



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

NATIONAL ADVISORY CHILD HEALTH  
AND HUMAN DEVELOPMENT  
COUNCIL

*MEETING SUMMARY*

January 11–12, 2022

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND  
HUMAN DEVELOPMENT  
NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT COUNCIL  
MEETING SUMMARY  
January 11–12, 2022<sup>1</sup>**

The National Advisory Child Health and Human Development (NACHHD) Council convened its 178th meeting at 12 p.m. on Tuesday, January 11, 2022, by National Institutes of Health (NIH) VideoCast. The meeting was open to the public on January 11 from 12 p.m. to 5:24 p.m. As provided in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of Public Law 92-463 for the review, discussion, and evaluation of grant applications and related information, the meeting was closed to the public on January 12, 2022, from 12:00 p.m. until 5:00 p.m.

Dr. Diana W. Bianchi, Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), presided.

**Council members present:**

Diana W. Bianchi, M.D. (Chair)  
Shari Barkin, M.D.  
Christina Bucci-Rechtweg, M.D.  
Michele Caggana, Sc.D.  
John P. Coughlin, M.D.  
Kathleen B. Egan, Ph.D.  
Damien Fair, Ph.D.\*  
Lucky Jain, M.D.  
Catherine E. Lang, Ph.D.

Yvonne Maldonado, M.D.\*  
Martin Matzuk, M.D., Ph.D.  
Genevieve S. Neal-Perry, M.D., Ph.D.  
Adam C. Resnick, Ph.D.  
David H. Rowitch, M.D., Ph.D.  
Alan Thenevet N. Tita, M.D., Ph.D., M.P.H.  
Rebeca Wong, Ph.D.  
Anthony J. Wynshaw-Boris, M.D., Ph.D.

\* Ad hoc Council members.

**Council members not present:**

Missy Lavender, M.B.A.  
Carmen L. Neuberger, J.D.

**National Advisory Board on Medical Rehabilitation Research Council liaison:**

Arthur English, Ph.D.

**Department of Defense:**

Melissa R. Miller, Ph.D.

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<sup>1</sup> 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.

***Ex officio* members:**

Patricia Dorn, Ph.D.

Aaron M. Lopata, M.D., M.P.P.

**Executive Secretary:**

Dennis Twombly, Ph.D.

**Others present:**

Members of NICHD staff

Members of NIH staff

Members of the public

**I. CALL TO ORDER AND INTRODUCTORY REMARKS**

Dr. Bianchi welcomed members of the NACHHD Council and other participants to this meeting. She introduced Dr. Miller, the new Department of Defense liaison. Dr. Bianchi also explained that until their appointments are finalized, Dr. Fair and Dr. Maldonado may attend open and closed Council meetings as non-voting *ad hoc* NACHHD Council members. She will formally introduce these two new Council members at the June 2022 meeting.

**Review of Confidentiality and Conflicts of Interest**

Dr. Twombly reminded Council members that all members were required to read, agree to, and sign the confidentiality and nondisclosure rules for special government employees on the Council member website before evaluating any NIH grant applications. Before the meeting, Council members had received a conflict-of-interest certification form, which they were required to sign. Dr. Twombly also reminded Council members that they are required to recuse themselves and leave the virtual meeting before any discussion involving any organizations or universities for which they are in conflict, in addition to those listed in the Council Action document. Council members are not allowed to serve on an 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.

**Council Minutes**

A motion to approve the September 9–10, 2021, NACHHD Council meeting minutes carried.

**Future Meeting Dates**

Dr. Twombly reviewed future Council 2022 meeting dates:

June 15, 2022 (6710B Rockledge Drive, Bethesda, Maryland)

September 13, 2022 (6710B Rockledge Drive, Bethesda, Maryland)

**II. NICHD DIRECTOR'S REPORT**

Dr. Bianchi began the director's report by showing a [video](#) that provides a timeline of NICHD's COVID-19 milestones since March 2020.

## **NICHD 60th Anniversary**

Dr. Bianchi encouraged Council members to save October 17, 2022, for a scientific symposium—“Healthy Pregnancies, Healthy Children, and Healthy and Optimal Lives”—to celebrate NICHD’s 60th anniversary. Details on the event and key advances and milestones in NICHD’s history will be available on the 60th anniversary [webpage](#).

## **COVID-19 Research Updates**

As a result of the highly transmissible omicron variant, the number of pediatric cases of COVID-19 has increased rapidly. Children now account for more than 17% of all COVID-19 cases.

The NIH-wide [Researching COVID to Enhance Recovery](#) (RECOVER) initiative supports research on the post-acute sequelae of SARS-CoV-2 infection. RECOVER will enroll up to 20,000 children and adolescents, including some with multisystem inflammatory syndrome in children (MIS-C), in its pediatric cohort. RECOVER is also collecting data from electronic health records (EHRs) and will have a pregnancy cohort. One RECOVER grant is supporting the development of an interactive pediatric COVID-19 severity dashboard that allows near real-time tracking of pediatric cases.

