Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Advisory Child Health and Human Development (NACHHD) Council

Meeting Summary

January 13–14, 2025

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 187th meeting at noon ET on Monday, January 13, 2025. It was a virtual meeting that was open to the public from noon to 5 p.m. ET. The Council reconvened on Tuesday, January 14, 2025, at 9 a.m. ET, for a session that was closed to the public. 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]

Anna Aizer, Ph.D., M.S.
Diana W. Bianchi, M.D. (Chair)
Susan L. Brooks, J.D.
Marcelle Ivonne Cedars, M.D.
Damien Fair, Ph.D.
Cynthia Gyamfi-Bannerman, M.D.
Ethylin Wang Jabs, M.D.
Yvonne A. Maldonado, M.D.
Ignatia B. Van den Veyver, M.D.

Ad Hoc and Subject Matter Expert (SME) Members

Shannon Cohn, J.D.
Francis Sessions Cole, M.D.
Edelle C. Field-Fote, Ph.D.
Kimberly Gregory, M.D., M.P.H. (SME)
Zhanzhi "Mike" Hu, M.D.
Ken Mandl, M.D.
Megan A. Moreno, M.D., M.S.Ed., M.P.H.
James Roberts, M.D. (SME)
Kishore Vellody, M.D.
Mariana Wolfner, Ph.D.

Council Members Absent

None

Ex Officio Members

Patricia Dorn, Ph.D.

Department of Defense

Gayle Vaday, Ph.D.

Health Resources and Services Administration

Reem M. Ghandour, Dr.P.H., M.P.A.

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 that follows each heading refers to the time stamp on the Day 1 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 applications from their own institutions are discussed by the Council, 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 (0:05)

Dr. Bianchi opened the meeting and welcomed the members of the NACHHD Council and all attendees who joined on Zoom or via NIH VideoCast. She reviewed the agenda and the logistics for speaking during the meeting. She then asked the eight ad hoc members of the Council, followed by two subject matter experts (SMEs) who were participating in this Council meeting, to briefly introduce themselves.

Review of Confidentiality and Conflicts of Interest (10:19)

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 they evaluate any NIH grant applications. Before the meeting, Council members—including ad hoc members and SMEs—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 with which they are in conflict, in addition to those listed in the Council action document. People are not allowed to serve on any NIH peer review panel while they serve as Council members, because NIH policy indicates that individuals may not serve on both the first and second levels of peer review.

Council Minutes (12:15)

Marcelle Ivonne Cedars, M.D., made a motion to approve the September 4–5, 2024, NACHHD Council meeting minutes as written. Ethylin Wang Jabs, M.D. seconded the motion. Council members voted to approve the minutes.

Future Meeting Dates (12:57)

Dr. Rasooly announced that future Council meetings are scheduled for June 9–10, 2025; September 9–10, 2025; January 26–27, 2026; June 8–9, 2026; and September 1–2, 2026.

II. NICHD Director's Report (13:37)

In her report, Dr. Bianchi reviewed the congressional updates and transition, described the NICHD Strategic Plan, provided highlights on ongoing women's health research and pediatric research, and shared staffing updates.

Congressional Update and Presidential Transition (14:48)

Given the Continuing Resolution (CR) until March 14, 2025, NICHD must operate on an uncertain budget for most of the remainder of the first half of Fiscal Year (FY) 2025. It will therefore need to be particularly conservative in its spending during that time.

Regarding the anticipated congressional timeline for the presidential transition, a new Speaker of the House has been elected, and the confirmation process for the new administration's nominees would take place once the incoming president was inaugurated. The NIH Director is a political appointee who requires U.S. Senate confirmation. During a presidential transition, all political appointees customarily submit letters of resignation that are either accepted or rejected by the incoming president. Current NIH Director Monica M. Bertagnolli, M.D., will submit her letter of resignation, and NIH has prepared transition informational documents to brief the incoming administration. President Donald Trump's nominee for NIH Director, Jay Bhattacharya, M.D., Ph.D., has been meeting with members of the Senate. After this, there will be a hearing of the Senate Committee on Health, Education, Labor, and Pensions (HELP). The Senate HELP Committee will then vote, followed by a full Senate floor confirmation vote. The exact timing of this process is not yet known.

NICHD Research Highlights (18:26)

NICHD has published its annual showcase of research highlights. Some of the topics featured in the 2024 Selected Research Advances include:

- Supporting women's health
- Improving postpartum health outcomes
- Advancing fetal and neonatal health
- Improving care for pediatric injury
- Advancing child and adolescent health
- Treating and understanding pediatric infections
- Addressing health disparities for people with disabilities
- Expanding research on intellectual and developmental disabilities

NICHD Strategic Plan 2025 (19:30)

The NICHD Strategic Plan 2025 is nearly finalized. The 2025 plan maintains the same five overarching scientific themes as the 2020 plan. However, the new plan features updated objectives within those themes, as well as updated scientific stewardship goals and management and accountability goals. Dr. Bianchi thanked Council members for their feedback throughout the process, which was incorporated into the plan.

Overview of Updates to Strategic Plan Objectives (21:27)

The NICHD Strategic Plan 2025 features the following highlights:

- **Theme 1: Understanding the Molecular, Cellular, and Structural Basis of Development.** New objectives leverage new technologies, including artificial intelligence (AI) tools.
- **Theme 2: Advancing Gynecologic, Andrologic, and Reproductive Health.** The new plan places a stronger emphasis on gynecologic conditions and contraception,

shifting the focus from developing fundamental knowledge to promoting translation to improve gynecologic health.

