8A. Provide specific funding.
- 9B. Consider a Biomedical Advanced Research and Development Authority–like model and the NIH vaccine model that takes clinical development up to Phase II.
- 11C. Encourage networks/collaborations to engage in public-private partnerships to facilitate research.

Cluster B: Education, Outreach, Training, and Career Development (4:02:40)

None of the recommendations have been implemented, but these five are in progress:

- 3A. Develop and support training and career development opportunities in obstetric and lactation pharmacology and therapeutics for both clinical and basic science.
- 3B. Develop mentors in obstetric and lactation pharmacology and therapeutics for both clinical and basic science.
- 5A. Highlight the importance of research on therapeutic products in pregnant women and lactating women.
- 6A. Increase the knowledge of health care providers regarding obstetric and lactation therapeutics and research needs.
- 6B. Increase the engagement of health care providers to disseminate information from research findings to their patients.

Dr. Bucci-Rechtweg noted that there are existing frameworks and infrastructure in place that could be leveraged or optimized to move several of the education, outreach, and training recommendations forward.

There are four recommendations that have not been implemented:

- 3C. Increase the knowledge and engagement of health care providers regarding obstetric and lactation pharmacology and therapeutics.
- 5B. Engage stakeholders such as HHS, professional societies, industry, advocacy groups, and public and global partners.
- 6C. Increase the engagement of health care providers to discuss participation in clinical trials, research, and registries.
- 6D. Develop appropriate strategies for sharing and interpreting research findings and risk.

Cluster C: Policy, Regulatory, and Liability (4:04:14)

Dr. Bucci-Rechtweg said that progress in this cluster may require congressional action. One recommendation has been implemented but still requires action at the trial level to be fully realized (e.g., on the IRB level):

- 1A. Remove pregnant women as an example of a vulnerable population in the Common Rule.

Four recommendations are in progress:

- 1B. The Food and Drug Administration (FDA) should harmonize with the Common Rule and remove pregnant women as a vulnerable population.
- 7A. Implement a liability mitigation strategy for conducting research and evaluating new therapeutic products in pregnant women and lactating women.
- 10A. Investigators/sponsors must specifically justify exclusion in study design.

- 10B. Ensure that studies are designed to capture the time dependency of physiologic changes in pregnancy and lactation.

Six recommendations have not been implemented:

- 1C. HHS should develop guidance to facilitate the conduct of research in pregnant women and lactating women.
- 4A. Modify Subpart B of the Common Rule.
- 7B. Consider implementing a targeted incentive program and/or strengthening FDA authority to require clinically relevant data on pregnant women and lactating women.
- 10C. Develop a systematic plan on how data for pregnant women and lactating women will be obtained in a timely fashion to include pharmacokinetics, pharmacodynamics, and safety.
- 10D. Develop guidance for IRBs and investigators about the inclusion of pregnant women and lactating women in research.
- 10E. Develop a systematic plan for when a woman becomes pregnant in a study to include whether a product should continue, whether unblinding is necessary, and how to capture opportunistic information on pharmacology, clinical data, and pregnancy outcome information.

Cluster D: Pregnancy Registries and Real-World Data (4:06:05)

For pregnancy, none of the recommendations in cluster D have been implemented, but these six are in progress:

- 12A. Design health record systems to link mother and infant records.
- 12B. Leverage large studies and databases.
- 12C. Use novel data resources.
- 12D. Use innovative methods of data analytics.
- 12E. Require CDEs to facilitate collaboration and use.
- 13B. Develop registry standards and CDEs that facilitate input of pertinent data in real time.

Three recommendations have not been implemented:

- 13A. Create a user-friendly website for registry listing.
- 13C. Facilitate access to data and transparency of information in registries.
- 13D. Develop disease- and condition-focused registries.

Dr. Bucci-Rechtweg said that the Implementation WG noted that developing and prioritizing the use of disease- and condition-focused registries, as opposed to product specific registries, would lead to a more robust ability to collect information in a timelier fashion. The WG also highlighted the fact that numerous registries exist but are missing cohesiveness, user friendliness, and the ability to be able to be used for multiple purposes by multiple stakeholders.

Cluster D: Lactation Registries and Real-World Data (4:07:55)

Unfortunately, when looking at lactation, none of the recommendations in cluster D have been implemented, and none are in progress. These nine recommendations have not been implemented:

- 12A. Design health record systems to link mother and infant records.
- 12B. Leverage large studies and databases.
- 12C. Use novel data resources.
- 12D. Use innovative methods of data analytics.
- 12E. Require CDEs to facilitate collaboration and use.
- 13B. Develop registry standards and CDEs that facilitate input of pertinent data in real time.
- 13A. Create a user-friendly website for registry listing.
- 13B. Facilitate access to data and transparency of information in registries.
- 13C. Develop disease- and condition-focused registries.

