NICHD Director’s Report

Diana W. Bianchi, MD
NICHD, Director
September 13, 2018
• Budget Update
• Noteworthy NICHD Research Initiatives
• Workshops/Conferences of Interest
• Progress Towards Inclusion
• NICHD Strategic Planning
• New NIH IC Directors
FY 2018 NIH Budget Update

- Federal government is funded through September 30, 2018 with FY 2018 Omnibus Appropriations Act (passed on March, 23, 2018)
- NIH was appropriated $37.084 billion for FY 2018, a historic $3 billion increase over FY 2017
- NICHD’s appropriated budget increased by $75 million
- Additional funds to come from special projects
  - ACT-NOW
  - INCLUDE
- On track for an ~$2 billion increase in FY 2019
How Did We Use the Increased Funding in FY 18? (Caveat: FY18 is Not Over)

• Helped early stage researchers achieve independence
  • Doubled from 29 → approximately 60

• Support for the inclusion of pregnant and lactating women in research
  • Used >$800K in research management support to facilitate Task Force activities

• Allocated $30 million to launch clinical trials to identify, treat and care for babies exposed to opioids *in utero*
  • ACT NOW: Act II

• Dedicated more than $39 million to sustain existing research programs in preeclampsia, maternal mortality, fertility/infertility, autism
Noteworthy NICHD Research Initiatives
The Trans-NIH Pediatric Research Consortium (N-PeRC)

- Harmonize efforts in child health research across 27 Institutes and Centers
- Identify gaps and opportunities for collaboration
- Enhance communication between NIH, advocacy groups and Capitol Hill
- Outreach effort to encourage senior pediatric researchers to serve on review panels
- Trans-NIH supported training to grow pediatric work force
- Held two meetings to date and will continue to meet bi-monthly
INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome)

- Investigate conditions that affect individuals with Down syndrome and the general population, such as Alzheimer’s disease/dementia, autism, cataracts, celiac disease, congenital heart disease and diabetes.
  - Conduct targeted, high-risk, high-reward basic science studies on chromosome 21
  - Assemble a large study population of individuals with Down syndrome
  - Include individuals with Down syndrome in existing clinical trials

- Truly trans-NIH (18 ICs involved)
INCLUDE Research Plan

• NIH is dedicating additional $23 million for INCLUDE research, bolstering total funding for Down syndrome research in FY2018 to an estimated $60 million
• FY2018 awardees will be notified by Sept 30
• Further support anticipated in FY2019 and beyond, pending availability of funds
Population-level pregnancy-related mortality ratios by age, race-ethnicity, and overall for 2011-2013

Data can be compared as absolute values
Birth Settings Study to Understand Maternal Mortality

- Rates of home and birth center births continue to rise and there is a need for further study on issues related to the choice of birth setting.
- NICHD was directed to enter into an agreement with the National Academy of Sciences to provide an evidence-based analysis of the complex findings in the research on birth settings, including but not limited to:
  - definitions and assessment of risk factors;
  - access to and choice in birth settings;
  - social determinants that influence risk and outcomes in varying birth settings;
  - financing models for childbirth across settings; and
  - the licensing, training, and accreditation issues impacting professionals providing maternity care across all settings.
Workshops/Conferences of Interest
New (2018) NICHD’s Young Investigators Conference

- Chairs of Pediatric, Ob-Gyn and Rehabilitation Medicine Depts were asked to nominate attendees
- Held on August 26-29, 2018, 140 participants
- Focused on skills needed by any and all young clinician investigators who are working in areas that we fund
- Held in Potomac, MD so more NICHD “faculty” could participate
- Activities included study design, mock study section, setting up a wet lab, work-life balance, networking with program staff
- Lesser known grant and career opportunities were presented
  - Lasker program for clinical researchers at NIH Clinical Center
  - Bench to bedside U01s
  - NIH intramural research
Menstruation: Science and Society Meeting

• September 20-21, 2018; 6700 Rockledge Drive Bethesda, MD
• Register at: https://palladianpartners.cvent.com/GHDB_Menstruation2018
• Videocast at https://videocast.nih.gov/
• Goals of meeting:
  • To discuss promising new discoveries and avenues of research surrounding menstruation
  • Encompass insights provided by the normally functioning endometrium and potential of diagnostics for abnormal function and disease
  • Incorporate the science of menstruation with the broader societal implications of that process, including the unique considerations necessary in menstrual health communications, population health research, and public health outreach.
• SAVE THE DATE: November 13-14, 2018, in Bethesda, Maryland

• Focus on challenges of clinical translation and low resource settings

• HPP grantee presentations, technology demonstrations and poster session

• REGISTRATION OPEN: https://palladianpartners.cvent.com/2018HPPMeeting
Progress Towards Inclusion
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Pregnant Women
- Task Force for Research Specific to Pregnant Women and Lactating Women (PRGLAC)
- New RCDC codes
- PregSource®
- NIH Clinical Center

Lactating Women
- PRGLAC
- New RCDC codes

Children
- Inclusion of children in NIH Research Workshop
- All of Us Strategic Vision
- Trans-NIH Pediatric Research Consortium

Intellectual/Physical Disabilities
- All of Us Advocacy
- INCLUDE

All
- Commentary: JAMA 2018; 319:337-8
Highlights of PRGLAC Recommendations

- Change the existing culture that has limited scientific knowledge of therapeutic product safety, effectiveness, and dosing for pregnant and lactating women
  - Protect *through* research instead of *from* research
  - Remove pregnant women as a vulnerable population through Common Rule
- Expand Workforce of clinicians and researchers with expertise in obstetric and lactation pharmacology and therapeutics
- Remove regulatory barriers
  - Modify subpart B of the Common Rule (maternal consent only, align with pediatrics)
- All 15 recommendations are available online: [https://www.nichd.nih.gov/About/Advisory/PRGLAC](https://www.nichd.nih.gov/About/Advisory/PRGLAC)
- Report due today in HHS and Congress
NICHD Strategic Planning Process

- This afternoon, 1:30-4:45 PM
  - Open session, live webcast and archived
  - Detailed presentation of process to date and what is upcoming
  - “Listening session” with Advisory Council members

- October 22: Session with the Friends of NICHD

- October 31: Live webinar, with interactive questions/answers

- Following Working Group meeting on October 15-16, there will be a “Request for Information” (RFI) in early December

- Visit NICHD Strategic Planning web page at any time:
  - https://www.nichd.nih.gov/about/org/strategicplan
  - Email comments to NICHDStrategicPlan@nih.gov
New NIH Institute/Center Directors
New Director for National Institute of Biomedical Imaging and Bioengineering (NIBIB)

• Bruce J. Tromberg, Ph.D., was named NIBIB’s new Director and is expected to start in the new year.
• His intramural laboratory will be located within NICHD
  • Imaging, Behavior and Genetic Integrity section
• A leader in the field of biophotonics, Dr. Tromberg is currently a professor at the University of California at Irvine (UCI), with dual appointments in the Departments of Biomedical Engineering and Surgery.
• He also directs UCI’s Beckman Laser Institute and Medical Clinic, an interdisciplinary research, teaching and clinical center for optics and photonics in biology and medicine.
New Director for National Center for Complementary and Integrative Health (NCCIH)

• Helene M. Langevin, M.D., C.M. is expected to join NCCIH in November 2018.

• Dr. Langevin comes to NIH from the Osher Center for Integrative Medicine, jointly based at Brigham and Women's Hospital and Harvard Medical School, Boston.
Thank You and Questions