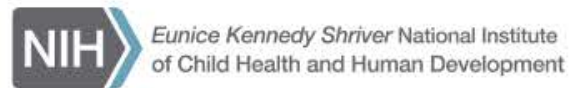


NICHD Director's Report

Diana W. Bianchi, MD
NICHD Director
January 24, 2019





Outline for Today's Director's Report

- Strategic Planning Updates Will Be in the Later Presentation
- Scientific Workshops/Meetings
- NICHD Research Initiatives of Note
- Staff Updates



Scientific Workshops/Meetings



Menstruation: Science and Society Meeting

- Organized by the Gynecologic Health and Disease Branch
- September 20-21, 2018 in Bethesda, Maryland





Why Did We Have This Workshop? Science

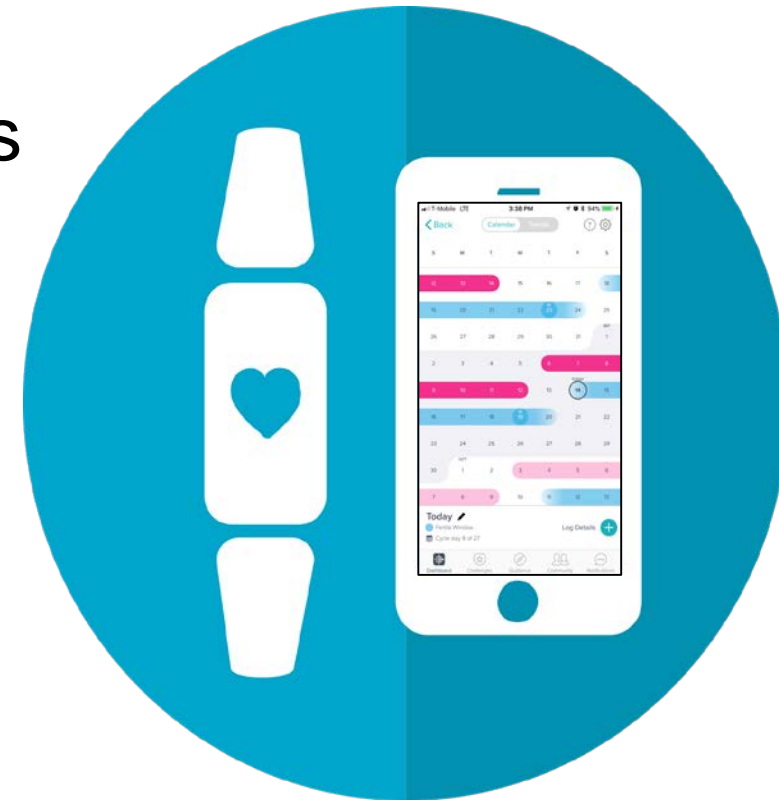
- Conditions such as endometriosis affect at least 10% of women and are extremely painful
- NICHD is a leader in research on women's health
 - Identify scientific gaps and opportunities
- Many areas were explored, including endometrial biology, comparative studies in other mammals, menstrual blood as a biofluid, menstruation as a diagnostic tool, global health
- Publication in a peer-reviewed journal covering the proceedings and conclusions from the meeting is in preparation





Growing Area Known as “FemTech”

- FemTech uses digital health applications such as software, diagnostics, products, and services to improve women’s health, specifically:
 - fertility solutions
 - period-tracking software
 - pregnancy-tracking software
 - nursing care software
 - women’s sexual wellness
 - female reproductive health care
- Opportunity for research using mobile devices





