



*Eunice Kennedy Shriver* National Institute  
of Child Health and Human Development

NATIONAL ADVISORY CHILD HEALTH  
AND HUMAN DEVELOPMENT  
COUNCIL

*MEETING SUMMARY*

January 24–25, 2023

**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)**  
**NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT  
(NACHHD) COUNCIL MEETING SUMMARY**  
**January 24–25, 2023**

The [NACHHD Council](#) convened its 181st meeting at 12:00 p.m. ET on Tuesday, January 24, 2023, by [NIH VideoCast](#). The meeting was open to the public from 12:00 p.m. to 5:00 p.m. The Council reconvened on Wednesday, January 25, 2022, at 12:00 p.m. for one presentation. 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 for the review, discussion, and evaluation of grant applications and related information, the remainder of the session on January 25 was closed to the public. Diana W. Bianchi, M.D., director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, presided.

**Council Members<sup>1</sup>**

*Those present are denoted with an asterisk (\*).*

- |                                 |                                       |
|---------------------------------|---------------------------------------|
| *Diana W. Bianchi, M.D. (Chair) | *Catherine E. Lang, Ph.D.             |
| *Shari Barkin, M.D.             | Missy Lavender, M.B.A.                |
| *Christina Bucci-Rechtweg, M.D. | *Yvonne Maldonado, M.D.               |
| *John P. Coughlin, M.D.         | *Genevieve S. Neal-Perry, M.D., Ph.D. |
| *Kathleen B. Egan, Ph.D.        | *Adam C. Resnick, Ph.D.               |
| *Damien Fair, Ph.D.             | *David H. Rowitch, M.D., Ph.D.        |
| *Lucky Jain, M.D.               |                                       |

***Ex Officio* Members**

- \*Patricia Dorn, Ph.D.
- \*Aaron M. Lopata, M.D., M.P.P.

**Department of Defense**

- \*Melissa R. Miller, Ph.D.

**National Advisory Board on Medical  
Rehabilitation Research Council Liaison**

- \*Jose L. Contreras-Vidal, Ph.D.

**Executive Secretary**

- \*Rebekah Rasooly, Ph.D.

The [NIH Day 1 VideoCast](#) time stamp appears in parentheses for each section below.

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<sup>1</sup>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 (0:03)**

Dr. Bianchi opened the virtual meeting and welcomed the members of the NACHHD Council and other virtual participants, especially those representing professional societies, advocacy, and research organizations.

### **Review of Confidentiality and Conflicts of Interest (0:42)**

Dr. Rasooly reminded NACHHD Council members that they were 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 form. Dr. Rasooly also reminded Council members that they were required to recuse themselves and leave the virtual meeting before any discussion involving any 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, Siri) that are capable of capturing confidential information.

### **Council Minutes (2:30)**

A motion to approve the September 12–13, 2022, NACHHD Council meeting minutes carried.

### **Future Meeting Dates (4:00)**

Dr. Rasooly announced that the future Council meeting dates were June 6–7, 2023 (NIH Bethesda Campus, Building 31); September 6–7, 2023 (6710B Rockledge Drive, Bethesda, Maryland 20892); January 22–23, 2024 (virtual); June 3–4, 2024 (NIH Bethesda Campus, Building 31); September 4–5, 2024 (6710B Rockledge Drive, Bethesda, Maryland 20892); and January 13–14, 2025 (virtual).

## **II. NICHD DIRECTOR'S REPORT (5:00)**

In her report, Dr. Bianchi described NIH and NICHD fiscal year (FY) 2023 budgets, recent congressional briefings, updates on NACHHD's Stillbirth Working Group, NIH and NICHD research, NIH-wide training and career development opportunities, the NIH Clinical Center's Pediatric Research Strategic Plan, Advanced Research Projects Agency for Health (ARPA-H) developments, and STRIVE (STRategies to enRich Inclusion and achieve Equity) Initiative progress and provided NIH and NICHD staff updates.

### **NIH and NICHD FY 2023 Appropriations (6:07)**

For FY 2023, Congress appropriated \$47.5 billion for NIH, of which NICHD will receive \$1.75 billion. These amounts are both increases from FY 2022. NICHD-specific appropriations included set-asides of \$30 million for the [Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone \(IMPROVE\) Initiative](#), \$10 million for research on multisystem inflammatory syndrome in children (MIS-C), \$3 million for research on [the impact of COVID-19 on pregnant and lactating women](#), and \$15 million for research on the health impacts of

technology and social media use on children. NIH-wide appropriations that affect NICHD research include \$90 million for the INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project, \$10 million for research on developmental delays (including speech and language delays in infants and toddlers and characterizing speech and language development and outcomes from infants through early adolescence), \$40 million for research on the health impacts of climate change, \$76.4 million to the Office of Research on Women's Health (ORWH, including \$5 million for [Building Interdisciplinary Research Careers in Women's Health \[BIRCWH\]](#) and \$10 million to establish an office on autoimmune disease research within ORWH), \$12.5 million for firearms research, and \$180 million for the [Environmental influences on Child Health Outcomes \(ECHO\) Program](#).

### **Congressional Briefings (9:23)**

Over the past several months, NICHD staff participated in congressional briefings on the INCLUDE Initiative, the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), and on maternal health.

### **NACHHD Stillbirth Working Group (10:44)**

Later in the meeting, the Stillbirth Working Group co-chairs will provide an update on the group's progress. Stillbirth is a major problem in the United States, where 65 stillbirths occur each day. The FY 2022 Appropriations Report required the HHS Secretary to establish a task force on stillbirth in the United States. This charge was delegated to NICHD, so the institute formed the Stillbirth Working Group as a subcommittee of the NACHHD Council. The working group's membership includes representatives from the Centers for Disease Control and Prevention (CDC), NIH, specialty organizations, and maternal and fetal medicine specialists. The working group held four meetings and a listening session in 2022 to form its findings and recommendations, which will be presented at this meeting. A final written report is due to Congress in March 2023.

