NICHD Director’s Report

Diana W. Bianchi, M.D.
NICHD Director
June 11, 2019
Talk Outline

• FY 2020 Appropriations
• Updates on Selected NICHD Initiatives
  • Maternal Mortality
  • Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)
  • INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE)
  • Data and Specimen Hub (DASH)
• Institute and Center Leadership at NIH
Testified at the FY 2020 House appropriations hearing with Drs. Collins, Fauci (NIAID), Gibbons (NHLBI), Lowy (NCI), and Volkow (NIDA)

Fielded questions about:
- Maternal mortality
- Task Force on Research Specific to Pregnant Women and Lactating Women
- Newborn screening
- Postpartum depression
- Pediatric research
Next Steps in FY 2020 Appropriations

• Strong bipartisan support expressed for NIH funding
• House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies marked up a bill that included:
  • $41.1 billion for NIH (+2 billion)
  • $1.580 billion for NICHD (+80 million over FY 2019)
  • $12.6 million for Gabriella Miller Kids First program
• House Appropriations Full Committee markup held May 8
• 5 of 12 appropriations bills (including Labor-HHS) packaged together to be considered on House floor this week
• Senate markup expected in June
Maternal Mortality – New CDC Analysis

• Every 12 hours a woman dies in the US as a complication of childbirth
• ~60% of maternal deaths deemed preventable
• Data confirm persistent racial disparities
• Obstetric emergencies cause most deaths at delivery
• Heart disease and stroke caused more than 1 in 3 deaths
• Cardiomyopathy leading cause of death 1 week to 1 year postpartum

Data from 2011-2015 national pregnancy-related death data and 2013-2017 data from maternal mortality review committees in 13 states

Death can happen up to a year after delivery.

SOURCE: CDC Vital Signs, May 2019
Maternal Mortality: A Public Health Priority

• NICHD is sponsoring a series of meetings aimed at updating the research agenda on maternal mortality

• Community Engagement Forum on Improving Maternal Health – April 8
  • Community-based and healthcare provider groups discussed community engagement strategies to improve maternal health
  • More than 400 participants, in-person and virtually
  • Facebook Live received 11,000 views within the first week following the Forum

Dr. LaQuandra Nesbitt
Director, DC Department of Health
Maternal Mortality: A Public Health Priority

• Manuscript - “Importance of Research in Reducing Maternal Morbidity and Mortality” – accepted for publication by American Journal of Obstetrics and Gynecology

• *Maternal Mortality in the United States: Future Research Directions* workshop – May 2-3
  • Goal: Develop a research agenda to address maternal mortality in the U.S.
  • Discussions included:
    • Data quality and trends
    • Disparities
    • Social determinants
    • Clinical causes

• NIH is establishing a working group with CMS to explore opportunities to use their data to address research questions

• NICHD is supporting a NASEM study on choice of birth settings, including risk factors, social determinants that influence risk, and maternal health outcomes,
  • Recommendations expected in 2020

• Upcoming workshop – co-morbid conditions (e.g., obesity, hypertension, diabetes) to be held in early 2020
Pregnancy and Lactation

• 6.3M women in the US become pregnant each year
  • >90% take medications; 70% of these are prescribed
  • 98% of medications have data insufficient to determine teratogenicity risk
  • 98% of dosing studies do not include pregnant women

• Pregnancy is complex
  • Fetus/placenta change over gestation, timing of exposure is important
  • Physiologic changes in mother due to pregnancy
  • Impact of external factors: maternal obesity, environment
  • Co-existing chronic or acute medical conditions in mother

• Concerns re: liability

• Lactation
  • 500,000 women have difficulty making milk
  • Must consider benefits of breastfeeding vs. medications
  • Limited assays for assessment of medications in breast milk
Brief Review of PRGLAC Recommendations

• Report submitted to HHS Secretary and Congress in September 2018
• Key recommendations included:
  • Change existing culture that has limited scientific knowledge of therapeutic product safety, effectiveness, and dosing for pregnant and lactating women
  • Protect pregnant women 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
• All 15 recommendations and full Task Force report are available online: https://www.nichd.nih.gov/About/Advisory/PRGLAC
Plan for PRGLAC – Phase 2

- Charter extended until March 2021
- Will hold 2 meetings of the full Task Force per year (required in legislation)
  - Charge call held on May 22, 2019
  - August 22-23, 2019
- Establish four working groups to address subsets of the recommendations and develop plans for implementation
  - Research/Training
  - Regulatory
  - Communication
  - Discovery
- Existing members divided into the four working groups
- Will add additional ad hoc members as needed to fill in missing expertise
Federal partners are included in all PRGLAC working groups

