



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

NATIONAL ADVISORY CHILD HEALTH  
AND HUMAN DEVELOPMENT  
COUNCIL

*MEETING MINUTES*

September 13–14, 2018

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  
SUMMARY MINUTES

September 13–14, 2018<sup>1</sup>

The National Advisory Child Health and Human Development (NACHHD) Council convened its 168th meeting at 8:00 a.m., Thursday, September 13 and Friday, September 14, 2018, at 6710B Rockledge Drive, Conference Rooms 1425–1427 of the National Institutes of Health (NIH) in Bethesda, Maryland. The meeting was open to the public from 8:00 a.m. to 5:00 p.m. on September 13. 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 from 9:00 a.m. until 2:30 p.m. on September 14.

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)

Michael Boninger, M.D.

Barbara L. Collura

Melissa L. Gilliam, M.D., M.P.H.

Catherine Gordon, M.D., M.Sc. (remote)

Richard D. Krugman, M.D.

DeWayne M. Pursley, M.D., M.P.H.

Lesli Rotenberg

Clifford Tabin, Ph.D.

Alyce Thomas, RD

**Council members absent:**

Anne C. Case, Ph.D., M.P.A.

Frederick P. Rivara, M.D., M.P.H.

Timothy P. Shriver, Ph.D.

**Department of Defense**

LTC Matthew R. Scherer, Ph.D., PT, NCS, SP

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

Kenneth Ottenbacher, Ph.D., OTR

**Ex officio members present:**

Patricia Dorn, Ph.D.

**Observers (pending members) present:**

Susan Bookheimer, Ph.D.

Atul J. Butte, M.D., Ph.D. (remote)

Stephen A. Foley, M.D.

Annette Sohn, M.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.

**Others present:**

Della M. Hann, Ph.D., Director, Division of Extramural Research and Associate Director for Extramural Research, NICHD

Constantine Stratakis, M.D., D.Sc., Director, Division of Intramural Research, NICHD

Meredith Temple-O'Connor, Ph.D., Senior Policy Advisor for Clinical Research, NICHD

Caroline Signore, M.D., M.P.H., Deputy Director, Division of Extramural Research, NICHD

Peter Basser, Ph.D., Senior Investigator, Division of Intramural Research, NICHD

Members of Staff, NICHD

Members of Staff, NIH

**Invited Guests:**

James Baumberger, M.P.P., American Academy of Pediatrics

Matthew Mariani, American Academy of Pediatrics

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

Dr. Bianchi began the meeting at 8:00 a.m. The meeting was videocast live.

**A. Review of Confidentiality and Conflict of Interest**

Dr. Hann reminded Council members that all members were required to read and sign the confidentiality agreement and nondisclosure rules for special government employees on the Council member website before evaluating any NIH grant applications. Council members also received a conflict-of-interest certification form, which they were required to sign before the closed session of the review of applications. Dr. Hann also reminded Council members that if there is a specific discussion involving any organizations or universities for which they are in conflict, in addition to those listed on the Council Action document, those members are required to recuse themselves from the discussion and leave the room. Council members are not allowed to serve on the NIH peer review panel while serving as Council members. It is NIH policy that individuals may not serve on both the first and second levels of peer review.

**B. Council Minutes**

Dr. Hann moved to approve the June 2018 meeting minutes. The minutes were approved unanimously.

**C. Future Meeting Dates**

Dr. Hann reviewed the future meeting dates:

January 24–25, 2019

June 11, 2019

September 19, 2019

**II. NICHD DIRECTOR'S REPORT AND DISCUSSION**

Dr. Bianchi provided the Director's report.

## **Budget Update**

In fiscal year (FY) 2018, NIH received \$37 billion, a \$3 billion increase in funding over FY17. NICHD received an increase of \$75 million between FY17 and FY18. In addition, NICHD received funding from the Office of the NIH Director for Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW) and for INCLUDE (Investigation of Co-occurring conditions across the Lifespan to Understand Down Syndrome).

NICHD used the increased funding to:

- Double the number of early-stage investigators receiving their first independent research grant from 29 in FY17 to an estimated 60 in FY18.
- Allocate \$800,000 to the Task Force Specific to Research on Pregnant Women and Lactating Women.
- Allocate \$30 million to launch ACT NOW clinical trials to identify, treat, and care for babies exposed to opioids *in utero*.
- Dedicate more than \$39 million to sustain existing research programs in preeclampsia, maternal mortality, fertility/infertility, and autism.

## **Research Initiatives**

The Trans-NIH Pediatric Research Consortium (N-PeRC) held its first meetings. The consortium aims to harmonize child health research across the NIH Institutes and Centers (ICs) and will help enhance communication between NIH and advocacy groups and between NIH and members of Congress. N-PeRC will also encourage senior pediatric researchers to serve on review panels and will take steps to increase the pediatric research workforce. N-PeRC has asked the ICs working on high-priority drugs to coordinate their work with researchers from the Best Pharmaceuticals for Children Act program.

Eighteen ICs will provide supplemental funding for INCLUDE, which will investigate conditions—such as Alzheimer’s disease, dementia, autism, and congenital heart disease—that affect the general population and individuals with Down syndrome. NIH is dedicating an additional \$23 million for INCLUDE. All told, NIH has funded \$60 million for Down syndrome research in FY18.

There has been a spike in maternal mortality, particularly among non-Hispanic black women who are older than 40. NICHD is working with the National Academy of Science to study birth settings (such as home births), risk factors (such as obesity), and maternal mortality.

## **Conferences**

The NICHD Young Investigators Conference took place in August, drawing 140 participants. The workshop focused on skills that all clinician investigators need, such as setting up a wet lab and understanding study design. Presenters also disseminated information about some of the lesser-known grant and career opportunities, such as the Bench to Bedside U01s. NICHD staff participated as faculty.

The Menstruation: Science and Society meeting will take place September 20–21. Attendees will discuss promising new discoveries and avenues of research on menstruation. The meeting will incorporate the science of menstruation with the broader societal implications, including public health outreach. The meeting will be videocast.

The Human Placenta Project will hold its fifth meeting in November. Attendees will focus on the challenges of translating the scientific and clinical findings for use in low-resource settings. Investigators will also present their research.

### **Progress Toward Inclusion**

NICHD's core mission includes a focus on populations such as pregnant women, lactating women, children, and those with physical and intellectual disabilities. NICHD is making progress on including these populations in research. NICHD requested and received changes to the Research, Condition, and Disease Categorization, that now make it possible to determine how much research funding goes to maternal health and mortality. NICHD is also working with the *All of Us* Research Program to ensure that children are included in the cohort of 1 million participants.

The Task Force on Research Specific to Pregnant Women and Lactating Women has completed its report, which includes 15 recommendations. One of the Task Force's major recommendations is to change the culture that has limited the participation of pregnant women in research. The Task Force recommends that pregnant women be protected *through* research, not *from* research. The Task Force also recommended expanding the workforce of clinicians and researchers in the field and modifying subpart B of the Common Rule to remove pregnant women from the list of vulnerable populations.