For next steps, the PRGLAC Implementation WG will finalize its report in mid-June 2024, then disseminate it by the end of July. Although several federal agencies will continue to implement the PRGLAC Task Force recommendations, ongoing monitoring of the implementation activities is strongly recommended.

Discussion (4:10:48)

Dr. Bianchi said that she had read the draft version of the Implementation WG's report and gave it high praise, calling it outstanding work. She added that many of the original 15 recommendations have been fully or partly completed, and that some of the recommendations are outside of NICHD's control. The report, she added, will be hugely impactful. Dr. Bucci-Rechtweg said that multiple federal agencies should be congratulated for the progress made to date. Dr. Bianchi said that there are also likely to be some downstream effects that cannot be captured (e.g., a recent report from the National Academies of Sciences, Engineering, and Medicine on some of the liability challenges).

Dr. Bianchi and Dr. Bucci-Rechtweg briefly discussed the importance of pregnant people being able to take medicines, the wide sphere of influence around pregnant people, and the Implementation WG's calls in the report for education, communication, and outreach around taking medicine during pregnancy. Some foundational work still needs to be done in these areas.

Dr. Barkin congratulated NICHD on having implementation WGs to affect real change from task force recommendations. She asked whether the Implementation WG would continue its efforts going forward. Dr. Abdel-Rahman said that the Implementation WG has now satisfied its legislative charge and has no further authority to proceed. Action would need to be taken to continue the activity. Laura Berkson, J.D., the director of the OLPPE, said that it might be useful for NICHD to revisit the status of the recommendations in a year or so by creating another WG to do a similar assessment.

Dr. Barkin asked whether nutritional supplements were included as medications for the purposes of this work. Dr. Bucci-Rechtweg said that the original PRGLAC Task Force discussed this topic and decided to focus only on FDA-regulated therapeutics; otherwise, the scope of the project might have been too broad. Dr. Cernich said that NIH has an Office of Dietary Supplements (ODS); that office recently met with the IMPROVE Initiative's Coordinating Committee for Maternal Morbidity and Mortality about a potential collaboration to fund research on dietary supplements for maternal health. Aaron Pawlyk, Ph.D., chief of OPPTB, said that the prioritization process and the follow-up RFI did include dietary supplements and vaccines (along with medications). OPPTB staff are working now on how to process that change. Dr. Pawlyk added that OPPTB is working with the ODS on a perinatal transporter pharmacology project, and it seems that the two organizations are building a good relationship. The ODS will be helping to collate all responses to the RFI. Rohan Hazra, M.D., NICHD's director for extramural research, acknowledged and thanked all NICHD program staff who have helped the PRGLAC Implementation WG, specifically OPPTB and the Pregnancy and Perinatology Branch (PPB), and noted that these staff members will also be helping with future PRGLAC implementation work.

Rui Li, Ph.D., asked for clarification on what motivated the formation of the PRGLAC Task Force. Dr. Bucci-Rechtweg said that for decades, clinical trials for pregnant and lactating people have been very limited; funding has therefore been limited as well. Neither including pregnant patients in clinical trials or designing trials specifically for pregnant or lactating women has been done. The task force began well before the COVID-19 pandemic, but the pandemic elucidated the problem for the public and made people think about what happened when their mother was pregnant with them and might have needed a medicine or vaccine that was not adequately studied. There is clear multi-stakeholder desire to find a path forward that is pragmatic and that can generate valuable information to inform therapeutic development, clinical practice, and patient safety. Dr. Abel-Rahman added that when the original legislation was passed, no research groups were involved. The motivation to form the PRGLAC Task Force was a grassroots effort to ensure that the medications being given to mothers and, indirectly, to the fetus were safe. It started with the participant and the patient, so there must be continued engagement with the patient and the participant. Staff at the Centers for Disease Control and Prevention (CDC) is doing some excellent work in this area, so they should continue to be part of the conversation going forward.

Dr. Gyamfi-Bannerman said that this information is important for all researchers who study obstetrics and for practicing obstetricians. She asked how to safely study medications in pregnant and lactating people and wondered whether R25 awards could be used to train obstetric-adjacent or therapeutics students to learn how to incorporate these populations in research. Dr. Hazra said that obstetric pharmacology and then pediatric pharmacology used to be isolated and siloed from one another, but Dr. Pawlyk has done a good job of creating interactions between obstetric and pediatric pharmacology researchers (e.g., in her earlier presentation, Dr. Samedy Bates described how CPTN is now including both areas in its training programs). Dr. Pawlyk added that OPPTB has been encouraging T32 applications for maternal pharmacology and thinking about ways that the R25 award can be used in this area. He said that it is impossible to train all clinical pharmacologists, but

having some who understand the language is critical. The UE5 program is another training mechanism that institutions are starting to use creatively. In the past, the lack of resources has been one of the major challenges, but Dr. Bianchi has allocated NICHD resources to move forward with many of the needed initiatives.