Society: Global Health

Meghan Markle: How Periods Affect Potential

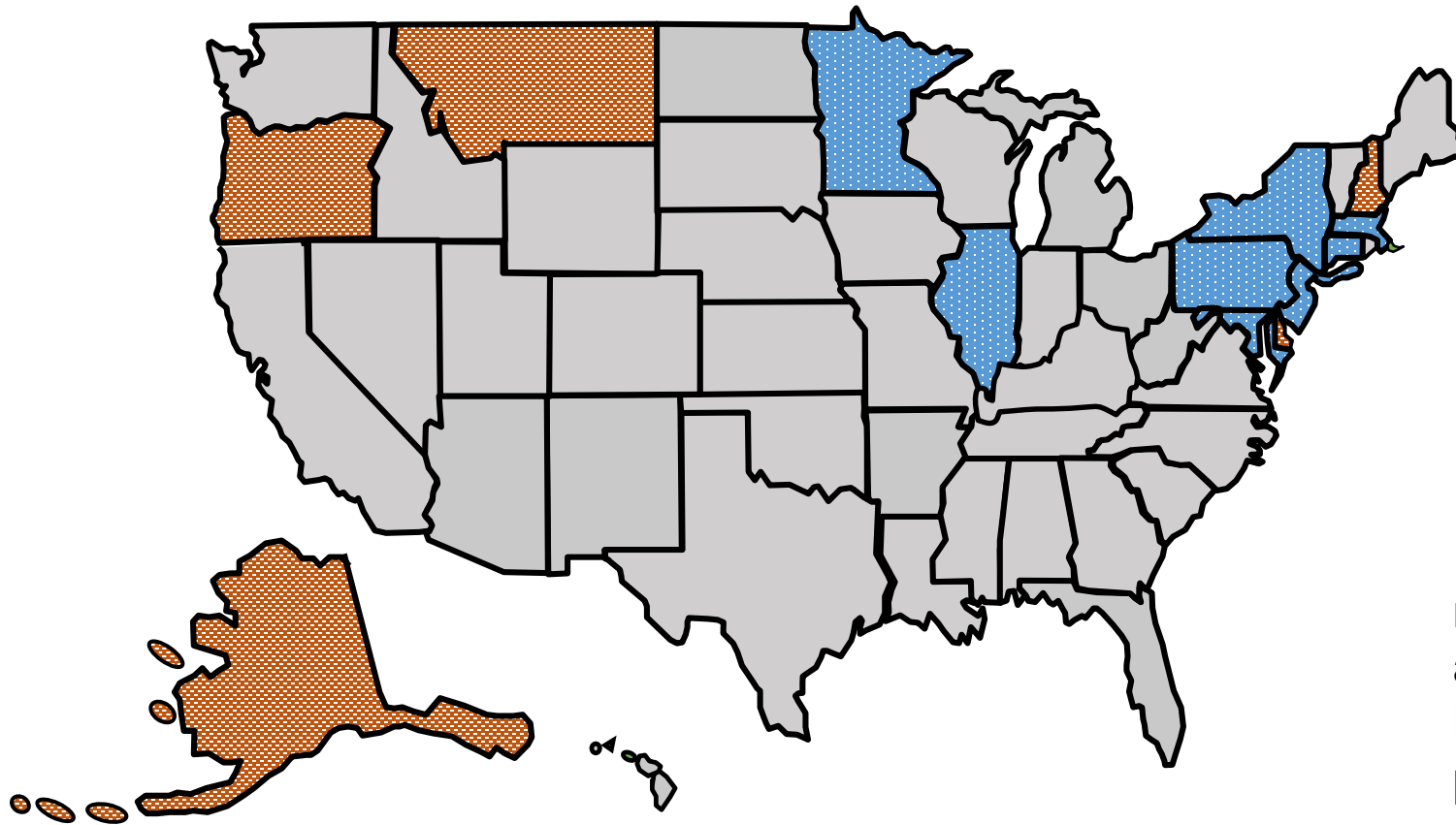
- Time Magazine – March 8, 2017
- Highlighted the stigma surrounding menstruation, especially in low resource settings
 - Lack of feminine hygiene supplies
 - Lack of access to proper sanitation/facilities
 - Lack of open dialogue
- Ultimately leading to girls falling behind at school or dropping out
- Encouraged breaking the cycle of “period poverty”






Photo: World Vision Canada



Society: In the U.S. – The Tampon Tax



-  States with no sales tax, including feminine hygiene products
-  States that exempt feminine hygiene products
-  States that tax feminine hygiene products

Recent article in the *New York Times* noted that a member of Congress was asked to reimburse the Committee on House Administration for menstrual products for his staff members.



