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DASH Quarterly eUpdate

In this issue:

- **DASH Updates**
 - [Promoting Data Interoperability: DASH Codebook](#)
 - [Coming Soon! DASH Codebook Webinar – June 22, 2022](#)
 - [Annotation and Visualization of Study Variables](#)
 - [DASH Enhancements](#)
 - [New Studies Available in DASH](#)
 - [Studies Offering Biospecimens in DASH](#)
 - [Publications Resulting from Data Reuse](#)
 - [DASH Data/Biospecimen Use Acknowledgments](#)
- **NIH Data Science and Sharing News and Events**
 - [NIH Data Sharing and Reuse Seminar Series – July 2022 Seminar](#)
 - [DataWorks! Prize Announced](#)
 - [Webinar Series on Implementing the NIH Data Management and Sharing Policy](#)
 - [Upcoming Events](#)
- **NICHD and NIH Funding Opportunities and Notices**
 - [Funding Opportunities and Notices](#)
 - [Final NIH Policy for Data Management and Sharing \(effective January 25, 2023\)](#)



DASH Updates

Promoting Data Interoperability: DASH Codebook

Investigators who plan to share data through DASH are now expected to submit a DASH Codebook as part of their study submission. The DASH Codebook is a templated data dictionary that captures information about datasets, variables, and coded values for all data submitted for a given study. The Codebook will support DASH quality assurance and data management workflows as well as facilitate search and discovery of study data by enabling visualization of annotated variables and associated statistics in DASH. The DASH team has already completed codebooks for many of the original studies in DASH, and it has proved to be useful for enhancing the searchability of DASH study data, as described in the [Annotation and Representation of Study Variables](#) section.

The DASH Codebook Template as well as a User Guide for filling out the Codebook are available for download from the [Submission Resources](#) page in DASH. The DASH Team is available to provide

user support as needed and will soon offer training sessions to assist investigators with completing the DASH Codebook Template.

Investigators are encouraged to develop their study's DASH Codebook early in the data collection process and to make use of the recommended data standards and ontologies provided in the template. Early planning will facilitate DASH data submission process and contribute to variable-level harmonization across DASH studies.

Coming Soon! DASH Codebook Webinar – June 22, 2022

The NICHD Data and Specimen Hub (DASH) will offer a webinar on the DASH Codebook Submission for Data Sharing on Wednesday, June 22nd from 10:00 – 11:00 AM EST. This webinar is specifically geared towards researchers and data managers that plan on sharing data through DASH and will cover the DASH Codebook requirement for study submission to DASH.

Researchers and data managers at any stage of their study are highly encouraged to attend. If you are interested in attending and have not yet received an invitation to the webinar, please email SupportDASH@mail.nih.com.

Annotation and Visualization of Study Variables

The annotation and visualization of study variables in DASH helps users 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 which has the variable-level information. This feature is currently available for datasets from twelve 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 \(BPCA Fluc Safety\)](#)

DASH Enhancements

We continuously update DASH to add new features and improve existing features. Some of the recent improvements include:

- **Variable Level Information Search Facet** – In the Study Details section on each Study Information page and in the Study Explorer, a new field is displayed where variable level information for a particular study is available. Please check out this feature when you select “Show Details” in this [example Study Overview page](#).
- **Study Release and Update Dates** are now exposed in the Study Information page so that users can determine whether the data are the originally submitted data or updated data. Please check out this feature in the header of this [example Study Overview page](#).
- **Workspace Study Item Search** has been enhanced to include a search bar that allows approved data requesters to find specific datasets and documentation of interest. We also added pagination to the Search Results pages to improve navigation of lengthy lists of study items.