NICHD has offered supplements to existing grants for research on the effects of COVID-19 vaccines on menstruation in otherwise healthy women. The first report from one of these studies, which was recently published, showed that one dose of a COVID-19 vaccine during a menstrual cycle increases cycle length by nearly one day, and two vaccine doses in the same cycle increase cycle length by approximately two days. These changes are temporary and are limited to one cycle. This finding received substantial media attention, which will be useful for combating the misinformation that arises when scientific evidence is lacking.

Several NICHD-sponsored investigators are studying maternal, placental, and fetal immune responses to the COVID-19 vaccines. Findings from these studies include the following:

- Levels of SARS-CoV-2 antibodies in pregnant people are higher after vaccination than after natural infection.
- Maternal immune responses to vaccination in the first and third trimesters are higher than to vaccination in the second trimester.
- Breast milk contains vaccine-induced SARS-CoV-2 antibodies.

These findings show that the best way to protect infants (who are not eligible for COVID-19 vaccination) from SARS-CoV-2 infection is to vaccinate the parent during the third trimester of pregnancy and for the parent to breastfeed the infant.

## **Data Challenge: Decoding Maternal Morbidity and Mortality**

NICHD’s first ever [data challenge](#) offered prizes for the development of computational methods to analyze existing data on people who were pregnant for the first time from NICHD’s [Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-Be \(nuMoM2b\)](#). Established in 2010, the nuMoM2b study compiled data on more than 10,000 pregnant people from the sixth week of pregnancy until delivery. NICHD awarded a total of \$400,000 to seven data challenge winners for innovation and addressing health disparities. The methods that the winners developed can be used to analyze data from other pregnancies.

## **Bespoke Gene Therapy Consortium (BGTC)**

NICHD is participating in the [BGTC](#), which is part of NIH's Accelerating Medicines Partnership® (AMP). AMP is a public-private partnership with the Foundation for NIH (FNIH), the Food and Drug Administration (FDA), and private organizations. The BGTC will develop platforms and standards to speed the development and delivery of customized (“bespoke”) gene therapies to treat rare diseases by optimizing the creation of adeno-associated viruses (AAVs) for use in clinical trials to treat rare diseases.

The BGTC is of interest to NICHD because it addresses the NICHD Strategic Plan 2020 theme of advancing safe and effective therapeutics by accelerating the path to gene therapy development for monogenic disorders relevant to the institute (e.g., Fragile X syndrome, Williams syndrome, and Phelan-McDermid syndrome). NICHD will help develop BGTC funding opportunity announcements, provide programmatic input during funding discussions, and encourage intramural involvement.

The BGTC has released two requests for proposals for high-throughput screens or other developments to optimize steps of the AAV vector generation and human gene expression pathways. The BGTC steering committee is seeking information on rare diseases and disorders that could be candidates for future AAV gene therapy trials.

## **National Center for Medical Rehabilitation Research (NCMRR) Update**

NCMRR recently published the 2021 [NIH Research Plan on Rehabilitation](#). In addition, NICHD released an NCMRR request for applications, Home and Community-Based Physical Activity Interventions to Improve the Health of Wheelchair Users (R01 Clinical Trial Required, [RFA-HD-22-017](#)). Applications are due on March 30, 2022.

## **NIH and NICHD Staff Updates**

Francis S. Collins, M.D., Ph.D., stepped down as NIH director on December 20, 2021, and Lawrence A. Tabak, D.D.S., Ph.D., is now serving as NIH's acting director. Dr. Tabak was previously NIH's principal deputy director.

NICHD staff updates are as follows:

- Una Grewal, Ph.D., M.P.H., is the new director of the Division of Population Health Research.
- NICHD is seeking an associate director for extramural research, a director of extramural activities, and an NICHD scientific director. Information on these and other intramural and extramural job opportunities is available on the [Jobs at NICHD webpage](#).
- Louis DePaolo, Ph.D., chief of NICHD's Fertility and Infertility Branch, is retiring after 28 years of service.
- Charisee Lamar, Ph.D., M.P.H., is leaving her position as director of NICHD's Office of Health Equity to become the deputy director of extramural activities at the National Institute of Mental Health.

## **Discussion**

Dr. Lang asked whether RECOVER includes children and adults with disabilities in its underrepresented populations and whether the initiative is evaluating the effects of long COVID in children with preexisting disabilities. Dr. Bianchi replied that both the adult and pediatric cohorts in RECOVER will include individuals with disabilities. Rohan Hazra, M.D., of NICHD added that RECOVER is collecting data from EHRs that contain phenotypic information, and NICHD is making sure that NIH-wide efforts like RECOVER address NICHD's target populations.

