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

DASH Data and Specimen Hub

March 2022

DASH Quarterly eUpdate

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DASH Updates

Upcoming Feature: DASH Codebook

DASH will soon begin collecting a DASH Codebook from data submitters as part of their study submission. The DASH Codebook is a data dictionary that captures information about datasets, variables, and coded values, for all data submitted for a given study. The Codebook will facilitate data submission, sharing, and data reuse processes in DASH. This Codebook also enables visualization of annotated variables and associated statistics in DASH, which facilitates search and discovery, as described in the following section.

The Codebook Template and associated User Guide will soon be available for download from the Submission Resources page in DASH. Please be on the lookout for more information on training sessions that DASH will be offering to assist investigators with preparing the DASH Codebook.

Annotation and Representation of Study Variables

The annotation and representation of study variables in DASH helps 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 currently available for datasets from certain studies in DASH. On the Datasets Search Results page, select any dataset title to access the Dataset Overview page with variable-level information (if any). This feature is currently available for datasets from 12 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)
- Consortium on Safe Labor (CSL)
- Antenatal Late Preterm Steroids: A Randomized Placebo Controlled Trial (MFMU ALPS)
- Clinical Trial of Low-Dose Aspirin (60 mg) as a Preventive of Preeclampsia (MFMU LRA)
- Clinical Trial of Low-Dose Aspirin to Prevent Preeclampsia in High Risk Women (MFMU HRA)
- Mid-Trimester Endovaginal Sonography in Women at High Risk for Spontaneous Preterm Delivery (MFMU CRVUS)
- Obstetrical Determinants of Neonatal Survival (MFMU ODNS)
- Screening for Risk Factors for Spontaneous Preterm Delivery (MFMU PREDS)
- Extremely Low Birth Weight (ELBW) Infants Exposed to Furosemide or Bumetanide in the Neonatal Intensive Care Unit (BPCA DPD01)
- Pharmacokinetics of Diazepam in Children with Status Epilepticus (BPCA DZP01)
- Safety of Fluconazole Prophylaxis in Infants (BPCA Fluc Safety)

New Studies Available in DASH

We are pleased to share the latest study additions in DASH, for a total of 193 studies in DASH. These 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:

- Parent Provider Alliance (PPA) from Pediatric Trauma and Critical Illness Branch (PTCIB)

  Study Description: Parents whose children die in pediatric intensive care units (PICUs) are at high risk for adverse health outcomes. The Collaborative Pediatric Critical Care Research Network (CPCCRN) previously demonstrated a high prevalence of complicated grief among parents whose children died in PICUs. Therapeutic alliance is the collaborative bond that develops between patients/families and their healthcare providers. The strength of therapeutic alliance has been shown to affect treatment outcomes for many conditions. What is not known is the extent to which therapeutic alliance can reduce complicated grief and other adverse health outcomes among parents after a child’s death in a PICU. During this multi-site longitudinal study, parents with a child that died in the PICU were surveyed at 6 and 13 months. The study found that among parents bereaved in the PICU, therapeutic alliance with physicians was moderately high. The study also found that mental health symptoms declined over time; however, symptoms persisted for many.
- Inhaled Nitric Oxide for Preterm Infants With Severe Respiratory Failure (Preemie iNO) from Pregnancy and Perinatology Branch (PPB)

Study Description: This was a multicenter, randomized, blinded, controlled trial to determine whether inhaled nitric oxide (iNO) reduced the rate of death or bronchopulmonary dysplasia (BPD) in infants. The study included 420 neonates, born at less than 34 weeks of gestation, with a birth weight of 401-1500 grams, and with respiratory failure more than 4 hours after treatment with surfactant to receive placebo (simulated flow) or iNO (5 to 10 ppm). Infants with a response (an increase in the partial pressure of arterial oxygen of more than 10 mm Hg) were weaned. The rate of death or BPD was 80% in the iNO group, as compared with 82% in the placebo group, and the rate of BPD was 60% versus 68%. In conclusion, use of iNO in critically ill premature infants weighing less than 1500 grams does not decrease the rates of death or BPD. Outcomes of surviving infants were assessed at 18 to 22 months corrected age; iNO did not reduce death or neurodevelopmental impairment or improve neurodevelopmental outcomes.