Diana Bianchi @DianaBianchiMD · 20 Sep 2018

Linda Griffith: Endometriosis should not be called a benign disease! Preferred term: non-cancerous #NICHDMensesScience

3 5



Frank Tu, MD, MPH @Dr_Tu_gynesurg · 21 Sep 2018

thread about building resources for patients while avoiding overloading clinicians - here is an example we shot for #pelvicpain for about \$15000 thanks to @amyravi funded by @PelvicPainOrg. Capture patient voices with deep experience next like @healthy_lawyer #nichdmensescience

2 4



Julie Kim @JulieKim20 · 20 Sep 2018

An outstanding day learning about the social, clinical, basic, diagnostic science of menstruation! We need more meetings with diverse coverage like this! #NICHDMensesScience

5



Period Podcast @periodpodcast2 · 21 Sep 2018

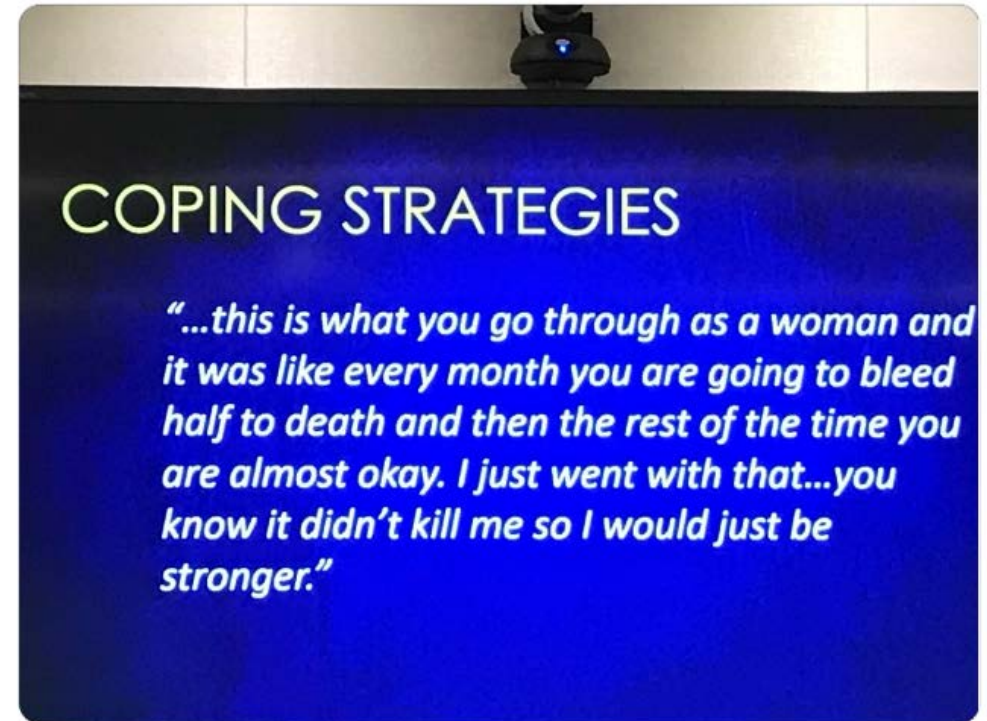
There are at least 2 ways in which women experience clinical sci: either made to feel abnormal and pushed to go on meds, OR forced to suffer because their doctors say their experience is normal. I'm so curious about how a woman ends up in one box or the other. #nichdmensescience

6 16



Marni Sommer @marnisommer · 21 Sep 2018

We need to change the bar women are setting for themselves around managing bleeding. - E.Marsh
#NICHDMensesScience



1 3



NICHD News & Info @NICHD_NIH · 20 Sep 2018

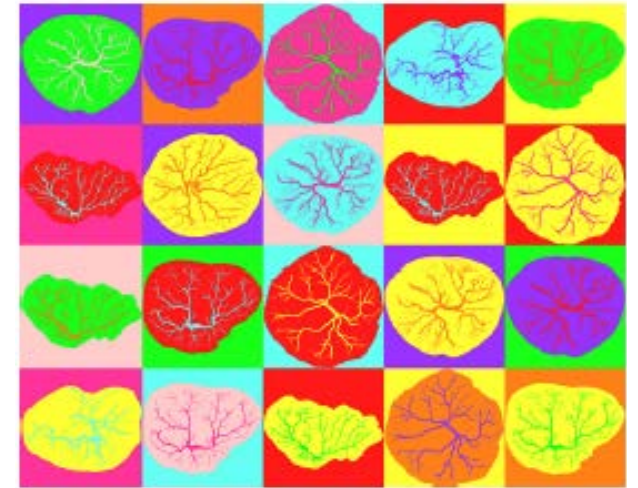
Changing the conversation from shame to celebration. #Menstruation #GlobalHealth @sandyclark @DaysForGirls #nichdmensescience