Dr. Barkin asked about the ability to determine distinctions among the sequelae of different COVID-19 variants. Dr. Maldonado said that NICHD networks are studying both the short- and long-term effects of COVID-19, but recruiting study participants and gathering data will take time. More data on the short- and long-term sequelae of COVID-19 in children will be released in the next few months.

Dr. Bianchi gave an example of NICHD's agility in responding to developments in the COVID-19 pandemic. NICHD became aware of potential effects of COVID-19 vaccines on menstruation in the spring of 2021. After institute staff developed a grant supplement program to study these effects in late spring, applications were reviewed in the summer, funds were issued in August, and the first report was published in January. This advance was possible because it leveraged existing infrastructure.

Dr. Caggana asked whether NICHD is planning a social media campaign to counter misinformation about COVID-19 vaccines in pregnant and lactating people. Dr. Bianchi explained that NICHD encourages its investigators to work with the institute's communications team to prepare press releases for upcoming study publications. NICHD and its investigators also disseminate study findings on social media.

Dr. Resnick asked for more information on the BGTC. Dr. Bianchi replied that this consortium is at an early stage. Instructions on nominating rare diseases for consortium clinical trials are available on the [BGTC website](#).

Dr. Jain asked whether NICHD is working with the National Institute of Allergy and Infectious Diseases (NIAID) and industry sponsors to accelerate the development of COVID-19 vaccines for young children. Dr. Bianchi explained that NIAID is the lead NIH institute for vaccine development. Dr. Jain suggested that a NIAID representative give a presentation at a future NACHHD Council meeting on plans for future pandemics.

## **III. INITIATIVES TO ADDRESS BIAS IN PEER REVIEW**

Noni Byrnes, Ph.D., director of the Center for Scientific Review (CSR) at NIH, discussed bias in the peer review process and CSR initiatives to mitigate such bias.

## **Evidence of Bias in the NIH Peer Review Process**

Dr. Byrnes first summarized the literature on bias in the peer review process, starting with a [2011 report](#) by Donna K. Ginther, Ph.D., M.A., and colleagues showing that Black and African American principal investigators (PIs) have a 13% lower likelihood of receiving NIH funding than do white PIs. In subsequent publications, the authors noted that reviewers do not know the race or ethnicity of applicants and that direct evidence of implicit bias in peer review has not been documented.

NIH has conducted its own analyses, which have shown the following:

- The [choice of research topic](#) contributes to more than 20% of the funding gap between African American or Black scientists and white scientists. For example, applications for studies of child obesity interventions or weight loss programs are less likely to be funded than are applications for research on corneal wound healing or cataract development.
- African American or Black investigators are more likely than white investigators to [choose research topics associated with a lower likelihood of funding](#). The lower rate of funding for these topics was found to result primarily from assignments to ICs with lower award rates, not peer-reviewer preferences.
- [Redaction of information](#) that could be used to identify applicants' characteristics did not affect the scores of Black applicants but worsened the scores for grants from white applicants. The findings support a review process that diminishes the impact of investigator identity.

## **Strategies to Mitigate Bias in the Peer Review Process**

CSR piloted a blinded review process for NIH Director's Transformative Research Award applications. Reviewers did not receive information on the investigator or institution during the initial stages of the review process (choice of top group of applications, assessment by subject matter experts, and assignment of preliminary scores). Identifying information was provided to the study section for its discussion and final scoring of applications. This approach resulted in a statistically significant increase in the demographic diversity of the applicant pool.

A CSR Advisory Council working group has recommended that NIH reorganize the five scored review criteria into three: importance of the science, feasibility and rigor, and investigators and environment. A trans-NIH working group is now considering this recommendation.

The annual summer study section chair orientation sessions include discussion of bias and fairness in review and address the role of the chair in setting expectations and culture. CSR also launched bias awareness training for all peer reviewers in August 2021 and has been sent to ~ 10,000 reviewers thus far. Survey results show that the training improves reviewers' ability to identify bias and intervene when it occurs in a review.

In March 2021, CSR launched a reporting avenue and encourages reviewers, program officers, applicants, and others to contact their scientific review officer (SRO) or the CSR associate director for diversity and workforce development to report disrespectful interactions, bias, or other issues that could affect the fairness of the review process. CSR has a procedure for managing PI reports of potentially flawed or biased reviews. If CSR management determines that a review is flawed or biased, CSR will re-review the application in the same council round. If

CSR management determines that the review is not flawed or biased, CSR refers the PI to a program officer for guidance on the council appeal process.

