

NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT COUNCIL

MEETING SUMMARY

January 22–23, 2024

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

NATIONAL INSTITUTES OF HEALTH (NIH)

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT (NACHHD) COUNCIL MEETING SUMMARY January 22–23, 2024

The NACHHD Council convened its 184th meeting at 12:00 p.m. ET on Monday, January 22, 2024. It was a virtual meeting that was open to the public from 12:00 p.m. to 5:00 p.m. ET. The Council reconvened on Tuesday, January 23, 2024, at 9:00 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 Present¹

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

Council Members Absent

None

Ex Officio Members Patricia Dorn, Ph.D.

Health Resources and Services Administration (HRSA) Rui Li, Ph.D.

National Advisory Board on Medical Rehabilitation Research Council Liaison José L. Contreras-Vidal, Ph.D. **Department of Defense** Melissa R. Miller, Ph.D.

Executive Secretary Rebekah Rasooly, Ph.D.

¹Council 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.

In each section below, the number in parentheses following each heading refers to the time stamp on the NIH VideoCast; go to that point in the recording to listen to the full presentation.

I. CALL TO ORDER AND INTRODUCTORY REMARKS (0:05)

Dr. Bianchi opened the meeting and welcomed the members of the NACHHD Council and all inperson and online attendees. She asked new Council members to briefly introduce themselves.

Dr. Aizer is the Maurice R. Greenberg Professor of Economics at Brown University. She is a labor and health economist with interests in education and child health and well-being.

Dr. Cedars is a reproductive endocrinologist and professor at the University of California, San Francisco. Her research areas are ovarian aging, polycystic ovarian syndrome, and long-term outcomes following assisted reproduction.

Dr. Jabs' research focuses on developmental genetics of normal and abnormal development, especially the causes, prevention, and treatment of structural birth defects and rare disorders. She currently conducts her clinical and research work at the Mayo Clinic.

Dr. Van den Veyver is a professor of obstetrics and gynecology (OB/GYN) and molecular and human genetics at Baylor College of Medicine. She conducts research on prenatal and reproductive genetics.

Prof. Brooks (introduced at 6:56) is a professor of law at Drexel University. Before beginning her law career, she received an M.A. and a B.A. in clinical social work. She has a longstanding interest in holistic child and family development.

Review of Confidentiality and Conflicts of Interest (3:52)

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 examining any NIH grant applications. Before the meeting, Council members received and signed the required conflict-of-interest certification forms. Dr. Rasooly also reminded Council members that they were required to recuse themselves and leave the 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) that are capable of capturing confidential information.

Council Minutes (5:01)

Dr. Lang made a motion to approve the September 6–7, 2023, NACHHD Council meeting minutes as written. Dr. Neal-Perry seconded the motion. Council members voted to approve the minutes.

Future Meeting Dates (6:04)

Dr. Rasooly announced that the future Council meetings were scheduled for June 3–4, 2024 (NIH Bethesda Campus, Building 31); September 4–5, 2024 (6710B Rockledge Drive); January 13–14, 2025 (virtual); June 9–10, 2025 (NIH Bethesda Campus, Building 31); September 8–9, 2025 (6710B Rockledge Drive); January 26–27, 2026 (virtual); June 8–9, 2026 (location to be determined); and September 1–2, 2026 (location to be determined).

II. NICHD DIRECTOR'S REPORT (7:50)

In her report, Dr. Bianchi described the fiscal year (FY) 2024 budget and recent NICHD congressional interactions; provided background on new NIH Director Monica M. Bertagnolli, M.D.; reviewed the latest NICHD research highlights and aspirational strategic planning goals; shared updates on the White House Women's Health Research Initiative and enhancing accessibility and disability research at NIH; introduced the Advisory Council to the Director (ACD) working group (WG) on re-envisioning NIH-supported postdoctoral training; and gave several kudos and staff updates.

FY 2024 Budget Update and Congressional Interactions (9:44)

For the FY 2024 budget that was supposed to begin on October 1, 2023, Congress recently passed a third continuing resolution to extend funding for NIH from February 2 until March 8. Importantly, Congress has agreed to topline funding numbers for non-defense discretionary funding for FY 2024. Congress is taking more time to complete work on the final FY 2024 appropriations bills.

Since the previous Council meeting, Dr. Bianchi had met with several members of Congress to discuss NICHD initiatives. Those interactions were with Rep. Yadira Caraveo, M.D., a pediatrician from Colorado, to discuss child health; Sen. John Boozman from Arkansas to discuss maternal health; and House and Senate appropriations staff to discuss the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative.

New NIH Director (12:31)

Dr. Bertagnolli is a clinician-scientist and surgical oncologist who maintains clinical privileges. She became the 17th director of NIH on November 9, 2023. During a recent town hall meeting, Dr. Bertagnolli shared some of her guiding principles:

- Progress is accelerated when advanced scientific methods, such as new data analytics, are
 applied to data that include everyone and when new discoveries are rapidly and equitably
 adopted in clinical care.
- NIH is committed to harnessing the power of artificial intelligence (AI) and machine learning (ML) to advance research across diverse fields, diseases, and scientific communities.
 - Advanced scientific methods, new data analytics, and new technologies are unlocking possibilities to harness data in ways that achieve faster and more definitive results.
 - o NIH has launched and will continue to launch innovative and ambitious initiatives to propel the fusion of biomedicine and AI/ML.

Looking Back on NICHD Research in 2023 (15:35)

The NICHD website has a new page dedicated to spotlighting the institute's most impactful <u>2023</u> research accomplishments. The following 10 activities are highlighted:

- Promoting healthy pregnancy, labor, and delivery
- Improving outcomes for newborns with opioid withdrawal
- Advancing treatments for gynecological conditions
- Creating new technologies
- Developing new contraceptives
- Reducing disparities for children with intellectual and developmental disabilities
- Enhancing safety in contact sports
- Improving care for pediatric injury and illness
- Advancing outcomes for children with a COVID-19 complication
- Boosting basic science research

The Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW) Program is funded by the NIH Helping to End Addiction Long-term® Initiative (NIH HEAL Initiative®). ACT NOW's successful Eat, Sleep, Console (ESC) study created a collaboration to combine data from two pediatric clinical trial networks: NICHD's Neonatal Research Network and the Environmental influences on Child Health Outcomes (ECHO) Program's Institutional Development Awards (IDeA) States Pediatric Clinical Trials Network and led to several research highlights in 2023, including the following:

- Compared with usual care, the ESC approach reduced the time until infants became
 medically ready for discharge from the hospital and significantly reduced the need for
 pharmacologic treatment.
- ESC data provided strong support for establishing a universal, evidence-based standard of care for treating opioid-exposed infants with neonatal opioid withdrawal syndrome.
- Because of the study, the state of Washington is now requiring ESC implementation by January 2025.

NICHD's <u>Data and Specimen Hub (DASH)</u> is a centralized resource for researchers to share deidentified data from studies funded by NICHD. DASH serves as a portal for biospecimens from eight selected studies. With the aim of accelerating scientific findings that improve human health, researchers have used DASH data to conduct 224 studies on 60 topics and have made 662 data requests and 16 biospecimen requests and have published 106 manuscripts to date.

Importantly, de-identified data from the more than 60,000 participants in the ECHO cohort are now freely available on DASH. More than 40 user requests have already been made for ECHO data, and common data elements are being used, along with the sharing of protocols across NIH studies. ECHO data include information on pregnancy and birth, early development, health conditions, public health crises, demographics, and environment.

NICHD Strategic Planning (20:00)

NICHD's <u>strategic plan</u>, which focuses on research, stewardship, management, and accountability, was last updated in 2020. Last fall, the institute began gearing up to write its 2025

strategic plan by documenting and tracking its activities and achievements. Leadership is now conducting virtual listening sessions to gather NICHD staff input on progress and potential new scientific opportunities, and this process will be followed by solicitation of external feedback from the scientific and advocacy communities and the public. The updated strategic plan will be available in March 2025.

