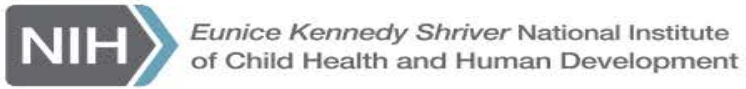
NICHD Director's Report

Diana W. Bianchi, MD
NICHD, Director
September 13, 2018



Presentation Overview

- Budget Update
- Noteworthy NICHD Research Initiatives
- Workshops/Conferences of Interest
- Progress Towards Inclusion
- NICHD Strategic Planning
- New NIH IC Directors

Budget Update

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)

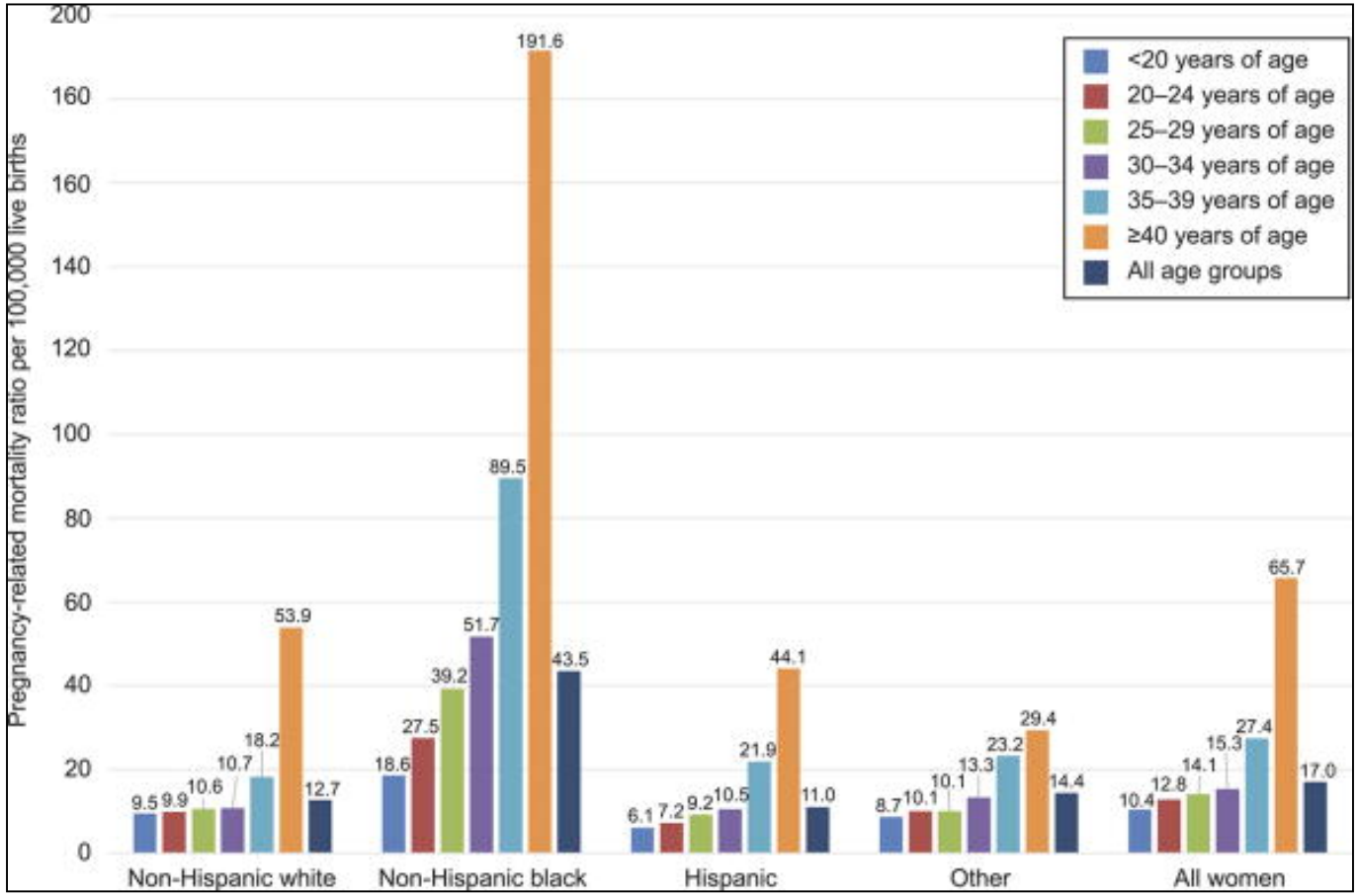
- Investigate conditions that affect individuals with Down syndrome and the general population, such as Alzheimer's disease/dementia, autism, cataracts, celiac disease, congenital heart disease and diabetes.
  - Conduct targeted, high-risk, high-reward basic science studies on chromosome 21
  - Assemble 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

