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

DASH Data and Specimen Hub

December 2024

DASH Quarterly eUpdate

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DASH Updates

Studies Available in DASH

There are 237 studies archived in DASH covering 62 research topics, including Pregnancy, Infant Care and Health, Infant Mortality, Pharmacology, Pediatric Injury, Child Health, and Traumatic Brain Injury.

Recently Released Studies

- Break It Up: A study evaluating breaking up daily sedentary behavior in youth (17-CH-0130)
  Study Description: The study sought to assess whether interrupting sedentary behavior for 6 consecutive days provides sustained improvements in carbohydrate metabolism without negatively impacting executive function, attention, mood, anxiety, dietary intake, or usual physical activity. If repeatedly interrupting sitting with short activity bouts has sustained beneficial effects among children, interventions examining the frequency, duration, and intensity of such interruptions could be developed for use in the community setting. Thus, the results have the potential to provide insight into novel behavioral intervention targets in youth. This project investigated whether consecutive daily interruption of sitting behaviors improves glucose tolerance, a potential negative health consequence of sedentary behavior in children. Using a randomized parallel group design, children ages 7-11.99 years completed an assigned randomized condition of either 6 consecutive days of 3 hours of monitored sedentary activity (sitting) or 6 consecutive days of 3 hours of interrupted sitting (in which they were prompted to

walk for 3 minutes every 30 minutes). The primary outcome was insulin area under the curve during the oral glucose tolerance test on day 6 during interrupted or uninterrupted sitting. Key secondary outcomes included glucose and c-peptide area under the curve, energy intake at a buffet meal on day 6, and free-living activity assessed using actigraphy.
Release Date: September 26, 2024

- Biobehavioral Study of Recently Adopted Children (Adopted Children)
  Study Description: This 2-year cohort study evaluated how stress-related changes in the hypothalamic pituitary adrenal axis are associated with changes in linear growth, neurocognitive measures, and behavioral measures in adopted children. Children adopted from Eastern Europe and Russia and controls (non-adopted children) were enrolled. Compared to controls, adopted children had significant deficits in growth, cognitive, and developmental measurements that improved over time; however residual deficits remained. Family cohesiveness and expressiveness were protective influences associated with fewer behavioral problems, while family conflict and greater emphasis on rules were associated with greater risk for executive dysfunction.
  Release Date: September 30, 2024

- A Randomized Trial of Induction Versus Expectant Management (ARRIVE)
  Study Description: This study was a randomized trial of 6106 pregnant women randomized at 38 weeks gestation to either elective induction of labor at 39 weeks gestation or expectant management. The primary research question was: does elective induction of labor in nulliparous women at 39 weeks improve perinatal outcome compared with expectant management? Women in the induction group were assigned to undergo induction of labor at 39 weeks 0 days to 39 weeks 4 days. Women in the expectant management group were asked to forego elective delivery before 40 weeks 5 days and to have delivery initiated no later than 42 weeks 2 days. The primary outcome was a composite of perinatal death or severe neonatal complications. There was not a statistically significant difference in the frequency of the primary outcome between groups. There was a significantly lower frequency of cesarean delivery, the principal secondary outcome, in the induction group than in the expectant management group.
  Release Date: September 30, 2024

- A Randomized Trial of Thyroxine Therapy for Subclinical Hypothyroidism or Hypothyroxinemia Diagnosed During Pregnancy (TSH)
  Study Description: The purpose of this study was to determine whether levothyroxine treatment of women who are identified as having subclinical hypothyroidism or hypothyroxinemia during pregnancy improves cognitive function in their children. Women with a singleton pregnancy before 20 weeks' gestation were screened for subclinical hypothyroidism, defined as a thyrotropin level of 4.0 mU/L or more and normal free T4 (0.86-1.9 ng/dL), and for hypothyroxinemia, defined by normal thyrotropin level (0.08–3.99 mU/L) but low free T4 (<0.86 dL). In separate trials for the two conditions, women were randomly assigned to levothyroxine or placebo. Thyroid function was assessed monthly and levothyroxine dose adjusted to attain a normal thyrotropin or free T4, respectively, with sham adjustments for placebo. Children underwent annual developmental and behavioral testing for five years. The primary outcome was death or IQ score at age 5 (3 if the 5-year examination was missing).
  Release Date: October 14, 2024