- **Theme 3: Setting the Foundation for Healthy Pregnancies and Lifelong Wellness.** Building on the success of the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative and other programs in reducing maternal mortality, the 2025 plan continues to focus on maternal and infant health, with a maintained emphasis on prevention of stillbirth and preterm birth and treatment of preterm conditions.
- **Theme 4: Improving Child and Adolescent Health and the Transition to Adulthood.** The new plan adds a focus on pediatric primary care for children of all ages. It also continues the work on adolescence and transition to adulthood started in the 2020 plan.
- **Theme 5: Fostering Safe and Effective Therapeutics and Devices for Pregnant Women, Lactating Women, Children, and People With Disabilities.** Building on the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) implementation progress and the Maternal and Pediatric Precision in Therapeutics (MPRINT) program, the 2025 plan recognizes the need for additional data on how pregnant women and lactating women metabolize therapeutics to reassure them about medication safety and emphasize opportunities for collaboration with other historically successful organizations.

Aspirational Goals and Cross-Cutting Themes (25:52)

Aspirational goals are areas in which NICHD aims to increase its efforts. In addition to retaining some of the 2020 aspirational goals—such as diagnosing, preventing, and treating endometriosis—the 2025 plan adds new aspirational goals related to:

- Improving function for people with neurological impairment
- Using menstrual effluent and semen to diagnose conditions
- Preventing preeclampsia and postpartum hemorrhage as major drivers in maternal mortality
- Improving quality of human milk and understanding how medications are metabolized and may appear in human milk
- Preventing stillbirth
- Improving the health of preterm infants
- Enhancing pediatric primary care
- Expanding gene therapy

The 2025 plan also maintained the five cross-cutting themes from the 2020 plan and added two new items at the end of the list, for a total seven cross-cutting themes:

- Health disparities and health equity
- Prevention
- Infectious disease
- Nutrition
- Global health

- Advanced technologies and AI
- Research training and career development

Women's Health Research (28:08)

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
- Intellectual and developmental disabilities
- Population dynamics

Dr. Bianchi provided updates on the National Academies' assessment of women's health research at NIH and an endometriosis Rapid Acceleration of Diagnostics Technology (RADx® Tech) research challenge. She also encouraged attendees to explore and distribute NICHD's series of one-page summaries on women's health topics.

National Academies' Assessment of NIH Research on Women's Health (28:18)

In December 2024, the National Academies of Sciences, Engineering, and Medicine (NASEM) released a report that assessed women's health research across all NIH Institutes and Centers (ICs). This assessment appeared to overlook some of NICHD's research scope and portfolio. The NASEM report stated, among other items, that a number of female-specific conditions, such as endometriosis, are "not within the purview of any specific IC," when in fact 42 USC 285g (Sec. 448) explicitly lists gynecologic health research as one NICHD's areas of focus.

Following the release of the NASEM report, the NIH Director released a statement that while the NASEM report provided valuable recommendations to expand NIH research efforts, it did not acknowledge the full breadth of NIH's work in women's health research. It also understated the significance of ongoing women's health initiatives supported by NICHD and other ICs. Women's health research at NIH was similarly highlighted in a 2025 article published in the *Journal of the American Medical Association*.

NICHD's investment in gynecologic health research is active and growing. The Gynecologic Health and Disease Branch in NICHD's Division of Extramural Research (DER) maintains a research portfolio that includes endometriosis, uterine fibroids, pelvic floor disorders, and polycystic ovary syndrome.

RADx® Tech Advancing Cures and Therapies and ending ENDOmetriosis diagnostic delays (ACT ENDO) Challenge (32:26)

This partnership between NICHD and the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is leveraging the RADx® Tech innovation funnel to accelerate the time to diagnosis of endometriosis, eliminate invasive techniques, and/or improve accessibility of diagnosis for endometriosis. The RADx® Tech ACT ENDO challenge received a robust response at the Phase I submissions stage, with a range of diagnostic approaches in the applications including imaging, stool-based biomarkers, gastrointestinal motility metrics, and menstrual effluent biomarkers. The next steps are the pitch presentation event (Phase II), followed by the technology development sprint (Phase III). Final winners are expected to be announced in March 2026.

Pediatric Research (33:48)

NICHD conducts pediatric research in:

- 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
- Pregnancy and perinatology
- Population dynamics

Dr. Bianchi provided updates on a NASEM study of NIH pediatric health research and on a collaborative pediatric research program.

NASEM Study of Strategies to Enhance Pediatric Health Research Funded by NIH (34:15)

As required by FY 2024 Appropriations Report language, NASEM is also conducting an analysis of pediatric health research supported by NIH. The committee's first meeting took place in December 2024, which will be followed by a series of public meetings over the next 18 months. The committee is tasked with examining the current NIH pediatric research portfolio and structure, which will culminate in a report with recommendations to advance pediatric research. The committee's work is ongoing, with NICHD providing information in response to data requests to help complete the analysis. The final report is expected to be published in early 2026.

Gabriella Miller Kids First Pediatric Research Program (36:54)

The Gabriella Miller Kids First Pediatric Research Program (Kids First) fosters collaborative research across NIH to uncover the causes of childhood cancers and

structural congenital anomalies and support data sharing within the pediatric research community. The Gabriella Miller Kids First Research Act 2.0 has been signed into law, extending the program through 2028.

In 2024 alone, more than 12,000 samples were sequences, more than 11,000 genomes were delivered to investigators, and more than 6,000 genomes were made available on the Kids First Data Resource Center portal, which allows users from more than 50 countries to access clinical data, phenotypes, and genetic variants. The program's next steps include enhancing its interoperability efforts, releasing more data to the Kids First portal, and continuing multimodal data integration in the portal.

NICHD Staff Updates (38:29)

Lindy Thaker, M.D., has been selected as chief of the Pediatric Growth and Nutrition Branch. A pediatrician and global nutrition expert, Dr. Thaker previously worked with the U.S. Agency for International Development (USAID) supporting nutrition programs.

Maranke Koster, Ph.D., has been selected as chief of the Developmental Biology and Congenital Anomalies Branch. She has held faculty positions at the University of Colorado Anschutz Medical Campus and East Carolina University's Brody School of Medicine, where her research focused on the mechanisms that control ectodermal tissue development and the pathological mechanisms that lead to ectodermal dysplasia.