### **NIH and NICHD Research Updates (12:42)**

A randomized controlled trial called Eating, Sleeping and Consoling for Neonatal Opioid Withdrawal to study neonatal opioid withdrawal syndrome (NOWS) was recently completed across 26 hospitals in two NIH pediatric clinical trial networks as part of the [Advancing Clinical Trials in Neonatal Opioid Withdrawal \(ACT NOW\)](#) Program. Data presented on December 5, 2022, showed that the trial's eat-sleep-console care approach substantially reduced the time until infants became medically ready for discharge from the hospital and significantly reduced pharmacologic treatment without negatively affecting safety outcomes through 3 months of age. The manuscript has been submitted for publication; when published, these data will provide strong support for establishing universal, evidence-based standard of care for treating infants with NOWS. ACT NOW is a part of the [Helping to End Addiction Long-term® Initiative \(NIH HEAL Initiative®\)](#).

The NIH-wide [IMPROVE Initiative](#), which supports research focused on reducing preventable causes of maternal deaths and improving health for women before, during, and after delivery, received \$30 million appropriations in NICHD's FY 2022 and FY 2023 base budgets. The initiative emphasizes health disparities and disproportionately affected populations. To advance

the initiative, funding awards have been announced for [research dissemination and implementation](#). A “connectathon” will improve electronic health records (EHRs) for the longitudinal tracking of maternal health outcomes, and NICHD has launched [technical challenges](#) and [prize competitions](#) to advance the IMPROVE Initiative. NICHD is also prioritizing funding of the [Maternal Health Research Centers of Excellence Initiative](#), which uses an integrated, multi-level community partnerships approach encompassing structural, social, and biobehavioral research strategies to address the multiple contributing factors that lead to adverse maternal health outcomes and health disparities, in 2023.

As of January 18, 2023, the *All of Us* Research Program has enrolled more than 584,000 participants, collected more than 342,000 EHRs, and stored 423,000 biosamples. More than 4,100 researchers, including Dr. Bianchi, have registered to use the program’s data. *All of Us* is pursuing rigorous five-year goals for increasing enrollment and retention, expanding the amount and types of data available to researchers, launching ancillary studies, diversifying researcher access and impact, and providing return of value to participants. A pediatrician, Sara Van Driest, M.D., Ph.D., was recently named the program’s first director of pediatrics.

### **Training and Career Development Opportunities (30:33)**

The number of early-stage investigators (ESIs) funded on first R01 equivalents has been steadily rising since 2013. NIH’s goal is to fund 1,100 ESIs per year, and in 2022, NIH funded a record 1,589 ESI applicants.

The NIH-wide [Pediatric Research Consortium \(N-PeRC\)](#) website will soon feature a list of training and career development opportunities for pediatric researchers. The list will include all funding opportunities from 17 Institutes, Centers, and Offices (ICOs) across NIH.

### **NIH Clinical Center Pediatric Research Strategic Plan (32:32)**

There are currently about 1,600 active research studies at the NIH Clinical Center, the largest research hospital in the world. Every patient in the Clinical Center is participating in a research protocol, although none of the studies currently enroll pediatric patients under age 3. The Clinical Center’s funding model provides opportunity for research equity, because all services are provided at no cost to the participant. The Clinical Center formed a Pediatric Research Strategic Plan Working Group and charged it with identifying the most impactful scientific areas of pediatric research where NIH can play a major role to substantially improve child health. The 15-member working group, which includes Dr. Bianchi, has been meeting for several months to scan the horizon and conduct long-term, strategic planning for intramural, NIH-wide clinical pediatric research for the next decade and beyond. The group’s strategic plan will address limitations for enrolling pediatric participants at the NIH Clinical Center and reduce hesitation about including pregnant people in research protocols. Pediatric department chairs should look out for an upcoming survey from the working group to recommend the types of research that are needed.

### **ARPA-H (36:51)**

Renee Wegrzyn, Ph.D., has been appointed as the permanent director of ARPA-H, which was created as an independent component of HHS within NIH that reports directly to the HHS

Secretary. ARPA-H was allocated \$1 billion in its initial budget during FY 2022. The agency has no internal research laboratories, and it is disease-agnostic, so there are potential opportunities to address needs in NICHD populations. ARPA-H's ideas and decision-making processes will be program manager-driven. The program managers that will be hired will have interdisciplinary track records and be rational risk-takers with recognized expertise, drive, insatiable curiosity, no fear of failure, and technical honesty. The agency will have a lean and nimble management structure for conducting high-risk/high-consequence research. ARPA-H has a specific program lifecycle, and its initial mission focus areas are health science futures, scalable solutions, proactive health, and resilient systems.

### **STRIVE Initiative (40:08)**

To meet the STRIVE mission, NICHD has formed three committees to develop comprehensive action plans that outline strategies to:

- Hire, train, retain and promote diverse talent within NICHD
- Train and support the careers of diverse scientific talent in the extramural community
- Propose health disparities research priorities and identify approaches to mitigate key drivers of health disparities

These action plans have been drafted to correspond with NICHD's overall strategic plan and NIH's UNITE activities. The eight action plan goals that have been identified have immediate, intermediate, and long-term associated actions.

### **NIH and NICHD Staff Updates (42:48)**

Internal reorganization resulted in the creation of a new branch at NICHD. The Developmental Biology and Structural Variation Branch is now called the Developmental Biology and Congenital Anomalies Branch (DBCAB).

Anthony S. Fauci, M.D., the director of the National Institute of Allergy and Infectious Diseases; Roger Glass, M.D., Ph.D., the director of the Fogarty International Center; and Andrea Norris, M.B.A., the director of the Center for Information Technology and NIH's Chief Information Officer, have all recently retired.

Joni L. Rutter, Ph.D., has been appointed director of the National Center for Advancing Translational Sciences; Monica M. Bertagnolli, M.D., has been appointed director of the National Cancer Institute; and Nina F. Schor, M.D., Ph.D. has been appointed deputy director of the Division of Intramural Research (DIR).

Chris McBain, Ph.D., has been named the new NICHD scientific director. He joined NICHD in 1993 as an investigator within the Laboratory of Cellular and Molecular Neurophysiology and has been serving as the acting NICHD scientific director since June 2021.

Two finalists are being interviewed for the clinical director of the DIR position. NICHD is also [seeking to hire](#) two branch chiefs, a deputy director, two directors, a scientific review officer, program officers, and program analysts. Many positions have the flexibility to work remotely.

### **Discussion (50:11)**

Dr. Barkin asked whether ARPA-H would form public–private partnerships to achieve its goals. Dr. Bianchi said that she had not yet met one on one with Dr. Wegrzyn but that NICHD was looking at the model used by the Foundation for the National Institutes of Health (FNIH) to create new public–private partnerships and gave a few examples of areas that might benefit from these partnerships.