During the September 2023 Council meeting, Dr. Bianchi reported progress on 4 of the strategic plan's 10 aspirational goals. At this meeting, she provided part 2 of the report on those goals.

Goal: Identify biomarkers of atypical neurodevelopment that can establish the likelihood of neurodegenerative disorders later in life.

According to a 2020 report from the National Center for Health Statistics, 17.8% of U.S. children ages 3 to 17 have been diagnosed with one or more developmental disabilities. These disabilities have the potential to create lifelong limitations and increase the risk of neurodegenerative diseases. To date, no reliable early neurodevelopmental biomarkers have been identified. From 2020 to 2023, NICHD increased funding but decreased the number of research projects from 46 to 40. The following discoveries were made: Alzheimer's risk was associated with specific cognitive phenotypes in Down syndrome, DNA methylation profiles were correlated with functional differences in genetic neurodevelopmental disorders, and differential DNA methylation from cord blood and increased neonatal caudate volumes were independently associated with severe neurodevelopmental delay at 2 years of age.

Goal: Identify genomic changes and exposure risks that explain or predict fetal loss by using advanced technological approaches and population-based study methods.

More than 20,000 U.S. families are affected by stillbirth each year, and 10% to 20% of pregnancies in this country end in miscarriage or fetal loss. These losses are painful for families and carry the risk of complications. Although 60% of tissue samples from early pregnancy loss showed evidence of chromosomal anomalies, they do not explain all stillbirths. NICHD funding from 2020 to 2023 and the number of research projects have remained steady. Other activities include the Stillbirth Working Group of NICHD Council and data sharing from NICHD projects and networks. Funded studies have shown no evidence of an association between maternal alcohol metabolism genetics and miscarriage, but they have shown copy number variations and placental anomalies associated with stillbirth, novel bacterial pathogens associated with stillbirth and early preterm birth, and that a fetal growth factor protein level in maternal blood could predict placental insufficiency.

Goal: Use the growing understanding of immune factors in pregnancy and placental development to determine reasons for pregnancy rejection, mechanisms to prolong at-risk pregnancies, and ways to transfer this knowledge to other medical needs, such as organ transplantation.

According to the Centers for Disease Control and Prevention (CDC), infections are a leading cause of maternal, fetal, and neonatal deaths in the United States. For 2022, CDC reported that the uptake rates of recommended vaccines among pregnant women were 48.4%, 45.8%, and 60.5% for influenza, Tdap (tetanus, diphtheria, and pertussis), and COVID-19, respectively. From 2020 through 2023, NICHD funding and the number of funded projects for infection and immune factors in pregnancy increased slightly. The Stillbirth WG of NICHD Council along

with data sharing from NICHD projects and networks are also addressing this goal. Funded studies have revealed that at full term, about 20 ounces of blood pass through the placenta every minute; sepsis screening tools perform best from 20 weeks of pregnancy through 3 days postpartum; a series of malformations in stillborn infants are linked to copy number variants; widespread COVID-19 vaccination likely halted a spike in preterm birth; and antibody treatment for cytomegalovirus appears to offer no longer-term benefit to children by age 2.

Goal: Optimize infant survival by synthesizing human milk, capturing all its components and properties, and individualizing it to the characteristics of the infant's mother.

According to CDC, 83% of infants born in the United States in 2019 started out receiving some breast milk; by 6 months old, 58% were still receiving some breast milk. However, the mechanisms behind the benefits of breast milk are not well understood. From 2020 through 2023, the number of funded projects increased from 69 to 132, while funding increased from \$23.77 million to \$58.12 million. Funded research has revealed that <u>lactoferrin in human milk has antimicrobial properties against group B streptococcus</u> and that <u>C-reactive protein, glucose, and insulin in breast milk differ for women who had gestational diabetes.</u> Furthermore, <u>concentrations of most oligosaccharides in breast milk decreased over time</u>, but there were several exceptions. Researchers also identified <u>six unique lactocyte subpopulations in human milk</u>.

Goal: Discover how technology exposure and media use affect developmental trajectories, health outcomes, and parent-child interactions in early childhood.

During the pandemic, the amount of daily screen time for children ages 6 to 10 increased, leading to reduced physical activity, learning loss, and an increase in mental health disorders. On May 20, 2023, the U.S. Surgeon General issued an advisory on Social Media and Youth Mental Health. From 2020 through 2023, NICHD funding for technology and social media exposure studies increased from \$3.41 million to \$16.83 million, and the number of funded projects increased from 11 to 35. Other activities included an NICHD Director's Blog post on this topic, along with additional communications and NIH-wide and HHS coordination. Funded studies have found that playing video games and watching videos are prospectively associated with newonset cases of obsessive-compulsive disorder (OCD) in early adolescents and that more than 2 hours per day of screen time is associated with an increased risk of problems at an early school age for children born extremely preterm. When toddlers were energetic before using media, they had less difficulty transitioning away, but when parents used media to calm down toddlers, it was harder to transition to the next activity. Finally, parental estimates of children's screen time and media use were inaccurate more often than they were on target.

White House Women's Health Research Initiative (29:55)

On November 13, 2023, President Biden announced the first-ever White House Initiative on Women's Health Research, to be led by First Lady Jill Biden, Ed.D., and the White House Gender Policy Council. The Initiative will deliver concrete recommendations to advance women's health research; take a targeted, high-impact approach in focus areas where additional investments could be transformative; engage the scientific, private-sector, and philanthropic

communities; and explore new public–private partnerships. NIH and NICHD staff contributed to the government-wide recommendations that were submitted on December 28, 2023.

Enhancing Accessibility and Disability Research at NIH (32:10)

The ACD has a Working Group on Diversity. Its Subgroup on Individuals with Disabilities issued a final report on December 1, 2022. The report recommended removing the language about "reducing disability" from the NIH mission statement, because the current mission statement could be interpreted as perpetuating ableist beliefs that disabled people are flawed and need to be "fixed." The current mission statement is, "To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability." The proposed mission statement is, "To seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to optimize health and prevent or reduce illness *for all people*." Public feedback was requested through November 24, 2023.

In October 2023, NIH designated people with disabilities as a health disparity population. This designation supports NICHD's mission area of including people with disabilities in research, and NICHD staff worked hard to obtain the designation. A new <u>funding opportunity</u> for innovative approaches and interventions that address the intersecting impact of disability, race and ethnicity, and socioeconomic status on health care access and health outcomes has been announced.

ACD Working Group on Re-Envisioning NIH-Supported Postdoctoral Training (35:10)

The <u>ACD Working Group on Re-Envisioning NIH-Supported Postdoctoral Training</u> was charged with evaluating evidence on the perceived shortage in Ph.D.s seeking U.S. postdoctoral positions, assessing and considering factors influencing the scope and persistence of the issue, reviewing and comparing other approaches to postdoctoral training, considering ways to support postdoctoral researchers' quality of life and work–life balance to increase retention, and engaging key internal and external parties. After holding four public listening sessions and issuing a request for information that received 3,252 comments, the WG's <u>final report</u> made the following recommendations:

- Increase pay and benefits for all NIH-supported postdoctoral scholars.
- Create and expand mechanisms to support the full talent pool of postdoctoral scholars.
- Facilitate transition of postdoctoral scholars into their next career stage, including roles beyond academic faculty.
- Promote training and professional development of postdoctoral scholars and their mentors
- Support safe, diverse perspectives and research environments within institutional research programs.
- Improve means to measure and share postdoctoral scholars' career progression.

Later in this meeting, NICHD's Extramural Training Working Group presented the institute's data on this topic. Council members discussed recruitment and retention of junior faculty, and colleagues from professional and research organizations and funded researchers responded.

Kudos (38:10)

A member of this Council, Dr. Maldonado, has been elected to the prestigious National Academy of Medicine along with Ursula Kaiser, M.D., and Catherine Spong, M.D., who are both NICHD supporters.

