



Eunice Kennedy Shriver National Institute
of Child Health and Human Development

NATIONAL ADVISORY CHILD HEALTH
AND HUMAN DEVELOPMENT
COUNCIL

MEETING MINUTES

February 2–3, 2021

**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
February 2–3, 2021**

The National Advisory Child Health and Human Development (NACHHD) Council convened its 175th meeting at 12:30 p.m. on Tuesday, February 2, 2021, by National Institutes of Health (NIH) videocast. The meeting was open to the public on February 2 from 12:30 to 4:50 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 February 3, 2021, from 12:30 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)
Susan Bookheimer, Ph.D.
Michele Caggana, Sc.D.
John P. Coughlin, M.D.
Kathleen B. Egan, Ph.D.
Lucky Jain, M.D.
Missy Lavender, M.B.A.

Martin Matzuk, M.D., Ph.D.
Carmen L. Neuberger, J.D.
Adam C. Resnick, Ph.D.
Annette Sohn, M.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 members (pending approval) present:

Shari L. Barkin, M.D., M.S.H.S.
Christina M. Bucci-Rechtweg, M.D.
Catherine E. Lang, Ph.D.
Genevieve S. Neal-Perry, M.D., Ph.D.
David H. Rowitch, M.D., Ph.D.

National Advisory Board on Medical Rehabilitation Research Council liaison:

Arthur English, Ph.D.

Department of Defense:

Colonel (Ret.) Paul F. Pasquina, M.D. (absent)

***Ex officio* members present:**

Patricia Dorn, Ph.D.
Aaron M. Lopata, M.D., M.P.P.

Executive Secretary:

Eugene G. Hayunga, 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.

Review of Confidentiality and Conflicts of Interest

Dr. Hayunga 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. Hayunga 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 the 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, 2020, NACHHD Council meeting minutes carried.

Future Meeting Dates

Dr. Hayunga reviewed the future Council meeting dates:

Monday and Tuesday, June 7–8, 2021

Friday, September 10, 2021

II. NICHD DIRECTOR’S REPORT

Dr. Bianchi delivered the director’s report.

NIH Budget

The fiscal year (FY) 2021 omnibus appropriation passed by Congress in December 2020 includes \$42.9 billion for NIH, a \$1.25 billion (3%) increase over the agency’s FY 2020 appropriation. The NIH appropriation provides \$12.6 million for the [Gabriella Miller Kids First Pediatric Research Program](#) and an additional \$5 million for the [INCLUDE \(INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE\)](#) project, raising the total INCLUDE budget to \$65 million.

NICHD will receive \$1.59 billion in FY 2021, a \$36 million increase from FY 2020, including a \$10 million increase for research on preterm birth. To support COVID-19 research, NICHD has competed successfully for funds from the NIH Office of the Director.

New Congress and Administration

Leaders in the 117th Congress who have a history of strong NIH support include Rosa DeLauro (D-CT), chair of the House Committee on Appropriations, and Cathy McMorris Rodgers (R-WA), ranking member of the House Committee on Energy and Commerce.

Vice President Kamala Harris has long advocated for maternal health and has proposed legislation in the Senate to address the high rate of maternal mortality, especially in Black women. Rachel Levine, M.D., the nominee for assistant health secretary, is a pediatrician with expertise in adolescent medicine. Eric Lander, M.D., is a geneticist nominated to serve as the director of the Office of Science and Technology Policy, a position that has been elevated to the Cabinet level for the first time. David Kessler, M.D., J.D., a former U.S. Food and Drug Administration commissioner, will lead the federal COVID-19 vaccine effort.

Selected NICHD Research Advances of 2020

Dr. Bianchi suggested that NACHHD Council members read the [2020 NICHD research advances](#) on NICHD's website, which include the following:

- **Women's health**: Development of a noninvasive way to shrink uterine fibroids, demonstration of links between endometriosis and DNA methylation (a type of DNA modification), and development of nonhormonal contraceptives and contraceptives that can protect users from sexually transmitted infections
- **Pregnant and postpartum women**: Demonstration that Black and Hispanic women in New York City were more likely to deliver their infants in poor-quality hospitals, women living in counties lacking hospitals that offer obstetric care have a higher risk of death during pregnancy and after delivery, and postpartum depression can persist for up to 3 years after delivery
- **Pediatric Populations**: Demonstration that personality traits influence the impact of screen time before bed on children; insights into the decision-making processes of adolescents that might be useful for developing interventions to encourage positive risk taking; better information on the drug labels of doxycycline, clindamycin, and caffeine citrate on usage and dosages for pediatric patients
- **Intellectual and developmental disabilities**: Adaptation of a tool used in neuroscience research for people with intellectual disabilities, development of a telehealth approach to improve clinical trial access for infants with tuberous sclerosis complex, and identification of a plant compound that reduces cognitive and memory deficits in a mouse model of Down syndrome
- **Rehabilitation**: Development of a flexible material that might transform surgical implants for neurological devices, use of machine learning to decrease retraining time for brain-controlled prosthetics, and identification of a way to use neuroimaging results as a biomarker for degree of injury and potential to regain ability to move after a stroke