Dr. Van den Veyver said that many of the medications that are prescribed to pregnant and lactating people are related to other health issues (e.g., mental health, cardiovascular conditions). She asked whether PRGLAC studies could be integrated into research at ICs that study those conditions. Dr. Pawlyk said that OPPTB recently created a maternal and child pharmacology subgroup under the N-PeRC umbrella, and the subgroup's next meeting (in July) will have moderators from each of the relevant ICs. Moving forward, conducting this type of research will be a trans-NIH effort. Dr. Bucci-Rechtweg added that the PRGLAC Implementation WG report (in Cluster B) contains carefully placed comments that speak to trans-NIH efforts, because the need goes beyond obstetrics and lactation research. Every therapeutic, every medicine in development could be needed by someone with an underlying condition who becomes pregnant.

Dr. Vaday said that with some autoimmune conditions (e.g., rheumatoid arthritis), when a pregnant person has to go off of the medication, the symptoms may go away for unknown reasons; then, after the pregnancy, the symptoms return more severely. She said that research could show whether continuing on a medication, even at a lower dose, could reduce the severity of the symptoms after pregnancy. Dr. Bucci-Rechtweg agreed, saying that clinical trials must be designed to understand not only the risk component but also the efficacy component. Neither efficacy nor clinical pharmacology (e.g., relevant dosing, effective dosing) across trimesters has been studied in most conditions.

Report Approval by Council (4:30:45)

Dr. Gyamfi-Bannerman moved to approve the WG's report. Multiple Council members seconded the motion. The Council voted to approve the report. Dr. Bianchi thanked the WG members, NICHD staff involved in the report, and the OLPPE.

IX. Stillbirth WG Report (4:32:25)

Dr. Bianchi reviewed the 2022 congressional mandate and charge of the NACHHD Stillbirth WG of Council. WG co-chairs Lucky Jain, M.D., M.B.A., George W. Brumley, Jr. professor and chair of pediatrics at Emory University School of Medicine (a former member of the Council); and Uma M. Reddy, M.D., M.P.H., professor and vice chair of research in the Department of Obstetrics and Gynecology at Columbia University (and a former medical officer in the PPB), presented this WG report. The last report from this WG was in January 2023, at the time that it made its initial recommendations.

Initial Findings and Recommendations (4:34:38)

After thanking the NICHD staff members who assist the WG and briefly providing background information on the formation of the WG, Dr. Jain said that the WG's initial

report to Congress, "Working to Address the Tragedy of Stillbirth," which was released on March 15, 2023, focused on (1) removing current barriers to collecting data on stillbirths throughout the United States, (2) identifying communities at higher risk of stillbirth, (3) understanding the psychological impact and treatment for mothers following stillbirth, and (4) elucidating the known risk factors for stillbirth.

The report included multiple recommendations for each of these four areas, as outlined below:

1. Removing Barriers to Collecting Data on Stillbirths

- HHS, led by CDC, should develop and implement revised procedures to address the barriers to collecting representative, comprehensive, reliable, and sufficiently detailed vital records on stillbirth to support the needs of families, public health officials, and researchers. Changes should include:
    - Procedures to improve the consistency and quality of data collection
    - Standardization of case definitions
    - Training for individuals involved in data collection for fetal death certificates
    - Improved processes for updating vital records once additional information is available, including a clear, uniform process for submission of autopsy data and other test results
    - Outreach to states and localities to raise awareness of and build public health capacity to collect accurate, timely, and complete stillbirth data
- CDC should expand current surveillance and data collection efforts involving risk factors for stillbirth (specifically) and all adverse pregnancy outcomes (generally). These activities may include, for example:
    - Conducting population-based stillbirth surveillance in a diverse range of jurisdictions
    - Exploring opportunities to leverage current data collection systems (e.g., expanding the CDC Pregnancy Risk Assessment Monitoring System [PRAMS] to conduct population-based surveillance among women with a recent stillbirth to identify risk factors)
    - Conducting or supporting validation studies of current data sources
    - Developing new methods to leverage other surveillance data for stillbirth research
    - Linking or enriching existing data
- HHS and professional societies should work together to improve and expand training in perinatal pathology, genetics, and other areas to advance the practice of fetal autopsy.

2. Identifying Communities at Higher Risk of Stillbirth

- CDC, NIH, and other HHS divisions should support surveillance and research to investigate health disparities in stillbirth, in conjunction with other adverse pregnancy outcomes. Such research should address racial, ethnic, socioeconomic, geographic, and other disparities.