- A Randomized Trial of 17 α-Hydroxyprogesterone Caproate for Prevention of Preterm Birth in High Risk Women (PROGESTERONE)
  Study Description: The primary objective of PROGESTERONE was to determine whether 17 alpha-hydroxyprogesterone caproate (17P) reduced the risk of preterm birth in women who had a previous early spontaneous preterm birth. Participants were enrolled at 16 to 20 weeks of gestation and randomly assigned in a 2:1 ratio to receive weekly injections of 250 mg 17P or placebo. Treatment with 17P significantly reduced the risk of delivery at less than 37 weeks of gestation. Infants of women treated with 17P had lower rates of necrotizing enterocolitis, intraventricular hemorrhage, and need for supplemental oxygen. A follow-up study of the children from the trial was conducted to determine whether there were differences in achievement of developmental milestones between treatment

groups. No significant differences were seen in health status or physical examination. Scores for Preschool Activities Inventory were within the normal range and similar between groups.
Release Date: November 27, 2024

Recently Updated Studies

- The Effect of Obesity on the Pharmacokinetics of Pantoprazole in Children and Adolescents (BPCA PAN01)
  Study Description: This was a prospective, multi-center, open-label pharmacokinetic (PK) and safety study of pantoprazole in children 6 to 17 years of age with obesity requiring treatment with an acid-modifying agent. The primary objective was to evaluate the PK of pantoprazole following administration of a single oral dose. All enrolled participants received study medication, were included in the safety population, and submitted at least one fresh plasma PK sample. The PK of pantoprazole was affected by obesity, with higher exposures observed in children and adolescents with obesity relative to historical controls without obesity. However, if weight-tiered dosing regimens are used according to the FDA label, children and adolescents with obesity may be given the same dose as peers without obesity. Pantoprazole was well-tolerated in this open-label study, with 9 adverse events (AEs) reported in 7 (17%) of the 41 safety participants during the study. Two AEs (headache and hiccups) in 2 participants (5%) were considered related to study drug. No severe AEs were reported.
  Updates: New biospecimens were added.
  Release Date: September 10, 2019
  Update Date: September 26, 2024

- Adolescent Master Protocol, PH200 (AMP)
  Study Description: The AMP study was designed to define the impact of HIV and antiretroviral therapy on pre-adolescents and adolescents with perinatally acquired HIV. Domains investigated include growth and sexual maturation; metabolic risk factors for cardiovascular disease; cardiac function; bone health; neurologic, neurodevelopment, language, hearing, and behavioral function; and adolescent gynecology and HPV infection. Biospecimens are available.
  Release Date: June 15, 2018
  Update Date: October 23, 2024

Studies Offering Biospecimens in DASH

More than 190,000 biospecimens and 29 sample types from eight studies are available for request through DASH. These collections span research topics including HIV/AIDS, Infant and Child Health, Women's Health, Pregnancy, Preterm Labor and Birth, and Breastfeeding. Additional biospecimen collections will also be added in the future. To explore available samples in DASH, select the **Study Name** in the following list of studies offering biospecimens

- 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

Additional Specimens Available: The Reproductive Medicine Network (RMN) has serum, semen, and DNA biospecimens available for request. If you are interested in obtaining biospecimens from these studies, please refer to the RMN Biospecimen Sharing Policy under the list of Descriptive Documents on the study pages:

- Pregnancy in Polycystic Ovary Syndrome II: A 25 Week Double-Blind Randomized Trial of Clomiphene Citrate and Letrozole for the Treatment of Infertility in Women with Polycystic Ovary Syndrome (PPCOS II) - serum
- Assessment of Multiple Intrauterine Gestations from Ovarian Stimulation (AMIGOS) - serum, semen, and DNA
- Males, Antioxidants, and Infertility Trial (MOXI) - serum, semen, and DNA

Publications Resulting from Data Reuse

Since the launch of DASH in August 2015, there have been 143 peer-reviewed publications resulting from DASH data reuse, with an average time of 1.6 years to publish. We encourage you to look through these publications on the Publications from DASH Data Reuse page.

Recent Publications:

- Antithrombin III supplementation during neonatal and pediatric extracorporeal membrane oxygenation
  Authors: Noy Meshulami, Robert Green, Shubhi Kaushik
  Publication Date: September 1, 2023
  DASH Study: Bleeding and Thrombosis During ECMO (BATE)
- The longitudinal association among student externalizing behavior problems, teacher-student relationships, and classroom engagement
  Authors: Leslie Hasty, Michaela Quintero, Tianyu Li, Seowon Song, Zhe Wang
  Publication Date: October 7, 2023
  DASH Study: The Impact of Grade Retention: A Developmental Approach (Project Achieve)
- Assessing lead exposure in U.S. pregnant women using biological and residential measurements
  Authors: Lindsay W. Stanek, Nicholas Grokhowsky, Barbara J. George, Kent W. Thomas
  Publication Date: December 20, 2023
  DASH Study: National Children's Study (NCS)
- Early-life digital media experiences and development of atypical sensory processing
  Authors: Karen Frankel Heffler, Binod Acharya, Keshab Subedi, David S Bennett
  Publication Date: January 9, 2024
  DASH Study: National Children's Study (NCS)
- Finger pulse plethysmography predicts gestational hypertension, preeclampsia and gestational diabetes
  Authors: Sobhan Salari Shahrbabaki, Xiao Liu, Mathias Baumert
  Publication Date: May 14, 2024
  DASH Study: Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b)
- The joint operations of teacher-student and peer relationships on classroom engagement among low-achieving elementary students: A longitudinal multilevel study.
  Authors: Tianyu Li, Zhe Wang, Gabriel Merrin, Wan, Kaiwen Bi, Michaela Quintero, Seowon Song
  Publication Date: June 1, 2024
  DASH Study: The Impact of Grade Retention: A Developmental Approach (Project Achieve)
- School belonging mediates the longitudinal effects of racial/ethnic identity on academic achievement and emotional well-being among Black and Latinx adolescents
  Authors: Seowon Song, Monica Martin, & Zhe Wang

Publication Date: June 13, 2024

DASH Data/Biospecimen Use Acknowledgments and DOI Usage

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. All DASH studies are uniquely identified with a Digital Object Identifier (DOIs), and investigators should use the DASH DOI to cite the study in any manuscripts or other published content resulting from the use of data from that study.

Specific guidance for acknowledgement text and DOI citation is provided in the following DASH resources:

- The Data Request Form obtained from DASH when processing a request online; the Data Request Form also includes any study-specific acknowledgements as specified by the data submitter.
- The respective study overview page in DASH.

Implementing the NIH Policy for Data Management & Sharing

DASH and the Data Management and Sharing Policy

The NIH Data Management and Sharing (DMS) Policy (DMS Policy) strongly encourages the use of established repositories such as DASH for sharing scientific data. DASH adheres to the desired characteristics for data sharing repositories described in Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research, including support for free and easy access, access controls for human participant data, curation and quality assurance, and security and integrity. DASH creates Digital Object Identifiers (DOIs) as unique persistent identifiers for tracking and citing all datasets shared through DASH.