The Task Force sent its report and recommendations to Alex Azar, Secretary of the Department of Health and Human Services. Secretary Azar will review the report and send it to Congress. The recommendations can be found online at <https://www.nichd.nih.gov/About/Advisory/PRGLAC>.

### **Strategic Plan**

NICHD staff have analyzed portfolio data in preparation for the NICHD strategic planning process. The Strategic Planning Working Group will meet on October 15–16, and NICHD will hold an interactive webinar on October 31. The Institute will issue a request for information in December. Individuals can also submit comments at [NICHDStrategicPlan@nih.gov](mailto:NICHDStrategicPlan@nih.gov).

### **New NIH Directors**

- Dr. Bruce Tromberg has been appointed the director of the National Institute of Biomedical Imaging and Bioengineering. His intramural laboratory will be at NICHD.
- Dr. Helene M. Langevin has been appointed the director of the National Center for Complementary and Integrative Health. One of her interests is in alternative therapies for children.

### **Council Discussion**

Dr. Tabin suggested that NICHD ask the chairpersons of developmental biology departments to nominate attendees to the Young Investigator Symposium in addition to the department chairs who were asked for nominations this year. Dr. Bianchi said that was an excellent suggestion. The plan for next year is to ask the NICHD Branch Chiefs for recommendations on what departments to contact.

Dr. Melissa Gilliam asked whether the Menstruation: Science and Society meeting would take a global perspective. Dr. Lisa Halvorson said that the meeting would cover the range of topics

related to menstruation within local, national, and international communities. One of the speakers is from the United States Agency for International Development.

### **III. REPORT OF THE DIVISION OF EXTRAMURAL RESEARCH**

Dr. Hann reported on the Division of Extramural Research (DER).

#### **Supporting the Researcher Pipeline**

The 21st Century Cures Act includes a section on helping young emerging scientists reach earlier independence. Congress is aware that NIH must support young investigators to ensure that there is a next generation of researchers. With increased funding in FY18, NICHD was able to double the number of independent research grants given to early-stage investigators. NICHD staff hope to maintain the same level of support, or even increase it, in FY19.

The DER training budget for FY17 was 6.6%, which is typical of what the DER historically spends on training. Training includes institutional training programs as well as individual F awards and K awards. Some of the K awards also involve institutional programs. Overall, six percent is a healthy amount of budget to devote to the career training.

NICHD spent an additional \$5.4 million for the loan repayment program, which amounts to about 0.5% of the DER budget. The program helps early-career investigators repay their student loans.

#### **Progress on NIH Clinical Trial Reforms**

Dr. Meredith Temple-O'Connor said that NIH began rolling out its initiative to enhance clinical trial stewardship about two and a half years ago. The initiative is meant to make clinical trials more efficient, transparent, accountable, and timely.

As of January 2018, all applications that propose a clinical trial must be submitted through the new funding opportunity announcement (FOA) designated specifically for clinical trials. There are new application review criteria that are specific to clinical trials.

Monitoring and oversight of trials will be more structured and formalized and will include periodic status reporting. NICHD staff and investigators will work together to develop a milestone plan for the trial to help track and monitor its progress.

Part of the milestone plan is to analyze risks, including risk to trial participants and financial and operational risks. High-risk trials may require more frequent status reports.

There is more information on the initiative at <https://grants.nih.gov/policy/clinical-trials.htm>.

#### **Staff Updates**

- Ms. Susan Parker of the Grants Management Branch has retired.
- Dr. Uma Reddy of the Pregnancy and Perinatology Branch has taken a position at Yale University.
- Dr. Jennie Conroy joined the Gynecologic Health and Disease Branch.
- Dr. Joseph Bonner has joined the staff of the National Center for Medical Rehabilitation Research.

- Dr. Bradley Cooke will work with the Scientific Review Branch.
- Ms. Shavon Artis Dickerson has taken a position with the Office of Health Equity.
- American Association for the Advancement of Science (AAAS) Fellow Dr. Travis Kent will be working with the Fertility and Infertility Branch.

Dr. Bianchi said that NICHD is recruiting for a deputy director to replace Dr. Catherine Spong. The search committee expects to meet for the first time by the end of September. The search committee will select three finalist candidates, and Dr. Bianchi will make the final selection.

#### **IV. HIV INFECTION AMONG OUR YOUNGEST: KNOWLEDGE, SURVIVAL, RESILIENCY, AND OPPORTUNITY**

Dr. Bianchi introduced Dr. Allison Agwu, whose clinical and research specialties are in HIV/AIDS and in health disparities. Dr. Agwu runs the Accessing Care Early (ACE) Youth/Young Adult Transition Clinic at Johns Hopkins University and the Pediatric Adolescent Young Adult HIV/AIDS Program (PAHAP), both HRSA-funded programs. She is the principal investigator (PI) of the International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Network and Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) sites at Johns Hopkins and is a site investigator of the AIDS Clinical Trial Group at Johns Hopkins. The ATN and IMPAACT are funded by NIH ICs, including NICHD.

Dr. Agwu said that HIV primarily affects countries outside the United States, but that her presentation would focus on HIV/AIDS within the United States. She briefly reviewed the history of HIV in the United States, dating to reports of the first known pediatric cases in 1981.

Although the first reports of AIDS surfaced in 1981, infections occurred earlier. The first pediatric case was traced back to infection in 1977.

Dr. Agwu said that the goals of therapy are to decrease HIV-associated morbidity, prolong survival, preserve immune function, suppress viral load, and prevent transmission. There has been significant progress since the first reported cases in 1981, to the point that there is now potential for remission.

A study of maternal-infant transmission published in 1994 found that treatment with AZT (zidovudine) reduced the transmission rate by 66%. After that finding, and as AZT was administered to women with HIV and to perinatally exposed children, the number of perinatally acquired AIDS cases dropped sharply. The risk of perinatal transmission for a woman who receives AZT is now less than 1%. The challenge now is diagnosing pregnant women and getting them into treatment.

New drugs have entered the market, and there is now a single-pill regimen for adults. The one-pill regimen is not yet available for children and adolescents, however. There is a need for pediatric pharmacokinetic studies to identify the best drugs, formulations, and doses for children. Other issues for children include the palatability of the medication, its toxicity, and the identification and treatment of comorbidities.

While treatments have mostly prevented children with HIV from developing AIDS, some will progress to AIDS during adolescence.

Some individuals who were infected perinatally are now 35 years old. Living with HIV and taking treatments for years can increase the risk of malignancies, cardiovascular disease, and organ damage.

Twenty-one percent of new HIV diagnoses are among youth between 13 and 21 years old. Most of the new HIV diagnoses among adolescents are the result of male-to-male contact. With the opioid epidemic, an outbreak of hepatitis C, and an increase in injectable drug use, an increase in HIV infections may be on the horizon.