Dr. Jain asked what percentage of NICHD R01 awards were given to ESIs and said that he was impressed that 1,589 ESI applications were funded in FY 2022. He also asked about the payline for ESI R01 awards. Dr. Bianchi said that she would obtain those data and send them out within a few days.

Dr. Jain congratulated Dr. Bianchi on appointing Dr. McBain as NICHD scientific director. Dr. Bianchi acknowledged the search committee for this position, all the people who participated in the interviews, and the input from NACHHD Council members.

Dr. Lang asked about the impact of inflation on the NICHD budget increases. Dr. Bianchi said that supply costs have been rising and that she planned to ask Council members for budgeting input during the closed session.

Dr. Lang said she was interested in learning about funding opportunities for predoctoral trainees outside of NIH. Dr. Bianchi said that Michael Lauer, M.D., deputy director for extramural research, was looking into this issue and developing awards to provide childcare supplements to ESIs.

Dr. Egan thanked Dr. Bianchi for participating in the congressional briefings on the INCLUDE Project, which is a program that should continue to strengthen and grow. Dr. Bianchi said that Senator Jerry Moran (R-KS) asked questions about the project for more than an hour and truly understood the impact of the investment in the program.

### **III. DIVERSITY, EQUITY, INCLUSION, AND ACCESSIBILITY (DEIA) AT NICHD (1:00:15)**

Together with Una Grewal, Ph.D., M.P.H., and Brett Miller, Ph.D., NICHD Deputy Director Alison Cernich, Ph.D.—who is also the acting director of the NICHD Office of Health Equity (OHE)—provided an update on NICHD’s DEIA efforts and STRIVE Initiative. STRIVE, which was launched in November 2020, is an internal NICHD initiative that works alongside other NIH initiatives, such as UNITE.

STRIVE has three committees: the DEIA Committee, the Scientific Workforce Diversity (SWD) Committee, and the Health Disparities Research (HDR) Committee. Each committee has its own objectives with immediate, intermediate, and long-term goals.

- The DEIA Committee, which is internally facing, was charged with examining all aspects of NICHD’s workforce, including policies, programs, and practices, and identifying focus areas to help improve DEIA across NICHD. The committee assessed the current state of the institute and submitted two reports, analyzed NICHD demographic data, conducted a pulse survey, analyzed federal employee data, and reviewed training offerings for staff at

all levels and tracts. Its current goals are to continue and increase the collection of use of data and to create an NICHD-specific evidence-based training curriculum on current DEIA issues.

- The SWD Committee was charged with evaluating baseline data on training and workforce diversity for NICHD intramural and extramural trainees, project directors, and principal investigators; identifying gaps within current DEIA programs and initiatives at NICHD that hinder its ability to promote an inclusive and equitable workforce and exploring strategies to revise policies and practices around DEIA enhancement; engaging internal and external stakeholders to gather additional insight regarding successes and pitfalls around developing an improved DEIA ecosystem; and creating an action plan that includes comprehensive actionable policy recommendations, a framework to monitor progress, suggestions for transparency, and long-term outcome metrics for the institute. The committee has written goals for addressing each of these areas.
- The HDR Committee was charged with addressing health disparities and systemic racism in NICHD-funded scientific research and with examining opportunities to address social determinants of health (SDOH), including structural racism, in NICHD's health disparities research portfolios. Its goals are to promote community partner research into health disparities, promote inclusion of populations experiencing health disparities in NICHD human subjects research, and incorporate the intersectionality of identities into health disparities research.

Next steps include gathering feedback on the committees' recommendations and proposed action plan before launching a targeted initiative; analyzing information across the action plan to better integrate intramural activities across all domains; beginning the process of assigning various NICHD leads to champion each activity in the action plan; and transitioning STRIVE into a sustainable model. OHE will work with NICHD staff to implement the action plan. An internal advisory committee will advise OHE and monitor the implementation of the action plan.

### **Discussion (1:23:50)**

Dr. Barkin congratulated the STRIVE team on its progress in this important work and said that academic centers across the country were also working on DEIA initiatives. She suggested gathering effective and value-added training tools that have already been developed by organizations pursuing similar goals to create a toolbox of resources. Dr. Barkin added that community partner research requires a different time frame, budget, and format than traditional research. She suggested that the STRIVE HDR Committee pilot several different templates for community partner research to determine whether it is implementable. Dr. Cernich asked NACHHD Council members to suggest DEIA tools and research templates for consideration.

Dr. M. Miller asked for NICHD's definition of *community partner research*. Dr. B. Miller said that the HDR Committee had discussed this definition and recognized that researchers would be starting at different points of community engagement, creating a wide spectrum of capabilities for engaging with research participants and diverse communities. Dr. Contreras-Vidal said that training researchers to conduct studies in diverse communities (e.g., using public spaces, visiting neighborhoods, conducting outreach) was equally important and required further defining of community partner engagement.



Dr. Cernich encouraged NACHHD Council members to provide additional input or share feedback via email to [nichd\\_strive@nih.gov](mailto:nichd_strive@nih.gov).

#### **IV. REPORT FROM THE NACHHD STILLBIRTH WORKING GROUP (1:30:34)**

Dr. Bianchi introduced the mandate and charge of the NACHHD Stillbirth Working Group and its co-chairs Dr. Jain, Pediatrician in Chief and Department of Pediatrics Chair at Children's Healthcare of Atlanta, as well as the George W. Brumley Jr. Professor, Chair of the Department of Pediatrics at the Emory School of Medicine, and Uma Reddy, M.D., M.P.H., Professor and Vice Chair of Research in the Department of Obstetrics and Gynecology at Columbia University. Dr Jain and Dr. Reddy presented the working group's findings and recommendations, which were divided into four focus areas: data collection, communities at higher risk, psychological impact of stillbirth, and known risk factors in stillbirth.

##### **Introduction (1:33:53)**

Stillbirth is a tragedy and a major public health concern in the United States. Between 2016 and 2020, stillbirth affected between 20,000 and 24,000 families each year. NICHD formed the Stillbirth Working Group of Council in 2022 in response to an HHS request to lead a task force to examine stillbirth in the United States. Creation of this task force was described in the FY 2022 House appropriations report. The working group was funded in the Consolidated Appropriations Act, 2022, which was enacted on March 15, 2022.