4 5



5th Annual Human Placenta Project (HPP) Meeting

- November 13-14, 2018 in Bethesda, Maryland
- Presentations by HPP grantees who are making significant progress in developing novel methods for placental assessment
- Moderated discussions of translational challenges and the challenges and opportunities of a global HPP
- Network opportunities for attendees during the poster/demo session
 - 30+ posters and 5 demos



Rosalind Aughwane, University College, London
“Placental Pop Art” in *BMJ* 2018; 360: k824





4th Annual Bill and Melinda Gates Foundation and NIH Collaborative Meeting

- Annual meeting to discuss future areas of collaboration
- Two largest funders of biomedical research in the world; considerable impact
- Working Groups:
 - Contraception (co-chaired by Dan Johnston)
 - Maternal Neonatal Child Health (co-chaired by Diana Bianchi and Sindura Ganapathi)
 - Three focus areas:
 - Adverse Pregnancy Outcomes (chaired by David Weinberg)
 - Growth and Nutrition (chaired by Drew Bremer)
 - Neurodevelopment (chaired by Vesna Kutlesic)



- Adverse Pregnancy Outcomes

- DASH for data sharing - e.g., collaborative machine learning analyses to generate predictive algorithms for pregnancy risk
- Possible collaboration on a clinical trial using the infrastructure of the NICHD Global Network to improve perinatal outcomes
- Women First: Preconception Maternal Nutrition Study – primary study published, secondary analyses under way



Study Topics in DASH

- | | |
|----------------------------------|-------------------------------|
| Autism Spectrum Disorders | Pharmacology |
| Cerebral Palsy | Pelvic Floor Disorder |
| Children's Bone Health & Calcium | Preconception & Prenatal Care |
| Diabetes | Preeclampsia & Eclampsia |
| Driving Risk | Pregnancy |
| Early Learning | Pregnancy Loss |
| High-Risk Pregnancy | Preterm Labor & Birth |
| HIV/AIDS | Primary Ovarian Insufficiency |
| Infant Care & Health | Rehabilitation Medicine |
| Infant Mortality | Sleep |
| Infertility & Fertility | Stillbirth |
| Labor & Delivery | Stroke |
| Neuroscience | Sudden Infant Death Syndrome |
| Necrotizing Enterocolitis | Women's Health |
| Obesity & Overweight | |

- **Centralized resource for researchers to store and access de-identified data from studies supported by NICHD**
- **Can help investigators meet NIH's data sharing requirements for their own studies and find others' study data for secondary analyses**
- **Aims to accelerate scientific findings and improve human health**
- **Launched in August 2015 and governed by the NICHD DASH Committee**



111 Studies Available



29 Study Topics



16.4K+ Users



110 Data Requests



10 Data Use Publications

Questions? Contact supportdash@mail.nih.gov

For NICHD studies not archived in DASH, visit: <https://dash.nichd.nih.gov/Resource/LinksToOtherArchives>



- Growth and Nutrition

- Discussion themes related to the overall NIH Strategic Plan for Nutrition Research
- Maternal nutrition during the periconceptional, gestational, and perinatal periods
- Factors affecting feeding
 - Lactation performance and human milk composition
 - Prematurity and low birthweight
- Predictors of adverse outcomes for infants and young children in low resource settings
- Resource development; including use of existing platforms to harmonize data and developing new tools to assess nutritional status and related outcomes

- Neurodevelopment

- Data harmonization and analysis of BMGF studies and NIH funded studies (e.g., ECHO)
- NIH Baby Toolbox – neurodevelopmental assessment tools for birth to age 3.5 years
- HEALthy Brain and Cognitive Development (HEALthy BCD) Study – cohort study of pregnant women and offspring to examine impact of opioid and other exposures on brain and cognitive development

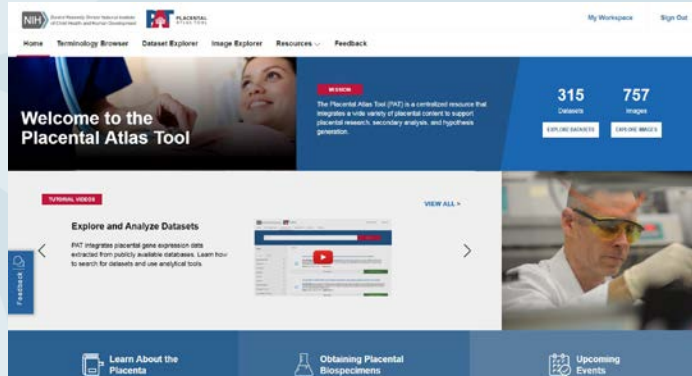


NICHD Research Initiatives of Note

Placental Atlas Tool (PAT)