COVID-19 Research

Ongoing [COVID-19 research at NICHD](#) includes the following:

- Gestational Research Assessments for COVID-19 (GRAVID) study: Examination of maternal and neonatal outcomes in up to 24,500 pregnant women with and without SARS-CoV-2 infection
- COVID-19 Infection Prevalence During Pregnancy and Impact on Pregnancy Outcomes: Comparison of maternal, fetal, and neonatal outcomes of 2,000 pregnant women with or without SARS-CoV-2 infection at eight international sites through NICHD’s Global Network for Women’s and Children’s Health Research
- SARS-CoV-2 and Breast Milk: Studies of breast milk as a potential source of viral transmission and of protective antibodies
- CARING for Children with COVID (Collaboration to Assess Risk and Identify loNG-term outcomes for Children with COVID): Studies on multisystem inflammatory syndrome in children (MIS-C) and other complications of illness related to SARS-CoV-2 infection in collaboration with other NIH institutes and centers (ICs)
- Intramural research: Studies of specific tissues (e.g., placental) to understand mechanisms of infection
- Predicting Viral-Associated Inflammatory Disease Severity in children with Laboratory Diagnostics and Artificial Intelligence (PreVAIL kIds): Development of novel, nontraditional approaches, testing strategies, and technologies to:
 - Understand the spectrum of pediatric SARS-CoV-2 illness
 - Rapidly diagnose and characterize MIS-C
 - Predict the longitudinal risk of disease severity after SARS-CoV-2 exposure, infection, or both

The trans-NIH [Rapid Acceleration of Diagnostics \(RADx\)](#) initiative is a technology-development program designed to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. RADx supplements to NICHD awards are supporting research on the health and well-being of children with intellectual and developmental disabilities during the pandemic and on the use of antibody testing to determine the impact of asymptomatic COVID-19 infection during pregnancy.

Congressional COVID-19 relief packages have provided funding to support research and clinical trials related to the long-term effects of COVID-19. NIH is developing a trans-agency approach to study these post-acute sequelae of COVID-19 in adults and children.

NICHD Strategic Plan

The [NICHD Check Our Progress](#) website provides details on NICHD’s progress in addressing the five research themes in its [2020 strategic plan](#). Dr. Bianchi encouraged all new NACHHD Council members to review the strategic plan, which guides the institute’s scientific focus. For each scientific research theme, the website highlights programs, activities, and selected research advances, and this information is updated throughout the year.

NICHD is continuing to refine its implementation plans for the scientific stewardship and the management and accountability portions of the strategic plan. It is also starting new activities to achieve the goals and objectives in each focus area and is developing metrics to track progress in meeting each objective.

Strategies to EnRich Inclusion and AchieVe Equity (STRIVE) Initiative

NICHD is committed to addressing the causes of health disparities, including tackling structural racism, and to diversifying the scientific workforce in its intramural program and in the extramural community.

NICHD established STRIVE in response to the protests that followed the killing of George Floyd and in coordination with a broader, comprehensive NIH initiative to identify and address structural racism within the NIH-supported and the greater scientific community. STRIVE is led by NICHD's Office of Health Equity, and it has formed three subcommittees to address:

- Equity, diversity, and inclusion in NICHD's workforce
- Training and support for the scientific careers of diverse extramural scientists
- Expansion of the institute's health disparities research portfolio

The subcommittees are developing 5-year comprehensive action plans that will be integrated into NICHD's Strategic Plan 2020.

An example of NICHD's commitment to working with diverse investigators is a new partnership between NICHD's intramural program and Howard University. Components of this arrangement will include scientific collaborations; mentorship, training, and professional development for Howard students and trainees; scientific exchanges through education and seminars; and, through the university, access to patient populations that cannot be cared for at the NIH Clinical Center.

The June 2021 Council meeting will feature a presentation on STRIVE.

NICHD Staff Updates

Dr. Bianchi announced the recent retirements of several staff members and the appointments of several new medical officers and other staff members. Open positions at NICHD are listed at [Jobs at NICHD](#).