##### **Methods (1:34:40)**

The 20 members of the working group met four times to gather information on NIH research, data collection procedures, barriers to data collection, communities at higher risk, environmental risk factors, the role of federal agencies, the psychological impact, known risk factors, and the impact of stillbirth on families and communities. The group was particularly moved by a listening session with families who shared their experiences of having a stillborn infant. The working group also issued a request for information ([NOT-HD-054](#)) to solicit input regarding the development of strategies to improve the impact of NIH-funded biomedical, behavioral, and clinical research on stillbirth.

##### **Data Collection (1:36:34)**

The working group found that:

- The current system for obtaining, updating, validating, analyzing, and releasing data on stillbirth in the United States needs significant improvement.
- Accurate, timely, and detailed vital statistics data on stillbirth are essential to enable researchers to advance scientific knowledge on stillbirth and stillbirth prevention. These data are also urgently needed by families affected by stillbirth.
- Current methods for collecting and recording data on stillbirth are not always fully standardized at the state and local levels and do not always align with best practices for the collection of vital statistics data.

- Stillbirth data are typically based on incomplete underlying information, due to the lack of fetal autopsy, placental analysis, genomic analysis, and other types of assessments required to accurately determine a cause of fetal death.
- Few individuals have the combination of skills necessary to assess a cause of death in the case of stillbirth, and for many stillbirths, a cause of death is never identified.
- Stillbirths are typically not linked to the mother's Electronic Health Record, and typically no EHR is created for the baby.
- Stillbirth records are often not amended or updated, even after autopsy or other information becomes available, limiting records' utility for researchers and public health officials.
- Barriers to effective collection of stillbirth data may include lack of legal authority to require specific types of standardization, limited awareness, lack of appropriate training for individuals involved in gathering and/or reporting data, state and regional differences, and lack of research surrounding best practices.

The working group made the following recommendations for data collection:

- Led by CDC, HHS should develop and implement 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; and 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 adverse pregnancy outcomes generally. These activities may include conducting population-based stillbirth surveillance in a diverse range of jurisdictions, exploring opportunities to leverage current data collection systems (e.g., expanding the [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, and/or 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.

### **Communities at Higher Risk (1:43:20)**

The working group found that:

- Survey and vital records data from CDC indicate that individuals from some racial and ethnic groups are at higher risk of stillbirth and other adverse pregnancy outcomes.
- The danger of stillbirth in the United States cannot be addressed unless stillbirth is significantly reduced in the communities at highest risk.

- In the United States, individuals of color face substantially higher risk of stillbirth. The fetal death rate in non-Hispanic Black people is more than twice as high as the rate in non-Hispanic Whites.
- Elevated risk of stillbirth is associated with higher risks of other adverse pregnancy outcomes.
- The reasons for stillbirth disparities are not fully clear, but structural factors contribute to differences in stillbirth risk across racial, ethnic, geographic, and socioeconomic groups.

The working group made the following recommendations:

- 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 the 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 larger shares of individuals from minoritized racial and ethnic backgrounds and other groups that experience disparities.

### **Psychological Impact of Stillbirth (1:47:40)**

The working group found that:

- There is a devastating, lifelong psychological impact on families that experience stillbirth.
- The overwhelming aftermath of stillbirth is felt not only by mothers but also by fathers, siblings, grandparents, and others.
- Improvements in clinical practice and public health care are essential to ensure that families receive the support they need after experiencing a stillbirth.
- Women have reported having their concerns dismissed or being blamed for stillbirth.
- Families report that obtaining information on cause of death is important to them.
- Best practices, such as procedures used in specialty clinics for women who have experienced stillbirth, are available but not widespread.
- Women who have experienced stillbirth often do not receive timely, sensitive, and effective support.
- Fathers, siblings, grandparents, and other family members also need support but seldom receive it.
- Research on the psychological impact of stillbirth has documented the need for psychological support and bereavement care, but further research is needed to develop more effective interventions.

The working group made the following recommendations:

- NIH and CDC should support or conduct systematic research to collect data from individuals who have experienced the psychological impact of stillbirth. Implementation

research should be designed to inform efforts 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 who have experienced 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.

### **Known Risk Factors (1:50:47)**

The working group found that:

- A wide variety of risk factors—including pregnancy complications, chronic health conditions, genetics, environmental factors, and social determinants of health (SDOH) have been associated with stillbirth and other adverse pregnancy outcomes.
- Known risk factors account for a limited proportion of the variation in stillbirth rates.
- Additional research is needed to identify additional risk factors, delineate how these risk factors affect stillbirth, explain racial disparities, and translate knowledge of risk factors into interventions.
- Numerous risk factors and potential causes are associated with stillbirth, including placental conditions, cord issues, infection, maternal conditions, both pregnancy-associated (e.g., preeclampsia) and chronic pre-existing conditions, genetic conditions, and environmental exposures. Known risk factors are insufficient to explain why stillbirths occur. In many cases, stillbirth occurs without any known risk factors.
- Risk factors associated with stillbirth are often also associated with other adverse pregnancy outcomes, suggesting common underlying mechanisms. Research into the pathophysiologic underpinnings is needed.
- Better identification of risk factors is needed for risk stratification, prediction, and, ultimately, prevention of stillbirth.
- Interventions for many known risk factors are not yet available.

The working group made the following recommendations:

- 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 to advance prevention of stillbirth and other adverse pregnancy outcomes. The research agenda should include efforts to identify implications for stillbirth prevention from NICHD'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, and fetal growth.
- 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 under-investigated areas to identify new risk factors and interactions, aid in understanding racial disparities in stillbirth, and 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 the chances of stillbirth and explain racial disparities; and develop and test indicators and clinical interventions for preventing stillbirth.

The working group made the following overall recommendations:

- Improve the quality of vital statistics, surveillance, and epidemiologic data on stillbirth at the local, state, and national levels.
- Use insights from the improved epidemiologic data to conduct additional research to explain and address disparities in stillbirth and identify prevention opportunities.
- Conduct implementation research and develop culturally sensitive interventions to support families who 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.

After this presentation to the NACHHD Council, the discussion and feedback will be incorporated into the final report, which is scheduled to be completed in February. The Working Group Report will be submitted and published in March 2023. Work on implementing the recommendations will begin in the spring and summer of 2023.