The ATN was instrumental in securing FDA approval of pre-exposure prophylaxis (PrEP), for those as young as age 15. The challenge is getting PrEP to adolescents that age.

While adolescents with HIV face many challenges, they are also resilient. Medical challenges for those with HIV include having a depressed immune system and mental health challenges such as anxiety, depression, and substance abuse issues. Other problems include neurocognitive delay and dysfunction and suboptimal response to vaccines.

Among the psychosocial challenges are the stigma of the illness, the burden of having to disclose their status, and having limited support systems.

Youth have worse treatment outcomes than adults; about 6% of youth with HIV have a suppressed viral load, compared with about 25% of adults.

Studies of anti-HIV drugs need to be done in pediatrics. Research should include finding a treatment regimen that requires fewer pills, reduces pill size, provides more delivery options (e.g., the patch), and provides better-tasting drugs. Research should also develop drugs with a higher barrier to HIV resistance and drugs with fewer drug-to-drug interactions.

One study in adults showed that a 2-shot regimen may be as effective as one of the three-drug regimens now available. In a survey, about half of adolescents were willing to have a shot that requires weekly visits, but 90% were willing if the shot took place every three months. Adolescents with high viral loads were the group that expressed the greatest interest in a periodic shot.

The IMPAACT Network is investigating a long-acting injectable therapy for youth, including those who are non-adherent. Research on patches and other delivery systems will likely be forthcoming for adults and should also take place in pediatrics and adolescents.

Dr. Agwu said that now is the time to think about achieving long-term HIV remission. There are babies who received early treatment and have remained in remission for many months. In one case, a child has remained in remission for more than eight years. IMPAACT is conducting an early-intensive treatment study with infants to find out more about treatment to achieve remission and to answer questions such as at what point after remission the treatment should be stopped.

The science should be moving toward more multimodal strategies, including developing monoclonal antibodies, activated T cells, latency reversing agents, and long-acting agents that rely on different delivery modes. All should be studied in pediatric populations, and the studies should be longitudinal. Studies should also include behavioral and community interventions, implementation science, and care models. Personalized medicine should also be employed.



## **Council Discussion**

Dr. Annette Sohn said that these are complex challenges, and it seems that more adolescents with HIV are dying. Are there any particular areas that need more research? What can be done to reverse the trend of a rising death toll among older youth who were infected perinatally?

Dr. Agwu said that pediatricians need to be aware that young people with HIV need support or else they may become non-adherent. They need mental health support, social structure supports, and more. Older youth who were infected perinatally can lose hope when they get older. One step is to connect them to multiple levels of care and to offer them support “even before they realize they need it.”

Dr. Patricia Dorn asked Dr. Agwu to comment on peer-to-peer support. Dr. Agwu said that there is a lot of work with peers, but that also has its challenges, because many youths do not want to disclose their status to their peers.

## **V. VOICE OF THE PARTICIPANT**

Dr. Agwu introduced her patient, Maurice Williams, and conducted an interview with him. Mr. Williams is 24 years old and grew up in Prince George’s County. He earned his bachelor’s degree in theater arts from Morgan State University and has an Instagram account that has about 280,000 followers.

When Mr. Williams was young, he did not understand why he had to take medicines and wanted to stop. His grandmother told him that he would die if he did not take them, and that was the first time that he absorbed what he was facing.

Mr. Williams’s mother had many health challenges and he began to suspect that she—and he—might have HIV. When he was 13 years old, he told his grandmother he would not take his medications until he was told what they were for. His grandmother brought him to a therapist who told him the medications were for HIV. He and his grandmother talked about his illness only twice. The second time was in 2013, when Mr. Williams’s mother died.

His support network during his childhood and early adolescence consisted of his case managers and his doctors at Children’s National Medical Center. He said his life would not have been the same without them.

Mr. Williams described how his treatment regimen changed over time, from a foul-tasting liquid when he was young to a regimen of six pills a day when he was 15 years old. He now takes two pills per day. “It’s great how medicine has evolved,” he said, but he looks forward to the day when he can take only one pill a day. He said that youth would prefer treatments that are quicker and longer-lasting.

Mr. Williams battled depression as a child, but a retreat with other HIV-positive youth helped him. That was the first time he had a chance to socialize with peers who were going through the same illness. Over the years, his network of friends with HIV has grown.

Mr. Williams said that the relationship between the provider and patient “is the first level of research.” Dr. Agwu is like family to him and is one of the few people he can talk to about his HIV. He does what she asks because he trusts her and his other physicians.

The stigma of HIV is a burden. Although he was infected perinatally, most people assume that his own actions led him to acquire the virus. The stigma is very loaded because it is connected to sexual activity.

Mr. Williams sometimes worries about the long-term health risks he faces, such as when he reads that some of the medications he is taking could lead to liver damage. His bigger worry, however, is whether researchers will continue to look for a cure. He wants to move beyond having an undetectable viral load.

“We’re in a war to eradicate AIDS. The fight on the front line shouldn’t end with treatment,” he said.

### **Council Discussion**

Ms. Alyce Thomas asked how Mr. Williams is able to overcome his fears. “I believe that I stopped being afraid to die when I wanted to live,” Mr. Williams said. When he stopped taking his medication, his doctor at Children’s reminded him that he had dreams of being on the stage. Having dreams has kept him going.

Ms. Thomas asked why he has continued to take his medicine when others stop taking it. Mr. Williams said that denial plays a part in patients who stop taking their medications. After so many years, taking his medication is like brushing his teeth. He is used to the routine.

Dr. Gilliam asked what researchers should do to get young people involved in research. Mr. Williams said that youth are more likely to get involved if they see that their peers are involved. Adolescents and young adults want to receive their main support from their peers. When participating in research, it is also important to know that he is more than a number to the researcher.

Dr. Krugman asked how to neutralize the adverse effects of stigma. What would allow people to have conversations about a stigmatized illness? Dr. Agwu said that normalizing sex discussions with youth would help to reduce the stigma of HIV and would promote education. Everybody in the clinic must be part of the de-stigmatizing effort. It is also important to ask people with HIV the best way to convey the message and how to make communications less stigmatizing.

Mr. Williams said that sometimes it is not the message content but how the content is conveyed. There is currently no optimism in messages about HIV. That tone has to change. Cancer fundraisers are more positive, but people with HIV are viewed as a burden.

Dr. Bianchi asked whether he has used social media to talk about HIV. Mr. Williams said that he talks about HIV in a way that he has dubbed “edutainment,” meaning that he provides education but delivers it in an entertaining way.

## **VI. REPORT OF THE DIVISION OF INTRAMURAL RESEARCH**

Dr. Stratakis said that the Division of Intramural Research (DIR) has about 900 employees and 60 PIs. The DIR has more than 70 clinical protocols, about two-thirds of which are at the NIH Clinical Center and runs or co-runs five accredited medical training programs.