Discussion (40:48)

Francis Sessions Cole, M.D., asked whether funding opportunities related to pregnancy-related conditions would be included in the NASEM report on pediatric research at NIH, given that gestation significantly influences pediatric outcomes. Dr. Bianchi said that the NASEM committee examining pediatric research had asked about the older age groups within pediatrics more than about pregnancy-related aspects, but the names of the committee members are publicly available, and they may be asked directly.

José L. Contreras-Vidal, Ph.D., asked whether NASEM would publish a correction regarding the NIH women's health research report to avoid perpetuating misconceptions. Dr. Bianchi said that NIH compiled a list of potential inaccuracies in the published NASEM report—which was a draft—and would be meeting with members of the NASEM committee to discuss corrections for the final version. Dr. Contreras-Vidal added that workforce development and global collaboration are critical and should be further emphasized throughout NICHD, noting Team Science efforts. Dr. Bianchi agreed. At the recent NIH leadership forum, there was an in-depth discussion about Team Science and how to recognize those researchers participating.

Cynthia Gyamfi-Bannerman, M.D., asked whether there were plans to increase the number of obstetrician–gynecologists (OB–GYNs), both in the Council and throughout NICHD. Dr. Bianchi said the Council is cognizant of the need to balance both medical and scientific expertise in this area and that 3 of the 18 Council members are OB–GYNs, with a fourth

slated to join the Council in June. She added that the 2025 NICHD Strategic Plan prioritizes women's health research and focuses on both gynecologic and maternal health.

Ethylin Wang Jabs, M.D., asked why the subset of total genomes sequenced in Kids First and available in the portal was relatively small. Dr. Bianchi said that she believes that Kids First plans to release all of them through the portal eventually, but she added that she cannot speak for the program.

Ken Mandl, M.D., suggested that the corrected NASEM report on NIH research on women's health recommend increasing NICHD funding for women's health research to replace their previous recommendation to create a new institute with duplicative purview. Dr. Bianchi agreed with this idea and encouraged all present to speak to their congressional representatives about it. Dr. Mandl also asked whether the new NICHD strategic priorities considered the impact of AI tools on pediatric care and the pediatric workforce and how NICHD would operate at these crossroads. Dr. Bianchi said that the pediatric workforce issue is significant and that NICHD is working with the American Medical School Pediatric Department Chairs (AMSPDC) to provide additional funding; it will present data to AMSPDC to show the different ICs' contributions to pediatrician training. NICHD has also significantly increased its commitment to the loan repayment program for pediatric researchers in FY 2024 over FY 2023.

III. Budget Report (53:28)

Alexis Clark, NICHD budget officer and Director of the Office of Financial Planning and Management, provided an overview of the NIH budget process and the different components of the NICHD budget.

Federal Budget Process (56:24)

Agencies begin developing budget requests more than 1 year in advance of the start of the FY, with the goal to have Congress appropriate funds by October 1. Congress holds appropriation hearings in the spring. Continuing resolutions (CRs) occur when funds are not appropriated by October 1. NICHD is under a CR until March 14, 2025.

NIH Budget Process (57:22)

The Office of Budget (OB) at the NIH Office of the Director coordinates budget from all the ICs and serves as the main contact for HHS and Congressional Appropriations staff. All ICs have their own budget office. At NICHD, FMB advises leadership and staff, helps develop spending plans and guide planning for future years, and monitors spending for adherence to the operating plan.

From the appropriation received, the ICs each create an operating plan for the FY; at the end of it, they must reconcile the final spending for the FY with the operating plan. ICs are prohibited from overspending their appropriation. Unspent funds generally cannot be used

in the next FY. The mechanism table then details the ways the IC will use the budget, and the table is updated throughout the FY to reflect actual spending.

NICHD Budget Overview (1:00:02)

In FY 2024, NICHD spent 55% of its budget on Research Project Grants (RPGs), 13% on intramural research, and 5% on administrative costs. Within intramural research, a large portion of the budget went to equipment, training, and laboratory support. In contrast, most of the spending for research management and support was on salaries.

From NICHD's appropriation, the budget has to plan for a certain portion of spending dedicated to mandated programs (e.g., AIDS Funding, Small Business Innovation Research and Small Business Technology Transfer programs), non-grant mechanisms (e.g., personnel costs, mandated increases in NIH-wide costs), and variable factors (e.g., unexpected needs, new legislative or policy mandates).

Grants Budgets, Allocations, and Paylines (1:05:37)

RPG allocations are reviewed and reevaluated every FY. To develop the budget for a grant, NICHD must consider other project grant costs for the FY, including noncompeting commitments from previous awards and planned supplements, Request for Applications (RFA) commitment levels, co-funding commitments, and early-stage investigator (ESI) funds. That leaves a limited portion of the budget for new investigator-initiated applications. The amount of money spent on each Council round is based on an estimate of available funds and the historical funding of investigator-initiated grants by using a 3-year average. Applications are reviewed at different score breaks to assess cost and determine allocations to be consistent across Council rounds. Overall, R01 success rates have remained constant at approximately 17% in recent years. NICHD and other ICs have had an added focus on supporting ESIs, with a success rate of approximately 25% over the past 6 years.

To develop paylines for other mechanisms aside from RPGs, there are other budget considerations. These include available offsets from large unobligated balances in recompeting grants, such as K12s and T32s. Training mechanisms also take into consideration NICHD Training Committee recommendations and NIH-wide stipend increases. Ultimately, the main driving factor is fund availability after noncompeting commitments.

NICHD also supports NIH external Loan Repayment Programs (LRPs). The funds from the six different LRPs go out directly to applicants who commit to pursuing research. NICHD has expanded its participation and funding in recent years. NICHD's contribution is subject to appropriation.