- NIH should review its data on inclusion of minorities in its pregnancy and stillbirth studies to ensure appropriate representation.
- NIH should expand community-based research in maternal health and adverse pregnancy outcomes and ensure that stillbirth is emphasized as a focus for community-based research. These efforts should focus on the patient experience in at-risk populations.
- Efforts to address the barriers to improving data on stillbirth in the United States should include geographic areas with strong representation of individuals from diverse racial and ethnic backgrounds and other groups that experience disparities.

3. Understanding the Psychological Impacts of Stillbirth

- NIH and CDC should support or conduct systematic research to collect data from individuals with lived experience on the psychological impact of stillbirth. Implementation research should be designed to inform efforts on how to develop culturally sensitive programs to support families after stillbirth. Results from this research should be shared with the clinical, research, and advocacy communities.
- Professional societies should consult individuals with lived experience about the psychological impact of stillbirth, as well as providers who care for those patients, to improve provider training and incorporate supportive practices into the care for affected families.

4. Elucidating Known Risk Factors for Stillbirth

- NIH should convene a group of basic, translational, clinical, and public health research experts, as well as parents who have experienced stillbirth, to develop a research agenda aimed at preventing stillbirth and other adverse pregnancy outcomes. The research agenda should include efforts to identify implications for stillbirth prevention from NIH's Human Placenta Project and related research.
- NIH should conduct or support research to establish baseline normative data on physiology in pregnancy, including potential indicators of health and disease. Such indicators may include, but should not be limited to, placental development and function, fetal movement, fetal growth, and others.
- NIH and CDC should support additional research on causes and risk factors, as well as prevention of stillbirth more broadly. Specifically, these efforts should:
    - Focus on un- and under investigated areas to discover new risk factors and interactions, to help understand the racial disparity in stillbirth, and to assess the preventability of stillbirth.
    - Investigate the feasibility and potential usefulness of developing a stillbirth registry.
    - Delineate the mechanisms of how specific risk factors affect stillbirth and explain the racial disparity.
    - Develop and test indicators and clinical interventions for the prevention of stillbirth.

Summary of Recommendations

- Improve the quality of vital statistics, surveillance, and epidemiologic data on stillbirth at the local, state, and national levels.
- Use insights from improved epidemiologic data and conduct additional research to explain and ultimately address disparities in stillbirth and identify prevention opportunities.
- Conduct implementation research and develop culturally sensitive interventions to support families that have experienced stillbirth.
- Create and support a full research agenda, including research on known and unknown risk factors and physiologic mechanisms, to support the development of interventions to prevent stillbirth.

2023 Mandate (4:45:49)

In response to the Stillbirth Task Force's March 15, 2023, report to HHS, Congress mandated the task force to continue its work for another year to identify current knowledge on stillbirth and prevention, areas of improvement for data collection, current resources for families impacted by stillbirth, and next steps to gather data and lower the rate of stillbirth in the United States.

To continue its work, the approximately 30 members of the task force formed three subgroups: I—Improving Data Collection, II—Stillbirth Prevention and Strategies, and III—Enhancing Resources for Families Impacted by Stillbirth.

WG Recommendations and Findings (4:48:05)

The findings and recommendations of each subgroup are outlined below.

General Recommendations

1. Standardize data reporting and collection to promote accurate and consistent surveillance.
2. Support population-based surveillance, such as expanding the PRAMS stillbirth project (the Study of Associated Risks of Stillbirths survey) to capture the diverse voices of those who experience stillbirth in jurisdictions with high stillbirth burden.
3. Explore artificial intelligence (AI) and machine learning (ML) as ways to improve risk prediction and stratification based on existing data, ensuring that sensitive health care information is safeguarded.
4. Create tools to educate patients and health care professionals on risk factors for stillbirth.
5. Create standardized training, appropriate infrastructure, and resources so that complete stillbirth workup (e.g., completion of autopsy, placental pathology, and genetic studies) can become more widespread and standards of care more uniform.

6. Create infrastructure for perinatal audits to enable analysis and discussion of stillbirth and further identification of risks factors and possible prevention strategies.
7. Support research on how structural, institutional, and interpersonal racism contributes to inequalities in stillbirth rates, the offering and completion of stillbirth workup, differential access to health care opportunities, quality of care after stillbirth, and bereavement care.

Stillbirth Prevention Strategies Subgroup

Findings:

- Lack of routine perinatal autopsy and placental examination leads to incomplete pathology or histology information that could improve understanding of causes of stillbirth and potential avenues of prevention.
- Genetic testing is often not done because of the cost and logistical challenges.
- Perinatal audit, the process of capturing information on the causes of stillbirth and analyzing the quality of care received in a no-blame, interdisciplinary setting to guide action to prevent similar deaths in the future, is not routinely performed.