One of the programs in NICHD's <u>Population Dynamics Branch</u> won a <u>Clio Health Award</u> for innovation and creative excellence in advertising, design, and communication. The Population Reference Bureau collaborated with the population research centers, TANK Worldwide, and Dr. Shalon's Maternal Action Project on "Lullaby," a national campaign to raise awareness of the Black maternal health crisis in America. The <u>award-winning video</u> includes findings from NICHD research.

NICHD received the 2023 <u>Charles A. Sanders, M.D., Partnership Award</u> from the Foundation for the National Institutes of Health (FNIH). The award recognizes NICHD's successful collaborations for conducting two maternal health clinical trials. The <u>Azithromycin Prevention in Labor Use Study (A-PLUS)</u> and NICHD's Global Network for Women's and Children's Health Research provided a single dose of a low-cost oral antibiotic (azithromycin) during labor to reduce maternal sepsis and death by about one third, and additional sub-studies and secondary analysis are ongoing. The <u>Prevention of Iron Deficiency Anemia Post-Delivery (PRIORITY)</u> trial is assessing the impact of postpartum intravenous iron therapy to treat anemia.

NIH and NICHD Staff Updates (41:41)

W. Kimryn Rathmell, M.D., Ph.D., is the new director of the National Cancer Institute.

Tara A. Schwetz, Ph.D., has been appointed deputy director for program coordination, planning, and strategic initiatives.

Andrew A. Bremer, M.D., Ph.D., is the new director of the Office of Nutrition Research.

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

Discussion (43:40)

Dr. Jabs asked how gene therapy research fits into NICHD's aspirational goals. Dr. Bianchi said that gene therapy research was not included in the 2020 strategic plan but was appropriate to suggest for the 2025 strategic plan, and this suggestion should be made during the comment period. Dr. Bianchi added that gene therapy is included and highlighted in the NIH Clinical Center's pediatric strategic plan. NICHD also participates in FNIH's <u>Accelerating Medicines Partnership® (AMP®) Program Bespoke Gene Therapy Consortium (AMP BGTC)</u> and the NIH Common Fund's <u>Somatic Cell Genomic Editing (SCGE)</u> program.

Dr. Barkin asked how NICHD would participate or lead the way in implementing the use of AI in its work. Dr. Bianchi said that NICHD is interested in training people to use AI and ML, but the ideas to put forward are not yet ready for public comment.

In the interest of data harmonization, Dr. Lang asked whether the use of common data elements (CDEs) would be implemented across all of NIH's current and future data repositories. Dr.

Bianchi said that she could not comment on any NIH-wide efforts, because coordination has not yet been prioritized. She added that the NIH Pediatric Research Consortium (N-PeRC) had recently created CDEs for pregnant people and recommended them to the Women's Health Research Initiative. NICHD has a long-standing interest in using CDEs for research on pregnancy, children, and rehabilitation. NICHD Deputy Director Alison Cernich, Ph.D., said that NICHD has been involved in promoting the use of CDEs for several NIH programs and will continue to participate in future efforts as much as possible. Rebecca Rosen, Ph.D., the director of NICHD's Office of Data Science and Sharing (ODSS), shared that CDEs are an ongoing priority for all ODSS offices and the National Library of Medicine.

III. SCIENTIFIC PRESENTATION: THE ROLE OF SIMULATION MODELS TO IMPROVE CARE FOR ADOLESCENTS AND YOUNG ADULTS AFFECTED BY HIV (53:35)

Anne M. Neilan, M.D., M.P.H., is an assistant professor of pediatrics and medicine at Harvard Medical School and practices in the Divisions of General Academic Pediatrics and Infectious Diseases in the Departments of Pediatrics and Medicine, respectively, at Massachusetts General Hospital. Her research centers on the use of simulation modeling to inform policy and relevant care strategies for adolescents and young adults (AYAs) living with human immunodeficiency virus (HIV) and at risk for HIV. NIH has supported Dr. Neilan's research since she was in training.

Snapshot of HIV Science

HIV treatment is a great success story. In the United States, the transmission of HIV to infants has been "virtually eliminated" compared to the peak of HIV transmission to infants in 1994. Today, antiretroviral therapy (ART) is well tolerated and effective. ART has made life expectancy for patients with HIV nearly the same as people without HIV. Treating HIV prevents HIV, because those who are virologically suppressed cannot transmit HIV to others (i.e., undetectable equals untransmittable). Antiretroviral medications can also prevent HIV infection. The current CDC recommendation is to inform all sexually active adults and adolescents about HIV pre-exposure prophylaxis (PrEP) as a way to prevent HIV infection.

Several HIV vaccines are in development in early-stage clinical trials. Other exciting research is advancing toward a functional cure (e.g., neutralizing antibodies, early ART in infants). However, AYAs with HIV have poorer HIV care continuum outcomes than adults have, and the highest rate of onward HIV transmissions by age is among AYAs with HIV.

NICHD-Supported Training and Science

Dr. Neilan has early personal experience in learning about how health policies affect individual patients and families and the transformative power of medical research. That experience led her to pursue a career in medicine at the intersection of clinical care, health policy, and research. Her clinical and research training inspired her interest in pursuing the study of AYAs affected by HIV. NIH and NICHD were instrumental in supporting the development of her career, and she was supported by gifted mentors throughout her training. She highlighted the following NIH support:

- 2014: a National Institute of Allergy and Infectious Diseases (NIAID) T32 early-career investigator award to study HIV testing among U.S. youth
- 2015–2017: early-career investigator support either with funding or data (to conduct secondary analyses) in the Adolescent Medicine Trials Network (ATN) for HIV/AIDS interventions; the International Maternal, Pediatric, Adolescent AIDS Clinical Trials Network (IMPAACT); the International Epidemiology Databases to Evaluate AIDS (IeDEA); the Pediatric HIV/AIDS Cohort Study (PHACS); the HIV Research Network (HIVRN); and the Centers for AIDS Research (CFAR)
- 2018: an NICHD K08 award to study HIV testing and PrEP among young men who have sex with men (MSM) in the United States
- 2022: an NICHD R01 to study novel medications for youth in South Africa, preceded by participation in the NIH Early Career Reviewer (ECR) program
- 2023: an ATN Modeling Core renewal plus an NICHD Critical Life Event Supplement during family illness
- She also benefited from participation in an NIH Loan Repayment Program (LRP) with two LRP renewals over five years

Projecting Clinical and Economic Impact of Policies to Improve Care for Adolescents

The longitudinal NIH funding listed supported research that is cited in national and international guidelines. Highlights include:

- Simulation model-based analyses have allowed researchers to consider the balance of health benefits, risks, and costs. These methods help inform decision making that is based on available data. Many questions cannot be answered by trials or cohort studies alone.
- Cost-effectiveness analyses have helped determine whether additional benefits are worth additional costs. "Cost-effective" does not mean saving money or that something is cheap (e.g., more effective interventions are usually more costly).
- The Cost-Effectiveness of Preventing AIDS Complications (CEPAC) group has developed Monte Carlo simulation models to predict disease progression for individual people.
- Researchers have developed an adolescent-focused simulation model to study ART
 adherence and engagement in care because adherence and engagement vary by age and
 over time (funded by the NIAID T32). Data to populate such models come from multiple
 sources, including the NICHD Data and Specimen Hub (DASH). DASH data have been
 valuable for additional purposes including new analytic methods and clinical methods
 that have also informed clinical guidelines.
- The ATN Modeling Core has been helpful for modeling the cost-effectiveness of adherence interventions and supports to new HHS pediatric treatment guidelines.
- Cost-effectiveness analyses of the U.S. Food and Drug Administration (FDA)—approved options for PrEP with dramatic price differences have led to the finding that generic oral PrEP would save both lives and money among young MSM (funded by the NICHD K08).
- Cost-effectiveness analyses of using long-acting, injectable PrEP versus daily oral PrEP resulting in a 69% risk reduction in the incidence of HIV have revealed that, given the availability of a highly effective oral generic alternative in the United States, the

- maximum price premium of the injectable version of PrEP would be less than \$7,000 annually over daily oral PrEP (funded by the NICHD K08).
- A collaboration with the Desmond Tutu Health Foundation examined how much South Africans should be willing to pay for the improved efficacy (92% risk reduction in the incidence of HIV) of injectable PrEP over daily oral PrEP in adolescent girls and young women. The analysis, as presented in abstract form, revealed that, to be cost-effective, the injectable version should be priced at less than twice the cost of the oral PrEP (funded by NICHD R01).
- After a federal court ruling against requiring health insurers to cover PrEP under the Affordable Care Act, researchers rapidly leveraged work conducted in the prior analyses to estimate that, for every 10% drop in PrEP coverage among U.S. men, an additional 1,140 HIV infections in MSM would occur in the following year.
- Analysis of the effect of a policy change in Tennessee that blocked millions of dollars in CDC HIV funding for marginalized groups led to the finding that funding reallocation would lead to 180 additional HIV infections in Tennessee over 10 years.
- Simulation modeling and cost-effectiveness analysis studies have been used to produce the evidence needed to inform guidelines for multiple organizations, including CDC, HHS, and the World Health Organization.