Discussion (1:12:56)

Dr. Mendl asked whether R01 success rates data include first submissions or revised applications. Ms. Clark said that the success rates combine amended applications (A1) as well. More information can be found through the NIH Research Portfolio Online Reporting Tools (RePORT).

Dr. Cedars asked how NICHD's R01 success rates compared with other ICs' metrics. Ms. Clark said that the data include grants under RFAs (which generally have higher success rates), as well as ESI and investigator-initiated applications. It is difficult to separate these, but overall success rates have improved significantly since 2010.

Anna Aizer, Ph.D., M.S., asked for clarification on co-funding commitments. Ms. Clark explained that this refers to collaborations between ICs. Other ICs may contribute funding for NICHD research that aligns with their priorities, which is known as incoming co-funding. Similarly, NICHD may contribute funding to research led by another IC, which is known as outgoing co-funding. Dr. Aizer asked whether the two are typically budget-neutral. Ms. Clark said that each IC would need to stay within its appropriated budget, so these mechanisms allow NICHD to fund a wider range of research projects. Dr. Aizer also asked about methods to link budget priorities with success metrics related to the quality and significance of research output. Ms. Clark said that the OB allocates funds to the scientific branches for their research portfolio. Dr. Aizer asked whether it would be advantageous to determine program allocations more retrospectively. Ms. Clark said that the Office of Science Policy, Reporting, and Program Analysis (OSPRA) evaluates where funding is invested and what outcomes it produces. DER Director Rohan Hazra, M.D., said that this retrospective process does occur; for example, LRP analyses found that recipients were more successful at securing subsequent NIH funding, which led to a decision to increase LRP funding support.

Dr. Cole asked about the advantages of an increase in the volume of applications over the years. Ms. Clark said that an overall increase would be positive as long as applications remain relevant to NICHD's research priorities. Dr. Bianchi added that, in the past, applications were incorrectly directed to NICHD at the sole mention of pediatrics. Having a strategic plan and clearly outlined research priorities helps ensure that received applications are aligned with NICHD's priorities. Dr. Cole added that the mention of AI in the strategic plan will encourage more applications related to the implementation of novel AI tools to study human development.

Dr. Jabs asked about the potential changes to NICHD priorities and budget that stem from the presidential transition. Ms. Clark said that priorities and funding allocations may shift based on mandates from Congress. Dr. Bianchi said that each administration has its own priorities, and NIH and NICHD have a long history of working with different administrations to find common ground.

Dr. Jabs asked how projects that are inherently more costly and require more funding, such as gene therapy research projects, are weighed against less costly areas, such as *Drosophila*

research. Ms. Clark said that Council round allocations typically consider the cost of different scientific areas, based on applications in hand and whether projects can be trimmed. Dr. Bianchi added that costly programs are often NIH-wide initiatives. The strategic plan helps clarify what research NICHD will not fund, and investigators are encouraged to contact program officials to inquire whether a research area is of interest to NICHD.

Dr. Cedars noted that women's health research only makes up 10% of the NICHD budget. She asked whether there are plans to increase funding for this topic at NICHD and other ICs and whether the White House Initiative on Women's Health Research is expected to continue. Dr. Bianchi said that it is unclear what the new administration may decide, but there has been substantial effort over the past year to prioritize women's health research and educate Congress about the need to support this research, including the NASEM report. Many of the women's health concerns are bipartisan, bicameral issues, and NICHD will continue to work with lawmakers to find common ground and support these research efforts.

IV. Invited Director: National Institute of Allergy and Infectious Diseases (NIAID) Update on Priorities for Research in Women and Children (2:00:08)

NIAID Director Jeanne Marrazzo, MD., M.P.H., presented on the new NIAID Strategic Plan, the NIAID budget, pediatric health advances, and opportunities for collaboration.

Background (2:05:17)

Before Dr. Marrazzo began her tenure as the sixth NIAID Director in 2023, she conducted research on pre-exposure prophylaxis for HIV and multicomponent prevention at the University of Washington and the University of Alabama at Birmingham.

NIAID's mission is to support and conduct biomedical research to better understand and treat infectious, immunologic, and allergic diseases. Most of the NIAID research portfolio is spread equally across infectious diseases, immunologic diseases, and HIV-related research. NIAID leads laboratory-based research in the field, but it also informs public health interventions. Examples include NIAID research on generating a protective immune response leading to COVID-19 vaccinations, Learning Early About Peanut Allergy (LEAP) trial results that informed peanut allergy guidelines, and advances in HIV pre-exposure prevention treatment. The public health impact of these advances is ongoing, as illustrated by a 2024 publication in *The Lancet* that showed the deaths averted, years of life saved, and years of full health gained globally via vaccination.

NIAID Strategic Plan 2025–2029 (2:11:52)

The new NIAID Strategic Plan, expected to be published in early 2025, focuses on an integrated, holistic approach to immunologic and infectious disease research. NIAID

distributes a significant portion of its funding across the United States outside NIH through research grants.

There is a significant focus on workforce, aimed at supporting clinicians and researchers throughout the career lifespan. NIAID is committed to increasing its funding allocation to its training budget.

NIAID Budget (2:14:30)

Over the past 25 years, NIAID's funding has received a number of increases, often related to bio-preparedness threats. NIAID budget generally receives bipartisan support. There is a decision pending following the House Appropriations Bill released in July 2024, which proposed splitting NIAID funding into two Institutes: the National Institute on Infectious Diseases and the National Institute on the Immune System and Arthritis.

Within the NIH budget for the ICs, the NIAID budget is second only to that of the National Cancer Institute. Notably, NIAID has had a relatively sustained pediatric funding increase over the past decade, approximately tripling between 2008 and 2023.

Advances in Child Health (2:16:46)

Advances in Peanut Allergy (2:17:03)

LEAP Trio is the last in a set of three studies on the introduction of peanut products at an early age. Almost 80% of the original LEAP study participants were enrolled in LEAP Trio. The first study came out in 2015 and showed that early introduction of peanut products reduced the risk of peanut allergy at age 5 by 81%. The second study, known as LEAP-On, further showed that this protection continued at age 6 after peanut products were avoided for one year. LEAP Trio, published in 2024, indicated that early-age peanut consumption provided lasting tolerance to peanut products into adolescence, regardless of subsequent peanut consumption.

