NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development

DASH Data and Specimen Hub

NICHD Home

DASH Quarterly Update

March 2021

New! Annotation and Representation of Study Variables

The annotation and representation of study variables in DASH will help users to explore dataset content by reviewing variable-level metadata (such as variable descriptions, units, and coded values) and associated statistics directly from the Dataset Explorer. This feature is available for datasets from the National Children's Study (NCS) and Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b) studies in DASH.

To view a listing of all datasets for a particular study, select the **Study Name** from the following list:

- National Children's Study (NCS)
- Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b)

This feature will soon be available for the Maternal-Fetal Medicine Units (MFMU) Network studies in DASH.

New Studies Available in DASH

We are pleased to share the latest study additions in DASH. These new studies cover 49 research topics including Infant Care and Health, Infant Mortality, Pharmacology, Pediatric Injury, Child Health, and Traumatic Brain Injury. To learn more about a recently submitted study, select the title of a **Study Name** in the following list:

1. **Human Microbiome Study-ESTEEM (HMS-ESTEEM)**

   Study Description: The overarching aim of the HMS-ESTEEM study was to describe the role that the urinary microbiome plays in disorders of the lower genitourinary system, namely, the female genitourinary microbiome. The primary aim of the study evaluated whether the urinary microbiome differs between women with mixed urinary incontinence (MUI) and unaffected controls. There were 212 women (128 affected and 84 controls) who participated in the study and had catheterized urine specimens, vaginal specimens sent for culture, and DNA analysis. From the catheterized urine samples obtained, v4–6 regions of the 16S rRNA gene were sequenced to identify bacteria. Women with MUI and controls did not differ in overall Lactobacillus predominance. In younger women, urinary bacterial community-types differentiated MUI from controls.

   NICHD Division/Branch/Center: DER - Gynecologic Health and Disease Branch (GHDB)

2. **Baclofen Efficacy and Safety Trials - A Multi-center Retrospective Chart Review of the Pediatric Population Using Oral Baclofen to Manage the Spasticity of Cerebral Palsy (BPCA BEST-CHART)**

   Study Description: This was a multi-center retrospective chart review of pediatric subjects started on oral baclofen as treatment for spasticity of cerebral palsy (CP). Primary objectives included describing the characteristics of this population and the safety, effectiveness, and treatment course of oral baclofen. Subjects at seven sites with eligible charts were screened to identify 185 subjects who had started on oral baclofen. All 185 subjects had a full chart review and were included in the safety population; and all 185 subjects had documentation in their chart of both a baseline and post-baseline report of effectiveness (Movement/Tone Abnormality assessments), and were included in the efficacy

population. Oral baclofen was used to manage spasticity of CP in pediatric subjects who mainly had 4 limb involvement, were on either none or one additional tone medication, and had low gross motor function and manual ability. As shown by the safety analysis, oral baclofen was safe and well tolerated in subjects with severe CP.

NICHD Division/Branch/Center: DER - Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)

3. **The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)**
   Study Description: This 2x2 factorial designed randomized clinical trial compared the use of continuous positive airway pressure initiated at birth to the administration of surfactant within 1 hour of birth for premature infants born at 24 to 27 weeks gestation. In addition, these infants within 2 hours of birth, had a special pulse oximeter placed to continuously monitor their oxygen saturation in two different target ranges (85-89% or 91-95%). This study helped determine whether or not these two management strategies affect survival without bronchopulmonary dysplasia (also called chronic lung disease) and survival without severe retinopathy of prematurity (an eye disorder that can lead to blindness).

   NICHD Division/Branch/Center: DER - Pregnancy and Perinatology Branch (PPB)

4. **Antibiotic Safety in Infants with Complicated Intra-Abdominal Infections – Clindamycin (BPCA ABS01-Clindamycin)**
   Study Description: NICHD-2013-ABS01 was a prospective, open-label, partially randomized, multicenter trial. The primary objective of this study was to evaluate the safety of drug regimens consisting of ampicillin, metronidazole, clindamycin, piperacillin-tazobactam, and gentamycin in assigned or standard of care groups of infants with complicated intra-abdominal infections. Secondary objectives included evaluations of efficacy and population pharmacokinetics (PK). Results demonstrate that clindamycin therapy at the protocol-specified doses was safe for premature infants with complicated intra-abdominal infections. Only one adverse event was attributed to the study drug, and mortality within 30 days post-treatment was 7% in the cohort receiving the ampicillin, gentamycin, and clindamycin drug regimen (Group 2). None of the outcomes of special interest were attributable to clindamycin. Therapeutic success was achieved in 87% of participants. Collected PK data validated the protocol-specified dosing regimen.