Dr. Neilan's future research will examine the clinical and economic value of long-acting injectable antiretrovirals among adolescents with and without HIV in South Africa (funded by the NICHD R01). Data from the ATN Modeling Core will be used to evaluate the lifetime costs of HIV infection among youth with HIV in the U.S.. Dr. Neilan is also working to identify new trainee opportunities for addressing current policy issues.

Dr. Neilan concluded by saying that simulation modeling and cost-effectiveness provide uniquely valuable evidence to inform health policy. The breadth and depth of NIH and NICHD support for early-stage investigators is vital to maintaining a strong pipeline of clinician-investigators. NICHD-supported research in HIV has dramatically improved lives and informed health policy worldwide.

IV. VOICE OF THE PARTICIPANT (1:17:33)

Dr. Bianchi introduced Eddie Diaz, from Revere, Massachusetts, a man who is Dr. Neilan's patient. Dr. Neilan interviewed Mr. Diaz about his experiences taking PrEP as a form of HIV prevention and about living with HIV.

Mr. Diaz shared that he is focused on his physical and mental health and on maintaining real connections with his friends. A graduate student at a private military college in Vermont, he is pursuing a master's degree in public policy and administration and holds a bachelor's degree in political science.

As a gay man, Mr. Diaz began taking PrEP to prevent HIV infection in 2015. He shared that he did not want his mother to know that he was taking it and that taking PrEP daily in secret was hard. He did not experience any side effects from the medication. Dr. Neilan highlighted the challenges for young people taking a daily pill.

Dr. Neilan met Mr. Diaz after he received his HIV diagnosis in 2020. The diagnosis was made at a routine medical examination, and he thought the test result must be wrong. When the test was confirmed to be positive, he initially stopped listening to the physician out of shock but later began to see the diagnosis as a roadblock. When he self-reported the test to the Army National Guard, however, he was threatened with being barred, which was devastating news for a person who had dreamed of a life of military service since childhood. He was later uplifted by his best friend and his mother. Dr. Neilan highlighted the diagnostic delays during the COVID-19 pandemic and the discriminatory policies that Mr. Diaz encountered. After obtaining legal counsel and challenging the discriminatory actions taken against him, Mr. Diaz was readmitted to military training.

Because Mr. Diaz was living away from home while attending college, he tried using long-term injectable ART to avoid the burden of obtaining the daily prescription each month. He said that he found the daily pill easier to remember than the bimonthly injection appointment. Dr. Neilan added that Mr. Diaz was also responsible for storing the injectable vial in his dorm room refrigerator.

Mr. Diaz has now participated in an HIV-related clinical trial and is interested in being part of others, especially knowing that a functional cure might be possible. He said that he is grateful to have access to the best clinician-researchers in the country, such as Dr. Neilan.

Discussion (1:36:58)

Dr. Bianchi asked Mr. Diaz what his day-to-day life is like now that he has reached a settlement with the military. Mr. Diaz said that he is allowed to participate in exercises, trainings, and classes but is still under investigation for full reinstatement. He is planning for the possibility of needing to find a job outside of the military, but currently he attends classes, is a member of the Army Reserve Officer Training Corps, and has a job with a private security company. Dr. Bianchi thanked Mr. Diaz for his service and said that his persistence, enthusiasm, and attitude are remarkable.

Many Council members posted comments in the chat thanking Mr. Diaz for sharing his inspiring story and for his service to the country. One member called him a "beacon of hope" for his positivity. Mr. Diaz thanked Dr. Bianchi for funding Dr. Neilan's research and thanked the Council for supporting NICHD's HIV work.

V. REPORT FROM THE NICHD EXTRAMURAL TRAINING AND CAREER DEVELOPMENT WORKING GROUP (1:41:50)

Co-chairs Theresa Cruz, Ph.D., the director of National Center for Medical Rehabilitation Research; Tessie October, M.D., M.P.H., a medical officer in the Pediatric Trauma and Critical Illness Branch; and Susan Taymans, Ph.D., deputy branch chief for the Fertility and Infertility Branch, reported the findings from NICHD's Extramural Training and Career Development Working Group. The WG's members represented every branch of NICHD's extramural program.

As part of scientific stewardship, NICHD periodically examines various programs for unmet opportunities and select areas of improvement. This WG's mission was to develop a set of

recommendations for the future of NICHD extramural training and career development programs to maximize alignment with the strategic plan and NICHD priorities, including a focus on addressing scientific workforce diversity.

The WG's four workstream goals were understanding the landscape of NICHD's current training and career development programs, reimagining NICHD's pre- and postdoctoral (F, T, and Supplement) programs, reimagining NICHD's career development (K) programs, and aligning training and career development goals with NICHD's strategic priorities.

After acknowledging the efforts of program officers and other staff who manage training and career development awards, the WG said that its recommendations are meant to be viewed as opportunities for successful programs to improve. The group noted that more graduate students and postdoctoral researchers supported by NICHD are paid through Research Project Grants (RPGs) than through Training and Career Development awards and that citizenship requirements for National Research Service Award (NRSA) fellowships preclude applications from many trainees. RPGs were not included in this analysis.

The WG's recommendations turned out to align well with the December 2023 recommendations of the <u>ACD Working Group on Re-Envisioning NIH-Supported Postdoctoral Training</u>. The ACD recommendations were:

- 1. Increase pay and benefits for all NIH-supported postdoctoral scholars.
- 2. Create and expand mechanisms to support the full talent pool of postdoctoral scholars.
- 3. Facilitate transition of postdoctoral scholars into their next career stage, including roles beyond academic faculty.
- 4. Promote training and professional development of postdoctoral scholars and their mentors.
- 5. Support safe and diverse perspectives and research environments within institutional research programs.
- 6. Improve means to measure and share postdoctoral scholars' career progression.

These NICHD WG recommendations are not meant to be implemented in a vacuum. Because other efforts (e.g., the ACD WG) are addressing training, the WG recommended actionable items for NICHD rather than action from groups outside NICHD. The final list of NICHD WG recommendations is outlined below.

Rethink How We Talk About Outcomes

A heavy reliance on R01s as the gold standard outcome for training programs excludes careers that contribute to the scientific workforce (e.g., STEM teaching, conducting non-NIH funded research, government, science communication, industry), work accomplished by research staff on RPGs, and nontraditional scholars (e.g., data scientists, engineers). There is a scarcity of faculty research positions at R01 institutions, and NICHD trains more people that it can fund at the R01 level. The action items for this recommendation are to:

• Track and encourage important career trajectories in the future and describe them all as valid and successful outcomes, not referring to other career trajectories as "alternative careers." This action item may require additional administrative support at NICHD.

 Redefine success of training awards as a "career that uses the training and educational experiences of the training award to advance biomedical research, clinical care, and scientific literacy."