New Studies Available in DASH

We are pleased to share the latest study additions in DASH, for a total of 200 studies in DASH. These studies cover 50 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:

- [Microbiome, Virome and Host Responses Preceding Ventilator-Associated Pneumonia \(VAP\)](#) from Pediatric Trauma and Critical Illness Branch (PTCIB)
Release Date: 6/13/2022
Study Description: Microbiome, Virome and Host Responses Preceding Ventilator-Associated Pneumonia (VAP) was a prospective longitudinal observational study of high risk mechanically ventilated children with systematic bacterial and viral analyses of the respiratory tract along with proteomic evaluation of the host response to determine whether specific taxa and patterns of bacterial microbiota contribute to ventilator-associated pneumonia (VAP) risk and whether bacterial communities are modulated by viral infection and host immune responses to increase risk of VAP. Analysis found that in mechanically ventilated children, microbial factors were subtly different at intubation between those who did and did not develop VAP, and changes over time were marginally associated with VAP risk, suggesting other factors may contribute to VAP.
- [Tailored Motivational Interviewing Implementation Intervention \(TMI\) Effectiveness Trial in Multidisciplinary Adolescent HIV Care Settings \(ATN 146\)](#) from Maternal and Pediatric Infectious Disease Branch (MPIDB).
Release Date: 5/5/2022
Study Description: ATN 146 Tailored Motivational Interviewing Implementation Intervention (TMI) was tested in multidisciplinary adolescent HIV care settings. TMI is an evidence-based practice for patient-provider communication and behavior change. Aims were to determine its effect on provider fidelity, HIV cascade-related outcomes, sustainment fidelity, implementation barriers and facilitators, and cost effectiveness. A Dynamic Wait-list controlled design was used to deliver TMI in community-based settings (190 providers enrolled across 10 sites). The intervention included a group workshop, individual coaching, and quarterly competency assessments. It was hypothesized that MI competency would be higher during the intervention phase than baseline, and successful implementation would be associated with improved cascade-related outcomes. TMI demonstrated significantly higher competence during the intervention phase, maintained with only small reductions through the sustainment window. Analyses are underway for cascade-related outcomes.
- [Evaluation of HELPING BABIES BREATHE in Belgaum, Kenya and Nagpur: Does Implementation of HELPING BABIES BREATHE Save Lives? \(HBB\)](#) from Pregnancy and

Perinatology Branch (PPB).

Release Date: 5/4/2022

Study Description: Neonatal deaths now account for over 40% of the under 5 years old deaths. The primary objective of the HBB study was to evaluate the impact of implementing an integrated package of neonatal resuscitation training and equipment among health facility birth attendants in three Global Network sites: Belgaum (India), Eldoret (Kenya), and Nagpur (India). The primary hypothesis evaluated that HBB training materials resulted in a 20% reduction in the observed rate of overall perinatal mortality among births of ≥ 1500 g, pre-versus post-implementation in the participating clusters served by these facilities. The total cohort of 835 active Birth Attendees (BAs) trained and retrained in the HBB curriculum in 71 facilities in India and Kenya showed the lack of resuscitation training was evident by a large initial knowledge-skills gap among the BAs: at the initial HBB training, 74% of BAs passed the pre-training knowledge assessment but only 5% were able to demonstrate effective ventilation of the neonatal mannequin.

- [A Phase IV Randomized Trial to Evaluate the Virologic Response and Pharmacokinetics of Two Different Triple Antiretroviral Regimens in HIV Infected Women Initiated Between 28 and 36 Weeks of Pregnancy for the Prevention of Mother-to-Child Transmission \(P1081\)](#) from Maternal and Pediatric Infectious Disease Branch (MPIDB)

Release Date: 3/31/2022

Study Description: P1081 was a Phase IV multicenter, randomized, open-label trial comparing the virologic response, safety, and tolerability of raltegravir. The study population included Human Immunodeficiency Virus (HIV)-1 infected pregnant women with a gestational age between 28 and 36 weeks who are antiretroviral (ARV) naïve or have received short-course zidovudine only for prevention of mother-to-child transmission in previous pregnancies, and their infants. The primary objectives were to compare the ability of two triple ARV regimens (one containing efavirenz and the other raltegravir) begun during the third trimester of pregnancy to achieve a viral load of < 200 copies/mL at the time of delivery and compare the safety and tolerability of two triple ARV regimens (one containing efavirenz and the other raltegravir) begun during the third trimester of pregnancy. All women received a randomized regimen from study entry through delivery. The study showed both regimens to be safe and well-tolerated. The rate of suppression at delivery was found to be higher with raltegravir, primarily with those enrolling in the third trimester. Pregnancy outcomes in this study were consistent with previous studies of initiation of other antiretroviral regimens in pregnancy. While the HIV perinatal transmission rate was not significantly different between treatment arms in our study, substantially fewer infants were infected in the raltegravir arm compared to the efavirenz arm. The results of this study support the use of raltegravir in pregnant women who present late for care.