- Improving Reproductive Fitness Through Pretreatment With Lifestyle Modification in Obese Women With Unexplained Infertility (FIT-PLESE) from Fertility and Infertility Branch (FIB)

  Study Description: A two-arm, multicenter, prospective, randomized clinical trial of a lifestyle modification program that tracked increased physical activity and weight loss (intensive) compared with a recommendation to track of increased physical activity alone with weight maintenance (standard) in women with obesity and unexplained infertility. This 16-week period of lifestyle modification was followed by an open label empiric infertility treatment regimen consisting of three cycles of ovarian stimulation with oral medication (clomiphene citrate (CC)), triggering of ovulation with human chorionic gonadotropin (hCG), and intrauterine insemination (IUI). The goal for both treatment groups was to maintain levels of physical activity and weight achieved during the pretreatment phase during the empiric infertility treatment phase. The primary outcome of this study was a good birth outcome which was defined as singleton or twin infant(s) born at ≥ 37 weeks between 2500 and 4000g without a major congenital anomaly.
- Translating an Adult Ventilator Computer Protocol to Pediatric Critical Care (Vent CDS R21) from Pediatric Trauma and Critical Illness Branch (PTCIB)

  Study Description: The purpose of this study was to evaluate a strategy for ventilator management (ventilator management protocol) that was developed in adult intensive care units for patients with Acute Lung Injury (ALI) or Acute Respiratory Distress Syndrome (ARDS). The goal was to investigate the changes related to the size and scale of usual ventilator management practices and to determine acceptability of recommendations from a computer protocol for ventilator management. Results found that ventilator management varies substantially in children with acute respiratory distress syndrome. Analysis also showed that although acceptance rates for a computer protocol were good, there was little consensus regarding the size/scale of ventilator setting changes for children with pediatric acute respiratory distress syndrome.
- Innovative Approaches for Minor Consent: Consent 2.0 (ATN 150) from Maternal and Pediatric Infectious Disease Branch (MPIDB)

  Study Description: ATN 150 examined how parental involvement in the consent process affects the acceptability of hypothetical participation in biomedical HIV prevention trials from the perspectives of minor adolescents and parents. The quasi-experimental design involved a simulated consent process for two HIV prevention trials to assess minors' willingness to participate (WTP) in such trials with varying degrees of parental involvement. The three

consent conditions were minor self-consent, adult permission required, and parental permission required. Adolescents were randomized to one of these three consent conditions. Parents underwent a similar simulated consent process and rated the acceptability of all three consent conditions. No effect of consent condition on adolescent WTP in biomedical HIV prevention trials was found. There were significant differences in the acceptability of the consent conditions from the perspectives of parents with parental permission required most acceptable.

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:

- National Children's Study (NCS) biospecimens and environmental samples: Available for a limited time only!
- Genomic and Proteomic Network for Preterm Birth Research Expression Profiling Study (GPN-PBR EP) biospecimens
- Genomic and Proteomic Network for Preterm Birth Research GWAS Case Control Study (GPN-PBR CC) biospecimens
- Genomic and Proteomic Network for Preterm Birth Research Longitudinal Cohort Study (GPN-PBR LS) biospecimens
- Prospective Study of Perinatal Transmission of HIV Infection and Developmental Outcome of Children Infected with HIV: Mothers and Infants Cohort Study (MICS) biospecimens
- A Prospective, Observational Study of HIV-Infected Pregnant Women and HIV-Exposed, Uninfected Children at Clinical Sites in Latin American Countries (NISDI LILAC) biospecimens
- A Prospective, Observational Study of HIV-Infected Pregnant Women and Their Infants at Clinical Sites in Latin American and Caribbean Countries (NISDI Perinatal) biospecimens
- A Prospective, Observational Study of HIV-Exposed and HIV-Infected Children at Clinical Sites in Latin American and Caribbean Countries (NISDI Pediatric) biospecimens
- NISDI Pediatric Latin American Countries Epidemiological Study: A Prospective, Observational Study of HIV-infected Children at Clinical Sites in Latin American Countries (NISDI PLACES) biospecimens

Publications Resulting from Data Reuse

Since the launch of DASH in August 2015, there have been 63 peer reviewed publications resulting from DASH data reuse – with an average time of 1.7 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.