Recent FDA draft guidances

- Scientific and Ethical Considerations for Inclusion of Pregnant Women in Clinical Trials (April 2018)
- Clinical Lactation Studies: Considerations for Study Design (May 2019)

FDA Center of Excellence for Perinatal and Maternal Health (PHCE) recently established

- Funded 14 proposals from across FDA, from end-user testing to improve communications around pregnancy and lactation labeling to testing placental drug transfer using tissue chips
The NIH INCLUDE Project

• Trans-NIH initiative included in FY 2018 budget legislation
• Purpose: 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
• Unique double benefit: understanding both Down syndrome and shared common conditions (risks or resiliencies)
The NIH INCLUDE Project

- $22.2M awarded in FY18 across NIH
- NICHD issued 4 FOAs in FY19; awards made by September
- Workshops in development
  - “Planning a Virtual Down Syndrome Cohort across Lifespan”
  - “The State of the Science for Meaningful Clinical Trials in Down syndrome”
- New NICHD project
  - Leveraging NICHD’s Pediatric Trials Network to establish infrastructure for Down syndrome clinical trials
  - Develop training programs on effective ways for practitioners to work with IDD populations
**Study Topics in DASH (*biospecimens available*)**

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

- **Centralized resource for researchers to store de-identified data and to access data and associated biospecimens from NICHD supported studies**
- **Can help investigators meet NIH’s data sharing requirements for their own studies**
- **Data sharing launched in August 2015; biospecimen request launched in March 2019**
- **Governed by the NICHD DASH Committee**
- **Aims to accelerate scientific findings to ultimately improve human health**

Questions? Contact supportdash@mail.nih.gov

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

**DASH**

Data and Specimen Hub

https://dash.nichd.nih.gov

134 Studies

35 Study Topics

141 Data Requests

15 Data Use Publications

8 Studies Offering Biospecimens

Last Updated 05/31/2019
Study Topics with Biospecimens in DASH

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
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<tbody>
<tr>
<td>HIV/AIDS</td>
<td>Preterm Labor &amp; Birth</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>More to come!</td>
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</tbody>
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|                     | [Genomic and Proteomic Network for Preterm Birth Research (GPN)]
|                     | Expression profiling, GWAS case control, and longitudinal cohort studies |
| NICHD International Site Development Initiative (NISDI) | 4 studies of pregnant women with HIV, their infants with and exposed to HIV, and children with and exposed to HIV in Latin American Countries |
| Mothers and Infants Cohort Study (MICS) | Study of perinatal transmission of HIV and developmental outcomes of children with HIV |

Biospecimens Currently Available

- Amniotic Fluid
- Blood
- Breastmilk
- DNA/RNA/Proteins
- Saliva
- Serum Plasma
- Tissue Samples
- Urine
- Vaginal Fluid

New DASH Function:
Managing Requests for NICHD Biospecimens

Questions? Contact supportdash@mail.nih.gov
For NICHD studies not archived in DASH, visit: https://dash.nichd.nih.gov/Resource/LinksToOtherArchives

Studies Offering Biospecimens: 8

Last Updated 04/30/2019
**Maternal and Neonatal Outcomes of Induction of Labor Compared with Planned Cesarean Delivery in Women with Preeclampsia at 34 Weeks’ Gestation or Longer**

Tetsuya Kanokita, MD1, Katherine Bowen, PhD1

1. Department of Obstetrics and Gynecology, University of Washington, Seattle, Washington, USA

Abstract: Objective: We examined the impact of gestational weight gain and pregestational body mass index on the prevalence of large-for-gestational-age infants in two cohorts of women with type 1 insulin-dependent diabetes: a cross-sectional population study.

Keywords: Diabetes, Gestational Weight Gain, Prepregnancy Body Mass Index, Large for Gestational Age, Insulin-Dependent Diabetes Mellitus

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**Open Access**

**BMJ Open**

Impact of gestational weight gain and prepregnancy body mass index on the prevalence of large-for-gestational-age infants in two cohorts of women with type 1 insulin-dependent diabetes: a cross-sectional population study

Kotred I, McWhirter,1,2,3 Katherine Bowen,4 Lawrence M Dones,1 Panay Deka,1 Chandan J. Laxhia,2,4,5 Jane C. Khwaya,5

1. Department of Obstetrics and Gynecology, University of Washington, Seattle, Washington, USA

Abstract: Objective: Despite improvements in maternal outcomes, large-for-gestational-age (LGA) prevalence remains high in women with type 1 insulin-dependent diabetes mellitus (T1DM). Our objective was to examine the association between gestational weight gain (GWG) and prepregnancy body mass index (BMI) with LGA among women with T1DM.