### **Discussion (1:56:40)**

Dr. Jain said that he was grateful to the families who shared their stories with the working group and that participating in this work was personal to him because of the loss his family experienced when his brother and sister-in-law had a stillborn baby 50 years ago. Although so much time has passed, his brother still wept when Dr. Jain told him about the work of this group. When families openly shared their unending grief, it inspired the working group members to do their best work. Dr. Jain encouraged Dr. Bianchi to invite these families to participate in other NICHD committees. Dr. Bianchi said that the fact that the families were so engaged from the beginning inspired the working group to set up an entire session devoted to capturing their experiences. The mothers, fathers, and families were incredibly honest about the toll that stillbirth had on their marriages and finances and shared their passion to search for answers and the corresponding lack of response from hospitals, medical systems, and care providers. The session with the families further inspired the working group to want to make a difference.

When considering all the unknowns about stillbirth, Dr. Barkin asked what the best way to start moving forward with the recommendations would be. She also asked whether existing data in biorepositories could be useful for studying stillbirth (e.g., fetal microchimerism). Dr. Reddy said that the working group report was a high-level overview, because the group had received many suggestions for specific research directions throughout the process (e.g., biomarkers, placental and fetal imaging, building on existing NIH and PRAM research).

Dr. Jain said that he was unaware of any complete data set in the United States that contained genetic information pertaining to stillbirth. Dr. Reddy said that the Stillbirth Collaborative Research Network had collected some data through its NIH-funded studies. Dr. Bianchi said that the *All of Us* Research Program had collected data, including EHRs, on at least 10,000 pregnant women to date. She said that she would find out whether stillbirth data were being collected.

Dr. Resnick said that the presentation highlighted the challenges of data integration. He suggested that creating medical records for fetuses prior to birth and linking the data to the

mother's medical record would be a good example for standardizing a better model of data collection. This could be part of the working group's recommendations, because it would be useful across many types of maternal-fetal research. Dr. Jain said that the data collection theme had both a research component and a public health component. Dr. Cernich said that the idea to create medical records earlier was a good one to raise with the Office of Research on Women's Health (ORWH) [Maternal Morbidity and Mortality \(MMM\) Web Portal Initiative](#), because the initiative is reviewing EHR workflows.

Dr. Rowitch shared his perspective from England, where pregnancy outcomes are collected in a national database. He suggested developing international collaborations and partnerships where researchers around the world could contribute to study design and resource sharing for investigating stillbirth. He added that promising studies (e.g., using biomarkers or ultrasound) that could lead to the development of interventional research were underway. Dr. Reddy agreed that much could be learned from colleagues in Europe and from the U.K. system of perinatal audits.

Dr. Cernich said that the working group's listening session with families who had experienced stillbirth was a testament to the power of people's voices, because it was difficult for the families to relive the trauma for the sake of sharing their stories. Their community is empowered to have an impact on research, and the sheer number of families affected is high. She also noted that NICHD with working with the Office of the National Coordinator (ONC) to try to develop data standards to facilitate the linkages that Dr. Resnick proposed.

Dr. Egan asked whether stillbirth was more common in first-time mothers who did not know what to look for during pregnancy, such as movement. Dr. Reddy said that stillbirth is more common in first-time pregnancies, but much research needs to be done to determine why.

Dr. Bianchi said that NICHD has become aware of the magnitude of the problem of stillbirth in the United States.

#### **Approval of Recommendations (2:15:48)**

A motion to approve the recommendations of the NACHHD Council Stillbirth Working Group carried.

#### **V. INVITED DIRECTOR: NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS) (2:17:25)**

Richard Woychik, Ph.D., director of NIEHS, described the mission and vision of NIEHS, its efforts to develop exposomic research, and its intersections with NICHD.

#### **Introduction to NIEHS (2:23:18)**

NIEHS's mission is to promote healthier lives by learning how the environment affects people. The institute's vision is to provide global leadership for innovative research that improves public health by preventing disease and disability. NIEHS studies the dozens of environmental factors

that can positively or negatively affect health. Each person responds differently to any given environmental exposure, which creates a need for precision environmental health.

### **The Exposome Concept (2:26:10)**

The international environmental health sciences community has come to recognize that scientists can no longer study one exposure at a time and is now using a framework called the exposome concept to factor in the totality of exposures over the life course. An operational definition of the exposome is needed, and scientists must build technology capabilities to study the exposome. While those capabilities are being developed, researchers can use currently available tools (e.g., high-resolution mass spectrometry) to model exposome data for the genomics community. NIEHS conducted workshops to determine how best to collect data to enable exposomic research for precision environmental health and medicine. The institute is also using its Human Health Exposure Analysis Resource (HHEAR) infrastructure to help funded investigators add or expand exposure analysis in biological and environmental samples and provide a public-access data repository.

### **NIEHS Research on Maternal and Child Health (2:31:07)**

NIEHS studies the windows of susceptibility and the developmental origins of health and disease (DOHaD) across the lifespan, from preconception to old age, and has developed targeted programs for the preconception, prenatal, and reproductive life stages. Dr. Woychik highlighted many of NIEHS's program areas, such as the [Pregnancy And Childhood Epigenetics \(PACE\) consortium](#), which consists of researchers at NIEHS and around the world who are interested in studying early life environmental impacts on human disease using epigenetics.

The six [NIEHS Collaborative Centers in Children's Environmental Health Research and Translation](#) facilitate interaction among experts in all fields of science; engage partners to move the science into public health and clinical practice; synthesize and translate extant children's environmental health research; stimulate pilot projects; test and implement new tools, methods, and intervention or prevention strategies; and form a collaborative network to respond to and protect children from environmental threats.

### **Intersections with NICHD (2:40:12)**

Beyond the maternal and child health programs described above, NIEHS intersects with NICHD to collaborate on the [Centers of Excellence on Environmental Health Disparities Research](#), the [Pediatric and Reproductive Environmental Health Scholars \(PREHS\) Program](#), and [environmental health chat podcasts](#) on children's health topics.

NICHD–NIEHS collaborations may make it possible to bring exposomics to bear on existing NICHD cohorts by using exposomic approaches to analyze existing tissue samples, using samples to study epigenetic profiles to determine whether their signatures reflect exposures, or using NICHD's Data and Specimen Hub (DASH) repository.