Recommendations:

- Consider conducting research on timing of delivery to develop personalized recommendations on the optimal time (induction of delivery may be offered at 39 weeks per the ARRIVE trial results*).
- Address health disparities and SDOH.
- Support population-based stillbirth surveillance, especially in jurisdictions with high stillbirth rates.
- Provide access to high-quality prenatal care and postpartum care.
- Additional research is needed to develop stillbirth prevention bundles that focus on patient and provider education, public health measures (e.g., advice to cease tobacco use, helping people achieve healthier body mass index), optimizing treatment of chronic medical conditions (e.g., diabetes, hypertension), and induction of labor.
- Link maternal and fetal medical records.
- Consider creating a stillbirth registry and collecting stillbirth biospecimens.
- Consider universal use of low-dose aspirin according to the U.S. Preventive Services Task Force guidelines.*

Improving Data Collection Subgroup

Findings:

- Surveillance and medical definitions (including gestational age and birthweight criteria that currently vary by state) for stillbirth, pregnancy loss, and miscarriage are not currently standardized; therefore, data collection is inconsistent.

- Clinical data collected from multiple sources (e.g., EHRs, monitoring data, imaging studies, genetic testing, pregnancy experience, patient history) are not integrated and linked across datasets so that all information is accessible for research and stillbirth prevention.
- There is a lack of uniform training of individuals completing fetal death certificates, which hinders more accurate record keeping.
- Currently, fetal death certificates are required to be filed within days of the fetal death, before results of the full workup are available. These workups may better identify causes of death. Full workup death results are often not incorporated in the fetal death certificate, because formal legal amendment is needed. Thus, information from the delivery and from subsequent testing may be delayed and not be integrated into the fetal death certificate, including final cause of death.

General Recommendations:

- Collect, transform, integrate, and maintain EHRs and other pertinent datasets in a format appropriate for future use to apply AI and ML to create a maternal child health data ecosystem serving as a major resource for research on stillbirth and other adverse pregnancy outcomes.
- Bridge the gap between data available at delivery and data available at workup completion. Specifically, focus data standardization and quality improvement on reporting, follow up, and workup of stillbirths.
- Design a case-control study by leveraging AI to collect data for prevention measures, maternal experience evaluation, and ascertainment surveillance.
- Enhance regional stillbirth evaluation through telehealth, the creation of stillbirth centers of excellence, and fetal and infant mortality reviews.
- Improve and develop quality indicators for evaluation, counseling, bereavement services, and follow up.
- Conduct regular audits to improve the quality of data collection.

Education Recommendations:

- Require state field representatives to provide ongoing, in-person training on how to collect fetal death data.
- Encourage providers to use guidance documents and e-learning tools developed by the National Center for Health Statistics (NCHS).
- Educate hospital personnel on using a flowchart developed by NCHS to understand a fetal death certificate.
- Train personnel to improve overall fetal death data accuracy and completeness and to ensure the filing of amendments (e.g., for autopsy results) as needed.

Enhancing Resources for Families Subgroup

Findings:

- Appropriate care at the time of bereavement, which is vital to meet the needs of families, is not always present.
- Health care professionals often lack standard training in the cultural sensitivity needed to speak with bereaved parents and families with empathy.
- There are insufficient local and national resources to support families that have experienced stillbirth, especially in smaller hospitals with limited resources.
- Health care professionals are inadequately trained regarding stillbirth.

Recommendations for caregivers at the time of diagnosis:

- Display empathy (i.e., understand and respect parental choices regarding the stillborn baby).
- Refer to the stillborn infant as a baby and use the name if one has been given.
- Provide families a roadmap with information about their delivery hospitalization, including items they may need or want in the hospital, what to expect around the delivery, what the baby might look like at birth, options for pain management, information on a cuddle cot if one is available, options for parenting activities (e.g., reading the baby a book, bathing them, dressing them), and options for mementos and photography.
- Have a bereavement health care professional (e.g., doula, social worker) available to support families during their hospital stay.

Recommendations for caregivers after delivery:

- Put the patient in a recovery area away from other pregnant people and the sounds of live-born infants.
- Place a marker on the door so that health care providers will know that the death of an infant has occurred.
- Conduct a religious ceremony if it is desired.
- Support the parents' decision to hold or not hold the baby.
- Support the parents' decision to engage in parenting activities if they so choose.
- Create photos, videos, or other mementos of the stillborn child.

Postpartum workup recommendations:

- Create resources to help parents better understand how the information collected from tests and exams can help determine the cause of their infant's death.
- Identify any immediate health concerns for the birthing parent, and guide management for subsequent pregnancies.
- Set expectations for how test results will be communicated to the family.
- Be explicit that testing may not determine causes of death, but emphasize that testing is the best that can be done to determine causes.
- Emphasize that the baby will be treated with care and respect.