Design: Cross-sectional study.

Setting: Regional data in Canada, the United States, and Europe from the Diabetes in Pregnancy Program (DIPP), a prospective cohort for the period 1997–2011, national data from one center in Spain, and one in the United Kingdom.

Participants: 1,247 women were included.

Results: Overweight women had a higher prevalence of LGA infants compared with normal weight women (28.8% vs 14.3%, P < .001) and women with prepregnancy BMI > 35 kg/m² had a higher prevalence of LGA infants compared with those with BMI < 25 kg/m² (18.9% vs 10.6%, P = .002).

Nonmedically Indicated Induction of Labor Compared with Expectant Management in Nulliparous Women Aged 35 Years or Older

Tetsuya Kanokita, MD1, Katherine Bowen, PhD1

1. Department of Obstetrics and Gynecology, University of Washington, Seattle, Washington, USA

Abstract: Objective: This study examined the relationship between gestational weight gain and prepregnancy body mass index on the prevalence of large-for-gestational-age infants in two cohorts of women with type 1 insulin-dependent diabetes: a cross-sectional population study.

Keywords: Diabetes, Gestational Weight Gain, Prepregnancy Body Mass Index, Large for Gestational Age, Insulin-Dependent Diabetes Mellitus

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**Original Article**

Racial and social predictors of longitudinal cervical measures: the Cervical Ultrasound Study

From Handel’s H Miller and A Khayat

OBJECTIVES: To evaluate whether the racial and socioeconomic disparities we present in cervical cervical measurements and if such disparities can be explained by social environment at birth.

Study Design: This was a cohort study conducted in the United States, with data collected from 1998 to 2003. The study population consisted of 1,000 women, and cervical measurements were taken at birth, age 17 years, and age 29 years. The study was conducted in two sites: a rural site in Alabama and a urban site in California.

Results: The cervical measurements were similar between rural and urban populations. Cervical length and width decreased from birth to age 17 years, followed by an increase from age 17 to 29 years. The cervical measurements were similar between rural and urban populations. Cervical length and width decreased from birth to age 17 years, followed by an increase from age 17 to 29 years.

Keywords: Cervical length, Cervical width, Cervical shape, Cervical maturation, Racial and social disparities.
Institute and Center Leadership at NIH
New Director for National Institute on Deafness and Other Communication Disorders (NIDCD)

- Debara L. Tucci, M.D., M.S., M.B.A., is expected to join NIDCD in September 2019
- Dr. Tucci comes to NIH from the Division of Head and Neck Surgery & Communication Sciences at Duke University
- 10 of 27 IC Directors are now women
NIH ICs and Directors

National Cancer Institute – Doug Lowy (Acting)
National Eye Institute – Paul Sieving
National Heart, Lung, and Blood Institute – Gary Gibbons
National Human Genome Research Institute – Eric Green
National Institute on Aging – Richard Hodes
National Institute on Alcohol Abuse and Alcoholism – George Koob
National Institute of Allergy and Infectious Diseases – Tony Fauci
National Institute of Arthritis and Musculoskeletal and Skin Diseases – Bob Carter (Acting)**
National Institute of Biomedical Imaging and Bioengineering – Bruce Tromberg
Eunice Kennedy Shriver National Institute of Child Health and Human Development – Diana Bianchi
National Institute on Deafness and Other Communication Disorders – Debara Tucci
National Institute of Dental and Craniofacial Research – Martha Somerman
National Institute of Diabetes and Digestive and Kidney Diseases – Griffin Rodgers

National Institute on Drug Abuse – Nora Volkow
National Institute of Environmental Health Sciences – Linda Birnbaum
National Institute of General Medical Sciences – Jon Lorsch
National Institute of Mental Health – Josh Gordon
National Institute on Minority Health and Health Disparities – Eliseo Perez-Stable
National Institute of Neurological Disorders and Stroke – Walter Koroshetz
National Institute of Nursing Research – Ann Cashion (Acting)**
National Library of Medicine – Patricia Brennan
National Institutes of Health Clinical Center – James Gilman
Center for Information Technology – Andrea Norris
Center for Scientific Review – Noni Byrnes
Fogarty International Center – Roger Glass
National Center for Advancing Translational Sciences – Christopher Austin
National Center for Complementary and Integrative Health – Helene Langevin
We are Hiring!

- Executive Officer – final stages of hiring process
- Deputy Director – interviews concluded
- Extramural Branch Chief Positions: Pregnancy and Perinatology, Child Development and Behavior
- Medical and Program Officers in Division of Extramural Research
Thank You and Questions