NIH Data Science and Sharing News

NIH Data Sharing and Reuse Seminar Series – March 2022 Seminar

The NIH Office of Data Science Strategy hosts a seminar series to highlight exemplars of data sharing and reuse on the second Friday of each month at noon Eastern time. The monthly series highlights researchers who have taken existing data and found clever ways to reuse the data or generate new findings. A different NIH institute or center (IC) will also share its data science activities each month. The seminar is open to the public and registration is required each month. View series topics and register for the next seminar

Carole Goble, CBE FREng FBCS CITP and Frederik Coppens, Ph.D. will present "RDMkit, a Research Data Management Toolkit Built by the Community for the Community" at the monthly Data Sharing and Reuse Seminar on March 11 at 12:00 PM EST. Learn more and register for the March Data Sharing and Reuse Seminar.

Meet the 2021 DATA Scholars

The NIH Office of Data Science Strategy hosts a cohort of Data and Technology Advancement (DATA) National Service Scholars. These talented professionals are working on high-impact data and technology projects across the NIH, advancing the landscape of biomedical data science. Learn more about the 2021 DATA Scholars.

New Resources for Implementing the NIH Policy for Data Management and Sharing

NIH continues to work with the research community to ensure we address resource needs associated with the NIH Data Management and Sharing (DMS) Policy. NIH has released a new set of FAQs and are seeking public comment on a new resource for researchers that promotes responsible management and sharing of American Indian/Alaska Native (AI/AN) participant data.

To learn more about the NIH approach to implementing the DMS Policy and next steps, please see the latest “Under the Poliscope” blog post by Dr. Lyric Jorgenson: Gearing Up for 2023: Implementing the NIH Data Management and Sharing Policy.

Feedback Sought on the NIH-Wide Strategic Plan Framework for Diversity, Equity, Inclusion, and Accessibility (DEIA)

NIH strongly believes that an inclusive and diverse pool of highly talented individuals is key for the country to remain a global leader in scientific discovery and innovation. This means actively considering factors that address DEIA principles and appropriately embed them within NIH and the wider scientific community. Embracing this DEIA vision will enhance NIH’s ability to drive biomedical innovation and serve an increasingly diverse U.S. population.

Your input on the framework as the plan is developed is encouraged. Feedback will help NIH ensure that DEIA principles continue to be embraced and integrated across NIH going forward. Learn more about the NIH-wide Strategic Plan Framework for DEIA and how to provide your feedback.

NICHD and NIH Events, Funding Opportunities, Notices

Upcoming Events

03-16-2022 Decoded: Winners from the NICHD Decoding Maternal Morbidity Data Challenge
05-02-2022 National Advisory Board on Medical Rehabilitation Research (NABMRR)

Funding Opportunities and Notices

To learn more about a funding opportunity or notice, select the **Name** in the following list. All active Funding Opportunity Announcements issued by NICHD can be found on the NICHD Grants and Contracts page.

- NOT-OD-22-065 Notice of Special Interest (NOSI): Administrative Supplements for Advancing the Ethical Development and Use of AI/ML in Biomedical and Behavioral Sciences
- NOT-OD-22-067 NOSI: Administrative Supplements to Support Collaborations to Improve the AI/ML-Readiness of NIH-Supported Data
- NOT-OD-22-068 NOSI: Administrative Supplements to Support Enhancement of Software Tools for Open Science
- NOT-OD-22-069 NOSI: Support for existing data repositories to align with FAIR and TRUST principles and evaluate usage, utility, and impact
- NOT-OD-22-064 Request for Public Comments on DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/ Alaska Native Participant Data
- NOT-HD-20-022 NOSI: 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)

To learn more about a policy, select the **Policy Name** in the following list of NIH Data Management and Sharing policies.

- 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