Plan to Submit Your Data to DASH

The DASH Submission Resources page contains information to guide researchers developing DMS Plans as part of their grant applications or intramural clinical protocols. Researchers planning to use DASH should include DASH submission-specific milestones and timelines in their DMS Plan and should consider those milestones when developing a DMS budget. Costs associated with biospecimen sharing should not be included in DMS budgets. DMS Plan milestones include:

- Researchers who plan to share data through DASH are required to submit an Institutional Certification to verify that study data are appropriate for sharing in DASH, **within the first year of grant award.**
- **By the second year of grant award**, investigators should submit a draft DASH Codebook, which is a templated data dictionary that captures information about datasets, variables, and coded values for all data submitted for a given study.
- As soon as the **data collection protocol is complete**, researchers should submit the final DASH Codebook to DASH.
- Investigators will share **data associated with a publication** through DASH no later than the first date of electronic publication and will share all study data by the end of the award performance period. Plan to submit data to DASH 4-6 months prior to expected publication release date for a given dataset.

All researchers funded by or seeking funding from NICHD for clinical research can share clinical data in DASH and do not need a Letter of Approval to include data sharing in DASH in their Data Management and Sharing Plan.

NICHD Office of Data Science and Sharing (ODSS) Web Resources

The NICHD Office of Data Science and Sharing (ODSS) is a trusted informational resource for NICHD staff and researchers on all NIH data sharing policies. The NICHD ODSS website contains a DMS Policy Resources section for the NICHD-funded researchers developing and implementing their DMS Plans, including Tips for Writing a DMS Plan, Example DMS Plans, the NICHD Data Repository Finder to help researchers find data repositories where they can share data, and links to data repository and informed consent informational resources.

- In June 2024, NICHD ODSS released a new DMS Policy Resource Common Issues in NIH Data Management & Sharing (DMS) Plans. The DMS Policy also encourages the use of data standards to improve the usability of shared data; visit our Data Standards page for more.
- In April 2024, NICHD ODSS made a number of updates to the DMS Policy Resource section of the website, including adding tips for "secondary analysis plans" to Tips for Writing a DMS Plan and additional NICHD-relevant data standards.

NIH Resources and Guidance for the DMS Policy

NIH continues to update the Scientific Data Sharing site resource. At this site, you and your investigators can stay up to date on public-facing NIH data sharing policy-related statements, FAQs, resources (including the DMS Plan format page), news, and events, and look for training opportunities.

NIH recently published NOT-OD-24-123 and NOT-OD-24-175 to outline new requirements for Research Performance Progress Reports (RPPRs) for projects subject to the NIH DMS Policy. RPPRs must now include details about how awardees are adhering to their approved DMS Plan. NIH updated the NIH RPPR Instruction Guide (PDF 5.4 MB) with information about drafting RPPRs to meet the new DMS Plan progress requirements.

- NIH also updated the processes for requesting revisions to approved DMS Plans as described in NOT-OD-24-176. NIH encourages awardees to consult the updated information before contacting a program official with questions.

Webinars and Trainings on Implementing the NIH Data Management and Sharing Policy

NIH is hosting several webinars to provide information and training on implementing the DMS Policy.

- NICHD ODSS presented at the third Federal Demonstration Partnership (FDP) DMS Town Hall. During this Town Hall, NICHD and other NIH program officials participating in the FDP Data Management and Sharing pilot shared their observations on the first rounds of DMS plans submitted to NIH. Information was also shared on Phase 2 of the pilot, which will focus on cost principles and budgeting issues related to data sharing. Slides and recording can be found on the NIH Learning webpage.

NIH Data Sharing and Reuse Seminar Series

The NIH Office of Data Science Strategy hosted a seminar series to highlight exemplars of data sharing and reuse. The monthly series highlighted researchers who took existing data and found clever ways to reuse the data or generate new findings. A different NIH institute or center also shares its data science activities each month. Recordings of past seminars are available on the Seminar Web page.