Another CSR strategy to mitigate bias is to broaden the pool of NIH reviewers. This effort includes communication to the external community and launching tools for SROs. For example, CSR expanded the [Early Career Reviewer Program](#), a group of reviewers that tends to be more diverse than the general pool of CSR reviewers. CSR also launched a database (Reviewer Finder) to help SROs find qualified but less well-known reviewers. Other CSR strategies for increasing the diversity of review groups are focused on communication and training of CSR scientific staff to ensure that all appreciate the critical need to have diverse perspectives represented in order to identify the best, most novel science.

These efforts are starting to yield results. The proportion of women and members of underrepresented minority groups serving as reviewers in standing study sections and special emphasis panels has increased over the last 3 years.

The CSR Advisory Council has formed a working group to consider how the review process for National Research Service Award fellowships could be strengthened. This working group is seeking [input](#) from stakeholders on this review process.

## **Discussion**

Dr. Neal-Perry said that diversity training needs to be offered at least once a year. She also pointed out that reviewers often look up information on applicants online. Dr. Byrnes agreed that reviewers can learn about applicants' gender, race, and ethnicity through online searches. She also noted that CSR plans to offer implicit bias training to reviewers every year and to refresh the content based on the feedback received.

Dr. Maldonado encouraged CSR to consider the impact of the COVID-19 pandemic on the career development of early-stage investigators in the review process. Dr. Byrnes said that NIH offers relief for applicants affected by the pandemic and guidance for reviewers on not allowing productivity gaps to affect their scores.

Dr. Tita asked why special emphasis panels tend to be less diverse than standing study sections and about any factors not mentioned in Dr. Byrnes's presentation that influence review outcomes. Dr. Byrnes said that special emphasis panels tend to be less diverse because program staff must assemble these panels quickly, so staff tend to use their existing networks to identify reviewers. In addition, although this presentation focused on diversity and equity, CSR is exploring several other issues that affect the fairness of the review process.

Dr. Barkin asked how to address content bias in the review process. She also noted that CSR cannot solve the bias problems in the review process on its own, and partnerships with other organizations are needed. Dr. Byrnes explained that the data show that the lower success rates for applications on certain topics do not result from different peer review outcomes, and CSR focuses only on the peer review process. Several NIH and IC programs are tackling biases in other parts of the research process.



Dr. Fair said that the greatest disparities experienced by investigators from marginalized communities occur in the final stages of the grant application process when award determinations are made. These disparities result from many structural and historic factors, and special grant programs for marginalized communities might reduce these disparities. Dr. Byrnes replied that NIH and all of the ICs have funding programs to address the causes of such disparities.

Dr. Jain said that his institution considers participation in a CSR review panel in its tenure decisions. He asked about NIH efforts to broaden the pool of CSR reviewers to make the review process less onerous and give NIH access to a larger pool of well-qualified reviewers. Dr. Byrnes said that institutions should support service on CSR study sections.

#### **IV. STRATEGIES TO ENRICH INCLUSION AND ACHIEVE EQUITY (STRIVE) INITIATIVE**

Charisee Lamar, Ph.D., M.P.H., director of the NICHD Office of Health Equity, described the [STRIVE initiative](#). STRIVE has formed three committees that are developing 5-year action plans with comprehensive, actionable policy recommendations and outcome metrics to:

- Enhance equity, diversity, and inclusion in the NICHD workforce
- Increase the diversity of the NICHD extramural workforce and its training programs
- Address key drivers of health disparities, including systemic racism in scientific research

The three STRIVE committees include more than 50 NICHD staff members who have scientific and administrative positions, as well as diverse skills and viewpoints. STRIVE coordinates its activities closely with those of the NIH UNITE initiative and other NIH and Department of Health and Human Services (HHS) programs, and it consults external stakeholders.

##### **STRIVE Committee Activities**

The STRIVE Internal Workforce Committee is in the process of analyzing NICHD employee demographic and personnel action data; and fielded a workforce pulse survey to measure the NICHD climate for equity, diversity, and inclusion among full time employees (FTEs). The results have been analyzed, and a report will be finalized soon. The committee's upcoming tasks include developing an action plan and a Racial Ethnic Equity Plan (REEP); contributing to the NIH diversity, equity, inclusion, and accessibility (DEIA) strategic plan for HHS; and developing staff training programs.

The STRIVE Scientific Workforce Diversity Committee is analyzing data on the more than 44,000 investigators and trainees supported by NICHD to determine how to enhance the diversity of the scientific workforce. This committee is planning a workshop series in spring 2022 on novel training models and pathways for the 21<sup>st</sup> Century. Upcoming activities include developing an action plan, analyzing the outcomes of intramural trainees, and developing a stakeholder engagement strategy.

The STRIVE Health Disparities Research Committee analyzed NICHD's health disparities research portfolio and hosted a five-part virtual workshop series that engaged more than 1,500

internal and external stakeholders. [Videos](#) of these workshops are available on the STRIVE website, and a list of recommendations from the workshops has been developed. Examples of these recommendations are to provide incentives for meaningful community partnerships in review and funding processes and to incorporate diversity, equity, and inclusion in all stages of the research process. The committee has launched an [IdeaScale](#) campaign to expand engagement in the discussions initiated during the workshop series. Upcoming activities include developing a community engagement strategy, manuscript, and action plan.