Council Discussion

Dr. Sohn asked whether NICHD was likely to receive funding for COVID-19 research directly from Congress. Dr. Bianchi replied that NICHD communicates with Congress at every opportunity about the needs of children, pregnant persons, and people with physical and intellectual disabilities, as well as the research that NICHD conducts. The initial focus of Congress was on testing and treatment. But as recognition of the long-term consequences of COVID-19 grows, Congress might turn its attention to children.

Dr. Bianchi reported that Francis Collins, M.D., Ph.D., director of NIH, and Norman E. Sharpless, M.D., director of the National Cancer Institute, submitted letters of resignation at the end of the previous presidential term, as was required for all political appointees. The President declined Dr. Collins' letter of resignation, and Dr. Bianchi expected the President to reject Dr. Sharpless' resignation letter as well.

Dr. Jain suggested that NIH bring members of all NIH IC advisory councils together with Dr. Collins and the institute, center, and division directors once a year to discuss cross-NIH

initiatives. Dr. Bianchi explained that the Advisory Committee to the Director addresses trans-NIH activities, and its meetings are open to the public. The NIH Council of Councils, which focuses on strategic directions for the agency, has representatives of the councils of all 27 ICs.

Dr. Barkin asked whether NICHD's efforts to increase investigator diversity include components targeted to early-stage investigators (ESIs), such as incentives for principal investigators to include ESIs on their research teams. Dr. Bianchi explained that NICHD has established higher paylines for applications from ESIs, and inclusion of ESIs on research teams could be a review criterion to suggest to the NIH Center for Scientific Review.

Dr. Caggana wondered about plans to address the psychological health effects of the COVID-19 pandemic on children. James A. Griffin, Ph.D., chief of NICHD's Child Development and Behavior Branch, reported that NICHD has encouraged research on this topic through trans-NIH initiatives and investigator-initiated grants. An example of the latter is a supplement to an international longitudinal study of parenting influences on impulsive, risky behaviors during the transition from adolescence to adulthood. The supplement added measures to the study interviews to assess socioemotional functioning in relation to each country's response to the pandemic. So far, the study has found increased rates of self-reported depression and substance use but also improved relationships between parents and adolescents.

Rebecca Clark, Ph.D., chief of the NICHD Population Dynamics Branch, explained that NICHD has ensured that children and adolescents are priority populations in virtually all NIH COVID-19 initiatives. Fortunately, other ICs are interested in supporting research on the mental and physical health of children and adolescents during the pandemic, so NICHD is not the only source of funding for this research. Similarly, NICHD is not the only IC funding research on the pandemic's impact on pregnant women.

Dr. Resnick asked about efforts to assess the initial impact of the newest SARS-CoV-2 variants on children and about trials of COVID-19 vaccines in children. Dr. Bianchi explained that NICHD's focus with respect to COVID-19 vaccination is on reopening schools. Alison Cernich, Ph.D., NICHD deputy director, added that some vaccine trials have begun in children aged 12 years and older, but de-escalation studies in younger children have not yet started. Furthermore, rates of COVID-19 testing and of sequencing in children in the United States are very low, which makes obtaining variant data challenging.

III. INTRODUCTION OF NEW MEMBERS

Dr. Hayunga introduced the following new NACHHD Council members:

- Shari L. Barkin, M.D., is the William K. Warren Foundation Chair and a professor of pediatrics, director of Pediatric Obesity Research in the Diabetes Center, and chief of General Pediatrics at Vanderbilt University Medical Center.
- Christina Bucci-Rechtweg, M.D., is the global head of pediatric and maternal health policy at Novartis Pharmaceutical Company.
- Catherine Lang, Ph.D., is a professor of physical therapy, occupational therapy, and neurology at Washington University in St. Louis.

- Genevieve Neal-Perry, M.D., Ph.D., is a professor of obstetrics and gynecology, chief of the Division of Reproductive Endocrinology and Infertility, and chair of the Department of Obstetrics and Gynecology at the University of North Carolina at Chapel Hill.
- David Rowitch, M.D., Ph.D., is a professor, the head of the Department of Pediatrics, and a Wellcome Trust senior investigator at the University of Cambridge.
- Paul Pasquina, M.D., is a professor and the chair of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University of the Health Sciences and chief of the Department of Rehabilitation at Walter Reed National Military Medical Center.

IV. SARS-CoV-2 INFECTIONS IN SCHOOLS

Kanecia Zimmerman, M.D., associate professor of pediatrics at Duke University Medical School, listed barriers to reopening schools for in-person learning during the COVID-19 pandemic. Examples include concerns about keeping students and staff safe, the challenge of making parents and teachers confident in the safety of in-person learning, and the process of creating a safe learning environment.