Maternal Mortality

Population-level pregnancy-related mortality ratios by age, race-ethnicity, and overall for 2011-2013



Data can be compared as absolute values

Creanga. Pregnancy-Related Mortality in the United States. Obstet Gynecol 2017.

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.

5th Annual Human Placenta Project Meeting

- 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

Progress Towards Inclusion

Pregnant Women

- Task Force for Research Specific to Pregnant Women and Lactating Women (PRGLAC)
- New RCDC codes
- PregSource®
- NIH Clinical Center

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

Lactating Women

- PRGLAC
- New RCDC codes

VIEWPOINT

Improving Public Health Requires Inclusion of Underrepresented Populations in Research

Catherine Y. Spong, MD
Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland.

Diana W. Bianchi, MD
Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland.

Supplemental content

Advances in genomics have ushered in promising therapies tailored to the individual. Personalized medicine is promoted and has begun to positively influence care. For example, medications such as trastuzumab for the 30% of breast cancers that overexpress *ERBB2* and vemurafenib for patients with late-stage melanoma who carry the V600E variant have been beneficial.[1] Despite these advances, for many sectors of the population—children, older adults, pregnant and lactating women, and individuals with physical and intellectual disabilities—limited evidence-based therapies optimized to their specific medical needs exist. Combined, these groups comprise as much as 58% of the US population (eTable in the Supplement). Research focusing on or at the very least includes members of these groups is critically needed.

Until the initial passage of the Best Pharmaceuticals for Children Act in 2002, pediatric drug doses were based on extrapolation from adults. Importantly, body composition and metabolic processes change as children develop, resulting in different safety and efficacy cations are often prescribed with minimal evidence to support their use, especially psychotropic drugs with significant adverse effects.

Recently, discussions have arisen about the need for inclusion in research and elimination these gaps. In 2017, the National Institutes of Health (NIH) held a workshop, "Inclusion Across the Lifespan," that highlighted current federal regulations that include protections for "vulnerable populations" (pregnant women, fetuses, neonates, prisoners, and children). Although these regulations were originally designed to protect these individuals, many investigators have called for reconsideration, opting to protect them *through* research, rather than *from* research. Inclusion will likely yield data that will benefit more people.

Many underrepresented populations encounter barriers to participation in research. In a review of 338 phase 3 and 4 NIH-funded actively recruiting studies in Clinicaltrials.gov, explicit exclusion was found in 68% for pregnant women, 47.3% for lactating women, 75.7%

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
- Report due today in HHS and Congress

NICHD Strategic Planning

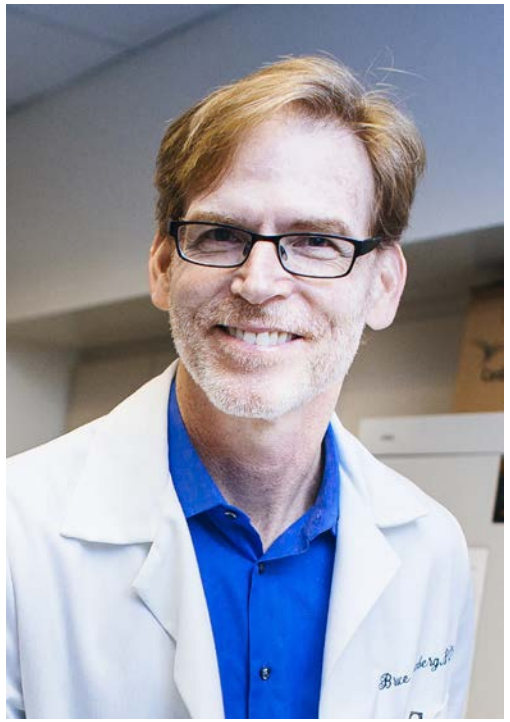
NICHD Strategic Planning Process

- 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 NICCIH 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