Postpartum care recommendations:

- Address the physical needs of the person giving birth.
- Provide information on recovery from childbirth, especially for first-time parents. This could include resources (and staff) that address milk production, physical recovery from childbirth, and postpartum depression.
- Risk of depression is high in parents who have experienced stillbirth. Provide close postpartum follow up and mental health support for grief, trauma, and depression.
- Provide national and local resources for support.
- Create standards of care for other professionals, such as social workers and chaplains, who might regularly interact with families experiencing stillbirth.
- States should consider the availability of stillbirth tax credits.

Recommendation Themes

- Standardize data collection and reporting, exploring new technologies such as AI and ML.
- Create a stillbirth prevention bundle.
- Create standardized training so that a complete stillbirth workup, including autopsies, genetic tests, and blood tests, is performed.
- Conduct perinatal audits after stillbirths so that specific protocols can be developed following fetal deaths.
- Research ways to reduce the health disparities in stillbirth.
- Establish continuing health care provider education related to stillbirth.
- Research the most effective mental health support after stillbirth.
- Make the costs of stillbirth workup more affordable, including access to autopsy and genetic testing and placental pathology (optimal when done by a perinatal pathologist).

Discussion (5:01:46)

Dr. Van den Veyver said that the barriers to perinatal autopsy are difficult to overcome. She asked whether the WG had considered suggesting a noninvasive, imaging-based autopsy as a solution. Dr. Reddy said that because of the shortage of perinatal pathologists, the group did consider fetal magnetic resonance imaging as a solution, along with using telehealth, developing regional centers of excellence, increased training, and shared expertise.

Dr. Van den Veyver asked, based on the fact that it takes a long time to receive an autopsy report, whether the WG's recommendations included a future preconception or follow-up, closure-type visit for families that have experienced a stillbirth (separate from the stillbirth delivery). Dr. Reddy said that not only do the reports take a long time, but sometimes families are also not given the results. It is important that autopsy results are both shared with families and incorporated into the fetal death certificate. Furthermore, it is difficult to get the death certificate corrected; it takes a formal legal amendment. The WG heard from many families that if the cause of death was wrong on the fetal death certificate, they had to pay all sorts of money to try to amend it, just to get it corrected. Dr. Reddy added that a later follow-up visit would be good for reviewing the results of the autopsy together and

providing ongoing mental health care support. Dr. Jain said that in lieu of fetal autopsy, the WG discussed anatomic autopsy or imaging coupled with detailed placental pathology and genetic information. This type of additional information could help families determine whether their next pregnancy was at risk. Families that experience stillbirth experience many sleepless nights wondering whether their next baby is also going to die.

Regarding the training and education recommendations, Dr. Rowitch said that it would be reasonable to recommend that the professional societies (e.g., the American Academy of Pediatrics [AAP], the American College of Obstetricians and Gynecologists [ACOG]) require bereavement training for instances of stillbirth. In the United Kingdom, the National Health Service has a national course on stillbirth. Physician training programs could develop the curricula and provide the tools for junior doctors to learn how to support parents going through this ordeal. Dr. Reddy said that the report does include training recommendations, so this is a good suggestion. She noted that the Rainbow Clinic has developed curricula that could be adapted for professional society and medical school training programs.

Dr. Barkin asked whether the definition of stillbirth had now been standardized across all U.S. states. Dr. Reddy said it has not, but that the report does have a bullet point that says that gestational age and birth weight vary across states for stillbirth, miscarriage, and pregnancy loss. Standardizing the definition will likely fall under CDC's responsibilities.

Dr. Barkin asked how the WG's recommendations would be implemented and paid for. Dr. Jain called that the million-dollar question. Dr. Reddy said that the research recommendations fall to NIH and the data collection recommendations fall to CDC. Funding will definitely be needed to carry out the recommendations. The cost of the needed medical workup after stillbirth—and the medical care after having a stillbirth—are real issues for families, because they are not currently covered by insurance. Dr. Jain said that this effort must inherently include CDC, HHS, the Centers for Medicare & Medicaid Services, and NIH, because there are so many different aspects to tackling a malady like stillbirths. Developing a universal definition of stillbirth needs to be validated and adopted in all states. CDC may be able to unite the states, but implementation science and implementation of the work itself must happen at the state level, where most health care is managed. It is hard to control.

Regarding placental pathology, Dr. Gyamfi-Bannerman agreed that incredibly specialized expertise is needed to produce informative results; creating centers of excellence therefore would be a good solution. She asked about the future plans for the WG. Dr. Jain said that the WG had completed its most recent mandate. Nahida Chakhtoura, M.D., branch chief of the PPB, provided the following updates on NICHD's efforts to continue the work of the task force:

- A Notice of Intent to Publish has been issued for the formation of a Stillbirth Consortium (rather than "centers of excellence").
- A small amount of funding has been received to expand data collection. The PPB's Maternal-Fetal Medicine Units Network and Neonatal Research Network will be asked to work together to improve the collection of data to include data on stillbirth

and preterm birth. There are more than 230,000 deliveries each year between the two networks, so that could be a significant amount of data.
- A Notice of Special Interest on stillbirth has been issued, and the applications that have been received should be reviewed in late June.
- A RADx® Tech fetal monitoring challenge may produce useful strategies for early diagnosis and prevention of stillbirth.