NIAID Clinical Genomics Program Tackles Pediatric Disease (2:19:20)

The NIAID Clinical Genomics Program has made significant contributions to public health generally, and to pediatric care specifically. One example of this is the work that resulted in the development of a treatment for CD55-deficient protein-losing enteropathy (CHAPLE disease), a rare immune disease that causes patients to die of starvation before age 30 if left untreated. Research from the NIAID Clinical Genomics Program contributed to identifying the genetic mutation that caused the disorder. This led to a series of clinical trials to assess the safety and efficacy of a drug called pozelimab to treat CHAPLE disease. Ultimately, this led to the FDA approval of a new treatment for this rare genetic disorder.

International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network (2:22:05)

The IMPAACT Network aims to foster the evaluation of novel treatments and interventions for HIV and its complications to improve pediatric health outcomes. One recent development stemming from the network is a multicenter study that assessed dolutegravir—a class of medications called HIV integrase inhibitors—for the prevention and treatment of HIV in newborns. Another IMPAACT Network accomplishment is the European Medicines Agency (EMA) approval of a medication for infants and young children living with HIV.

NIAID Supported Research to Combat Malaria (2:23:57)

Malaria is a significant cause of complications in pregnancy. It is also often fatal in young children. NIAID's intramural program developed a series of monoclonal antibodies that will bind to the pathogen before the hepatic phase, before it can replicate. In a phase 2 clinical trial, researchers studied the efficacy of a single injection of the monoclonal antibody in children 6 to 10 years old, which showed a dose-dependent reduction in infection during the 6-month malaria season.

Opportunities for Collaboration (2:26:01)

Sexually Transmitted Infection (STI) Research (2:23:57)

With an increase in newborn syphilis cases over the past 10 years, increased funding is needed for syphilis research. NIAID has funded research on congenital syphilis, placental interactions, and treatment during pregnancy. This also includes implementation science to uncover the socioeconomic barriers that can affect diagnosis and treatment. Offering optional screening at emergency departments led to a substantial increase in diagnosis and treatment, especially among pregnant women. Critically, most screened women who had syphilis did not exhibit STI symptoms.

There have been advances in the prevention of mother-to-child transmission (MTCT) of HIV. However, MTCT of HIV remains a major public health challenge. If antiretroviral treatment during pregnancy is not available, perinatal infections will continue to occur. The ethical inclusion of pregnant women and breastfeeding women in prevention research is critical to address vertical transmission. U.S. guidelines to reduce perinatal HIV transmission have helped reduce transmission risk, but perinatal HIV transmission cases still occur, and prevention will require targeted interventions.

Immune Mechanisms at the Maternal–Fetal Interface (2:33:07)

NIAID has worked closely with NICHD on an initiative that began in 2019 to support research on the roles and interactions of immune cells at the maternal–fetal interface throughout pregnancy. An example of this collaboration was the cohort study to examine the COVID-19 vaccine response in pregnant women and lactating women.

Translational Research in Maternal and Pediatric Pharmacology and Therapeutics Program Announcement (2:34:18)

NICHD, NIAID, and other ICs co-sponsored a notice of funding opportunity on Translational Research in Maternal and Pediatric Pharmacology and Therapeutics, aimed at improving safe and effective precision therapeutics for pregnant and lactating populations. This would include developing new tools and therapeutics, improving understanding of the underlying mechanisms of drug action, and refining the usage of existing drugs.

Looking to the Future (2:03:42)

Over the next 5 years, NIAID aims to continue to make advances and provide funding to:

- Apply genomics to treat pediatric infectious diseases
- Eliminate perinatal infectious disease transmission
- Reduce the burden of childhood asthma and allergies
- Develop vaccines to prevent infectious disease and improve pediatric outcomes

Discussion (2:36:05)

Ignatia B. Van den Veyver, M.D., asked about NIAID efforts in implementation science to address vaccine hesitancy. Dr. Marrazzo said that NIAID has traditionally been focused on vaccine discovery rather than implementation and that there is a research need to understand what is causing individual reluctance to use approved and tested vaccines. Understanding the drivers of reduced vaccine acceptance rates is as important as implementing strategies to address those factors.

Dr. Cole said that a list of implementation science tools would be a valuable resource for NIAID to share. Dr. Marrazzo said that NIAID will explore ways to do this.

Yvonne "Bonnie" Maldonado, M.D., asked about the potential overlap in global efforts to combat infectious disease. Dr. Marrazzo agreed that it is critical for this work to be implemented globally and added that approximately 10% of the NIAID budget is spent in global initiatives.

Dr. Gyamfi-Bannerman said that STI screening protocols can vary state to state, and she suggested a public health initiative to unify policies. Dr. Marrazzo said that the Centers for Disease Control and Prevention (CDC) updated the guidelines for routine screening during pregnancy to make this more consistent.

V. Voice of the Participant: A Maternal Sepsis Patient's Story (2:43:32)

April Chavez, a maternal sepsis survivor and spokeswoman and a board member at End Sepsis, shared her experience in trying to receive care for maternal sepsis.

In 2017, Ms. Chavez learned that she was pregnant. On September 2 of the same year, her son Cruz was born. On September 4—the day she was supposed to be discharged from the hospital—she started feeling very unwell. She experienced fever, chills, a racing heart, shortness of breath, and fatigue. Her health care providers dismissed her symptoms as normal signs following childbirth.

Though Ms. Chavez persisted in reporting her symptoms, her health care providers repeatedly disregarded her complaints. She was discharged on September 6 with a prescription for an anxiety medication.