## **Discussion**

Dr. Barkin asked about NICHD's plans to implement the principles that Dr. Lamar had described. Dr. Lamar explained that STRIVE activities have focused on collecting baseline data on NICHD's current workforce and grantees. Future activities will focus not on eliminating existing practices but on identifying areas with the greatest potential impact and on enhancing existing practices that work well. No single activity will have the desired results, and STRIVE must examine all aspects of the issue, which will require more discussions. Implementation will happen after all of the baseline data have been collected and opportunities for the greatest impact have been identified.

Dr. Rowitch asked whether NIH has considered requiring patient and public involvement in research planning before grant applications are submitted. Dr. Lamar said that no single approach will be sufficient, and STRIVE will determine the most effective ways to engage community members in research development. Community partnerships require the development and maintenance of trust over the long term.

## **V. TRIENNIAL ADVISORY COUNCIL REPORT ON INCLUSION IN NICHD CLINICAL RESEARCH: FISCAL YEARS 2019–2021**

Ronna Popkin, Ph.D., program director in the Population Dynamics Branch at NICHD, provided highlights from the most recent triennial report on inclusion in NICHD clinical research in fiscal years 2019 to 2021. This triennial report is mandated by the Public Health Service Act.

### **NIH Inclusion Policies**

The main goal of NICHD's inclusion policies is to minimize bias in research design to ensure that NIH-supported clinical research is generalizable to the broadest possible populations. The NIH Revitalization Act of 1993 required the inclusion of women and of racial and ethnic minority groups in NIH-supported clinical research in a manner appropriate to the scientific question. The act also required Phase III clinical trials to produce accurate estimates of differences in outcomes by sex and gender and by race and ethnicity.

The 21st Century Cures Act of 2016 broadened this policy to require the following:

- Submission of valid analysis results from Applicable Phase III clinical trials to [ClinicalTrials.gov](https://ClinicalTrials.gov)
- Publication of data on the sex or gender, race, and ethnicity of research participants in the [Research, Condition, and Disease Classification \(RCDC\) Inclusion Statistics Report](#)
- Inclusion of participants from across the lifespan in studies

To implement these inclusion policies, NIH requires applications and proposals to describe the sex or gender, racial, ethnic, and age makeup of the study population; provide a rationale for participant selection and plans to recruit and retain the study population; and provide a scientific or ethical justification for exclusions based on sex or gender, race, ethnicity, or age. Scientific peer review groups assess whether the inclusion criteria based on these factors are acceptable, and program officials review enrollment data each year.

### **Analysis Summary**

Some highlights from the analyses of data on the inclusion of women in NICHD research projects between 2019 and 2021 in the report are provided below:

- Almost one-quarter of NICHD clinical research projects and more than one-third of its Phase III clinical trials included only women.
- Between 72% and 93% of Phase III trials were required to provide valid analyses by sex and gender and by race and ethnicity.
- Women made up 56% to 63% of NICHD clinical research participants.
- The proportions of men and women were more similar in NICHD clinical research projects at U.S. sites than in projects in other countries.

The analyses of data on the enrollment of racial and ethnic minority populations in NICHD clinical research showed the following:

- Almost half of the participants in NICHD clinical research at U.S. sites were members of racial and ethnic minority populations.
- The proportion of members of racial and ethnic minority populations in NICHD clinical studies was 50% higher than in all NIH clinical research.
- The proportions of members of racial and ethnic minority populations in NICHD clinical studies exceeded the proportions of these groups in the U.S. population.

The analyses of data on age are preliminary because the relevant policy was first implemented in 2019, and ongoing studies that began earlier are not required to comply with this policy. The preliminary data show that almost 70% of participants in NICHD clinical studies were children, whereas the proportion for other ICs was just 15%. In addition, the children enrolled in NICHD studies were much younger than those enrolled in studies funded by other ICs.

### **Discussion**

Dr. Resnick suggested that NICHD analyze the race or ethnicity and sex or gender of adult and pediatric participants in NICHD research separately. Dr. Popkin said that such analyses will be conducted for future reports but were not possible for this report because the 2019 implementation of the lifespan inclusion policy limits the amount of age data available. The full report does provide all of the data stratified by racial and ethnic group and by sex and gender.

Dr. Wong asked whether the report addresses the inclusion of different subgroups within populations. Dr. Popkin agreed that women, men, Hispanics, and other populations are not monolithic. The triennial report uses the categories identified by the Office of Management and Budget and by NIH to ensure adherence to congressionally mandated policies. However, the full report can discuss subgroups, such as people with intellectual and developmental disabilities,

within these populations. In addition, NICHD funds research on subpopulations beyond the Census Bureau categories used for the triennial report.