NICHD Funding Opportunities and Notices

All active Notices of Funding Opportunities (NOFOs) issued by NICHD can be found on the NICHD Grants and Contracts page. To learn more about a funding opportunity, select the **Name of the Funding Opportunity** in the following list:

- PAR-25-109 Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data (R03 Clinical Trial Not Allowed)

- PAR-25-185 Screening and Functional Validation of Genomic Variants Associated with Human Congenital Anomalies (R01 Clinical Trial Not Allowed)
- NOT-OD-24-084 Archiving and Documenting Child Health and Human Development Data Sets (R03 Clinical Trial Not Allowed)
- NOT-OD-24-096 Notice of Special Interest (NOSI): Promoting Data Reuse for Health Research
- NOT-MH-24-115 Notice of Special Interest (NOSI): Translation of BRAIN Initiative Technologies to the Marketplace
- PAR-24-081 Omics Phenotypes Related to Down Syndrome for the INCLUDE Project (X01 Clinical Trial Not Allowed)
- NOT-DC-24-010 Notice of Special Interest (NOSI): Tackling Acquisition of Language in Kids (TALK) R01 Research Projects
- RFA-NS-24-019 HEAL Initiative: Non-addictive Analgesic Therapeutics Development [Small Molecules and Biologics] to Treat Pain (UG3/UH3 Clinical Trial Optional)
- PAR-25-092 Archiving and Documenting Child Health and Human Development Data Sets (R03 Clinical Trial Not Allowed)
- PAR-25-311 Leveraging Network Infrastructure to Advance Research for Women, Children, Pregnant and Lactating Individuals, and Persons with Disabilities (UG3/UH3 Clinical Trial Optional)

NICHD – Relevant Funding Opportunities and Notices

Additional active NOFOs relevant to NICHD are included below. To learn more about a funding opportunity, select the **Name of the Funding Opportunity** in the following list:

- RFA-OD-24-011 NIH Research Software Engineer (RSE) Award (R50 Clinical Trials Not Allowed)
- RFA-OD-24-010 Building Sustainable Software Tools for Open Science (R03 Clinical Trial Not Allowed)
- NOT-GM-24-020 Topic Areas of Interest for Joint NIH/NSF Science of Science Approach to Analyzing and Innovating the Biomedical Research Enterprise (SoS:BIO) Program
- PAR-23-237 Enhancement and Management of Established Biomedical Data Repositories and Knowledgebases (U24 Clinical Trial Not Allowed)
- NOT-OD-23-165 Notice of NIH Participation in the National Science Foundation Solicitation NSF 23-614: Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science
- NOT-OD-23-166 Notice of Special Interest in Research on Family Support and Rejection in the Health and Well-Being of SGM Populations
- PAR-23-132 NIDCR Small Research Grants for Analyses of Existing Genomics Data (R03 Clinical Trial Not Allowed)
- PAR-23-133 NIDCR Research Grants for Analyses of Existing Genomics Data (R01 Clinical Trial Not Allowed)
- NOT-OD-23-068 Notice of Special Interest (NOSI): Revision Applications to add a Curation and Informatics Component to existing Animal and Biological Material Resource Centers (P40) (Clinical Trials Not Allowed)
- NOT-LM-23-001 Notice of Special Interest (NOSI): Computational and Statistical Methods to Enhance Discovery from Health Data
- NOT-CA-23-026 Notice to Correct and Clarify Eligibility Requirements in PAR-21-306, NCI Research Specialist (Clinical Scientist) Award (R50 Clinical Trial Not Allowed)
- NOT-GM-23-015 Notice of Special Interest (NOSI): Optimization of Data Storage and Utilization for the Sequence Read Archive (SRA)

Previous issues of the DASH Quarterly eUpdate are available on the NICHD ODSS Website in the NICHD Data and Specimen Hub (DASH) section.

Questions? Please contact the DASH Administrator at SupportDASH@mail.nih.gov.

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