Ms. Chavez kept a note on her smartphone to list any symptoms she noticed, including shortness of breath, heart palpitations, dry cough, loss of appetite, constant abdominal pain, and swollen legs. Many of these are known symptoms of maternal sepsis. If some kind of informational signage had been available to Ms. Chavez, she would have been able to identify the warning signs.

Ms. Chavez later had to return to the hospital. Her mother insisted she needed to seek care, though Ms. Chavez was hesitant because of how dismissive her providers had been. When she finally returned to the hospital, her whole health care provider team made her feel like a burden. She said she did not feel treated with respect or empathy. She was put on triage, with no urgency, and was asked no questions. Meanwhile, she got sicker and sicker. When her blood pressure plummeted, her providers insisted that this was normal.

Finally, when her health care team was unable to find a vein to start an IV, a rapid response nurse was called. The nurse immediately realized that Ms. Chavez needed urgent care and brought her to the intensive care unit (ICU). When she was taken to the ICU, her family was told that she was in septic shock. She was placed on a ventilator and dialysis, and eventually her family was advised to call her loved ones and prepare to say goodbye.

During this time, her son Cruz had to be taken care of by family. Ms. Chavez missed the entire first month of her son's life. She recovered, but she had to learn to walk again. When she was finally released from the hospital, more than a month after she gave birth, she could not care for herself or her son.

Maternal sepsis deaths are often preventable if diagnosed and treated early. Ms. Chavez often wonders how different her experience would have been if any of her health care providers had listened to her instead of being dismissive and branding her as "the anxious crazy lady." It was a scarring experience—and it was preventable.

Ms. Chavez has been doing advocacy work over the past 6 years to help prevent this experience from happening to others, pushing health care providers to do better and helping disseminate information about early maternal warning signs to seek care. Despite not having medical or scientific training, she has been able to discuss maternal sepsis and use her voice to improve how this information is communicated with women and how women are empowered. She hopes that speaking about her experience and sharing her perspective will help improve outcomes for other women. Advocacy work has also allowed her to move forward from her rough experience.

Discussion (2:58:47)

Dr. Bianchi asked about Rory Stanton, whose name was mentioned in Ms. Chavez's slides. Ms. Chavez explained that Rory was a boy who died from sepsis at age 10. Ms. Chavez said that she met Rory's mother when she became involved with End Sepsis; it was Rory's story that inspired Ms. Chavez to speak about her experience and to do a lot of the advocacy work that she does.

VI. Scientific Presentation: Improving Maternal Sepsis Care Through Patient and Community Engagement (3:00:13)

Melissa Bauer, D.O., associate professor of anesthesiology at Duke University, presented her research team's work leveraging patient and community engagement to improve maternal sepsis care.

Background (3:02:27)

According to a 2024 CDC report, maternal sepsis is the leading cause of maternal mortality, with significant racial inequities among those who experience maternal sepsis. These deaths are largely preventable through appropriate care.

There are resources to provide guidance on sepsis care in hospital settings, but patients spend little time in these settings. This research aimed to understand how to make the most impact in reducing maternal sepsis outside the hospital.

Community Engagement (3:04:02)

The research approach involved leveraging community engagement to identify barriers and to help disseminate research findings within communities. One of the first steps was to create the Maternal Sepsis Community Leadership Board (MSCLB) to engage in research activities designed to understand and reduce maternal morbidity and mortality from maternal sepsis and incorporate community voices. MSCLB members included maternal sepsis survivors, health equity advocates, public health experts, and representatives from rural, urban, and Tribal communities. The goal of this program was for hospitals to implement a series of recommended engagement practices around maternal sepsis. This included regular meetings with hospital teams to offer mentorship about implementation and share feedback from community leaders and other important voices.

Deadly Delays Leading to Maternal Sepsis Deaths (3:06:52)

Maternal sepsis mortality is often related to delays in three key aspects: (1) recognition, (2) treatment, and (3) escalation of care. The research team worked with the MSCLB to develop strategies to address each of these three delays.

Delay in Recognition (3:07:58)

Sepsis can be challenging to diagnose, because some of its symptoms—such as increased heart rate—are similar to normal changes in maternal physiology. To address this, the team evaluated screening criteria for maternal sepsis by analyzing electronic health records for more than 2,900 cases of maternal sepsis from hospitals across the country.

The study assessed multiple screening systems, including systemic inflammatory response syndrome (SIRS), maternal early warning criteria (MEWC), and maternal early warning triggers (MEWT). The study also evaluated pregnancy-adjusted screens for sepsis, including the California Maternal Quality Care Collaborative (CMQCC) sepsis toolkit and the U.K. Obstetric Surveillance System (UKOSS). The analysis aimed to find the balance between sensitivity and the screen positive rate. Most of the tools showed relatively high sensitivity, but their screen positive rate varied widely. The pregnancy-adjusted sepsis screening tools had the best balance between sensitivity and false positive rates for intrapartum screening.

Beyond hospital settings, the research team aimed to find ways for patients to identify when to seek care, because most cases occur outside the hospital. The team conducted patient interviews to identify barriers to care. The study found that patients did not remember receiving education about the warning signs of sepsis and when to seek care. Patients reported that they wanted information accessible through their phones.

To address these needs, the team turned to an infographic on urgent maternal warning signs developed by the Council on Patient Safety in Women's Health Care, available in multiple languages. The team also developed a badge buddy with a QR code to help patients bookmark on their phone discharge education and other mobile-first resources. In addition, to help patients advocate for themselves and seek the care they need, the team collaborated with patients with lived experience to create a resource on advocacy language, follow-up questions, and action tips. The team also worked on community dissemination of information about sepsis warning signs. This meant educating not only patients but also communities in contact with pregnant women, such as doulas, public health departments, houses of worship, and community-based organizations.

Delay in Treatment (3:28:16)

Prompt antibiotic therapy in pregnant patients substantially reduced mortality. The team provided strategies to foster the early delivery of antibiotic treatment.