Dr. Maldonado suggested engaging with AAP from an advocacy perspective (as well as from the training perspective mentioned above). She said that AAP and ACOG might be able to help implement policies or publish a white paper for pediatricians and medical schools that recommends current approaches and best practices for supporting families. AAP could also provide advocacy on Capitol Hill for insurance reimbursement and other issues. Dr. Maldonado added that because stillbirth is a global issue and the true worldwide burden is unknown, collaborating with the World Health Organization (WHO) might be useful in the future. Dr. Jain said that these points are well taken. He added that asking AAP and ACOG (along with all of the federal agencies, private foundations, and even WHO) to collaborate on disseminating and socializing the WG's findings was a great idea. Dr. Jain noted that the Stillbirth WG of Council membership roster included several international experts. Dr. Reddy echoed Dr. Jain's comment that engaging with AAP is a good idea, especially because the impact of stillbirth on siblings and future pregnancies is quite high. Dr. Reddy added that the Bill & Melinda Gates Foundation and the Global Network are both doing important international work on stillbirth, so the idea to collaborate private foundations was well taken. Another expert in the United States who has formed an international movement around stillbirth prevention is Robert M. Silver, M.D., chair of the Department of Obstetrics and Gynecology at the University of Utah School of Medicine. Dr. Jain agreed that it would be good to expand the impact of the WG's work internationally.

Regarding the educational recommendations, Dr. Neal-Perry said that trainees, particularly residents, are also (along with families) traumatized by stillbirth; therefore, training must include not only how to interface with the patients but also how to manage one's own feelings around death and loss. She commended the WG on such important work and for highlighting the disparate and real experiences of different populations, because they have significant effects on the entire family. Dr. Bianchi agreed, recalling the intense emotions evoked by families, including fathers, during the lived experience listening sessions. Drs. Jain and Reddy agreed with Dr. Bianchi's comments on families, adding that needed follow-up care for all members of the family—and for medical providers—is not being provided.

Report Approval by Council (5:23:28)

Dr. Barkin moved to approve the WG's report. Multiple Council members seconded the motion. The Council voted to approve the report.

X. Closing Remarks (5:24:35)

Dr. Bianchi thanked all presenters and attendees and announced the schedule for Day 2.

XI. Day 1 Adjournment

Dr. Bianchi adjourned Day 1 at 4:39 p.m. A total of 289 people viewed the live Day 1 NIH VideoCast.

XII. Day 2 Call to Order and Introductory Remarks (0:03)

Dr. Bianchi opened Day 2 of the 185th meeting of the NACHHD Council. In each section below, the number in parentheses after each heading refers to the time stamp on the Day 2 NIH VideoCast; please go to that point in the recording to listen to the full presentation.

XIII. Council Statement of Understanding (0:21)

Dr. Rasooly said that the 2024 Statement of Understanding between NICHD and the NACHHD Council was updated and posted on the Council website. This document describes the Council's membership and structure, grant application review procedures, concept clearance review procedures, and emergency procedures. Two policy changes have been made in the past year. Dr. Gyamfi-Bannerman moved the approve the statement, and Dr. Barkin seconded the motion. Council members voted to approve the 2024 Statement of Understanding.

XIV. Concept Clearance (2:36)

Dr. Rasooly led the Council through the review of six concepts. She noted that many of these concepts (marked with an asterisk) are not new; they were recently approved. Their existing NOFOs must be reissued, however, because of the newly revised simplified grant review criteria that are going into effect January 2025.

Archiving and Documenting Child Health and Human Development Datasets* (4:28)

Susan Jekielek, Ph.D., presented this concept from the Population Dynamics Branch (PDB). Dr. Barkin expressed support for the concept. She asked how the ease of data access and tools could be advanced. PDB Branch Chief Rebecca Clark, Ph.D., said that the NOFO includes langauage about ease of data access and tools. Dr. Van den Veyver suggested adding a training component to the NOFO. Dr. Jekielek said that the ODSS provides data access training resources for researchers and that training can be proposed in this grant. Dr. Clark added that PDB also provides training free of charge for anyone who needs it. **Decision: Approve.**

Early Immune System Development and Ontogeny (9:05)