Dr. Twombly explained that the purpose of the triennial report is to demonstrate to the NACHHD Council that NICHD is complying with NIH inclusion policies. NICHD will send Council members the full report, and members will have 2 weeks to review it and suggest edits. NICHD will then ask for the Council's concurrence by email that the report is final and ready to be submitted to Dr. Bianchi. Once the Council certifies the report and Dr. Bianchi signs it, NICHD will submit the report to the NIH Office of the Director.

## **VI. INVITED DIRECTOR: NATIONAL EYE INSTITUTE (NEI)**

Michael F. Chiang, M.D., director of NEI, is a pediatric ophthalmologist. Dr. Chiang described his training in ophthalmology and biomedical informatics, as well as his research on the use of telemedicine and artificial intelligence technology to diagnose retinopathy of prematurity.

NEI studies eyes and vision. This research is important because blindness has a major impact on quality of life, ability to complete activities of daily living, experiences of the world, and risk of isolation and depression. In addition, many seminal innovations have occurred initially in the visual system because it is accessible, and the results can be generalized to other areas of research. Examples of these innovations are as follows:

- First FDA approval of a gene therapy for an inherited disease, Congenital Amaurosis
- First-in-humans CRISPR procedure, conducted in the retina
- First FDA-cleared autonomous artificial intelligence system, for diabetic eye disease
- Advances in imaging, including use of retinal photography, optical coherence tomography (OCT), and OCT angiography

One of Dr. Chiang's first tasks when he joined NEI as its director approximately a year ago was to revise the institute's mission statement and develop a new strategic plan. NEI's new mission is to eliminate vision loss and improve quality of life through vision research. The institute's 2021 to 2025 [strategic plan](#) describes seven areas of emphasis, including the biology and neuroscience of vision, data science, individual quality of life, and public health and disparities research.

Potential areas of collaboration between NEI and NICHD include:

- Curation of databases to publicly share data and establish standard data representations. NEI hopes to develop incentives for data sharing, including giving research teams academic credit for publishing datasets in a new type of publication.
- Research on neurodevelopment and plasticity. Amblyopia, for example, results from maladaptive plasticity. Better understanding of visual subsystems and circuits can lead to the development of better treatments.
- Research on the neural basis of cerebral visual impairment (CVI), the leading cause of childhood blindness. CVI is associated with prematurity and perinatal brain damage, and it causes visual acuity and field deficits as well as higher-order deficits (e.g., in attention and recognition). Research is also needed on the distinctions between the neural basis of CVI and that of traumatic brain injury and stroke, requiring interdisciplinary approaches.

- Characterization of the interacting roles of genes and environmental factors on the incidence, progression, and stabilization of refractive error in different populations; cellular mechanisms of eye growth; and the impact of refractive error on development and education. There might be ways to involve NEI's Pediatric Eye Disease Investigator Group clinical trials network or trans-NIH programs.

## **Discussion**

Dr. Egan suggested that NEI collaborate with NICHD and the INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromeE) Project to study eye disease in children with Down syndrome.

Dr. Jain asked how NEI plans to implement its strategic plan's objective of recruiting and training a diverse new generation of scientists. Dr. Chiang said that ophthalmology and pediatrics, like other biomedical research disciplines, are competing with pharmaceutical and technology companies for new scientists. Academic institutions cannot offer potential recruits more money than the private sector, but they can provide opportunities to make a difference.

Dr. Jain asked about curiosity-driven science, which is mentioned in the strategic plan. Dr. Chiang explained that he struggles with the balance between science for a purpose and science for curiosity. He hopes to create better pipelines between purpose-driven and basic science by identifying the questions that need to be answered to achieve a given purpose. NEI is experimenting with this approach.

## **VII. SCIENTIFIC PRESENTATION: THERAPEUTIC ALLIANCE IN THE PEDIATRIC INTENSIVE CARE UNIT (PICU): A STUDY OF BEREAVED PARENTS' MENTAL HEALTH**

Markita Suttle, M.D., a pediatric intensive care physician at Nationwide Children's Hospital, explained that the NICHD-sponsored [Collaborative Pediatric Critical Care Research Network \(CPCCRN\)](#) conducts research on the safety and efficacy of treatment management strategies used for the care of critically ill and injured children. The network has 12 clinical sites, 12 ancillary sites, and a data coordinating center at the University of Utah.

Since Dr. Suttle was a pediatric critical care fellow, her research interest has been in improving end-of-life care in the pediatric intensive care unit (PICU). The catalyst for her work was the excellent end-of-life research that CPCCRN conducted on parental bereavement and functioning at the end of a child's life in the PICU.