- PAT is a Web-based resource freely accessible to all interested researchers
- Released (PAT v1.0) October 2018
- PAT retrieves placental molecular datasets into an integrated resource and provides the analytical tools for secondary analysis to encourage a systems biology approach to placental research
- Facilitates:
 - Hypothesis generation
 - Identification of potential biomarkers
 - Identification of potential therapeutic targets





Key Functionalities

- Dataset Explorer that retrieves placental gene expression datasets from publicly available databases based on a search term
- Robust Analytics to manipulate and analyze retrieved datasets. Analytical features include generation of heat maps, pathway analysis, and network relationships
- Image Explorer to browse and search placental images of various modalities extracted from NLM Open-i as well as proprietary pathology images
- Taxonomy Browser that allows researchers to view standardized taxonomies for molecular pathology as well as metadata and images related to placental concepts
- Workspace Area that provides researchers with a secure environment to save, manage, and analyze data available through PAT for secondary analysis and hypothesis generation



The Trans-NIH Pediatric Research Consortium (N-PeRC)

- Harmonize efforts in child health research across 27 Institutes and Centers
- Meetings are held bi-monthly (4 so far)
- Identify gaps and opportunities for collaboration
 - Pediatric drugs and devices
 - **Data sharing**
 - Trans-NIH supported training to grow pediatric work force
 - Transition from adolescence to adulthood
- Enhance communication between NIH and research advocacy organizations
- Outreach effort to encourage senior pediatric researchers to serve on review panels





NIH HEAL (Helping to End Addiction Long-term) Initiative

- Launched in April 2018 as a trans-agency effort to develop faster scientific solutions to stem the national public health crisis of opioid misuse/addiction
- NIH doubled funding for research on opioid misuse/addiction and pain from approximately \$600 million in fiscal year 2016 to \$1.1 billion in fiscal year 2018, made possible by Congressional support





Funding Opportunities for HEAL

- HEAL will:
 - Improve treatments for opioid misuse and addiction
 - Emphasis on non-pharmacologic
 - Enhance pain management
- ACT-NOW is now formally included in HEAL initiative
- Recent funding announcements focus on biomarkers, novel targets for treatment, and -omics

The screenshot shows the NIH website's navigation bar with 'Grants & Funding' selected. The main content area is titled 'NIH HEAL INITIATIVE' and features a sidebar with a 'Funding Opportunities' section. This section includes social media icons, a 'New Funding Opportunities' link, and a note about technical assistance. A right-hand sidebar contains 'Email Updates' and 'Contact Us' sections.

- Funding opportunities found at:
 - <https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative/funding-opportunities>



HEAL Initiative: Antenatal Opioid Exposure Longitudinal Study Consortium (PL1 Clinical Trial Not Allowed)

- **FOA Number:** RFA-HD-19-025
- **Posted:** December 10, 2018
- **Application Due Date:** March 29, 2019, by 5:00 p.m. local time of applicant organization
- **Purpose:** Invites applications from consortia composed of a Data Coordinating Center and 2 or more Clinical Sites to conduct a multi-center prospective cohort study of infants exposed to opioids *in utero* compared to unexposed infants. During a 2-year follow-up period, infants will be assessed with serial measures including neuroimaging, medical, neurodevelopmental, behavioral, and home, social, and family life assessments.



