



March 2024

DASH Quarterly eUpdate

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DASH Updates

Studies Available in DASH

There are 227 studies archived in DASH covering 60 research topics including Pregnancy, Infant Care and Health, Infant Mortality, Pharmacology, Pediatric Injury, Child Health, and Traumatic Brain Injury.

Recently Released Studies

APEX Registry: Assessment of Perinatal Excellence (APEX)

Study Description: The Assessment of Perinatal EXcellence (APEX) study is an observational study designed to assist in the development of quality measures for intrapartum care. The specific aim was to assess whether and to what extent hospital differences in the frequency of adverse obstetric outcomes are related to patient and hospital characteristics and to types of care provided. Data were collected on eligible patients if they delivered during the 24-hour period of selected days during a 3-year period. Days were chosen via computer-generated random selection and stratified by weekdays, weekends, and holidays. On selected days, the labor and delivery logbook at each center was screened to identify eligible women. The medical records of all eligible women and their newborns were abstracted by trained research personnel at the hospital and entered into a web-based data entry system. Maternal data were collected until discharge and neonatal data were collected until discharge or 120 days of age, whichever came first.

Release Date: March 22, 2024

• <u>Long-term Effectiveness of Abdominal Sacrocolpopexy for the Treatment of Pelvic Organ Prolapse:</u>
The Extended Colpopexy and Urinary Reduction Efforts (E-CARE) Study (E-CARE)

Study Description: This study extended follow-up of eligible women enrolled in the CARE (Colpopexy and Urinary Reduction Effort) trial, a two year randomized trial designed to assess whether a Burch colposuspension, when added to a planned sacrocolpopexy for the treatment of prolapse, improves the rate of urinary stress continence in subjects without pre-operative symptoms of stress urinary incontinence. Participants were followed for up to 10 years from the time of their initial surgery completed during the CARE trial. The trial concluded that during 7 years of long-term follow-up, abdominal sacrocolpopexy failure rates increased in both groups. Urethropexy prevented stress urinary incontinence longer than no urethropexy. Researchers concluded that abdominal sacrocolpopexy effectiveness should be balanced with long-term risks of mesh or suture erosion.

Release Date: February 12, 2024

Studies Offering Biospecimens in DASH

Over 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:

- <u>Genomic and Proteomic Network for Preterm Birth Research Expression Profiling Study (GPN-PBR EP) biospecimens</u>
- 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
- <u>A Prospective, Observational Study of HIV-Exposed and HIV-Infected Children at Clinical Sites in Latin</u> 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/or 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 116 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:

 Causal Effects of Competing Obstetrical Interventions: Mediators of Placental Abruption and Perinatal Mortality (Manuscript not yet published)

Authors: Cande V. Ananth, and WenWei Loh

Publication Date: February 27, 2024

DASH Study: Consortium on Safe Labor (CSL)

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)

• The effect of 12-month postoperative weight change on outcomes following midurethral sling for stress urinary incontinence: a secondary analysis of the ESTEEM and TOMUS randomized trials.

Authors: Getaneh Feven, Ringel Nancy, Kolm Paul, Iglesia Cheryl, Dieter Alexis

Publication Date: September 26, 2023

DASH Study: Effects of Surgical Treatment Enhanced with Exercise for Mixed Urinary Incontinence (ESTEEM)

• 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)

• Follicular phase length is not related to live birth outcome in women with unexplained infertility undergoing ovarian stimulation with intrauterine insemination cycles in a multicenter trial

Authors: Pardis Hosseinzadeh, Jennifer D. Peck, Heather R. Burks, Irene Souter, Angela Xing, LaTasha B. Craig, Michael P. Diamond and Karl R. Hansen

Publication Date: August 8, 2023

DASH Study: Assessment of Multiple Intrauterine Gestations from Ovarian Stimulation (AMIGOS)

 Predicting the risk of gestational diabetes using clinical data with machine learning: a predictive model study

Authors: Adesh Kadambi, Isabel Fulcher, Kartik Venkatesh, Jonathan S Schor, Mark A Clapp, Timothy

Wen

Publication Date: July 5, 2023

DASH Study: Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b)

Anti-Xa testing for pediatric and neonatal patients on extracorporeal membrane oxygenation.

Authors: Nov Meshulami, Robert Green, Shubhi Kaushik

Publication Date: June 1, 2023

DASH Study: Bleeding and Thrombosis During ECMO (BATE)

Association between obesity and fecundity in patients undergoing intrauterine insemination

Authors: LaTasha B. Craig, Christen L. Jarshaw, Karl R. Hansen, and Jennifer D. Peck

Publication Date: May 20, 2023

DASH Study: Assessment of Multiple Intrauterine Gestations from Ovarian Stimulation (AMIGOS)

• Small babies, big risks: global estimates of prevalence and mortality for vulnerable newborns to accelerate change and improve counting

Authors: Lawn JE, Ohuma EO, Bradley E, Idueta LS, Hazel E, Okwaraji YB, Erchick DJ, Yargawa J, Katz J, Lee ACC, Diaz M, Salasibew M, Requejo J, Hayashi C, Moller AB, Borghi E, Black RE,

Blencowe H.