Dr. Stratakis presented the organizational structure of the DIR. Investigators are organized into 13 intellectually-based affinity groups

The Board of Scientific Counselors (BSC), a group of scientists from outside NIH, help to oversee the work of the DIR scientists. Two members of the BSC are retiring this year: Dr. Jeanne Brooks-Gunn and Dr. Antonios Mikos. Dr. Petra Hüppi, Dr. Joseph A. Majzoub, and Dr. William T. Dauer are the newest members on the Board.

### **Budget**

The DIR FY18 budget was \$186.7 million. Salaries account for 34% of the budget, while the operating budgets of the labs account for 24%. The DIR pays about 19% of its budget to the management fund, which goes to overhead, and 16% goes to support the NIH Clinical Center.

### **Personnel**

The size of the DIR staff has been decreasing. For example, there were 996 personnel in FY15 and 888 in FY18. Much of the decline is in the trainee population. Personnel changes this year included the following:

- Dr. Stephen Suomi retired. With his retirement, NICHD no longer has a non-human primate research program.
- Dr. Chi-hon Lee left to become the director of the Institute of Cellular and Organismic Biology, Academia Sinica, in Taiwan.
- Dr. Marc Bornstein retired. The DIR is working to make data from his longitudinal studies available to other investigators.
- Dr. Maya Lodish, formerly the head of the Pediatric Endocrinology Training Program, left for a position at the University of California, San Francisco.
- Dr. Pedro Rocha joined the DIR as a Stadtman Investigator to head the Unit on Genome Structure and Regulation.
- Dr. Ryan Dale was recruited as the Scientific Information Officer and head of the Bioinformatics and Scientific Programming Core.
- Dr. Fady Hannah-Shmouni will be a staff clinician and co-chief of internal medicine and associate program director of the Inter-Institute Endocrinology Training Program.

The DIR is recruiting in the areas of developmental neurosciences and chromosome biology, transcription, or RNA biology. NICHD will be using the NIH Stadtman Investigator Search but is open to having candidates apply directly. The Division is also recruiting for physician-scientists through the Lasker Clinical Research Scholars Program.

Three personnel within the Division of Intramural Population Health Research (DIPHR) recently received tenure: Dr. Pauline Mendola, Dr. Stephen Gilman, and Dr. Zhen Chen. Dr. Stratakis is currently the acting director of DIPHR.

### **Honors and Awards**

Dr. Tom Dever was elected a Fellow of the American Academy of Microbiology. Dr. Peter Bassler was inducted into the American Institute for Medical and Biological Engineering.

The DIR has successfully competed for additional funding, including the Opportunities for Collaborative Research at the NIH Clinical Center (U01). The DIR supported twelve applications with DIR Director's Awards in its FY18-FY19 cycle. The applications are based on an R21 format. The competitive awards are meant to promote collaborations among investigators and to support new research ideas. In addition, intramural investigators have successfully

competed for other funding opportunities within NIH, including funding from the Office of AIDS Research.

### **Diversity and Training Initiatives**

The DIR has several initiatives to train, support, and sustain individuals from groups traditionally underrepresented in science. The awardees range from high school students to postdoctoral fellows.

The DIR also offers second- and third-year postdoctoral and clinical fellows the opportunity to compete for Intramural Research Fellowships as a way to provide training in grant writing. The awards are \$30,000 for one year and the fellow she prepares a grant application under the guidance of their mentor.

The Three-Minute Talks program offers fellows and graduates professional training in speech development and presentation delivery. Dr. Stratakis ended his presentation with the video of Dr. Jakob Gutzmann, who won 3<sup>rd</sup> place in the final competition.

### **Council Discussion**

Dr. Susan Bookheimer asked what steps the DIR would take to increase diversity among DIR investigators, including recruiting more women and people of color. Dr. Stratakis acknowledged that the faculty is not as diverse as it should be but pointed out that the faculty's diversity is similar to other NIH intramural programs. Since he became DIR Director, the percentage of tenure-track faculty who are women has gone from 23% to 35%. Also, during his tenure, Dr. Stratakis appointed four women as associate scientific directors out of a total of eight associate scientific directors. Previously, there were 11 associate scientific directors, only one of whom was a woman. He said that a lot of work remains to be done.

## **VII. NEW DIRECTIONS IN MICROSTRUCTURE AND FUNCTIONAL MRI: TOWARD IN VIVO IMAGING OF CORTICAL ARCHITECTURE AND FUNCTION**

Dr. Peter Basser said that his Section within the DIR works to elucidate structure/function relationships in the nervous system and in extra-cellular matrix (ECM). Their aim is to use that information to invent and develop *in vivo* quantitative imaging biomarkers "to make the invisible visible."

His laboratory had been working on microstructure imaging but has branched out to working on microdynamic imaging. He provided some of the highlights of his laboratory's work.

One of the principles underlying microstructure imaging is that water diffuses at different rates in the white matter of the brain, depending on whether it is migrating parallel to the white matter tissue fibers or perpendicular to them. By following the direction of maximum diffusion of water in white matter, it is possible to trace out pathways, which were previously invisible.

When Dr. Basser began working at NICHD, he became interested in obtaining information at a higher resolution than the MRI voxel. He and his colleagues increased voxel resolution by using low-resolution diffusion MRI data and mathematical models to obtain microscopic-scale features of cells and tissues. Using this method revealed the cell orientation, cell shape, cell size, cell

orientation distribution, and the extracellular matrix fraction. This field of study is now called microstructure imaging.

One of his lab's goals is to parcellate the human cortex *in vivo* -- even assess function. Dr. Basser explained some of the techniques that members of his lab had developed to do this, including Mean Apparent Propagator (MAP) MRI. The lab's goal is to perform cortical parcellation in less than 45 minutes.

The lab has been working on developing another multi-dimensional imaging approach using relaxometry-diffusion MRI. To get this technique to be clinically feasible, the laboratory had to find a way to reduce the large amount of data involved previously required by this nuclear magnetic resonance approach. Without addressing this bottleneck, the imaging would be prohibitively long. The laboratory tried different approaches that were partially successful but achieved the most success by developing the Marginal Distribution Constrained Optimization (MADCO) approach to perform Multispectral Imaging. This, combined with knowledge of brain tissue histology, can be used to assign different spectral peaks in two-dimensional images of spine and brain tissue.

Using human brain tissue obtained from colleagues in the CNRM, Dr. Basser's laboratory has performed pilot studies to suggest they can resolve up to six different layers with fixed cortical tissue. The laboratory has also been able to model diffusion in complex tissue using the DiffSim Monte Carlo Modeling Framework with colleague Larry Frank in UCSD.

The laboratory has also been working on functional MRI (fMRI) and has developed a novel fMRI test system that provides simultaneous calcium fluorescence imaging and magnetic resonance acquisition in neuronal tissue and cell cultures.

One question the laboratory is exploring is whether it is possible to use active transmembrane water cycling as a proxy for neuronal activity and whether this could lead to a new fMRI method that does not require the use of contrast agents. Dr. Basser said that he believes that this is an achievable goal.