The NIH INCLUDE Project (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE)

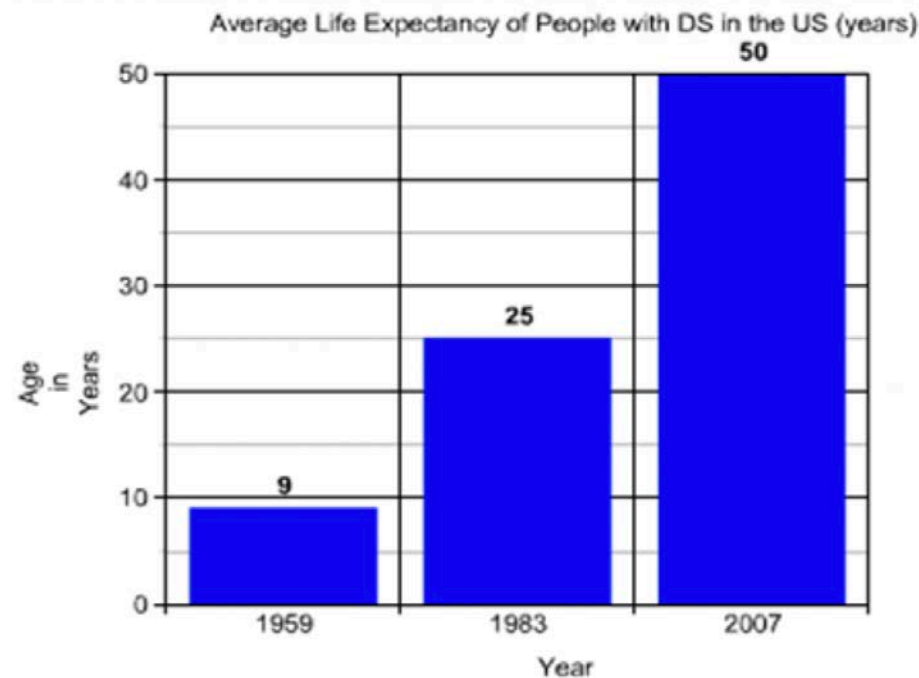


Mr. Frank Stephens' testimony to the House Appropriations Committee on October 25, 2017



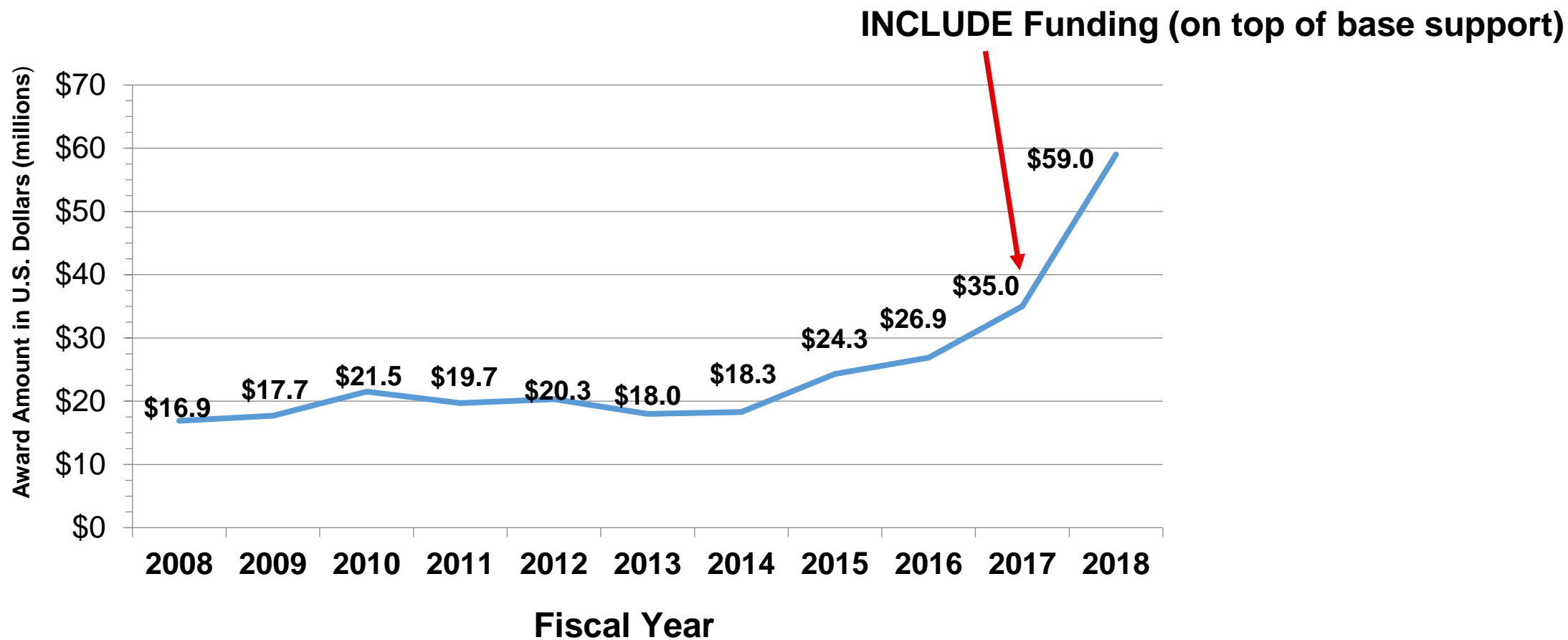
The Case for More Research in Down syndrome