### **NIH Climate Change Initiatives (2:43:46)**

Beyond NIEHS, NIH has several climate change and health research efforts. President Clinton launched the [President's Task Force on Environmental Health Risks and Safety Risks to](#)

[Children](#); its [Subcommittee on Climate, Emergencies, and Disasters](#) was created in 2021. A collaborative group of NIH leaders proposed the strategic framework for the NIH-wide [Climate Change and Health \(CCH\) Initiative](#). The CCH Initiative's strategic framework was developed to guide future climate change and health research. New funding announcements will be posted on the Initiative's website.

### **Discussion (2:50:26)**

Dr. Lang asked what the time frame would be for developing the new technology capabilities and tools to study the exposome. Dr. Woychik said that the timeline would depend on how soon the exposome can be functionalized and how creative science can be in developing the tools to explore it.

## **VI. SCIENTIFIC PRESENTATION: THE DOUBLE BURDEN OF HEAT STRESS AND MATERNAL MALNUTRITION ON MATERNAL-CHILD HEALTH OUTCOMES (2:53:51)**

Nancy F. Krebs, M.D., M.S., professor of Pediatrics and head of the Section of Nutrition in the Department of Pediatrics at the University of Colorado School of Medicine; and Kartik Shankar, Ph.D., a professor in the Department of Pediatrics at the University of Colorado School of Medicine, presented their NICHD-funded work studying the effects of maternal malnutrition and heat stress on maternal-child health outcomes. The Women First Preconception Nutrition Trial (WFPNT) is a randomized controlled clinical trial that began in 2014, and was conducted at four international research sites in Guatemala, India, Pakistan, and the Democratic Republic of the Congo. Researchers sought to examine the effects of providing a daily, lipid-based, multi-micronutrient supplement to women prior to conception, at the end of the first trimester or not at all (control) on birth length.

Using existing data and biospecimens from this study, the investigators studied the effect of heat stress on pregnancy, because according to UNICEF's 2022 data, 559 million children worldwide are exposed to high heatwave frequency (more than 4.5 heatwaves per year). Moreover in 2020, around 740 million children (1 in 3) lived in countries with at least 83 days per year exceeding 35°C. UNICEF predicts that by 2050, virtually every child on the planet (about 2 billion) will face more frequent heatwaves, irrespective of warming scenarios. One of the WFPNT sites, located in rural Pakistan (Sindh Province), was evaluated for the effects of heat stress on neonatal outcomes, because the site's participants face dual burdens of chronic malnutrition and exposure to recurrent cycles of high ambient temperatures.

The research team found that birth length differences were influenced by season of birth. Specifically, excessive heat stress in the first trimester was associated with lower birth length and lower head circumference scores. First-trimester heat stress also led to significant changes in the placental gene expression signatures, but in both the WFPNT trial and in animal models, improving maternal nutrition provided resilience against these changes. Using the Maternal Newborn Health Registry of the NICHD's Global Network for Women's and Child's Health Research (GN), the researchers also examined the effects of heat stress on other obstetric outcomes (e.g., pregnancy hypertension, stillbirth, low birth weight, preterm birth) in GN sites in



India and Pakistan. They used those data to design and conduct a wide range of preclinical genetic studies and to develop prediction models.

Together, the WFPNT study and preclinical genetic work produced the following take-home messages:

- In the context of maternal malnutrition, ambient heat stress in the first trimester has detrimental effects on intrauterine growth.
- Improved maternal nutrition prior to conception and throughout pregnancy may provide resilience against heat-induced growth restriction.
- Heat exposure alters expression of placental genes involved in protein translation.
- Ambient heat during pregnancy and lactation is likely to have effects through multiple pathways.
- Prospective intervention and mechanistic studies are necessary to further elucidate mechanisms.

### **Discussion (3:18:23)**

Dr. Barkin asked how the nutrition intervention for the WFPNT was chosen. Dr. Krebs said that finding a product that could be used across all four international sites was challenging and that it was not easy for some women to take the chosen supplement (an MMN-fortified, lipid-based supplement composed of dried skimmed milk, soybean and peanut extract, sugar, maltodextrin stabilizers, and emulsifiers) for nine or more months.

Dr. Barkin asked whether any placental changes (e.g., size, function) were observed in the study. Dr. Shankar said that the researchers were unable to quantify any changes in placental volume, but untargeted metabolomics data may provide some information on maternal circulation. The team also does not have individual-level heat exposure data.

## **VII. VOICE OF THE PARTICIPANT: IMPACT OF CLIMATE CHANGES ON THE DAY-TO-DAY LIVES OF THE WOMEN AND THEIR FAMILY MEMBERS IN THATTA, PAKISTAN (3:20:36)**

Dr. Bianchi introduced Sumera Aziz Ali, M.D., M.Sc., an epidemiologist and graduate student in Columbia University's Mailman School of Public Health, who shared her experience working with WFPNT participants in the rural area of Thatta, Pakistan. She used focus group interviews to collect information from local community research participants, research staff, and health care providers. Climate challenges in Thatta include annual heat stress in June and July, annual heavy rainfall in August and September, and major floods in 2010 and 2022.

Dr. Aziz shared the following comments from participants and researchers about living with each of these challenges (*emphasis added by Dr. Aziz*):

### *Heat Stress*

- “During pregnancy, we cannot eat iron tablets in this high heat, because it causes burning, and we feel like *our bodies (mainly hands) are burning in the summer* when the sun is scorching. We can take calcium tablets in water, because that gives us more relief, but it is *hard to take iron tablets* during heat.” —WFPNT participant

- “After we cook food on the stove during summer, *appetite decreases* due to high heat, and we fulfill our tummy with water to quench our thirst. Since we cannot eat, we *become weak* and *get tired* after working for some time.” —Woman from Thatta
- “I have observed more *miscarriages* during June and July when the sun is scorching. This may be because during heat stress, families need more water to drink, and *pregnant women fetch water from remote areas by carrying heavy pots* on their heads and walking for around 1.5 miles in the sun. The heavy weights may result in *abortions*.” —WFPNT research staff member
- “Pregnant and lactating women support the male members (farmers) in the fields during crop harvesting (e.g., tomatoes or okra). After lifting heavy weights during hot weather, women feel thirsty and drink water from small canals in the fields that are *polluted with pesticides*. The exposure to pesticides (drinking and breathing) *may be dangerous for mothers and their babies*.” —Local health care provider