Reinvigorate Institutional Training and Career Development Programs (T32 and K12)

NICHD's T32 and K12 programs have become deeply entrenched, making it difficult for new programs to launch. Many established K12 programs receive only one or two applications, limiting their competitiveness. Established programs have little need to adapt, even as NICHD's funding priorities change. There is significant overlap in K12 and T32 institutions, with approximately 20 institutions continuously having both types of awards for 20 years.

The T32 action items for this recommendation are to:

- Cluster Type 1 and Type 2 T32s separately in peer review.
- Establish a differential pay line for new versus renewed programs.
- List high-priority areas before making funding decisions, especially for multidisciplinary training programs or those that would support more general training, to be paid with institute or center funds.
- If the previous three action items do not improve levels of competition and turn-over, consider term limits for awards (e.g., two cycles per principal investigator [PI] per program).
- Hold PIs accountable for diversity recruitment plans in the Terms and Conditions section of each award.

The K12 action items for this recommendation are to:

- Create better metrics to determine when a K12 program has achieved its goal or to indicate that another tactic for growing a workforce should be attempted.
- In new Notices of Funding Opportunities (NOFOs), add language about term limits (e.g., about ending programs entirely or limiting the number of cycles that one PI or institution may hold a K12 program).
- Where appropriate, add language to funding announcements for national K12s indicating that NICHD will fund one to three awards, depending on availability of funding.
- In NOFOs, require diversity recruitment plans. Diversity includes geographic diversity.
- In NOFOs, indicate that renewal applications must provide metrics addressing how programs have evolved throughout the funding cycle in response to relevant scientific and technical knowledge or educational practices.

Create Community Among Trainees

Pre- and postdoctoral trainees are shifting from institutional to individual awards, leading to a decline in connection and community across the trainee population. Examples of community-building programs include the National Institute on Aging <u>Butler-Williams Scholars Program</u>, the NIH Blueprint for Neuroscience <u>Diversity Specialized Predoctoral to Postdoctoral Advancement in Neuroscience (D-SPAN)</u> Award Program, and the Common Fund's <u>High-Risk</u>, <u>High-Reward Research Symposium</u>. The action items for this recommendation are to:

- Create a distribution list of scholars and fellows to advertise NICHD-wide events.
- Host an annual or biennial workshop with fellowship trainees at NICHD.

- Craft welcome language and have regular contact with NICHD fellows.
- Include the Office of Health Equity (OHE) to encourage connection with fellows from diverse backgrounds.
- Include highlights from trainees or mentors in the NICHD Director's newsletters.
- Establish a trainee or career development representative slot on Council.
- Require inclusion of trainees in organizing and presenting at scientific conferences.
- Create a mentorship prize to recognize excellence in mentorship.

Use Training and Career Development to Diversify NICHD's Reach

Fellowship awards represent an opportunity for early entry into biomedical research. It is important to foster research at a broad variety of institutions and for more diverse candidates, including those without T32/K12 awards or non-R01 institutions. Upcoming changes to the NIH peer review of fellowship applications present an opportunity to broaden the applicant pool. The current process for signing on to diversity-focused NOFOs is not systematic. The action items for this recommendation are to:

- Conduct equitable outreach across institutions to increase the number of fellowship applications from institutions without a history of significant NIH funding.
- Use high program priority to solicit meritorious applications from institutions without T32 awards or who otherwise do not receive significant NIH funding (e.g., IDeA states, minority-serving institutions, historically Black colleges and universities, Academic Research Enhancement Award schools).
- Recommend that OHE develop a systematic process for evaluating and signing on to diversity-focused training NOFOs.

Reinvigorate the LRPs

LRPs can be used to reduce education loan debt and incentivize trainees to remain in research careers. LRPs at NICHD are concentrated with one program officer. Some program officers may possess only basic knowledge of the program and not consistently advertise it to their grantees. Internal funding decisions at NICHD are separated from the training and career development program officers. The action items for this recommendation are to:

- Expand LRP programs to include the L32 Clinical Research for Individuals from Disadvantaged Backgrounds award (NICHD joined September 2023).
- Increase LRP funding from \$7.5 million per year to \$10 million per year.
- Diversify the team involved in the LRP selection process to include representation from OHE and the training committee team.
- Increase outreach of the LRP through automation and contact people who apply for individual K awards, PIs of K12 and T32 programs, and Diversity Supplement recipients to encourage them to apply for LRPs.
- Target a higher success rate for the L32 mechanism.

Use Training Programs to Support Strategic Research Priorities

Training and career development goals are not delineated in the 2020 NICHD Strategic Plan. The 2025 refresh is an opportunity to reinforce commitment to training the workforce. Individual fellowship and career development applications do not receive special consideration for funding

when they address strategic priorities. K awards are funded solely by priority score or percentile, with no consideration of whether they address a high-priority area. The action items for this recommendation are to:

- Create a new cross-cutting theme in the upcoming strategic plan refresh to specifically address the commitment to and priorities for advancing the careers of trainees and scholars.
- Define NICHD priorities for training in the core competencies.
- Promote alignment of training and career mechanisms with strategic priorities by making F and K awards eligible for the "Director's Reserve" nomination process.
- Use Referral and Program Analysis Branch (RPAB) coding systems for individual F and K applications to assess alignment of application research goals with published RPAB high-priority areas and NICHD's strategic priorities as outlined in the current strategic plan.

When the recommendations are implemented, the expected outcomes include greater turnover in the T32 and K12 programs, allowing new programs to begin, diversifying the locations of the training across the country, and casting a broader net for trainees; greater community among trainees who feel connected to the NICHD mission and who view NICHD as a resource; an increase in diverse perspectives and broadening of the pool of PIs working on NICHD mission—relevant research; and an increase in the likelihood that disadvantaged individuals remain in research careers and better identify people who are more likely to remain active in NICHD-funded research careers.

Discussion (2:14:24)

Dr. Lang expressed concerns about institutions losing long-standing T32 awards. She asked whether established programs would be pushed in different directions to respond to new priorities while remaining eligible. Dr. Cruz said yes and added that the institute may encourage a new PI to apply for the award at established institutions. Dr. Cruz said that this long-standing issue also applied to K12 awards.

Dr. Cedars agreed that it was important to focus on outcomes rather than the R01 career path, because many trainees want to take nontraditional paths by incorporating engineering or AI into their work, especially in reproductive medicine. Dr. Cruz said that developing alternative pathways would also take more resources.

Beyond T32 and K12 awards, Dr. Van den Veyver asked whether individual award programs (e.g., K23 awards) would also be elevated. Dr. Cruz said that the institute was already shifting from more institutional to more individual K awards. The idea now is to create more turnover in K12 awards as appropriate.

Dr. Van den Veyver asked whether the eligibility limitations for K12 awards would be updated. Dr. Cruz said that it is true that K awards are not available to everyone, so the institute intends to incorporate those trainees through the RPG program. The pie is not getting any bigger, but the WG wants to ensure that there is a slice for everybody.

Dr. Miller commended the recommendation to create community among trainees, saying that this was an important part of career development—especially given the shift from institutional to individual-focused awards. Dr. Li suggested incorporating a webinar series for trainees and fellows, something that has been successful at HRSA, where the webinars, along with work group meetings, are opportunities for fellows to present and discuss their work with one another.

Dr. Li said that because of its complicated application process, HRSA offered application tips for trainees, including those from underserved populations. She asked which performance measures NICHD intends to use to assess the training program's success (e.g., trainee diversity). Dr. Cruz said that NICHD was in the process of developing new metrics for measuring performance.

Dr. Barkin said that these scientific stewardship projects created rich conversations; she expressed her appreciation for the presentation, adding that the summary of recommendations was quite solid. Dr. Barkin said that it was important to incorporate the life course perspective, which Dr. Neilan articulated well, and noted the number and quality of mentors and students who have been instrumental in advancing Dr. Neilan's work. Partners could help create support over trainees' life course.