Through the ABC Science Collaborative, public health scientists and physicians at Duke University and the University of North Carolina at Chapel Hill help school leaders throughout North Carolina make informed decisions about reopening schools. The goal is to keep teachers, children, and their local communities healthy and safe, and the program’s components are as follows:

- Support for evidence-based decision making for superintendents in coordination with state and local health departments, with stakeholder input
- Delivery of educational resources—including webinars, videos, and handouts—on such topics as hand-washing, safe mask wearing, and responses to COVID-19 symptoms
- Advances in public health by, for example, creating a platform that schools and districts can use to monitor numbers of COVID-19 cases, asymptomatic individuals, and people vaccinated in school buildings

Public health experts and physicians from the ABC Science Collaborative have attended more than 60 school board meetings to provide expertise and answer questions, had hundreds of calls with school district leaders, participated in 10 districtwide staff meetings, and met with dozens of community members.

The program has resulted in the successful return of students, teachers, and school staff to in-person learning environments. It is now North Carolina State policy that K-12 schools offer in-person instruction with 6’ distancing for all students; and schools may additionally offer in-person instruction with minimal distancing for elementary students. Other accomplishments include collaboration with the Centers for Disease Control and Prevention to ensure that school reopening has top priority, development of school-specific metrics, and identification of 12 principles for reopening.

An ABC Science Collaborative study tracked the incidence and secondary transmission of SARS-CoV-2 in 11 school districts. During the first 9 weeks of in-person instruction, more than 90,000 students and teachers attended school in person. During this period, North Carolina

residents with the virus infected an average of 1.1 other individuals. If secondary transmission were as common in schools as in the community, up to 900 secondary infections would have occurred in schools, but the actual number was just 32. The results showed that enforcing mitigation policies (including masking, physical distancing, and hand hygiene) led to minimal clusters of infection, low rates of secondary transmission in schools, and no increase in community infection burden.

Danny Benjamin, M.D., Ph.D., Kiser-Arena Distinguished Professor of Pediatrics at the Duke University School of Medicine, described the need for research to inform decisions about schools. Research gaps include the incidence of secondary transmission in schools, effects of quarantining on school staff availability, educational impact of COVID-19, incidence of long-hauler syndrome in children, and rates of adherence to masking rules inside school buildings. The ABC Science Collaborative has provided physician and epidemiologist consultations to at least 50 school districts, and these services should be available to all school districts in the country to ensure equity.

School reopening has continually been delayed as the pandemic has changed over time. Initially, schools were closed because of the belief that children were super spreaders. When data showed that children are not super spreaders, schools nevertheless remained closed because community transmission rates were too high. Once community transmission rates dropped, the concern was the upcoming surge in cases. The current argument is that all adults need to be vaccinated before schools can reopen, and Dr. Benjamin predicted that once the adults are vaccinated, schools might remain closed until all children are vaccinated.

Plans are in place to expand the ABC Science Collaborative using a hub-and-spoke model. Duke University will be the coordinating center, six hubs will consist of North Carolina (50 school districts) and at least five other states (each with one or more school districts). Duke will offer a customized playbook for each state along with educational materials and other resources, as well as data management support.

Council Discussion

Dr. Bianchi asked about levels of parental hesitation to send children back to school in different populations. Dr. Zimmerman replied that many Black families are reluctant to send their children back to school because of concerns about whether schools can keep their children safe. Furthermore, many of these families find that online learning diminishes the impact of systemic racism, and they are more comfortable with this form of instruction than with in-person learning. Some of these concerns can be overcome through education.

Jennifer Guimond, Ph.D., a health policy analyst at NICHD, asked about the use of hand sanitizer in schools when hand-washing is not possible. Dr. Benjamin replied that the collaborative has not collected these data. However, it has learned that schools need to choose approaches that work for their populations and that teachers and staff need to be role models for hand hygiene.

Dr. Barkin reported that in her region, teachers are more concerned about returning to school than parents are. She asked whether the collaborative is collecting data that can show teachers

the real risk of returning to in-person teaching. Dr. Zimmerman explained that the 90,000 individuals assessed in the study she had described included teachers, and no cases of child-to-adult transmission occurred. Other studies in the United States and elsewhere have had similar findings. One reason for this concern is misinformation, including the belief that infection rates in teachers are higher than in the general population. For comparison, healthcare workers are infected at twice the rate of the general population, but only 11% of these infections occur in hospitals, and only 30% of infections in hospitals come from patients with COVID-19; most infections result from infected colleagues. These important lessons need to be shared.