### Heavy Rainfall

- “Due to heavy rains, we need to save our cattle from mosquitoes by moving to the mountains. In the new place, we cannot find food easily as we move far from the city or our village to save our animals. Sometimes, we *sleep without eating*.” —Woman from Thatta
- “Due to heavy rains, families move to the mountains with limited access to water and food. Women and their families have to drink unhygienic rainwater, resulting in *diarrhea and weakness*. Also, there is a burden on the health care system, because one health facility gets overburdened.” —WFPNT research staff member
- “Women and family members sleep with animals, and now they are used to it and do not feel bad or uncomfortable, but that can develop *unknown diseases*.” —WFPNT research staff member
- “During monsoons, families move on the carts with luggage, and their *husbands do not care about the pregnant women*. The carts are heavily loaded with luggage and women. There is a *risk of falls*. Also, it is too high to climb the cart, and women may feel uncomfortable or may lose babies. The roads are not smooth, and there are jumps on the way, which may lead to *miscarriages or premature delivery*.” —WFPNT research staff member

### Flooding

- “During floods, crops are affected badly. Having money from crops helps villagers to buy flour and household items. They do not earn money and face hunger. Lactating women do not eat more, and their milk is not formed. *Both baby and mother become weak*, but baby becomes *malnourished* as infant relies heavily on mother’s milk.” —Local health care provider
- “Due to lack of food, if a pregnant mother is not eating properly, her baby in the womb may not get enough food, and *a weak baby will be born*.” —WFPNT research staff member
- “Pregnant women and their families are displaced and migrate to new places with limited water and food supply. Women drink unhygienic water and develop *vomiting and diarrhea*. If women are not well, they end up giving birth to *low birth weight babies* or deliver prematurely.” —WFPNT research staff member

- “Roads are affected badly, with no access to health care facilities. Big vehicles, such as Suzuki and cars cannot move in heavy water. If a woman enters labor, her husband or another family member will take her to the health facility on the motorbike, which is dangerous for a woman, because she can either *deliver on the way or start bleeding* and sometimes *even may die* on the way if not reached on time due to poor road infrastructure.” —WFPNT research staff member

Dr. Aziz also shared some of the effects of climate change on research activities that WFPNT research staff observed and experienced. The supplement sachets started melting in the heat, affecting the taste and texture of the supplement. When the heavy rains led to migration, participants had no electricity to charge their phones, leading to a loose connection with participants, and biweekly visits were missed. Migration also led to poor connection with facilities. Babies were delivered at home, so research staff could not collect placental tissue or other biological samples. When the heavy rains led to migration and participants moved to new places, more resources (e.g., vehicles, human resources) were needed to find the women and collect the data. During heat stress, the productivity of research staff also decreased.

Further complicating the research study, Dr. Aziz shared the following detrimental coping mechanisms reported by WFPNT participants and researchers:

- “In the heat, women and their kids take baths in small canals and streams where animals also take baths. They use the *same water for bathing, washing, and drinking.*” —WFPNT research staff member
- “We drink buttermilk (*lassi*) to quench our thirst or drink water if that is available. Milk is only available with families who own the cows or buffaloes.” —WFPNT research participant
- “Women fetch water from hand pumps, but that water contains *heavy metals* that may produce bad effects in the long term.” —Local health care provider
- “Not all villages can use groundwater. For example, Jungshahi (one area in Thatta) has bitter/salty groundwater, so hand pumps cannot be built. Therefore, families purchase water trough tanks and that is *costly* and not safe.” —WFPNT research staff member

Dr. Aziz said that relief organizations set up clean drinking water stations on the roads and that families keep cool cloths on their heads and try to stay under large trees to avoid the direct sun.

### **Discussion (3:42:55)**

Dr. Bianchi thanked Dr. Aziz for putting a human face on this study by sharing the experiences of participants and researchers.

## **VIII. CONCEPT CLEARANCE (3:44:14)**

Dr. Rasooly provided an update from the September 2022 NACHHD Council meeting. She said that NIH recently changed the dollar threshold for applications that require Special Council Review. After more data are collected and analyzed, Dr. Rasooly will provide responses to Council questions from that meeting.

The Council reviewed three concepts.

### **New Approaches for Measuring Brain Changes Across Longer Time Spans (3:46:17)**

No comments or questions. Decision: Approve.

### **Collaborative Rare Diseases Research for Long-Term Follow-Up of Newborn Screening Conditions (3:48:20)**

Dr. Barkin asked for additional information on the follow-up and tracking components of the concept. Dr. Barkin suggested adding a technological component to make it possible to track patients who move from one state to another. Dr. Resnick suggested that the consortium model may not be the best strategy for collecting general newborn screening genomic data if it precluded participation in disease-specific consortia. He said that newborn screening could be a part of many NICHD research programs, and the consortium model may be more expensive than other frameworks and data sharing strategies. Decision: Approve.

### **NICHD High-Priority Research Projects (3:57:51)**

Caroline Signore, M.D., M.P.H., deputy director of the Division of Extramural Research (DER), presented a proposed operational paradigm for shortening the time between identifying an emerging scientific need and making awards to fund research in that area. Dr. Barkin, Dr. Dorn, Dr. Bucci-Rechtweg, and Dr. Miller spoke in favor of this concept. Dr. Bucci-Rechtweg asked whether implementing the concept would affect capacity to accommodate the more efficient timeline. Dr. Miller asked for additional information on the relative length of time for preparing funding announcements compared to the time required to approve them. Dr. Signore noted that there is a relationship between the length of the written announcement and the time to review and approve them. . Decision: Approve.

## **IX. CLOSING REMARKS (4:11:36)**

Dr. Bianchi thanked Council members, NICHD staff, presenters, and members of the audience. She welcomed everyone to join the 45-minute open session scheduled for January 25, 2023, at 12 noon ET, where the topic would be NICHD's Data Sharing Policy.

## **X. DAY 1 ADJOURNMENT**

Dr. Bianchi adjourned Day 1 at 5:15 p.m. A total of 200 people viewed [the live VideoCast](#).

## **XI. DAY 2 CALL TO ORDER AND INTRODUCTORY REMARKS (0:01)**

Dr. Bianchi opened Day 2 of the virtual meeting and once again welcomed the members of the NACHHD Council and other virtual participants. She announced that the new NIH [Data Management and Sharing \(DMS\) policy](#) to promote the sharing of scientific data went into effect this morning, making the next presentation timely.