- Each year, ~ 6000 infants with Down syndrome born in U.S.
- Lifespan for people with Down syndrome has doubled in 25 years





Total NIH Funding for Research on Down Syndrome FY 2008 – FY 2018





New Opportunity for NIH on Down Syndrome

- In the FY 2018 budget legislation for NIH:

“Develop a new trans-NIH initiative to study trisomy 21, with the aim of yielding scientific discoveries to improve the health and neurodevelopment of individuals with Down syndrome and typical individuals at risk for:

- Alzheimer's disease
- Leukemia
- Heart defects
- Immune system dysregulation
- Autism
- and other conditions...”

Protected from:

- Many cancers
- Heart disease and heart attacks

- Unique double benefit: understanding both **Down syndrome** and **shared common conditions** (risks or resiliencies)



INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE)

- Trans-NIH initiative to investigate conditions that affect individuals with Down syndrome and the general population
- Three components to address key quality-of-life issues:
 1. Conduct targeted, high-risk, high-reward basic science studies on chromosome 21
 2. Assemble a large study population of individuals with Down syndrome
 3. Include individuals with Down syndrome in existing clinical trials



FY 2018 INCLUDE Funding

- \$22.2 M support for 49 awards across NIH
- NICHD funded projects within INCLUDE include:
- High risk, high reward basic science
 - A Novel Approach to Molecular Cell Pathologies of Human Down Syndrome and DS-AD (chromosome silencing)
 - Generation of isogenic trisomy 21 iPSC resource
- Identify Down Syndrome cohorts
 - Gabriella Miller/Kids First Studies (NIH Common Fund)
 - Genomic Analysis of CHD and ALL in Children with Down Syndrome
 - Germline and Somatic Variants in Myeloid Malignancies in Children
 - Intellectual and Developmental Disabilities Research Center at Vanderbilt - Mining EMR information and biosamples for Down Syndrome
- Inclusion of Down syndrome cohorts in clinical trials
 - Autism ACE Network adding DS cohort in early treatment intervention
 - Encourage INCLUDE investigators to use DS-Connect® for recruitment



2019 Support and Beyond

- FY19 Funding Opportunity Announcements planned
- Workshops in development for early 2019:
 - “Planning a Virtual Down syndrome Cohort across Lifespan”
 - “The State of the Science for Meaningful Clinical Trials in Down syndrome”

Notice of Intent to Publish a Funding Opportunity Announcement for INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) Project

Notice Number: NOT-OD-19-051

Key Dates

Release Date: January 03, 2019

Estimated Publication Date of Funding Opportunity Announcement: January 31, 2019

First Estimated Application Due Date: March 29, 2019

Earliest Estimated Award Date: September 30, 2019

Earliest Estimated Start Date : October 30, 2019

Related Announcements

None

Issued by

National Institutes of Health (NIH)

Purpose

The Office of the Director of the National Institutes of Health (NIH) intends to publish four Funding Opportunity Announcements (FOAs) for the INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) project (<https://www.nih.gov/include-project>). Individuals with Down syndrome (DS) face significant and changing health challenges but have often been excluded from



Staffing Updates



New Chief of Staff, Elizabeth Baden

- Comes to NICHD from the Office of Science Policy in the OD
- Will help to
 - Ensure consistent communication across NICHD
 - Implement strategic plan
 - Serve as Executive Secretary for new working groups of our Advisory Council and N-PeRC





We are Hiring!

- Deputy Director: Formal search committee is completing its first round of interviews this month
- Executive Officer: Search committee has been charged, application window to open soon
- Extramural Branch Chief Positions: Pregnancy and Perinatology, Obstetrics and Pediatrics Pharmacology and Therapeutics, Child Development and Behavior
- Medical and Program Officers in Division of Extramural Research



Questions?