Dr. Benjamin explained that 20% of teachers were always ready to return to school; 20% will never be ready, regardless of what the science shows; and the 60% in the middle need to be educated. Public health experts and physicians who come from the district or a similar district can become trusted sources of data-driven information. Opening schools is the easiest step; ensuring that vulnerable children return to school and closing the achievement chasm will be more challenging and will require a national strategy.

Dr. Jain asked about the impact of the loss of midday school meals on children. Dr. Benjamin said that some children are receiving school meals, but children are more vulnerable to other threats, such as suicide ideation and child abuse. Dr. Cernich offered to send information on the nutritional impact of the loss of midday meals to the NACHHD Council.

Dr. Tita asked whether the infections described in the presentation were symptomatic. Dr. Benjamin replied that data presented were on both symptomatic and asymptomatic infections, but he believes that rates of asymptomatic transmission in schools are not high.

Dr. Bianchi asked about teachers who have a high risk of severe COVID-19 complications. Dr. Benjamin replied that the proportion of these teachers is high, especially if this group includes teachers older than 50 years and those with obesity. In addition, teachers are concerned about transmitting the virus to vulnerable individuals in their households.

Dr. Barkin reported that online learning is resulting in delayed development, but only in some populations, and it increases family anxiety and problems with sleep and obesity. Identifying effective interventions will be critical.

V. NICHD ANTI-HARASSMENT PLAN

Dr. Bianchi explained that the goals of the NICHD anti-harassment plan are to:

- Raise awareness of the status and types of harassment within the NICHD workplace
- Reaffirm NICHD's commitment to anti-harassment policies and procedures
- Promote transparency and establish clear expectations for changing the NICHD workplace culture
- Use innovative approaches and provide integrated channels for communication and resources to engage all staff
- Ensure accountability of all staff

NICHD has engaged all senior leaders in improving NICHD's workforce climate, overseeing implementation activities, and educating the workforce. Onboarding packages for new staff now include anti-harassment materials, and performance requirements for all staff, including leaders, now address harassment. NICHD is forming an anti-harassment committee to establish and implement a framework and best practices to prevent and address workplace harassment. In all these activities, NICHD is collaborating with the NIH Civil Program; Office of Equity, Diversity, and Inclusion; Employee Assistance Program; and Office of Intramural Training & Education.

NICHD managers are required to report certain types of conduct to the appropriate component of the NIH Office of Human Resources. For example, common workplace disagreements or communications issues must be reported to the NIH Office of the Ombudsman, conduct of a sexual nature must be reported to the NIH Civil Program, and property damage or physical violence must be reported to the NIH Police.

All NIH staff members must undergo anti-harassment, bystander, and NIH Civil Program training. The NIH Office of Equity, Diversity, and Inclusion lists optional additional training opportunities on its website, and NICHD will keep staff informed of these opportunities.

Council Discussion

Dr. Bookheimer asked about the distinctions between harassment, discrimination, and microaggression. Some problems in the workplace that involve unequal treatment of men and women, for example, might not meet the definition of harassment. Dr. Bianchi replied that microaggression might fall under the harassment category of disrespectful or inappropriate conduct. Dr. Cernich added that NICHD has processes to address allegations related to discrimination, microaggression, and structural difficulties. Rodney Rivera, M.S., executive officer at NICHD, noted that the institute encourages all staff to report cases of even suspected harassment to the NIH CIVIL Program, which conducts independent investigations. If concerns arise about an employee's safety, NICHD takes immediate management action to ensure the employee's safety and does not wait for the investigation to conclude. The CIVIL Program is responsible for determining whether a situation involves harassment, and supervisors are responsible for reporting situations that might involve harassment.

Dr. Bookheimer asked about NICHD's rules for transparency when problems arise and are reported so that staff know that people who violate the anti-harassment rules face consequences. Dr. Bianchi explained that NICHD encourages employees to report harassment because the institute cannot address these situations unless it knows about them. However, many types of employee relations issues are confidential, and the institute may not share details on these cases.

Dr. Egan asked whether NIH offers psychological services to both abusers and victims. Dr. Cernich replied that the NIH Employee Assistance Program provides services to all employees, regardless of their roles in an incident. Dr. Bianchi added that unless NICHD determines that an employee must be removed, it offers services to the individual responsible for the harassment.

Dr. Wynshaw-Boris pointed out that trainees and ESIs are particularly vulnerable to harassment. Dr. Bianchi noted that because of the power mentors and supervisors have over trainees' careers, trainees are often reluctant to report harassment. NICHD is paying attention to this issue.