The [NIH Day 2 VideoCast](#) time stamp appears in parentheses for each section below.

## **XII. NICHD DATA SHARING (0:17)**

Dr. Bianchi introduced Rebecca Rosen, Ph.D., the director of the NICHD Office of Data Science and Sharing (ODSS). Dr. Rosen described ODSS, the NIH DMS policy, and data sharing resources for NICHD staff and investigators.

### **ODSS (1:11)**

ODSS was established in July 2021 to facilitate data sharing and access to biospecimens. Its vision is to provide a culture of responsible and innovative use of data and biospecimens that accelerates research and improves health for NICHD populations. Its mission is to develop a diverse, secure, and interoperable research data ecosystem and to advise on best practices for data collection, standards, management, sharing, and use across the research and funding lifecycles. ODSS has developed high-priority use cases to help define its data and specimen ecosystem. The office leads NICHD-wide activities by providing technical structure, overseeing policy implementation and compliance, establishing standards, and facilitating training and partnerships. DMS policy is developed by intramural and extramural data sharing committees and governed by the ODSS Division of Extramural Activities Data and Specimen Ecosystem Working Group.

### **NIH DMS Policy (9:00)**

The DMS policy became effective this day, January 25, 2023, for 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 DMSP expects researchers to maximize data sharing and share data in established repositories at the time of publication or the end of the performance period, whichever comes first. DMS policy requires compliance with approved DMSPs as a term and condition of any award.

The structure of the extramural DMSP is outlined [on the NIH Scientific Data Sharing website](#), and additional funds for data sharing costs can be requested by [submitting a budget form with a budget justification](#). After a grant application is submitted, peer reviewers only review and score the DMSP when data sharing is integral to the Funding Opportunity Announcement (i.e., the DMSP flag is set to “Data Sharing Focus”). An approved DMSP becomes a term and condition of the award, so grantees report progress of the approved DMSP in their annual Research Performance Progress Report (in the Mechanisms and Tools to Support Oversight Under Development section). Failure to comply may result in an enforcement action and affect future funding decisions.

### **NICHD Data Sharing Resources (16:33)**

The following DMS resources are available on the internal or public websites:

- [DMS Policy Resources](#) (public)
- [Tips for Writing a Data Management and Sharing \(DMS\) Plan](#) (public)
- [Example DMSPs](#) (public)
- [NICHD Data Repository Finder](#) (public)
- NICHD Extramural DMS Policy FAQs (internal)

- NICHD Intramural DMS Policy FAQs (internal)
- NICHD DMSP Assessment Guidance (internal)

[DASH](#) is a centralized resource that allows researchers to share and access de-identified data and biospecimens from 207 NICHD-funded clinical studies. It serves as a portal for requesting biospecimens from nine studies and aims to accelerate scientific findings to improve human health. DASH recently released several new DMS policy-specific features, and new features are planned for the coming year.

Additional resources and data linkages are being developed through the NICHD data ecosystem analysis process. ODSS staff are also developing researcher training courses, such as “[Elements of Style in Workflow Creation and Maintenance](#),” which is available as an in-person or online class.

### **Discussion (26:37)**

Dr. Resnick said that he appreciated the leadership role that NICHD was taking in the DMS ecosystem. He added that there will be challenges and opportunities for improvement going forward and asked how best to increase uniformity of interpretation of NIH’s DMS policy across all the enterprise. Dr. Rosen said that consistency in implementation of the policy would be key, along with the continued development of plain language resources for improved understanding and compliance.

Dr. Barkin asked how the deconstruction of certain data elements and data types from various repositories would allow them to be reconstructed from their original source. Dr. Rosen said that there were ways to connect the data to maintain its integrity while simultaneously connecting it to other resources. She added that data from different repositories would not yet be integrated into a single researcher workbench, because it would be a large undertaking, but it may be possible in the future.

Dr. Barkin asked about how biospecimen storage would be managed. Dr. Rosen said that biospecimen storage was not covered under the data sharing policy.

Dr. Bianchi asked Council members to serve as ambassadors for the use of DASH in their institutions, especially for trainees who want to develop hypotheses.

Dr. Rowitch asked whether NIH was interested in setting metadata standards for human cell atlasing and suggested collaborating with researchers currently working in this field (e.g., the Allen Institute, the Brain Research Through Advancing Innovative Neurotechnologies [BRAIN] Initiative, the Chan Zuckerberg Initiative) to do so. Dr. Rosen said that NIH does not typically get involved in setting data standards but does support collaborative public-private data analysis projects.

Dr. Fair asked about how researchers could balance competing data resources at NIH, their own academic institutions, and private research institutes. Dr. Rosen said that NIH policy was most interested in broad data sharing. The ultimate goal is to have all of the systems working together.

Dr. Fair said that some of the competing resources are funded by NIH, making it difficult to balance when the competing interests are very broad.

Dr. Egan asked whether the researchers who own/produced the data feel protected, especially when states' data protection policies differ. Dr. Rosen said that the policy acknowledges limitations on data sharing, so researchers are encouraged to list each limitation in their applications.

Dr. Egan said that one gap in the field is psychometric data. Dr. Rosen said that ODSS is watching this field as it develops data standards.

Dr. Bianchi asked Dr. Rosen to follow up on several questions that were posted in the chat.

### **XIII. CLOSED SESSION (46:25)**

The meeting was then 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 members provided second-level review of DER applications. A total of 56 people viewed [the Day 2 live VideoCast](#).

### **XIV. ADJOURNMENT**

There being no further business, the meeting adjourned at 5:00 p.m. on Wednesday, January 25, 2023. The next meeting, scheduled for June 6–7, 2023, will take place at the NIH Bethesda Campus in Building 31.

I hereby certify that, to the best of my knowledge, the foregoing minutes and attachments are accurate and complete.<sup>2</sup>

\_\_\_\_\_  
Diana W. Bianchi, M.D.  
NACHHD Chair  
NICHD Director

\_\_\_\_\_  
Date

\_\_\_\_\_  
Rebekah Rasooly, Ph.D.  
NACHHD Executive Secretary  
Associate Director, NICHD DER

\_\_\_\_\_  
Date

\_\_\_\_\_  
<sup>2</sup> These minutes will be formally considered by the Council at its next meeting, and any corrections or notations will be incorporated into the minutes of that meeting.