Dr. Barkin said that improvement of mentoring had to extend beyond NIH to other organizations, including the development of mentoring curricula and evaluation and cohorts. She shared an example from her U award consortium. Dr. Barkin said that developing safety nets (e.g., asynchronous learning, mentoring cohorts) for vulnerable transition points in trainees' career trajectories could also help fill some of the holes in the leaky pipeline.

Dr. Neal-Perry said that good mentoring programs can help reduce disparities in who goes into research. She noted that national platforms for building community do not always work well for everyone, especially people who are introverted. Additionally, some platforms work better for disseminating information, while others are better for sharing experiences and networking. Dr. Neal-Perry agreed with the focus on diversity and on holding programs accountable for creating diversity, which takes time to develop. Reviewers need instruction on developing diversity, especially when reviewing applications from less established or junior researchers. Dr. Cruz agreed that multiple pathways are needed to create the desired solutions, and she appreciated the suggestions for building community.

Dr. Rowitch shared that the U.K. system has a good option for developing clinician scientists in its clinical Ph.D. training pathway. These physicians are allowed to spend 3 to 4 years out of a residency or fellowship program to pursue a Ph.D. later in their clinical career, after they have had a few years to reflect and develop their research questions. He suggested that NIH consider this as another alternative pathway.

Dr. Taymans said that another aspect of creating community among trainees is finding ways to get them to engage more deeply in their interactions with NICHD program staff.

Under the third recommendation, Dr. Contreras-Vidal suggested also creating a community for the mentors; he cited a meeting hosted by the National Science Foundation as a good example for helping mentors learn how colleagues handle mentoring challenges. Dr. Maldonado agreed with this suggestion.

Dr. Neal-Perry reminded the group to consider technology that is on the horizon to prevent stifling innovation in these programs.

VI. PANEL DISCUSSION ON RECRUITMENT AND RETENTION OF JUNIOR FACULTY (2:39:16)

As department chairs at their respective institutions, Dr. Barkin, Dr. Cynthia Gyamfi-Bannerman [pending Council member], Dr. Neal-Perry, and Dr. Rowitch formed a panel to discuss how they approach the recruitment and retention of junior faculty. The Q&A session was preceded by a 5-minute presentation from each panelist.

Dr. Barkin shared recruitment, retention, and mitigation strategies from her experiences at both Vanderbilt University (private) and Virginia Commonwealth University (VCU, public):

- For recruitment, one strategy is a 3-year start-up package for fellows, along with a dynamic scholarship oversight committee that meets quarterly to provide mentoring and to measure outcomes.
- Loan repayment programs help with recruitment.
- The ability to participate in team science is a recruiting incentive, along with novel and entrepreneurial approaches to projects. These approaches also require the development of new types of mentoring.
- Continually developing longitudinal relationships over time is important for recruiting. Mentor—mentee relationships are not one-size-fits-all; the right match is needed.
- For retention, there are gaps between funding award opportunities, where bridge funding is needed. A safety net must be put in place during the recruitment process to anticipate and address these gaps. Institutions can partner with philanthropists, nonprofits, and community corporations with foundations to assist with bridge funding.
- Dynamic churn and turnover in the research world create the need for a "deeper bench." Mentors-in-training can be recruited earlier than when they are needed.
- Research time must be protected to create diverse portfolios.
- For mitigation strategies, the entire life span of the career must be taken into consideration, along with building community over time. One idea is a "K club" to build specific skills, brainstorm solutions, and socialize outside of work.

Dr. Gyamfi-Bannerman shared slides from the University of California San Diego (UCSD) to illustrate the financial challenges in recruiting junior research faculty. UCSD is an NICHD Women's Reproductive Health Research (WRHR) career development site. She made the following points:

- Compensation data from 2017 to 2019 for career development of faculty funded by grants at the time of their appointment reveal that the average starting salary for a WRHR K-award physician-scientist totaled \$160,000. In contrast, the 3-year median salary from 2019 to 2022 was \$515,085 (Medical Group Management Association), and the 3-year average for an assistant professor was \$368,358 (Association of American Medical Colleges). The contrast in these compensation levels make it difficult for young physician-scientists to choose the research route.
- At UCSD, comparing the salary for a WRHR-funded faculty member with the standard compensation for a newly hired junior faculty member revealed a \$155,000 gap. The gap

is due to the bulk of the salary being based on relative value unit (RVU) clinical production (plus additional incentives for a clinical service agreement, subspecialty coverages, and departmental incentives). WRHR-funded faculty who want to conduct research beyond clinical care receive less RVU compensation, creating the gap.

- The Department of Obstetrics, Gynecology, and Reproductive Sciences invests an extra \$55,000 in the salary of the WRHR-funded faculty to bring their salaries more closely in line with non-research first-year faculty—but this still leaves a gap of \$100,000.
- At Year 6, after the WRHR K award ends, the salary of the clinician-scientist drops drastically, and the gap grows to \$240,000. If the physician-scientists transition to more clinical work, they have less time to conduct their research, despite having the knowledge and tools to do so. They are in the bridge period before receiving their first R01 award. Even after receiving an R01, the salary cap leaves them with a salary well under that of colleagues who are doing only clinical work.

Dr. Neal-Perry said that the University of North Carolina at Chapel Hill (UNC) achieves salary parity between its clinicians and clinician-researchers through a cost-share system that helps reduce disparity, especially given that average debt for graduating students is \$250,000. UNC's methods of recruiting and retaining junior faculty include the following:

- Protecting research time for clinicians who want to conduct research, up to 50% of their time for approximately 3 years, until additional grant funding can be obtained
- Helping new recruits find funding from NIH, nonprofit foundations, and philanthropic gifts
- Articulating clear job expectations and monitoring to ensure that the time is used well
- Providing pre- and post-award assistance through the UNC center for women's health research, which also assists with mentoring and the development of collaborative projects
- Co-recruiting faculty with other departments to help with retention
- Encouraging portfolio development for diverse funding sources
- Helping faculty achieve promotions by offering faculty development programs and leadership opportunities
- Using faculty retention office resources to provide additional compensation and incentives (e.g., providing clinical scribes)

Dr. Rowitch described his collaborative work conducting surveys on neonatal fellows and junior faculty in neonatal intensive care. The <u>surveys revealed</u> that division chairs and department chairs need a clear understanding of the resources required for clinician-scientists to be successful. He made the following suggestions:

- Offer clinician-scientists a start-up package equivalent to what a good basic science department would offer to a scientist.
- Do not implement restrictive policies that affect how award funding is used.
- Value the research mission. Medical centers are under pressure to use fund flow models and RVUs to make financial decisions. Departments that were previously led by academics are now being led by clinical administrators, sending a message about the value of research. If the priority for research is not front and center, the field does not progress.
- Use a salary scale algorithm (e.g., using clinical experience and the academic ladder) to achieve salary parity between clinicians and clinician-researchers.

• Take inspiration from the U.K. tenure system, which allows research flexibility and promotes collaboration and mentorship.

Discussion (3:03:00)

Dr. Maldonado said that there are major hurdles to overcome, especially in the pediatric and OB/GYN subspecialties. Even in a compassionate academic setting, the ability to provide compensation is decoupled from hospital revenue, leaving academic leadership quite challenged. Every dollar that comes in from research reduces operating revenue. At Stanford, for basic science, dedicated funds from philanthropy or reserve accounts are used to support Ph.D. students. Faculty are supported through NIH grants or the dean's office. This model is impossible in a clinical setting. In their lifetime, medical subspecialists earn less money than if they went straight into general practice. NIH models of funding can really help, and the awards are worth their weight in gold in terms of advancing science and helping to sustain outstanding academic and clinical missions.

Dr. Bianchi said that the salary discrepancy between clinicians and clinician-researchers affects morale, and it directly or indirectly communicates to the next generation that people doing research are less valuable than full-time clinicians. The situation is even worse if the department chairs are full-time clinicians or clinicians with M.B.A.s. Medicine needs to reach a place where everyone's contributions are equally valued and equally compensated. Dr. Neal-Perry agreed that department chairs need to understand all of the issues.