Ms. Neuberger asked how NICHD measures the effectiveness of its anti-harassment program. Dr. Bianchi explained that the institute is using staff surveys to collect baseline information and to measure changes in the institute's workplace culture.

Dr. Wong asked about the impact of training on staff who have harassed another employee. Dr. Bianchi explained that NIH provides coaching and mentoring in positive supervision, and it sometimes requires employees who are responsible for harassment to undergo specialized training. Mr. Rivera added that the impact of training for supervisors accused of harassment has been positive, and no repeat offenses have occurred.

VI. RADx and Other National Institute of Biomedical Imaging and Bioengineering Activities

Bruce J. Tromberg, director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), explained that NIBIB uses modeling, computation, and machine intelligence for research on therapeutic devices, imaging technologies, engineered biology, and sensors and other point-of-care technologies.

At the start of the COVID-19 pandemic, NIBIB decided to focus its COVID-19 activities on three areas: imaging and artificial intelligence, digital health platforms, and diagnostic test technologies. For example, NIBIB created the Medical Imaging and Data Resource Center (<https://www.midrc.org>) to foster machine learning innovation through data sharing for rapid and flexible collection, analysis, and dissemination of imaging and associated clinical data related to COVID-19. This initiative is creating a thoracic imaging and clinical data repository for COVID-19 (<https://data.midrc.org>). Three professional societies are providing data and are helping the institute develop and validate machine learning approaches for COVID-19 detection and diagnosis.

Using a congressional COVID-19 appropriation, NIBIB launched RADx Tech to identify candidates for at-home and point-of-care tests for COVID-19. Another component of RADx, Advanced Technology Platforms (ATP), is rapidly scaling up advanced technologies to increase testing capacity and throughput. RADx-ATP identifies testing platforms for COVID-19 that are advanced enough for rapid scale-up or expanded geographical placement in a short time. The goal of RADx Tech/ATP is to expand the number and type of COVID-19 testing technologies, increase access to these technologies, and optimize their performance (<https://www.nibib.nih.gov/covid-19/radx-tech-program>).

NIBIB was able to launch RADx Tech/ATP quickly by leveraging the Point-of-Care Technologies Research Network, which develops point-of-care devices that have clinical applications (<https://www.poctrn.org>). This network has core resources dedicated to test validation, clinical studies, and deployment.

The test development process began with a national call for innovative COVID-19 testing technologies. More than 700 applications received were winnowed down through a “shark tank” process, followed by validation and risk review. Twenty-five technologies that completed these phases underwent clinical testing, regulatory approval, and manufacturing scale up (<https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-phase2-awards>). By the end of 2020, RADx Tech/ATP Phase 2 awards had supported the production of 94 million tests and other products (<https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-dashboard>). By March 2021, more than 2 million tests developed through RADx Tech/ATP are expected to be produced per day.

The RADx Tech Validation Core ensures test feasibility, verifies limits of detection with different strains of SARS-CoV-2, and assesses test performance using patient specimens. This core also calculates the sensitivity, specificity, and positive and negative predictive values of each test that reaches this stage. The RADx Tech Clinical Studies Core is evaluating Phase 2 RADx platforms in clinical studies to develop real-world guidance on each platform’s use, performance, and digital health integration. The RADx Tech Deployment Core, which focuses on test use, developed the [When to Test - COVID-19 Testing Impact Calculator](#) a modeling tool that shows the effects of different COVID-19 mitigation strategies, such as mask wearing, testing, and contact tracing. Users can rapidly determine the type of test and test frequency they require. This core is also developing playbooks for businesses, schools, and colleges and universities.

NIH is investing approximately \$1 billion in diagnostic technologies that it hopes will be used for other infectious and noninfectious diseases in the future. Dr. Tromberg also hoped that the RADx approach, which provides a good platform for acceleration, will spread to other ICs and federal agencies.

Council Discussion

Dr. Rowitch asked about the potential of moving beyond individual testing to mass screening tests of large populations (e.g., towns or cities) for early detection of new outbreaks. Dr. Tromberg said that the purpose of test development in RADx is to remove barriers to testing by, for example, enabling individuals to take COVID-19 tests at home and to make the tests inexpensive. These tests are not ready for large-scale use to screen populations for variants, for example. However, use of the RADx tests for large-scale screening and sharing of the results with public health agencies is an important goal.