Publication Date: May 8, 2023

DASH Study: Preconception Maternal Nutrition Trial Women First (Enrollment to 24 Months After Birth)

(Women First)

• <u>Vulnerable newborn types: analysis of subnational, population-based birth cohorts for 541 285 live births in 23 countries, 2000–2021</u>

Authors: Erchick DJ, Hazel EA, Katz J, Lee ACC, Diaz M, et al.

Publication Date: April 7, 2023

DASH Study: Preconception Maternal Nutrition Trial Women First (Enrollment to 24 Months After Birth)

(Women First)

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 (DOI) 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

DASH is a key resource for many NICHD extramural and intramural researchers to comply with the new NIH Data Management and Sharing (DMS) Policy (DMS Policy), which went into effect on January 25, 2023. The final 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

All researchers funded by or seeking funding from NICHD for clinical and population health research can share data in DASH. Researchers seeking funding from another NIH Institute or Center in a research area relevant to the NICHD mission may also be able to share data through DASH. You may Contact SupportDASH@mail.nih.gov with a request to obtain a Letter of Approval for sharing your study data in DASH.

The new DASH <u>Submission Resources</u> page contains information to guide researchers developing Data Management and Sharing 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 <u>Institutional Certification</u> 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 <u>NICHD ODSS website</u> contains a Data Management and Sharing (DMS) Policy Resources section for the NICHD researchers developing and implementing their DMS Plans, including <u>Tips for Writing a DMS Plan</u>, <u>Example DMS Plans</u>, the <u>NICHD Data Repository Finder</u> to help researchers find data repositories where they can share data, and informed consent informational resources.

Check out the new <u>Data Standards page that describes common data standards that may be relevant</u>
 to NICHD research and how adopting them can improve data usability and interoperability throughout
 the data lifecycle!

NIH Resources and Guidance for the DMS Policy

NIH continues to update their <u>Scientific Data Sharing</u> 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.

OER announced that instructions and processes for extramural researchers to budget DMS costs will change on October 5, 2023. See: <u>NIH Application Instruction Updates – Data Management and Sharing (DMS) Costs (NOT-OD-23-161)</u>

Additionally, researchers can use the following NIH-wide resources to identify data repositories for sharing their data:

- NIH Repositories for Sharing Scientific Data: <a href="https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data/policy/sharing-scientific-data/repositories-for-sharing-scientific-data/policy/sharing-scientific-
- **Genomic Data Repositories**: https://sharing.nih.gov/genomic-data-sharing-policy/submitting-genomic-data/where-to-submit-genomic-data
- National Library of Medicine repository resources:
 - o https://www.nnlm.gov/finder
 - o https://www.nlm.nih.gov/NIHbmic/domain specific repositories.html

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.

- Data Sharing Presentations from 2023 NIH Grants Conference Available
 - The 2022-2023 conference season is over, but the opportunity to learn from it isn't. Explore the
 recordings, slide sets, and transcripts. If you have questions, check out the FAQs and other
 resources on the NIH Grants & Funding site.
 - o **Genomic Data Sharing, Other Sharing Policies, and Open Q&A:** Video, PowerPoint, Transcript
 - The NIH Final Policy for Data Management and Sharing is in Effect: Planning for Success!: Video, PowerPoint, Transcript
- NICHD Implementation of the DMS Policy at a FASEB DataWorks! Salon
 NICHD ODSS Deputy Director Valerie Cotton presented findings from NICHD implementation of the
 DMS Policy at a FASEB DataWorks! Salon on January 17, 2024. The Salon is a virtual conversation
 series about best practices and emerging issues in data management. January's topic is creating a

quality data management plan, which focused on guidance to understand the DMS Policy and how to create quality plans as well as learnings/common mistakes to avoid as investigators make plans now that we have information from the policy's first year.

- Federal Demonstration Partnership (FDP) NIH Data Management & Sharing (DMS) Pilot

 NICHD's Office of Data Science & Sharing (ODSS), in collaboration with the FDP, is seeking feedback
 on DMS Plan templates as part of this newly launched pilot effort. The Alpha and Bravo templates are
 available on the FDP website or through the DMPTool. ODSS encourages researchers to review and
 use the templates to develop their DMS Plans, and provide feedback on the templates' effectiveness
 and usability. The Alpha template guides the user through a structured, modular approach to limit the
 need for free text entry, while the Bravo template provides detailed prompts for each type of data and
 options for more free text entry. FDP and NIH will use feedback collected through the pilot to refine the
 templates and make the final versions available.
- NICHD ODSS presented at the third FDP DMS Town Hall. During this Town Hall, NICHD and other NIH
 program officials participating in the <u>FDP Data Management and Sharing pilot</u> shared their preliminary
 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 <u>NIH Learning webpage</u>.