## **VIII. PREGSOURCE: CROWDSOURCING TO UNDERSTAND PREGNANCY**

Dr. Caroline Signore said that very little is known about what the average pregnancy is like and how the experience affects women's lives. PregSource® is an online research registry for pregnant women to crowdsource their data in real time. PregSource also offers a library of information of interest to pregnant and postpartum women.

The scientific goals are to:

- Build a complete picture of a typical pregnancy.
- Develop ways to improve maternal care and pregnancy outcomes.
- Gather information on understudied groups, such as pregnant women with disabilities.
- Build a large de-identified dataset for research by approved researchers.
- Inform participants about the opportunity to participate in research in their areas.

NICHD worked with 19 partner organizations to develop PregSource. Experts developed questionnaires that met readability requirements for the general public and a contractor set up the website and database programming. Much of the work built on the experience of DS-Connect®.

Women complete the consent online. They enter data through questionnaires and trackers. There are more than 40 questionnaires that include topics such as health history, demographics, and gestational age. Online trackers capture data on, for example, weight, mood, sleep, or nausea. The women can show the completed questionnaires and trackers to their providers by downloading the information or viewing it on their smartphone.

The platform allows women to compare their experiences with those of other pregnant women.

PregSource is tracking how many women join, how often they visit the site, and whether they answer questionnaires and respond to the trackers. There is also interest in finding out whether women will continue using the site after they give birth.

PregSource has a resource library with more than 450 articles about pregnancy, pregnancy complications, and infant health.

PregSource had its soft launch in October 2017 and its full launch earlier this year. Now that there is some data on which outreach methods work well and which don't, NICHD and the partners will revise the campaign as needed.

Currently, 579 women have enrolled in PregSource. Summer recruitment has been slow, but there are ideas about how to increase recruitment. Participants are not representative of the U.S. population of pregnant women: They are less ethnically and racially diverse, more highly educated, and probably more affluent than the overall population of U.S. pregnant women. PregSource will work to diversify the participants.

The staff is using Google Analytics to track how the website is used. During one week, women who logged on to the website stayed an average of more than 14 minutes, suggesting they are actively using the site. About two-thirds are new visitors; the remaining one-third are returning.

One of the recommendations of the Task Force Specific to Research on Pregnant Women and Lactating Women is to support new infrastructure to conduct research in pregnant women and lactating women.

With the addition of a new medication tracker, PregSource is directly addressing this recommendation. In this tracker, PregSource is collecting information about what medications women take during pregnancy, who suggested they take the medication, what dose they are taking, and why they are taking it. The module is linked to RxNorm at the National Library of Medicine.

Coming up, PregSource will be launching a Spanish-language version, will have new questionnaires tracking postpartum and infant health (eventually up to 36 months), and include topics for special populations, such as women with disabilities. PregSource is developing a professional portal for approved researchers to access de-identified data.

### **Council Discussion**

Dr. Dorn asked whether including more natural language processing might be a part of PregSource in the future. The information could be of interest to medical anthropologists. Dr. Signore said that PregSource does not yet provide the opportunity for narrative answers, although women can answer "Other" and add some text when none of the multiple choice options apply to them. That may offer an opportunity for text mining.

Dr. Boninger said that he has done work with the disability community and has found that the digital divide is a huge problem. He had some ideas for how to deal with that and expressed interest in discussing this further with Dr. Signore, who said that she would be interested in working with Dr. Boninger on that problem. Smartphones are becoming more common, which has helped, but there are still those who have neither a smartphone nor Internet access.

Dr. Gilliam said that having personas in mind while developing materials could help reach people with lower literacy. For example, it is possible to include a one-sentence summary of articles in the library and to use more images. Dr. Signore said that this has been a concern from the outset. The questionnaires were geared to be between a sixth-grade and an eighth-grade reading level. The staff has also attended health fairs that were in disadvantaged areas and will go to public clinics to further spread the word.

## **IX. CONCEPT CLEARANCE REVIEW AND DISCUSSION**

NICHD staff presented the following concepts for review:

**Neonatal Opioid Longitudinal Study** (Dr. Rose Higgins, Pregnancy and Perinatology Branch). Dr. Bookheimer commented that it is important to follow opioid-addicted infants long-term, because the outcomes from the addiction may not show up until they attend school. Dr. Higgins said that the project is currently funded for three years but that doing research for a longer period of time would be important.

**Innovative Epidemiologic Approaches for Understanding Long-Term Health Outcomes of HIV-Exposed Uninfected Populations** (Dr. Sonia Lee, Maternal and Pediatric Infectious Disease Branch). Dr. Sohn asked whether this is a short- or long-term assessment, since many outcomes, such as metabolic disorders, would appear much later in life. Dr. Lee agreed and said that NICHD encourages applications that leverage existing registries and cohorts as a way to more easily obtain longitudinal data.

**Pediatric Critical Care Conferences Initiative** (Dr. Valerie Maholmes, Pediatric Trauma and Critical Illness Branch). The Council members had no questions about this concept.

**Women's Reproductive Health Research Career Development Program** (Dr. Lisa Halvorson, Gynecologic Health and Disease Branch). Dr. Michael Boninger said that it was his understanding that NICHD would use fewer of the institutional K awards (K12s) that are being proposed to fund this program. He asked whether NICHD had decided against reducing the use of K12s. Dr. Bianchi said that NICHD intends to put greater emphasis on the individual K awards and to bring the proportion of the institutional K12s more in line with the proportion that other ICs use. Dr. Bianchi said that staff could present an overview of the K programs at a future Council meeting.

**Technologies to Advance Precision Medicine Diagnosis and Treatment of Infertility, Reproductive Tract, and Gynecologic Disorders Affecting Fertility** (Dr. Esther Eisenberg, Fertility and Infertility Branch). No discussion.

**Characterization and Quantification of HIV Reservoirs in Children** (Dr. Rohan Hazra, Maternal and Pediatric Infectious Diseases Branch). Dr. Sohn suggested encouraging partnerships with other disciplines, such as bioengineering. Dr. Hazra said that was one of the

aims and that the Branch would write the RFA to encourage those from many disciplines to apply.

**Centers for Collaborative Research in Fragile X and FMR1-Associated Conditions** (Dr. Tracy King, Intellectual and Developmental Disabilities Branch). No discussion.

### **Council Discussion**

Each of the concepts was approved unanimously.

Dr. Krugman asked about the process to determine which projects are presented to the Council. Dr. Hann said that she can arrange a presentation on how the concepts are chosen. She also noted that the Council receives concepts at each meeting.

## **X. COMMENTS FROM RETIRING COUNCIL MEMBERS**

The four members whose terms are expiring as of November 30 are Dr. Anne Case, Ms. Barbara Collura, Dr. Gilliam, and Dr. Frederick Rivara. In addition, Dr. Theresa L. Bringer retired and has been replaced by LTC Matthew Scherer, Ph.D., PT. The two retiring members who were present at the meeting were asked to reflect on their experience.