Dr. Jain reported that within 7 days of receiving a large RADx grant, Emory University had a biosafety level 3 laboratory ready to start validating COVID-19 tests, and the Validation Core has now collected 10,000 specimens. This experience demonstrates the program’s success at completing validation at warp speed. Dr. Tromberg said that Dr. Jain had captured the spirit of RADx. NIBIB knew that the community of thousands of investigators could rise to this occasion.

VII. SOMATOSENSORY MODULATION OF SALIVARY GENE EXPRESSION AND ORAL FEEDING IN PRETERM INFANTS

Jill L. Maron, M.D., M.P.H., professor of pediatrics at Tufts University, reported that approximately 450,000 infants are born prematurely (before 37 weeks of gestation) in the United States each year. Most of these infants do not have the developmental maturity to feed by mouth successfully and safely. According to guidelines from the American Academy of Pediatrics, infants must be able to do so before they can be discharged from the neonatal intensive care unit. Oral feeding competency is therefore a major determinant of length of stay and a significant driver of healthcare costs.

Oral feeding requires mature and coordinated sucking, swallowing, and breathing. Different infants might have lags in different developmental systems (e.g., sensory integration, hunger signaling, or oral motor control) that limit their ability to feed. Biological variability (including sex, race, and ethnicity) can also affect feeding success. For example, oral motor and upper airway skills tend to mature earlier in female than in male premature infants.

Several tools are available to improve oral feeding. For example, a pacifier-activated device can play music or the mother's voice when the infant sucks on it. The nfant[®] Feeding Solution and Analytics system uses a cue-based approach to oral feeding and provides real-time feedback. Finally, the NTrainer System, developed by Steven Barlow, Ph.D., M.S., Corwin Moore Professor of Special Education and Communication Disorders at the University of Nebraska–Lincoln, reinforces non-nutritive sucking, a key pre-feeding skill, by delivering an oral stimulation pulse through a pacifier. This device captures data on the infant's suck dynamics.

None of these devices can assess the infant's overall developmental status in real time to determine why the infant is unable to feed orally. Furthermore, the devices do not provide insights into the developmental windows in which an intervention might be most effective.

While Dr. Barlow was developing the NTrainer System, Dr. Maron was developing salivary diagnostic assays to assess infant readiness to feed orally, identify developmental delays limiting oral feeding success, and personalize the approach to treatment strategies that address each infant's salivary profile. She identified the Neonatal Oral-feeding Readiness In Salivary High-throughput Diagnostics (NOuRISH) panel of five genes; two are related to hunger signaling, two to sensory integration, and one to facial development. The expression profile of the five NOuRISH genes along with the infant's post-conceptual age and sex has 78% accuracy for predicting oral feeding ability. Alterations in any of these genes affects feeding ability, so this panel can be used to personalize treatment for premature infants.

Dr. Maron and Dr. Barlow combined Dr. Maron's research with Dr. Barlow's machine to better understand responses to NTrainer treatment at the molecular level, identify key developmental windows for maximizing NTrainer therapy outcomes, and identify infants who are likely to respond well to NTrainer therapy to personalize care. This 5-year randomized controlled trial randomly assigns infants born before 29 weeks of gestation to receive sensorimotor stimulation with the NTrainer feeding device or a sham assessment for up to 34 weeks. Assessments continue until the infant learns to feed orally, and saliva samples are collected throughout treatment. The trial has enrolled 110 infants (51% Hispanic) of the target 140.

The interim analysis of results from 77 infants found that 63 genes are differentially expressed in oral feeders and non-feeders. Genes in this cluster are related to palatal shelf formation, maturation of circadian rhythms, morphology of hindgut and mesenchyme, and abdominal development. The results also showed differences in the genes expressed in male and female infants. For example, only male infants who do not feed orally have genetic variants associated with memory and learning disruption, whereas the genetic variants in female infants who do not feed orally tend to be related to facial, palate, and gastrointestinal function.

Council Discussion

Dr. Neal-Perry asked whether Dr. Maron has identified what regulates the expression of genes involved in oral feeding. Dr. Maron replied that she hopes that her study can answer this question. A related issue is whether oral feeding maturation can be accelerated by intervening during the appropriate developmental window.

Dr. Egan asked whether the study includes children with Down syndrome or intellectual disabilities. Dr. Maron replied that the study excludes infants with Down syndrome or other conditions that could delay their oral feeding progression. However, these infants could benefit from the findings of this study.

VIII. VOICE OF THE PARTICIPANT

Sarah Koumantzelis described her daughter Olivia's participation in the study that Dr. Maron had described. Olivia was born at 26 weeks' gestation and weighed only 1 lb., 13 oz. She spent 82 days in the Tufts Medical Center Neonatal Intensive Care Unit. Before joining Dr. Maron's study, Olivia was having difficulty remembering to breathe during oral feedings, which had led to weight loss.