Sai Majji, Ph.D., presented this concept for the Maternal and Pediatric Infectious Disease Branch. Dr. Maldonado expressed support for the concept and suggested securing additional funding (via private foundations such as the Gates Foundation) to further build out these projects. **Decision: Approve.**

Contraceptive Development Research Centers (13:19)

Chris Lindsey, Ph.D., presented this concept for the Contraception Research Branch. Dr. Maldonado expressed support for the concept and asked whether there were any legal guardrails to protect this research. Dr. Cernich said that state laws vary, so awardees must

sign an agreement to comply with all laws in their respective states. When needed, NICHD addresses political pressure on specific grants or lines of research at the departmental, congressional, or White House levels. An attendee asked whether OBSSR was participating in this concept. Dr. Lindsey said it was not, but that was an excellent suggestion. The group further discussed ways to include OBSSR expertise in this concept, as recommended by Council members. Dr. Cernich said that the collaboration with OBSSR would be done internally. **Decision: Approve.**

NICHD Small Research Grant Program* (21:27)

Maria Nurminskaya, Ph.D., presented this concept from the National Center for Medical Rehabilitation Research (NCMRR). Dr. Van den Veyver asked for clarification on the differences between this concept and the NIH parent R03 NOFO. Dr. Nurminskaya said that the parent R03 NOFO does not allow for clinical trials. Dr. Lang asked Dr. Nurminskaya to describe some of the previous successes from this program. Dr. Nurminskaya said that she could not speak to specific successes, but this program receives about 25 applications each funding cycle, so it is clearly a useful mechanism. Theresa Cruz, Ph.D., NCMRR's director, said that this is a small program. Dr. Lang asked whether the awards go to junior investigators who go on to receive larger awards. Dr. Cruz said they do, but that she did not have the exact numbers. Dr. Cruz added that the award is often used for analysis of secondary data and pilot clinical trials. Dr. Li suggested using this mechanism to encourage applications from investigators with diverse backgrounds. **Decision: Approve.**

Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data* (27:20)

Marcia Fournier, Ph.D., presented this concept from the Developmental Biology and Congenital Anomalies Branch. Dr. Van den Veyver asked whether re-phenotyping data and harmonizing access to it were included in this concept. Dr. Fournier said that the NOFO based on this concept allows investigators to study longitudinal information for enrolled subjects. She added that the data are harmonized when they are released to the public and that general data access can be approved via email; however, access to genomic data requires dbGaP enrollment, which takes about one week for approval. Dr. Jabs said that her research team has been able to successfully access the entire dataset for all studies, but phenotype harmonization may be more complicated. She expressed support for this concept and suggested adding more omics datasets going forward. A brief discussion of expanding the database and its uses followed. **Decision: Approve.**

In-Depth Phenotyping and Research Using International Mouse Phenotyping Consortium (IMPC)–Generated Knockout Mouse Strains* (37:09)

Mahua Mukhopadhyay, Ph.D., presented this concept from the NICHD Developmental Biology and Congenital Anomalies Branch. Dr. Rowitch asked whether researchers must have mice generated by IMPC to qualify for funding. Dr. Mukhopadhyay said most mice

must be generated by IMPC, but other strains could also be used. Dr. Rowitch asked whether this NOFO based on this concept used an R01 mechanism, and Dr. Mukhopadhyay said that it did. Dr. Jabs expressed support for this project. Dr. Mukhopadhyay said that many NICHD branches use these mice. **Decision: Approve.**

XV. Closing Remarks (42:07)

Dr. Bianchi thanked all attendees and concluded the open session.

XVI. Closed Session

The meeting was closed to the public in accordance with the provisions set forth in Section 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2). NACHHD Council members provided second-level review of NICHD extramural applications.

XVII. REVIEW OF APPLICATIONS

The session included a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions, and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect. The council considered and approved 780 HD-primary applications requesting $293,077,636 in direct costs and $411,279,400 in total costs.

XVIII. Adjournment

There being no further business, Dr. Bianchi adjourned the meeting at 12:05 p.m. on Tuesday, June 4, 2024. The next Council meeting is scheduled for September 4–5, 2024, split between NIH Bethesda Campus, Building 35A, on September 4 and 6710B Rockledge Drive in Bethesda, Maryland, on September 5.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.[2]

[2] These minutes will be formally considered by the Council at its next meeting; any corrections or notations will be incorporated into the minutes of that meeting.

Diana W. Bianchi -S

Digitally signed by Diana W. Bianchi -S
Date: 2024.09.23 15:45:09 -04'00'

Diana W. Bianchi, M.D. Date
NACHHD Chair
NICHD Director

Rebekah S. Rasooly -S

Digitally signed by Rebekah S. Rasooly -S
Date: 2024.09.23 14:38:21 -04'00'

Rebekah Rasooly, Ph.D. Date
NACHHD Executive Secretary
Director, NICHD Division of Extramural Activities