Ms. Collura thanked the Council for the warm welcome she received as an advocate who is neither a physician nor a scientist. She appreciated that NICHD has ensured that patients' voices are heard at the Council table. She said she will continue to be involved in advocating on behalf of research on infertility.

Dr. Gilliam thanked the Council staff and said that she has witnessed NICHD's professionalism and commitment to science. The Council experience helped her understand more about funding and has enabled her to help her colleagues apply for grants. She also appreciated the work that NICHD is doing on diversity, its commitment to academic freedom and freedom of expression, and its openness to different ideas, which is a key to innovation.

## **XI. STRATEGIC PLANNING PROCESS**

Dr. Bianchi provided background on the 2018 NICHD Strategic Plan and said that this meeting would include a listening session in which staff obtain input from Council members.

### **Why a Strategic Plan and Why Now?**

The questions that the Council will be asked to consider include the following:

- What is the identity of the Institute?
- Should the Institute continue its focus on health and development, or should it focus more on diseases and conditions?
- Should NICHD focus more on clinical research and less on basic or translational research?
- How should NICHD integrate and align its science with its stakeholders?

NICHD produced its last strategic plan in 2000 and completed a visioning in 2012. A strategic plan has resources attached and is specific to the Institute. The visioning was for the fields that NICHD represents, and external experts provided the bulk of the input.



Much has changed since 2000. The strategic plan must take advances in science and technology into account and also be ready to respond to emerging public health crises. The Institute must determine what types of funding, training, and infrastructure are needed for the next 5 to 10 years.

The strategic planning process provides an opportunity for those inside and outside NICHD to look at the portfolio with fresh eyes. Through the process, NICHD will review and refocus its science, align its resources with its priorities, and improve the health of the population.

NICHD needs a new plan in part because of a budget that has increased in dollars but has lost purchasing power. The new plan will provide an opportunity for NICHD to align the goals across its divisions and across NIH.

The guiding principles of the strategic planning process are to be focused on the science, guided by the evidence, and informed by the community, with an emphasis on transparency and accountability. NICHD has not made any *a priori* decisions about the strategic plan.

### **Strategic Plan Schedule**

NICHD began preplanning activities in January by collecting and analyzing data. A working group of multidisciplinary broad thinkers, whose members include 27 NICHD staff and 53 outside experts, will be convened. Diversity was considered when forming the group. About one-third of the members are young investigators.

To-date, the NICHD preplanning has involved:

- Collecting and analyzing key data.
- Reviewing other strategic plans, including internal scientific research plans.
- Reviewing areas of emphasis in the NICHD Vision and 2000 strategic plan.
- Analyzing the Institute's portfolio.
- Analyzing the impact of select networks and centers within the DER.

Among the opportunities to provide input into the plan are the following:

- The working group meeting on October 15–16.
- The “Friends of the NICHD” discussion on October 22.
- An interactive public webinar on October 31.
- A request for information in December.
- Further Council input at the next meeting in January.

NICHD expects to be able to communicate and begin developing implementation plans using the strategic plan by June 2019.

Dr. Bianchi said that the goal for this afternoon was to elicit comments on five key questions related to the plan:

- What are the five most important research priorities for NICHD over the next 10 years?
- What is the most important thing NICHD could accomplish for the public, patients, and providers over the next 5 to 10 years?
- What are the most important kinds of partnerships for NICHD to develop and maintain to achieve the identified priorities?

- What types/areas of training are needed to prepare the next generation of leaders?
- What emerging technologies and techniques will impact the types and methods of research conducted in the next 10 years?

### **Council Discussion**

Ms. Collura asked whether Dr. Collins or any entities within NIH must approve the final strategic plan. Dr. Hann said that the plan must be congruent with the overall NIH plan, but there is no requirement that it be approved by an entity outside of NICHD. Dr. Bianchi said that the 21st Century Cures Act requires that all NIH strategic plans be expressed in a specific format.

Dr. Bookheimer asked to receive a listing of the expertise of the working group members. Dr. Bianchi said that staff would take note of the request.

### **Five Key Questions**

Scott Wheeler of Strategy Arts facilitated the next portion of the meeting by leading the discussion on the first two of the five key questions: What are the five most important research priorities, and what is the most important thing NICHD could accomplish for the public, patients, and providers over the next 5 to 10 years?

#### *Listening Session One*

Dr. Bookheimer said that she is most interested in behavioral disorders, including autism and other neurogenetic disorders. Treatment of these disorders focuses on behavioral approaches, because animal researchers and researchers who work with humans are not coordinating their work. Dr. Bookheimer made the following suggestions:

- Integrate animal and human research.
- Determine the validity of existing animal knockout models.
- Develop common biomarkers across species—something that would require collaboration between animal researchers and those who conduct human research.
- Adopt a more precise approach; in the case of autism, separate phenotypes within a condition.
- Invest in neuromodulation, which can go deep into the brain but is noninvasive.

Ms. Lesli Rotenberg said that she is interested in having new brain research to examine the impact of adverse childhood exposures and toxic stress. She also wants research to examine the impact of interactive media and technology on children.

Dr. Boninger said that precision medicine and biomarkers are very high on his list of priorities, because they could apply to so many different scientific areas. Another thing that crosses NICHD scientific areas is neuromodulation, which is involved in behavior, childhood disability, and the neural impact of the environment among disadvantaged groups. He recommended probing the neural system and neuromodulation as a way to intervene in outcomes.

Dr. Clifford Tabin said that basic research also cuts across the NICHD scientific areas. If NICHD focuses only on the different diseases and conditions, it will miss the broad underlying research problems.

Dr. Gilliam said that contraception research is important, because the methods currently available do not meet everybody's needs. Biomarker research is needed because too much

research is based on self-report. There is a need for research on the possible long-term outcomes of young people who survive childhood diseases, including what happens to children who suffer cognitive disabilities and how they can be cared for as they transition to adulthood. It would also be important to explore ways to take advantage of studies that have a large, diverse population, such as that of the Maternal-Fetal Medicine Units Network, which has data on a large population of pregnant women.

Dr. Steven Foley said that developing polycystic ovarian syndrome (PCOS) biomarkers and information about the condition, such as its treatment course, is important. PCOS is a precursor to diabetes and heart disease.

Ms. Thomas said that research on precision nutrition is needed. Food affects health and should be tracked in many areas of research.

Dr. Sohn said that longitudinal research on *in utero* exposures—such as to opioids, Zika virus, HIV, unclean water, and environmental toxins—is needed. The research should extend to the second generation. Another area is the transition from adolescent to adult care, an area of transition medicine. There is a gap here. Can NICHD take a stronger leadership role?

Ms. Collura, noting that maternal age at first birth has been increasing, said that it is important that NICHD research stay abreast of this and other societal changes affecting child and reproductive health. She also seconded the suggestion of research on PCOS.

Dr. Dorn said that Council members have made several suggestions for research on mitigating factors against the long-term consequences of diseases and conditions. That is an overarching approach that should be considered.