As science and medical care have advanced, the number of pediatric deaths in the United States has fallen over the past few decades. Many of these advances occurred in the PICU, where most pediatric deaths in the United States occur. In spite of these advances, however, more than 30,000 children in the United States die each year.

The loss of a child is devastating to parents. Most parents whose children die in a PICU exhibit signs and symptoms of prolonged grief. Prolonged or complicated grief is a maladaptive form of grief whose symptoms include intense yearning or preoccupation with the deceased, a sense of

loss of meaning or purpose without the deceased, and an inability to accept the reality of the death. Beyond prolonged grief, bereaved parents often experience declines in their physical health and an increased risk of illness as a result of both biological and behavioral factors.

Dr. Suttle was the PI of the [parent-provider alliance study](#), a multicenter observational study in eight children's hospitals affiliated with CPCCRN. The study's aims were to describe the therapeutic alliance between bereaved parents and pediatric intensivists, the frequency and intensity of adverse mental health symptoms among parents, and additional factors associated with parents' mental health symptoms. Therapeutic alliance is a multifaceted construct that reflects the strength and quality of the relationship between a patient and family and their physician, and it can have positive effects on health outcomes for adults and children. In the study, bereaved parents completed questionnaires measuring grief, depression, and post-traumatic stress disorder (PTSD) symptoms 6 months and 13 months after their child's death.

The results showed the following:

- Parents whose children die in a PICU experience high levels of adverse mental health symptoms.
- Symptoms improve during the first 13 months, but high symptom levels persist for many parents.
- Parents experienced a moderate degree of post-traumatic growth (positive change in their struggle with a challenging life crisis) in the first 13 months after their child's death.
- Greater therapeutic alliance with PICU physicians could improve parents' mental health, at least early in bereavement.
- Bereaved Black parents form weaker alliances with PICU physicians compared to White parents.

## **Discussion**

Dr. Rowitch asked about Dr. Suttle's plans to test interventions for the symptoms experienced by bereaved parents, such as cognitive behavioral therapy, which is effective for PTSD. Dr. Suttle was not aware of any randomized controlled trials of cognitive behavioral therapy for PTSD in a bereaved population, although randomized controlled trials have tested prolonged grief therapies.

Dr. Maldonado asked whether Dr. Suttle's study analyzed results in parents from different racial and ethnic groups. Dr. Suttle said that the results showed no differences between White and Hispanic or Asian American parents, but the sample might not have been large enough to show such differences. She wondered whether parents who speak English as a second language might experience additional stress during the bereavement process.

Dr. Neal-Perry asked whether Dr. Suttle has studied the bereavement process in family members other than parents. Dr. Suttle said that most participants in her study were parents, although the study included a few grandparents who were legal guardians of the deceased children. Dr. Suttle would like to explore the impact of a child's death in the PICU on surviving siblings.

## VIII. VOICE OF THE PARTICIPANT: A FATHER'S PERSPECTIVE ON PEDIATRIC CRITICAL CARE RESEARCH AND BEREAVEMENT

Whit Coleman, M.R.A., RN, is a husband and the father of five children. He lives in Salt Lake City, where he is a research nurse and educator at the University of Utah.

Mr. Coleman was introduced to the work of critical care research when his two oldest children were diagnosed with spinal muscular atrophy (SMA). Neither Mr. Coleman nor his wife knew that they carried the SMA genetic mutation, because neither had a family history. Their son Jonas was diagnosed with SMA at the age of 6 weeks. With this diagnosis, the Colemans' lives were turned upside down. They decided to give Jonas the most comfortable and fun life possible and to avoid using invasive support. The Colemans took Jonas on boating and swimming trips and to Disneyland many times.

The Colemans' second child, Maggie, was born when Jonas was 3 years old. Before she was born, amniocentesis and genetic testing told the Colemans that Maggie was also affected. They were better prepared this time and ready to give Maggie the same adventurous and supported life they had given Jonas.

Jonas died at home, in the presence of his parents and grandparents, when Maggie was 3 months old. His parents provided consent for a research autopsy. Because the hospice team had told them what to expect, the family was prepared for Jonas's death and the decision to remove life support technologies. Maggie was much stronger than her brother, and the Colemans expected to have more time with her than with Jonas. However, Maggie took a sudden turn for the worse when she was 3 years old and was admitted to the PICU with respiratory failure. The Colemans decided against intubation, and Maggie died peacefully.

The Colemans agreed to participate in several research studies in the hope that the lessons learned might help other children and families. Mr. Coleman offered the following suggestions for researchers:

- Let families know how the research benefits other children and families once the study is complete.
- Ensure that the decision not to participate in a study does not affect the child's care, which is a great concern to families.

After each death, the Colemans received support from family members and friends as well as their religious congregation. But Mr. Coleman still has symptoms of extended grief; for example, he does not watch certain movies or listen to certain music to avoid the associated pain.