Delay in Escalation of Care (3:28:30)

The team provided escalation of care resources for those using the sepsis in obstetrics score calculator. This resource was available in the badge buddy as well.

Next Steps (3:28:42)

The next steps in this project included completing implementation in hospitals, finishing data analysis, and conducting a qualitative patient-centered assessment of the tools.

VII. Concept Clearance (3:40:15)

Dr. Rasooly led the Council through the review of four concepts.

Advancing Prevention and Treatment of Bacterial STIs in HIV-Affected Adolescent and Maternal Populations (3:43:04)

Franklin Yates, M.D., M.A., presented this concept from the Maternal Pediatric Infectious Disease Branch. Dr. Cedars asked whether there is coordination with NIAID given the strong goal overlap. Dr. Yates confirmed that there has been coordination with the NIAID Division of Microbiology and Infectious Diseases. Mariana Wolfner, Ph.D., shared a similar comment via the Zoom chat. Dr. Cole asked whether the notice of funding opportunity will likely include an intentional expectation of engaging populations who have experienced health disparities, highlighting the importance of having identifiable and reviewable strategies to measure this. Dr. Yates confirmed this will be the case. **Decision: Approve.**

Maternal and Pediatric Precision in Therapeutics (MPRINT) (3:49:16)

Lesly Samedy-Bates, Pharm.D., Ph.D., presented this concept from the Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB). Dr. Cole asked about the primary collaborative connection with FDA and whether pharmaceutical vendors would be included. FDA is an important partner, and having an internal FDA liaison involved early on may be a key consideration. Dr. Bates said that MPRINT investigators are collaborating with FDA and that pharmaceutical vendors have not yet been included. OPPTB Chief Aaron Pawlyk, Ph.D., added that OPPTB has interactions with multiple FDA offices to discuss pediatric and maternal therapeutic and drug development and has worked with them to develop the initial MPRINT RFAs. **Decision: Approve.**

Effects of Contraception as Treatment for Gynecologic Disorders (3:52:19)

Leigh Allen, Ph.D., presented this concept from the Contraception Research Branch. Dr. Aizer asked for clarification on assessing determinants of contraception use and whether this will be included in this initiative. Dr. Allen said that this will be taken into consideration. Megan A. Moreno, M.D., M.S.Ed., M.P.H., asked about the age ranges that this approach might reach. Dr. Allen said that programmatic priorities cover a wide range of ages for those who use contraception, including adolescents. Dr. Van den Veyver asked whether the initiative will include only other existing hormonal contraceptives but exclude those not currently on the market. Dr. Allen said that the wording refers to marketed contraceptives, but this was subject to further consideration. **Decision: Approve.**

Biological Testing Facility (3:57:01)

Min S. Lee, Ph.D., presented this concept from the Division of Population Health Research. Dr. Aizer asked what proportion will focus on contraception for men versus women. Dr. Lee said that the program will focus on male and female contraceptives alike, estimating the focus will be split equally between the two. Dr. Aizer asked whether that will continue to be the case. Dr. Lee said that this is unclear. Dr. Cedars asked whether this is a continuation of the concept discussed at the NACHHD Council meeting in September 2024. Dr. Lee confirmed that this concept was approved at the previous Council meeting and explained that it has been presented again to clarify that this work will include reproductive health. **Decision: Approve.**

VIII. NIH Research Plan on Rehabilitation (4:07:10)

National Center for Medical Rehabilitation Research (NCMRR) Director Theresa Cruz, Ph.D., presented on NIH's 2026 Research Plan on Rehabilitation.

Background (4:08:32)

NCMRR was established in 1990, after the American with Disabilities Act was signed. NCMRR's mission is to foster development of scientific knowledge to enhance the health, productivity, independence, and quality of life of people with physical disabilities. This includes supporting research grants, training and career development activities, and research infrastructure in this space.

Previous Research Plans (4:11:22)

NCMRR established a research plan in 1993. The next update was in 2016, for which NCMRR developed six themes:

- Rehabilitation across the lifespan
- Community and family
- Technology use and development
- Research design and methodology
- Translational research
- Building research capacity and infrastructure

These themes were refreshed and maintained in 2021, which highlighted a need for more action. Having a research plan helped grow the NIH rehabilitation portfolio over the years to involve most ICs.

2026 Research Plan on Rehabilitation (4:12:50)

The process to build the new plan began in February 2024 with a Request for Information (RFI). Goals were discussed at the May 2024 Board meeting. The NIH Medical

Rehabilitation Coordinating Committee (MRCC)—composed of representatives from 20 ICs—met monthly between June and September 2024 to draft new themes. In 2025, the themes will be refined, and after additional feedback is gathered, the research plan will be completed. The final research plan is expected to be published in 2026.

2026 Proposed Themes (4:14:42)

The new themes represent areas for growth in the next 5 years, though they do not include all rehabilitation research. These areas will require input from people with disabilities. The following are the proposed themes for 2026 and their potential objectives:

- **Basic and Mechanistic Studies:** To improve understanding of individual recovery from disabling disease or injury, to help people have the function they want, and to advance precision medicine approaches to guide prescription of rehabilitation interventions.
- **Social Determinants of Health:** To understand and mitigate systemic causes of health disparities and ableism and to understand the barriers and facilitators to receiving care.
- **Rehabilitative and Assistive Technology:** To support early-stage technology development and to advance technology transfer and commercialization.
- **Implementation Research:** To work with consumers of rehabilitation to ensure that therapies are aligned with consumer priorities and to engage continuing medical education and professional societies to translate findings into practice.
- **Training, Career Development, and Infrastructure:** To develop training programs and infrastructure that advance rehabilitation science and to build a robust network of rehabilitation researchers.

These draft themes went through a second round of feedback between October and December 2024, with a second RFI planned for January 2025.