   NICHD Division/Branch/Center: DER - Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)

Studies Offering Biospecimens in DASH

Biospecimens from nine DASH studies, spanning HIV/AIDS, Child Health, Women's Health, Pregnancy, Preterm Labor and Birth, and Breastfeeding are available for request. Over 350,000 samples are available from 51 sample types for request through DASH. More biospecimen collections will be added in the future. Explore available samples, by selecting the **Study Name** in this list of studies offering biospecimens through DASH:

1. National Children's Study (NCS): Biospecimens and environmental samples are available only for a limited time!
2. Genomic and Proteomic Network for Preterm Birth Research Expression Profiling Study (GPN-PBR EP)
3. Genomic and Proteomic Network for Preterm Birth Research GWAS Case Control Study (GPN-PBR CC)
4. Genomic and Proteomic Network for Preterm Birth Research Longitudinal Cohort Study (GPN-PBR LS)
5. Prospective Study of Perinatal Transmission of HIV Infection and Developmental Outcome of Children Infected with HIV: Mothers and Infants Cohort Study (MICS)
6. A Prospective, Observational Study of HIV-Infected Pregnant Women and HIV-Exposed, Uninfected Children at Clinical Sites in Latin American Countries (NISDI LILAC)

7. A Prospective, Observational Study of HIV-Infected Pregnant Women and Their Infants at Clinical Sites in Latin American and Caribbean Countries (NISDI Perinatal)
8. A Prospective, Observational Study of HIV-Exposed and HIV-Infected Children at Clinical Sites in Latin American and Caribbean Countries (NISDI Pediatric)
9. NISDI Pediatric Latin American Countries Epidemiological Study: A Prospective, Observational Study of HIV-infected Children at Clinical Sites in Latin American Countries (NISDI PLACES)

Top 20 Sample Types

- Blood (13,080)
- Cervicovaginal Fluid (5,785)
- Cord Blood (8,838)
- Cord Buffy Coat and RBC (3,796)
- Cord Dried Blood Spot (4,173)
- Cord Plasma (21,563)
- Cord Serum (922)
- Dried Blood Spot (3,812)
- Environmental Samples (2,980: air filters, dust wipes, infant formula, vacuum dust, and water)
- Hair (802)
- Lymphocyte (18,614)
- Neonatal Saliva (1,380)
- PBMC (28,830)
- Placenta (2,397)
- Plasma (119,052)
- Saliva (6,248)
- Serum (53,613)
- Tissue (1,461)
- Urine (53,408)
- Vaginal Fluid (4,189)

Noteworthy News

Publications Resulting from Data Reuse

Since the launch of DASH in August 2015, there have been 47 peer reviewed publications resulting from DASH data reuse – with an average time of 1.8 years to publish. View a listing of Publications from DASH Data Reuse to browse the outcomes of investigator's research.

DASH Data/Biospecimen Use Acknowledgments

As a reminder, NICHD requires all investigators who access research data and biospecimens from NICHD DASH to acknowledge the contributing investigator(s) who conducted the original study, the funding organization(s) that supported the original study, and NICHD DASH in all resulting oral or written presentations, disclosures, or publications of the analyses. Specific guidance for acknowledgement text is provided during the data and/or biospecimen request process.

Recommendations for Common Data Elements for COVID-19 Studies, Including Pregnant Participants

In early 2020, NICHD invited representatives from NIH-funded pregnancy cohort studies to collaborate on recommended sets of CDEs for use across studies that explore COVID-19 in reproductive-age, pregnant, and postpartum women and their neonates. CDEs are a key data-harmonization strategy for accelerating research and investigating outcomes for which individual studies may be underpowered. Through a modified Delphi approach. NICHD-led working groups prioritized an inventory of 425 biomedical and psychosocial CDEs down to 64 CDEs across 13 domains. These recommended (and, when possible, validated) CDEs are now available to researchers who are collecting or planning to collect data on the impact of COVID-19 in pregnant and postpartum women and their infants. Visit the NIH Public Health Emergency and Disaster Research Response (DR2) webpage to see more information about this CDE Collection (currently item 9 on the page).

NICHD Funding Opportunities

NOT-HD-20-022 Notice of Special Interest: Small Grants for Secondary Analyses of Existing Data Sets and Stored Biospecimens

PAR-20-064 Archiving and Documenting Child Health and Human Development Data Sets (R03 Clinical Trial Not Allowed)

Final NIH Policy for Data Management and Sharing (effective January 25, 2023)

NOT-OD-21-013 Final NIH Policy for Data Management and Sharing

NOT-OD-21-014 Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan

NOT-OD-21-015 Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing

NOT-OD-21-016 Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research

Visit the NICHD Grants and Contracts page to view other active FOAs issued by NICHD.