Mr. Coleman is a member of the CPCCRN Family Network Collaborative, which gives input to researchers on various aspects of clinical trials. Collaborative members meet monthly and attend steering committee meetings remotely. Working with other parents so dedicated to improving clinical research has been a privilege for Mr. Coleman.

### **Discussion**

Dr. Bianchi commented that nusinersen, the first drug treatment for SMA, has profoundly changed the outlook for children with SMA. Mr. Coleman said that when his two oldest children were still alive, he and his wife underwent preimplantation testing to ensure that their next two children did not have SMA. However, once the new SMA therapies became available, the Colemans decided against using this technology for the third child (who does not have SMA) because SMA outcomes are so different now.

Dr. Resnick asked Mr. Coleman to elaborate on his recommendation that researchers tell families more about the impact of their participation in research. Mr. Coleman said that participating in research for many disorders does not benefit the family's child, and many parents enroll in these studies in the hope that their participation will benefit other children and families. In addition to receiving the study results, parents would like to learn about the impact of the research on other children in the future.

Dr. Jain asked about the grieving process the Colemans experienced and how they supported each other. Mr. Coleman said that an SMA diagnosis keeps parents very busy with many types of therapy, and these activities distracted him and his wife from their grief.

## **IX. CONCEPT CLEARANCE**

The NACHHD Council reviewed the following five concepts and voted to approve each one:

- **Capstone Centers for Multidisciplinary Studies in Child Abuse and Neglect** (Valerie Maholmes, Ph.D., Pediatric Trauma and Critical Illness Branch)
- **Learning Disabilities Research Centers** (Brett Miller, Ph.D., Child Development and Behavior Branch)
- **Neonatal Research Network** (Andrew Bremer, M.D., Ph.D., M.A.S., Pediatric Growth and Nutrition Branch)
- **Physiometrics and Organoids for Reproductive Health** (Neelakanta Ravindranath, D.V.M., Ph.D., Fertility and Infertility Branch)
- **Integrative Research in Gynecologic Health** (Candace Tingen, Ph.D., Gynecologic Health and Disease Branch)

### **Capstone Centers for Multidisciplinary Studies in Child Abuse and Neglect**

Dr. Barkin asked whether the four capstone centers to be funded are already part of this program. Dr. Maholmes explained that this initiative currently funds three centers, and the upcoming competition will be open to both existing and new centers.

Dr. Barkin asked whether dissemination and implementation science fits the initiative's goals. Dr. Maholmes replied that centers may propose plans to bridge the gap between research and clinical practice.

### **Learning Disability Research Centers**

Dr. Barkin asked whether these centers will collaborate with other NICHD networks. Dr. Miller replied that collaborations will occur between the centers and networks that are addressing



related issues, such as the NICHD Intellectual & Developmental Disabilities Research Centers. NICHD also hopes that the centers will engage communities bidirectionally.

Dr. Egan suggested changing the name of the centers to “Learning Difference Research Centers,” because some of these children do not have disabilities. Dr. Miller explained that the centers have had this name for some time, but perceptions of terms like “disabilities” matter, and NICHD staff will consider Dr. Egan’s suggestion.

### **Neonatal Research Network**

Dr. Tita said that the Neonatal Research Network has advanced the science on the care of newborn infants who are ill. He was pleased that NICHD plans to provide opportunities to participate in this research to investigators outside the network.

Dr. Wong asked whether this initiative and the others presented at this meeting will provide incentives for applicants to include investigators from institutions with less research experience. Dr. Bremer replied that NICHD aims to make the networks diverse, and the centers do work with other institutions to help meet their recruitment and diversity goals. NICHD will continue to encourage these approaches.

### **Physiomimetics and Organoids for Reproductive Health**

Dr. Matzuk asked whether the initiative will develop technologies for both female and male systems, and Dr. Ravindranath replied that it will.

## **X. ADJOURNMENT**

Dr. Bianchi adjourned the open session on Day 1 at 5:24 p.m.

## **XI. CLOSED SESSION:**

This portion of the meeting is 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).

## **XII. 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 541 HD-primary applications requesting \$181,164,551 in direct costs and \$247,712,855 in total costs.

### XIII. ADJOURNMENT

There being no further business, the meeting adjourned at 5:00 p.m. on Wednesday, January 12, 2022. The next meeting, scheduled for June 15, 2022, will take place at 6710B Rockledge Drive in Bethesda, Maryland.

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

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Diana W. Bianchi, M.D.  
Chair, National Advisory Child Health and  
Human Development Council  
Director, *Eunice Kennedy Shriver* National  
Institute of Child Health and Human  
Development

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Date

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Dennis Twombly, Ph.D.  
Acting Associate Director, Division of  
Extramural Activities, *Eunice Kennedy  
Shriver* National Institute of Child Health  
and Human Development

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Date

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