During the study, Ms. Koumantzelis witnessed her daughter's growth and progression, and the study taught Olivia lessons that she would have learned in the womb if she had not been so eager to leave it. The skills she gained through the study, which she needed for survival but that most people never think about, included sucking, chewing, and swallowing at the same time.

Olivia Koumantzelis is now 3 years old and weighs 33 lb. She is in the 70% percentile of weight for her age. And she is sassy, smart, and perfect in every way! Ms. Koumantzelis will always be grateful that Olivia had an opportunity to participate in the study. The Koumantzelis family built a wonderful relationship with Dr. Maron during and after the study, and Ms. Koumantzelis is so grateful for Olivia's successful outcome.

IX. CONCEPT CLEARANCE

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

- **Biomarker Research to Support Fertility Regulation Methods by Small Business** (Christopher J. Lindsey, Ph.D., Contraception Research Branch)
- **User-Based Design to Aid in Contraceptive Development by Small Business** (Travis Kent, Ph.D., Contraception Research Branch)

- **Pelvic Floor Disorders Network** (Lisa Halvorson, M.D., Gynecologic Health and Disease Branch)
- **Pediatric Immune System – Ontogeny and Development** (Sai Majji, Ph.D., Maternal and Pediatric Infectious Disease Branch)
- **Dyadic Interpersonal Processes and Biopsychosocial Outcomes** (Ronna Popkin, Ph.D., Population Dynamics Branch)
- **Human Milk as a Biological System** (Andrew Bremer, M.D., Ph.D., M.A.S., Pediatric Growth and Nutrition Branch)
- **Adolescent Medicine Trials Network for HIV/AIDS Interventions** (Sonia Lee, Ph.D., Maternal and Pediatric Infectious Disease Branch)

Dr. Tita asked for more details on the Pelvic Floor Disorders Network, including the numbers of funding cycles and centers to be funded. Dr. Halvorson explained that decisions about these issues are still being made, and the plan is to provide bridge funding from the end of the current cycle in July 2021 until the next cycle begins in July 2023. Dr. Tita asked whether any changes are being made to the initiative. Dr. Halvorson explained that common protocols will be used at several sites. Dr. Tita noted that factors that have made this program effective include its central coordination, ability to conduct studies during more than one cycle, and nimble review process.

Dr. Resnick suggested that the Pediatric Immune System concept capture other development and disease variables, in addition to infection, that interact with immune development, such as cancer or trisomy 21. Dr. Majji said that NICHD will take this suggestion into consideration.

Regina Bures, Ph.D., a program director in NICHD's Population Dynamics Branch, explained that the Dyadic Interpersonal Processes concept would not require NICHD funds.

Dr. Bremer reported that the [Breastmilk Ecology: Genesis of Infant Nutrition](#) meeting series has featured presentations on such topics as maternal inputs and infant inputs to human milk as well as translation of findings on the systems biology of human milk.

Dr. Sohn commented that the last time that the Adolescent Medicine Trials Network for HIV/AIDS Interventions was renewed, NICHD made several substantial changes to it. These changes enhanced network productivity and increased numbers of patients who enrolled in the trials and numbers of studies. Dr. Sohn praised NICHD for these changes.

When asked about the types of information that NICHD staff can provide about concepts, Dr. Hayunga explained that NICHD presents ideas to the NACHHD Council to determine whether these ideas should be developed into funding opportunity announcements (FOAs). Presentations of these concepts do not provide such details as budget or type of funding mechanism because this information could create conflicts of interest that would preclude Council members from submitting applications in response to the FOAs developed from the concepts. Dr. Bianchi added that the Council's review of the concepts is just one step in a series of events that can lead to the setting aside of funds for an initiative. NICHD wants to hear from Council members about whether to stop developing any of the concepts, but the Council's approval of a concept does not necessarily mean that the concept will be developed into an FOA with set-aside funding.

X. 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).

XI. 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 653 HD-primary applications requesting \$219,006,462 in direct costs and \$303,220,868 in total costs.

XII. ADJOURNMENT

There being no further business, the meeting adjourned at 5:00 p.m. on Wednesday, February 3, 2021. The next meeting is scheduled for June 7–8, 2021.

I hereby certify that, to the best of my knowledge, the foregoing minutes and attachments are accurate and complete.¹

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

Date

Eugene G. Hayunga, Ph.D.
Acting Committee Management Officer,
Eunice Kennedy Shriver National Institute
of Child Health and Human Development
Attachment: Council Roster

Date

¹ 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.