Ms. Thomas suggested research to decrease maternal mortality, especially among women of color.

Dr. Butte made several points:

- More basic science is needed, including more cellular research.
- Researchers must be trained on how to use data and specimen repositories.
- Researchers should be trained to do much larger clinical studies. Small clinical studies are not productive.
- NICHD should encourage the use of consortia data and other sources of real-world data.
- Every child who is under treatment with an off-label drug should be in a study.
- Find out how to scale up the findings of research on social determinants of health to provide treatments.

LTC Scherer suggested conducting more pragmatic trials and using existing resources to research heterogeneous populations to identify patient characteristics that contribute to a favorable or unfavorable outcome. It is also important to improve understanding of advanced modeling techniques to help leverage disparate datatypes to understand long-term prognosis. NICHD should conduct studies to understand biomarkers in a broader way, not simply limiting the study to genetic biomarkers. Overall, LTC Scherer recommended research that is methodologically oriented.

Dr. Kenneth Ottenbacher said that longitudinal analysis often focuses on only a single variable or a few variables, but it should focus on a much wider range of variables. NICHD should support repositories that lend themselves to a multivariate longitudinal analysis.

Dr. Krugman said that one priority should be to research the importance of external influences on the developing embryo and child, particularly the long-term impact of neglect and abuse. This one of the least developed fields in health and medicine. The strategy must provide support to the fields that need it most, even those that have been ignored.

Dr. Catherine Gordon said that the brain, behavioral, and cardiovascular effects of giving exogenous sex steroids to adolescents should be investigated. Although the transgender model falls into that area of research, transgender individuals receive cross-sex steroids.

Dr. Boninger suggested research on technology and its potential adverse effects. Interactive technology is a broad category that could impact across areas, including the field of disability. Interactive technologies can be either negative or positive influences in growth and development.

### **Strategic Planning Context and Background**

Dr. Sarah Glavin provided information about NICHD resources, Congressional mandates, an analysis of the research portfolio, and measures of the impact of NICHD research. Following her presentation, the Council will have a second chance to provide their input.

In budgetary terms, NICHD is a mid-sized Institute. The DIR has about 940 employees, including 73 PIs and 295 trainees. It is currently conducting more than 70 clinical protocols. The DER has 2,578 grants, 2,783 PIs, and 442 funded institutions. More than 80% of NICHD grant money goes to fund extramural grants. The NICHD research grants management budget is 5% of the total grants budget.

Congress mandates that NICHD support a number of specific programs and topics. The mandates do not come with designated appropriations but are supported from the overall budget.

#### *Portfolio Analysis*

This analysis includes the extramural and intramural programs, with a look at the scientific domains and the public health domains that occur in the portfolio.

NICHD spending for FY17 by scientific domain is as follows: \*

- Basic sciences, 59%
- Population/epidemiology, 15%
- Screening and diagnosis, 14%
- Biomedical interventions, 19%
- Behavioral interventions, 23%
- Other, 1%

NICHD spending for FY17 by broad public health category is as follows: \*

- Pediatrics, 55%
- Gynecological and reproductive health, 15%
- Pregnancy and maternal health, 14%
- Intellectual, developmental, learning, and physical disabilities, 18%

- Other, 7%

\*Because categories overlap, the total is more than 100%.

The condition that received the most funding in pediatric research was typical child development, followed by infectious diseases, preterm birth, and rare diseases. Other funding areas noted were congenital anomalies, obesity, unintentional injury, and violence. The scientific domains in pediatric research that received the most funding were basic science, followed by behavioral interventions, biomedical interventions, screening and diagnosis, and population/epidemiology.

The condition that received the most funding within gynecology and reproductive health was infertility. The next highest funding area was contraception. Other funding included was for urological diseases, pelvic floor disorders, and PCOS. The scientific domains that garnered the most funding within gynecology and reproductive health included basic science, behavioral interventions, biomedical interventions, population health, and screening and diagnosis.

Preeclampsia was the condition that received the most funding in pregnancy and maternal health, followed by obesity, gestational diabetes, and depression. Basic science is the most funded in this category, followed by behavioral interventions and biomedical interventions.

For intellectual, developmental, learning, and physical disabilities, the most funding goes to intellectual and developmental disabilities, followed by rehabilitation, physical rehabilitation, and autism. The largest amount of funding goes to basic science. Population science gets only a small slice because there is little epidemiological research since the conditions are rare.

One way to evaluate the impact of NICHD-funded research is to look at the publications and their relative citation ratio (RCR), which shows the impact of an article relative to the impact of the average NIH-funded paper. An RCR of 1.0 indicates that a paper has average impact compared with other NIH-funded papers.

The DER, DIR, and Division of Intramural Population Health Research all had scores greater than 1.0 (1.27, 1.47, and 1.78, respectively). Each of the divisions had at least 20% of their papers rated within the top 10% of all papers. A further analysis of the impact of R01s compared with other ICs found that NICHD impact is close to the midrange.

The Fertility and Infertility Branch had the largest number of patents associated with its R01 grants. Six large programs—the Pelvic Floor Disorders Network, the Maternal-Fetal Medicine Units Network, the Reproductive Medicine Network, the Neonatal Research Network, and the Pediatric HIV/AIDS Cohort Study—had research results that were cited in clinical guidelines.

### *Listening Session Two*

Mr. Wheeler asked whether there were any surprises in what they heard about the portfolio.

Dr. Boninger said that the percent of funding that neuroscience receives was surprising.

Dr. Sohn said it was surprising how little funding NICHD gets, given the scope of its mission and the number of Congressional mandates it has. It should be receiving a higher level of funding.

Ms. Collura asked how NICHD compares to other ICs in terms of how many Congressionally mandated programs it has. Ms. Kaeser said that, other than the Office of the NIH Director,

NICHD has the most individual mandates, but NICHD works with other ICs on many of them. Ms. Rotenberg asked whether there are prescribed amounts of funding for any of the mandates. Ms. Kaeser said that the amounts that NICHD must spend are not usually prescribed.

Mr. Wheeler asked whether, in light of Dr. Glavin's presentation, Council members had a different perspective on the priorities it identified earlier in this session.

Dr. Krugman said that another question is NICHD's structure: Why is it structured the way it is, and how should it be structured given the relative paucity of funds?

Dr. Gordon said that NICHD's breadth of mission is wider than the budget it receives.

Dr. Gilliam asked whether there is a way to build in funding for discovery and for "making mistakes." This would build in a mechanism for innovation.

Dr. Boninger suggested identifying more work that crosses disciplines within NICHD as a way to break down silos. Dr. Bookheimer agreed and said that team science and multidisciplinary science are part of that.

Mr. Wheeler asked Council members what they think is the most important thing that NICHD can achieve for patients, families, and providers in the next 5 to 10 years.

Dr. Bookheimer said that early diagnosis of autism and other developmental disorders would be important, as would conveying current research findings to clinicians to encourage much earlier intervention.

