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
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
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

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 #nichdmensesscience

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

Marni Sommer @marnisommer · 21 Sep 2018
We need to change the bar women are setting for themselves around managing bleeding. - E.Marsh #NICHDMensesScience

COPING STRATEGIES

“...this is what you go through as a woman and it was like every month you are going to bleed half to death and then the rest of the time you are almost okay. I just went with that...you know it didn’t kill me so I would just be stronger.”

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. #nichdmensesscience

NICHD News & Info @NICHD_NIH · 20 Sep 2018
Changing the conversation from shame to celebration. #Menstruation #GlobalHealth @sandyclark @DaysForGirls #nichdmensesscience
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)
NIH-Gates MNCH Scientific Focus Areas

• 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

<table>
<thead>
<tr>
<th>Study Topics</th>
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<tbody>
<tr>
<td>Autism Spectrum Disorders</td>
<td>Pharmacology</td>
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<td>Cerebral Palsy</td>
<td>Pelvic Floor Disorder</td>
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<td>Children’s Bone Health &amp; Calcium</td>
<td>Preconception &amp; Fetal Care</td>
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<td>Diabetes</td>
<td>Preeclampsia &amp; Eclampsia</td>
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<td>Driving Risk</td>
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<td>Early Learning</td>
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<td>High-Risk Pregnancy</td>
<td>Preterm Labor &amp; Birth</td>
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<td>HIV/AIDS</td>
<td>Primary Ovarian Insufficiency</td>
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<td>Infant Care &amp; Health</td>
<td>Rehabilitation Medicine</td>
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<td>Infant Mortality</td>
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<td>Infertility &amp; Fertility</td>
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<td>Labor &amp; Delivery</td>
<td>Stroke</td>
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<td>Neuroscience</td>
<td>Sudden Infant Death Syndrome</td>
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<tr>
<td>Necrotizing Enterocolitis</td>
<td>Women’s Health</td>
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- 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

**Statistics**

- **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](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
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

• 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

Award Amount in U.S. Dollars (millions)

Fiscal Year

INCLUDE Funding (on top of base support)
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…”

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

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**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?