Dr. Neal-Perry suggested that one way NIH could help remedy the salary gap would be to allow the research salary cap to reflect the medical discipline. Another idea would be to allow competitive renewal of K awards, and a third suggestion would be to expand programs like WRHR. Dr. Bianchi said that she would be following discussions about the NIH cap very closely, along with the news that NIH fellows have unionized to push for higher salaries.

Dr. Barkin said that financial innovation and new models were needed to continue to conduct research (e.g., former Council member Lucky Jain, M.D., worked with the hospital system to create an innovative endowed research fund in Atlanta). Dr. Gyamfi-Bannerman agreed, adding that her institution is also trying to diversify its funding portfolio. She commented that the decision to support research is institutional rather than department-wide, so the department must work within the institution's mission. UCSD is employing academic RVUs, but the entire system needs to change.

Dr. Contreras-Vidal asked how partnering with industry for sponsored research could factor into the discussion. He suggested that partnerships between private institutions, government, and industry could be part of a solution to the research funding problem. Dr. Bianchi said that such partnerships were possible and that there were good examples of them in Boston where the hospitals negotiate for full overhead, so they do not lose money.

Dr. Cedars said that many of the problems were a matter of trying to make everyone feel valued and that compensation does not necessarily need to be equal but should be equitable.

VII. DISCUSSION WITH REPRESENTATIVES OF STAKEHOLDER GROUPS (3:17:45)

For this session, four experts were invited to share their thoughts on the report from the NICHD extramural training and career development working group. Each speaker is listed under the organization that they represented for this discussion.

Association of Medical School Pediatric Department Chairs (AMSPDC)

Joseph St. Geme, M.D., physician-in-chief and chair of the Department of Pediatrics and Leonard and Madlyn Abramson Endowed Chair in Pediatrics at Children's Hospital of Philadelphia (CHOP), shared the following reaction:

The working group presented a thoughtful assessment of the current state, along with its recommendations. I agree that it is important to think more broadly about outcomes in terms of contributions to advancing science and medicine. I hope that NIH study section reviewers will be able to incorporate this new perspective as they review applications. I like the ideas of creating communities and networks of trainees at NICHD and increasing funding for LRPs, which is critical for mitigating debt and attracting people into pediatrics, OB/GYN, and the related fields that are supported by NICHD.

Regarding the approach to institutions that are successful in garnering K12 and T32 support, I hope that we do not disadvantage the programs that are competing for renewal funding. In pediatrics, subspecialists are trained at a limited number of institutions. We would be creating a disadvantage if we did not take that into consideration. Rather than adjusting pay line or implementing term limits, I would advocate for more PI turnover for these grants. Another idea would be to promote relationships between larger, more research-intensive universities and smaller departments so that applications might be combined. Combining programs could leverage the environment at existing programs and share it with others.

It is important to continue to promote diversity recruitment with realistic expectations. Establishing a pathway program between T32 applications and K12 support could strengthen linkages between T32 and K12 programs. The National Institute of Diabetes and Digestive and Kidney Disease's new approach to training grants and career development awards could be a nice model to follow.

Society for Reproductive Investigation (SRI)

Irina Burd, M.D., Ph.D., the Sylvan Frieman, M.D., Endowed Professor and chair of the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Maryland School of Medicine, shared the following reaction:

As a recipient of LRP, K08, and R01 awards from NICHD and having served as an internal reviewer for K12 and T32 awards, I know that all of the issues mentioned by the WG are important. The WG's recommendations are clear. Regarding creating community among trainees, including plans for improving diversity and community building should be a part of every award application.

I agree that there are no alternative careers. Creating NIH and industry tracks to train postdoctoral researchers for NIH and industry jobs could be directly subsidized by NIH and industry and provide a way to diversify our workforce in the future.

Regarding the panel discussion on the recruitment and retention of junior faculty, we have to be careful about saying, "No money, no mission." As a department chair, I appreciate that margin is not our mission; we have an academic mission. I like the idea of obtaining philanthropic and industry support and packaging these other types of support with NIH awards. Money is money, and research is research. We need to move OB/GYN and pediatrics forward.

National Academies of Sciences, Engineering, and Medicine (NASEM) Committee on the Pediatric Subspecialty Workforce

Frederick P. Rivara, M.D., M.P.H., the Seattle Children's Guild Association Endowed Chair in Pediatric Outcomes Research and vice chair and professor in the Department of Pediatrics at the University of Washington, shared the following reaction:

I would like to disclose that I am a PI on a T32 award. The NASEM Committee on the Pediatric Subspecialty Workforce report is complementary to this WG's report. There is a crisis in the number of individuals going into many of the pediatric subspecialties, including endocrinology, infectious diseases, rheumatology, and developmental pediatrics. Only 50% to 60% of the fellowships are filled. Even programs for gastroenterology and pediatric critical care are having trouble filling their slots. As NICHD applies its WG's recommendations, it needs to think about the shortage of people going into these particular specialties and the use of a more focused approach rather than a blanket approach.

Regarding career development awards, the NASEM report suggested that NICHD increase the number of career development awards in pediatrics, both to individuals who are underrepresented in pediatrics and also to these high-priority subspecialties.

NICHD staff must think about how they can address major problems with geographic diversity in the training programs. With the limited pool of money in many of the pediatric programs, especially in geographically diverse areas, one solution could be higher stipends for T32 fellows and for K awards.

Secure outcome tracking data are essential for measuring the effectiveness of these projects. N-PeRC, NICHD leadership, the NIH scientific workforce diversity office, and AMSPDC should collaborate to create a central qualitative and quantitative data repository to understand the success rate for training pediatric physician-scientists. The lack of data is hindering our ability to understand the full extent of the problem and devise solutions.

Training Diverse Clinician Scientists in Rehabilitation Research

Elizabeth Skidmore, Ph.D., OTR/L, FAOTA, FACRM, associate dean for research and professor in the Department of Occupational Therapy at the University of Pittsburgh School of Health and Rehabilitation Sciences, shared the following reaction:

Some of the challenges in rehabilitation research parallel what has been presented today but are applied a bit differently. Rehabilitation research has grown dramatically over the past 20 years, in part due to the NICHD investment in T32 and K12 programs. This has resulted in a much more active portfolio across all of the ICs. Now we are at risk of losing those gains.

First, there is a reduction in trainees coming into predoctoral and postdoctoral training programs, because most of our professions have moved to an entry-level doctorate. We now have the same challenges that M.D.s have been facing for decades: a high debt burden that makes continued training less appealing, combined with low postdoctoral salaries. The NIH LRP helps but seems too far off and a bit of a gamble.

Second, junior faculty are leaving research for clinical practice or industry. There is no clinical service as the basis for the operation of high-volume, high-tuition, revenue-generating programs, to which many universities are turning to balance their budgets. It is becoming more difficult to protect time for research. These are not new challenges in medicine, but they are new to rehabilitation research, and we do not have as deep of a bench.

Training grants and increasing salaries and support for postdoctoral trainees are great ideas. Investing more in transition training programs, from K99 to R01 grants would be helpful. The National Institute on Aging now has a K22 mechanism that a postdoctoral researcher can carry into a faculty position. Elevating funding in the LRP is meaningful and could make a difference. Our institution is investing in program leaders. It is looking at cost sharing and other mechanisms that free up faculty to write grant applications and then lead the grant (beyond what is supported).

Most importantly, these issues are compounded for trainees who come from vulnerable populations that are underrepresented in biomedical science. Beyond funding, building community is important. I co-lead an R25 faculty education program that trains current faculty scientists on how to optimize their training environment to be more welcoming, inclusive, and supportive of clinician-scientists from diverse backgrounds (i.e., specific racial and ethnic groups, social disadvantage, people with disabilities). It is key to the mission of rehabilitation research that those voices are heard, and that they lead our science, for us to reach our full impact.