Next Steps (4:21:12)

NCMRR will be seeking additional feedback through April 2025, presenting the plan at meetings of the Association of Academic Physiatrists and the American Society of Neurorehabilitation, as well as the NIH Rehabilitation Conference. The next step will be to finalize the plan, seek concurrence with the themes at the May 2025 Board meeting, and obtain clearances. After the research plan is submitted to Congress and the President, NCMRR will publish and disseminate it.

Discussion (4:22:27)

Dr. Maldonado highlighted issues in surveying individuals and whether they identify as being disabled versus having a disability. Perception of being disabled was found to be much lower in a recent study that surveyed health care workers. Individuals' perception of their own disability status may be influenced by factors such as bias, stigma, and other social determinants. Dr. Cruz said that measurement of disability is a key focus area, as are

stigma and self-reporting. NCMRR is now working across multiple fronts to address some of those issues. Examples of this include the recently published resources for investigators with disabilities.

Dr. Cole said that neonatology may be an important area where precision medicine intersects with rehabilitation. Dr. Cruz agreed, and she added that a R01 recent awardee trained through a K award from the Pregnancy and Perinatology Branch would be providing this expertise. Dr. Cole added that anything that can be done to increase involvement of neonatology specialists would be beneficial and that he would be excited to contribute to this.

Edelle C. Field-Fote, Ph.D., asked about restrictions to physical disabilities, as opposed to including cognitive, hearing, visual, and other disabilities. Dr. Cruz said that this is an effort to divide the work across teams, with NCMRR focusing on physical disabilities and the Intellectual and Developmental Disabilities Branch focusing on another set of disabilities.

IX. Triennial Advisory Council Report on Inclusion in NICHD Clinical Research Fiscal Years 2022–2024 (4:29:13)

Ronna Popkin, Ph.D., NICHD's inclusion officer and program director in the Population Dynamics Branch (PDB) at NICHD's Division of Extramural Research (DER), presented on key enrollment findings from the Triennial Advisory Council Report on Inclusion in NICHD Clinical Research FYs 2022–2024. Dr. Popkin acknowledged the team that worked on the development of the report, as well as the NIH Inclusion Office.

Background (4:32:26)

NIH inclusion policies emerged in response to findings that showed certain populations were systematically excluded from clinical research. The goal of these policies is to minimize bias and enhance generalizability.

NIH inclusion data is a subsample of study data collected to assess and ensure adherence to NIH inclusion policies. NIH requires clinical researchers to report participant demographics. Every 3 years, NIH assembles all of its enrollment data to create a triennial report for Congress.

The NICHD triennial report on inclusion is publicly available. NICHD inclusion is robust and strongly aligned with the Institute's mission and priorities.

Enrollment in NICHD Clinical Research (4:36:14)

Analysis of enrollment in NICHD clinical research by sex in foreign and domestic sites showed that women constitute a majority of NICHD clinical research participants. This reflects NICHD's research priorities and its focus on gynecologic and maternal health.

Assessment of enrollment in NICHD clinical research by minorities showed that almost half of NICHD clinical study participants belong to racial or ethnic minorities. This analysis included U.S. sites only, because racial and ethnic minority groups vary heavily, depending on the culture and the country. Minority enrollment in NICHD studies was approximately 50% higher than overall NIH clinical research minority enrollment at U.S. study sites. The greatest differences were disproportionately driven by the inclusion data of Black or African American individuals—particularly women.

Analysis of enrollment in NICHD clinical research by age showed that children were 34% of NICHD participants, compared with only 9% at other ICs. Again, this reflects NICHD's focus on pediatric health. In contrast, NICHD's enrollment of older adults was only 2% of participants, as opposed to 16% across other ICs. NICHD is also very successful at collecting age information from participants; just 3% of NICHD participants belonged to unknown age groups, in contrast to 29% at other ICs. Children enrolled in NICHD studies were also younger than at other ICs.

As explained in the triennial report, limitations exist to the interpretation of NIH inclusion data.

Conclusions and Next Steps (4:50:58)

NICHD has effective research inclusion practices in place and excels at including women, minorities, and children. Future efforts will include improving inclusion metrics across ICs and continuing NIH-wide collaborations to expand inclusion categories to track enrollment of pregnant women, breastfeeding women, and individuals with disabilities.

Discussion (4:52:09)

Dr. Mandl said that it would be useful to differentiate women of reproductive age rather than wider age groups and to differentiate neonates from other young children. Dr. Popkin said that NICHD research often includes this level of detail with respect to participant ages and that it should be possible to determine whether women are of reproductive age per NICHD policy.

Dr. Gyamfi-Bannerman said that understanding the numbers of pregnant women included in clinical research is critical for professionals who work in the maternal–fetal medicine space. Dr. Popkin said that there are many efforts within NICHD pushing to include pregnant women in clinical studies across the ICs. Dr. Bianchi added that there has been substantial progress in the inclusion of pregnant and infant populations in NIH clinical research, but there is still a long way to go.

Dr. Gyamfi-Bannerman made a motion to approve the triennial report. Dr. Cedars seconded the motion. Council members voted to approve the motion.

X. Closing Remarks (4:58:32)

Dr. Bianchi thanked all Council members, presenting staff, and attendees, then announced the logistics for Day 2.

XI. Day 1 Adjournment

Dr. Bianchi adjourned Day 1 at 4:59 p.m. ET. A total of 197 people viewed the live Day 1 NIH VideoCast of the open session.

XII. Day 2 Call to Order and Introductory Remarks

Dr. Bianchi opened Day 2 of the 187th meeting of the NACHHD Council at 9 a.m. ET.

XIII. 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.

XIV. 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 reviewed 837 applications, requesting $308,557,720 in Direct Costs and $430,733,566 in Total Costs.

XV. Adjournment

There being no further business, Dr. Bianchi adjourned the meeting at 11:41 a.m. ET on Tuesday, January 14, 2025. The next Council meeting is scheduled for June 9–10, 2025, at 6710B Rockledge Drive in Bethesda, Maryland.

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

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

Date

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

Date

[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.