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 (IC) also shares its data science activities each month. Recordings of past seminars are available on the <u>Seminar Web page</u>.

The next seminar will be held on April 12, 2024 by Mr. Andrew Smith who will present "ELIXIR: Working Together to Accelerate the Understanding of Life". Please visit the Webinar Page for more information.

NICHD Funding Opportunities and Notices

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

- 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-HD-25-008 <u>Development of Novel Nonsteroidal Contraceptive Methods (R61/R33 Clinical Trial</u> Not Allowed)
- RFA-NS-24-019 <u>HEAL Initiative: Non-addictive Analgesic Therapeutics Development [Small Molecules</u> and Biologics] to Treat Pain (UG3/UH3 Clinical Trial Optional)
- RFA-NS-24-028 <u>BRAIN Initiative Connectivity across Scales Data Coordinating Center (BRAIN CONNECTS DCC)</u> (U24 Clinical Trial Not Allowed)
- RFA-NS-24-023 <u>HEAL INITIATIVE</u>: Development and validation of remote or patient wearable device derived objective biosignatures or functional assessments to monitor pain for use as endpoints in clinical trials (UG3/UH3 - Clinical Trial Optional)
- PAR-22-261 <u>Archiving and Documenting Child Health and Human Development Data Sets (R03 Clinical Trial Not Allowed)</u>

- PAR-23-075 <u>Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data</u> (R03 Clinical Trial Not Allowed)
- PAR-23-037 <u>Multisite Clinical Research: Leveraging Network Infrastructure to Advance Research for Women, Children, Pregnant and Lactating Individuals, and Persons with Disabilities (U01 Clinical Trial Optional)</u>
- PAR-21-229 <u>Screening and Functional Validation of Human Birth Defects Genomic Variants (R01 Clinical Trial Not Allowed)</u>

NICHD – Relevant Funding Opportunities and Notices

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

- NOT-GM-24-020 <u>Topic Areas of Interest for Joint NIH/NSF Science of Science Approach to Analyzing and Innovating the Biomedical Research Enterprise (SoS:BIO) Program</u>
- NOT-OD-24-031 Notice of Special Interest (NOSI): Administrative Supplement for Research and Capacity Building Efforts Related to Bioethical Issues (Admin Supp Clinical Trial Optional)
- RFA-DA-25-021 Effect of HIV and Substance Use Comorbidity on the Placenta and Maternal Outcomes (R01 Clinical Trial Optional)
- RFA-NS-24-023 <u>HEAL INITIATIVE</u>: Development and validation of remote or patient wearable device derived objective biosignatures or functional assessments to monitor pain for use as endpoints in clinical trials (UG3/UH3 - Clinical Trial Optional)
- PAR-23-237 <u>Enhancement and Management of Established Biomedical Data Repositories and Knowledgebases</u> (U24 Clinical Trial Not Allowed)
- RFA-HG-23-002 <u>Broadening Opportunities for Computational Genomics and Data Science Education</u> (UE5 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
- NOT-OD-23-123 <u>Notice of Special Interest (NOSI)</u>: <u>Administrative Supplements to Enhance Institutional</u>
 <u>Data Science Capacity</u>
- PAR-23-132 NIDCR Small Research Grants for Analyses of Existing Genomics Data (R03 Clinical Trial Not Allowed)
- PAR-23-133 <u>NIDCR Research Grants for Analyses of Existing Genomics Data (R01 Clinical Trial Not Allowed)</u>
- PAR-23-089 <u>Data Harmonization</u>, <u>Curation and Secondary Analysis of Existing Clinical Datasets</u> (R61/R33 Clinical Trial Not Allowed)
- NOT-OD-23-068 <u>Notice of Special Interest (NOSI)</u>: <u>Revision Applications to add a Curation and Informatics Component to existing Animal and Biological Material Resource Centers (P40) (Clinical Trials Not Allowed)</u>
- NOT-LM-23-001 Notice of Special Interest (NOSI): Computational and Statistical Methods to Enhance
 Discovery from Health Data
- PAR-22-261 <u>Archiving and Documenting Child Health and Human Development Data Sets (R03 Clinical Trial Not Allowed)</u>
- 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 <u>NICHD ODSS Website</u> in the NICHD Data and Specimen Hub (DASH) section.

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

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