Discussion (3:33:45)

Dr. Cruz clarified that NICHD funds many types of researchers (e.g., basic scientists, engineers, data scientists, social scientists) as well as clinician-scientists. She asked whether anyone had special training concerns for other types of researchers. Dr. Skidmore said that she recently met

two neuroscience trainees who had a good idea for a K award but no institute home for their specific cross-cutting ideas.

Dr. St. Geme said that some of NICHD's career development awards have shrunk in the level of support to increase the number of awards offered, but the expansion of two specific programs—AMSPDC's Pediatric Scientist Development Program and NICHD's Child Health Research Career Development Award program—could have a significant effect on the pool of individuals prepared for successful careers as pediatric physician-scientists. Dr. Burd asked Dr. St. Geme whether national or institutional K12 programs were more effective. Dr. St. Geme said that national programs were quite effective, even in other specialties, and provided a way to "spread the wealth" and find the best candidates across the country. Dr. Burd agreed, saying that statewide or national programs created larger pools of candidates. Dr. Bianchi said that candidates from smaller institutions may not have access to the right mentor, but one of the benefits of the pandemic was making everyone more comfortable with virtual meetings. Dr. Neal-Perry said that there is great value in national training grants, but she cautioned that trainees from smaller institutions might have challenges with some facets of statewide or national programs.

Ralph Nitkin, Ph.D., said that multidisciplinary training was becoming more important. Crossing administrative boundaries can be a challenge for trainees if their mentors are in different departments. Dr. Contreras-Vidal said that working across disciplines is important for both trainees and mentors. Dr. Burd noted that multi-PI awards specify responsibilities and financial arrangements, so multi-mentor awards could do the same. Dr. Rivara said that he has a T32 award with fellows from pediatrics, social work, surgery, and criminology; he added that multidisciplinary training is feasible and important. Dr. Gyamfi-Bannerman said that UCSD is becoming well versed in multidisciplinary recruiting for team science. The university uses full-time equivalents, or FTEs, to split resources and mentorship across departments. Dr. St. Geme agreed that multidisciplinary mentoring was important and that each individual institution could create strategies for accomplishing it.

Dr. Barkin said that mentoring means different things at each level of training and that different levels of mentoring are required for T and K awards. Increasing diversity in the career pathway may require rethinking each level of mentorship. Dr. Burd added that she agreed with Dr. Neal-Perry about allowing the renewal of K awards for several years to allow some researchers to continue their paths.

Dr. Fair said that the University of Minnesota is working to incentivize diverse team science and that these types of incentives could also be built into NICHD's funding award process. He added that team science projects can create cultural shifts. Dr. Bianchi said that she may invite Dr. Fair to present outcomes from that program at a Council meeting.

Dr. Skidmore advocated for engaging people who are earlier in the pathway to research and who have not been exposed to large research institutions with ample mentors. There are evidence-based strategies for developing better pathways and multiple types of mentoring. Structural barriers also need to be removed.

Dr. Bianchi asked whether any institutions reward mentors for their time and efforts. Dr. St. Geme said that CHOP has identified a cadre of senior faculty who are responsible for implementing a grant review program for trainees; CHOP also has a mentorship award. Dr. Burd said that she has also advocated for additional mentor support at the University of Maryland School of Medicine. Dr. Neal-Perry said that her institution, UNC, offers financial incentives for mentoring. Dr. Rowitch said that faculty at the University of Cambridge are expected to offer mentorship and are recognized when their mentees are promoted. Dr. Rivara said that the NASEM Committee report recommended funding support for mentorship of K awards. Dr. Gyamfi-Bannerman said that UCSD offers a mentorship retreat and a mentor of the year award but no financial incentives. Dr. Van den Veyver said that Baylor recently launched a new mentorship program with facilitated matching.

Dr. Bianchi asked how the various institutions handle indirect costs. Dr. Burd said that a portion of her indirect funds were available but that most of them went to the dean's fund. Dr. St. Geme said that he did not have access to indirect costs, because they were used to support research infrastructure. Dr. Barkin said that VCU incentivized researchers to obtain more grants by returning a proportion of indirect costs for reinvestment. Dr. Skidmore said that her institution, the University of Pittsburgh School of Health and Rehabilitation Sciences, returns a portion of the indirect costs to the investigator and the department chair in the school of medicine, but at other schools, the costs go to support research infrastructure. The models are currently being reviewed. Dr. Gyamfi-Bannerman said that her department receives a proportion of the indirect costs.

VIII. CONCEPT CLEARANCE (4:00:25)

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

Advancement and Innovation in Measurement of Language Development and Predictors

Virginia Salo, Ph.D., presented this concept from the Child Development and Behavior Branch (CDBB). CDBB was seeking approval for this concept. Dr. Barkin asked for clarification of the callout for advances in wearable devices. Although wearable devices can be used to measure the number of words children hear and speak in a day, they have limitations in quality. Dr. Rowitch asked whether the concept was agnostic to first or second language. The concept builds the knowledge base for all language development, including multilingual language development. Dr. Rowitch suggested making the program as inclusive as possible across various spoken languages. Dr. Li asked whether the concept included measuring learning ability in preschool and school beyond language development. At this point, the concept is solely focused on language development, but it may be broadened in the future. **Decision: Approve.**

Pediatric HIV/AIDS Cohort Study (PHACS)

Denise Russo, Ph.D., presented this concept from the Maternal and Pediatric Infectious Disease Branch (MPIDB). MPIDB was seeking approval for this concept. Council members did not ask any questions before voting. **Decision: Approve.**

Intellectual and Developmental Disabilities Research Centers

Alice Kau, Ph.D., presented this concept from the Intellectual and Developmental Disabilities Branch (IDDB). IDDB was seeking approval for this concept. Dr. Aizer said that this concept had the potential to affect future federal policies and programs if it were further developed. Dr. Barkin asked whether this concept was intended to analyze existing longitudinal cohort data or develop new cohorts. The centers would each have their own unique projects, including a mix of longitudinal and novel studies. Dr. Rowitch said that NICHD has pioneered this transformative work, and he commented on the value added by other programs in the research landscape. **Decision: Approve.**

Advancing Cures and Therapies and Ending Endometriosis Diagnostic Delays to Improve Outcomes (ACT ENDO)

Candace Tingen, Ph.D., presented this concept from the Gynecologic Health and Disease Branch (GHDB). GHDB was seeking approval for this initiative. Dr. Barkin suggested including early-stage investigators in the concept proposal. **Decision: Approve.**

Sustaining the Gabriella Miller Kids First Data Resource

James Coulombe, Ph.D., presented this concept from the Developmental Biology and Congenital Anomalies Branch (DBCAB). DBCAB was seeking approval to sustain this program. A Council member asked whether this program could be part of the *All of Us* Research Program but was told that *All of Us* is not yet enrolling pediatric participants. **Decision: Approve.**

NICHD Resource Program Grants in Bioinformatics

Kathryn Stein, Ph.D., presented this concept from DBCAB. DBCAB was seeking approval for this concept. Council members did not ask any questions before voting. **Decision: Approve.**

IX. CLOSING REMARKS (4:36:08)

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

X. DAY 1 ADJOURNMENT

Dr. Bianchi adjourned Day 1 at 4:36 p.m. A total of 165 people viewed the live VideoCast of the open session.

XI. DAY 2 CALL TO ORDER AND INTRODUCTORY REMARKS

Dr. Bianchi opened Day 2 of the meeting at 9 a.m. ET.

XII. 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.

XIII. REVIEW OF APPLICATIONS

The session included a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions, and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect. The council considered and approved 682 HD-primary applications requesting \$243,423,966 in direct costs and \$338,897,846 in total costs.

XIV. ADJOURNMENT

There being no further business, Dr. Bianchi adjourned the meeting at 11:00 a.m. on Tuesday, January 23, 2024. The next Council meeting is scheduled for June 3–4, 2024.

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

Diana W. Bianchi, M.D.	Date
NACHHD Chair NICHD Director	
Rebekah Rasooly, Ph.D.	 Date
NACHHD Executive Secretary	Date
Director, NICHD Division of Extramural	
Activities	

²These 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.