Dr. Boninger said that one goal should be to strive for scientific discoveries that change practice guidelines or policies. The ultimate goal is to achieve discoveries that changes lives for the better.

Dr. Tabin said that it is important not to cut back on basic science for the next five years. Cuts in basic science slow progress in clinical science in the following five years. One area of basic science that is nearing readiness for clinical use is the study of biomarkers. The current potential of biomarkers was not available 20 years ago.

Dr. Scherer said that preclinical models are very valuable because they can lead to meaningful clinical outcomes. Dr. Tabin said that he agreed with the need for preclinical models and the need for research related to curing a specific disease. But it is also important to give equal weight to basic science research that is not directed at a specific disease.

Dr. Krugman said that one priority is to support work that looks at the health and well-being of children, pregnant women, and families. Health and well-being are different from the absence of disease.

Dr. Sohn said that it takes several years from the time a project receives funding to the time that findings are published. Given that lag, the most important thing that NICHD could do to affect families in the next five years is to synthesize today's emerging science and translate it for the public right now.

Dr. Gordon said that NICHD can build the bridge between scientific discovery and care delivery.

### *Training and Career Development, Research Infrastructure, and Data Sharing Partnerships*

Mr. Wheeler said that the Council would be asked to provide its input on key questions around training and career development, research infrastructure, and key partnerships and collaborations during this portion of the meeting.

Dr. Glavin provided background in these areas.

Training takes up 6% to 7% of the extramural budget, supporting more than 1,000 individuals. There are about 265 trainees through the intramural program. Trainees range from high school students to early-career investigators and mentoring awards to senior investigators, but most of the training occurs from the pre-doctoral to the early-career levels.

Between 50% and 60% of the extramural training is through institutional grants. The remainder is through grants to individuals. NICHD is rebalancing the institutional and individual awards by reducing the number of institutional awards. One reason to begin providing more individual awards is the finding that physicians who have an M.D. only (not M.D. and Ph.D.) are more likely to apply for and retain NIH funding if they had individual awards, not institutional awards.

The NICHD research infrastructure and data sharing includes research centers and special set-aside programs, animal models, and biospecimen banks. Data sharing includes the Data and Specimen Hub and Data Sharing for Demographic Research.

The clinical research infrastructure includes the clinical research networks. These networks facilitated a rapid response to the Zika outbreak and promoted collaborations. The Clinical Research Center includes protocols for research on pediatric rare diseases and pediatric endocrinology.

NICHD collaborates with more organizations on more topics than any other IC. The collaborations extend from informal to formal, across ICs and other federal agencies, and with private organizations.

### *Listening Session Three*

Mr. Wheeler began with the following question: What types/areas of training are needed to prepare the next generation of leaders? What role should NICHD play?

Dr. Bookheimer said that knowing how to analyze big data will be important in many areas of science, including genomics, behavior health, and imaging. Machine learning needs to be taught.

Dr. Gilliam said that she agrees on the importance of big data and using existing datasets, but cautioned that research must also remain people-centered and patient-centered. It will be important to engage people and patients in the research from the beginning. It is also important to train researchers how to write scientifically and in a way that can inform policy and practice guidelines.

Dr. Boninger said that the Council created a list of priorities that should provide the training blueprint. For example, if NICHD decides that biomarkers are a priority, then there should be training on biomarkers.

Ms. Collura said that a whole generation has missed out on training in certain aspects of infertility. She asked whether NICHD has a role in filling gaps in training in research.

Dr. Sohn said that training awards tend to be focused in the large academic centers. It is time to think more broadly about the types of training and the types of skills that are needed and to balance where the funding goes. Some of the training might go to individuals with clinical expertise in infertility who have not conducted research.

Ms. Thomas said that training for the next generation of researchers should include seeing the subject/patient as a person, not a number or a disease.

Dr. Bianchi said that NICHD funds only 18% of pediatric research at NIH but may be funding 100% of the pediatric research training. This represents an opportunity to bring in other ICs to help.

Dr. Bianchi introduced the next question: What emerging technologies and techniques will impact the types and methods of research conducted in the next 10 years?

Dr. Bookheimer said that remote data collection and digital data collection—for example, directly from the doctor's office—could be the low-hanging fruit. There are many kinds of technologies that could be used to acquire data. Dr. Bookheimer also suggested investing in neuromodulation technology.

Ms. Collura said that new technology is exciting, but it is important to remember that some communities do not have digital access. NICHD can be a leader in ensuring that all communities are reached. Dr. Bookheimer said that more people could be provided with digital access by placing the technologies in doctor's offices and clinics where everybody can access it.

Dr. Krugman said that the list of research priorities should include firearms and violence. Mr. Wheeler will add that topic to the research priorities list.

Dr. Boninger said that rehabilitation in the disabled population should be included among the priorities. In terms of technologies, he said that virtual reality and the Internet of things have potential for high impact. Emerging technology that crosses the disciplines of computer science, robotics, and engineering also have potential for high impact.

Dr. Tabin said that cross-training engineers in medical research would be important.

Dr. Gilliam said that it is important to include mentoring and to use mentoring to help build workforce diversity. There is also a need to include training in how to run a lab.

Dr. Bookheimer said that ethics training for researchers in light of the MeToo movement should be included.

Mr. Wheeler asked for the Council's thoughts on partnerships and collaborations.

Dr. Dorn said that partnerships work best when the partners agree on their common goals and when they understand each other's individual goals.

Dr. Ottenbacher said that NICHD should not form partnerships for the sake of partnerships, but should have a way to measure their productivity. He asked what metrics NICHD would use to evaluate partnerships.

Dr. Bianchi said that the NICHD role in global health will also be important to consider.



## **XII. Closing Remarks**

Dr. Bianchi said that the last time this type of wide-ranging discussion occurred was at the visioning meetings that took place six years ago. The visioning process was not specific to NICHD, but was a look at future research in the fields that NICHD funds.

Dr. Bianchi thanked the Council members, NICHD staff, and Mr. Wheeler for their work.

## **XIII. DAY ONE ADJOURNMENT**

Dr. Bianchi adjourned the open session of the meeting at 4:28 p.m.

## **XIV. DAY TWO CLOSED SESSION**

This portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosures under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

### **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 564 HD-primary applications requesting \$141,759,635 in direct costs and \$200,891,725 in total costs.

### **Review of the Scientific Director—Closed to All Staff**

### **DIR Closed Session**

## **XV. ADJOURNMENT**

There being no further business, the meeting adjourned at 2:30 p.m. on Friday, September 14, 2018. The next meeting is scheduled for January 24–25, 2019.

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

\_\_\_\_\_  
/s/  
Diana W. Bianchi, M.D.  
Chair, National Advisory Child Health and  
Human Development Council

12/17/18  
Date

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

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

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Eugene Hayunga, Ph.D.  
Acting Committee Management Officer,  
*Eunice Kennedy Shriver* National Institute  
of Child Health and Human Development

Attachment: Council Roster