- [A Randomized Trial of Vaginal Surgery for Uterovaginal Prolapse: Vaginal Hysterectomy with Native Tissue Vault Suspension vs. Mesh Hysteropexy Suspension \(SUPeR\)](#) from Gynecologic Health and Disease Branch (GHDB)

Release Date: 3/28/2022

Study Description: The primary purpose of this randomized clinical trial was to compare the effectiveness and safety of two transvaginal apical suspension strategies for uterovaginal prolapse: a mesh augmented hysteropexy versus vaginal hysterectomy and uterosacral ligament suspension (USLS). Postmenopausal women requesting surgery for symptomatic uterovaginal prolapse were randomized to receive one of the procedures and were then followed at 6-month intervals for 60 months. The primary treatment failure composite outcome (retreatment of prolapse, prolapse beyond the hymen, or prolapse symptoms) was evaluated with survival modeling. The study found that sacrospinous hysteropexy with graft resulted in a lower composite failure rate than vaginal hysterectomy after 5 years of follow-up.

- [Supplemental Data to Provide Additional Evidence of Safety and Efficacy for the Proposed Dosing Regimens of Fluconazole in Infants and Young Children \(Fluconazole\)](#) from Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)

Release Date: 3/14/2022

Study Description: This was a multi-site retrospective data collection from the Pediatric Trials Network (PTN) Repository and Duke University Hospital electronic health records. The objective of this data collection was to provide supplemental data to support label change for fluconazole, and particularly evaluate adverse events associated with loading high-dose fluconazole compared to standard dose fluconazole in infants and children using real-world data.

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](#)
- [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 69 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 and Events

NIH Data Sharing and Reuse Seminar Series – July 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](#)

Drs. Alan Hutson and Qian Liu will present "NCI Funded Coordinating Center Strategies and Tools for Promoting Data, Software and Model Sharing to the Scientific Community" at the monthly Data Sharing and Reuse Seminar on July 8, 2022, at 12 p.m. EDT. [Learn more and register for the July Data Sharing and Reuse Seminar.](#)

DataWorks! Prize Announced

The Federation of American Societies for Experimental Biology (FASEB) and the National Institutes of Health (NIH) are championing a bold vision of data sharing and reuse. The DataWorks! Prize fuels this vision with an annual challenge that showcases the benefits of research data management while recognizing and rewarding teams whose research demonstrates the power of data sharing or reuse practices to advance scientific discovery and human health. We are seeking new and innovative approaches to data sharing and reuse in the fields of biological and biomedical research. To incentivize effective practices and increase community engagement around data sharing and reuse, the 2022 DataWorks! Prize will distribute up to 12 monetary team awards, in two categories: data sharing and data reuse. June 28, 2022 is the deadline for Round 1 registrations and Round 1 submissions are due July 18, 2022. [Learn more about the challenge](#)

Webinar Series on Implementing the NIH Data Management and Sharing Policy

On January 25, 2023, the new NIH Policy for Data Management and Sharing (DMS Policy) will go into effect. This policy is designed to promote the management and sharing of scientific data generated from NIH-funded or conducted research. Several webinars are planned or are available to view to provide information and training on implementing the new policy:

- The Office of Data Science Strategy (ODSS), in partnership with the National Library of Medicine (NLM), is organizing an event series led by the Data Curation Network (DCN). To prepare for the implementation of the NIH Data Management and Sharing Policy, researchers will need to gain new skills in managing and sharing their data. This event series will provide new approaches, methods, and best practices from representatives of the Data Curation Network on management, curation, and sharing to promote transparency, reproducibility, and reuse of research data. The second event in this series, "Towards Authenticity: Critical Appraisal of Data Management Plans" will be held July 19, 2022, 12:00 - 3:00 P.M. EST. [Learn More...](#)

- The NIH Office of Extramural Research is planning a 2-part webinar series for this summer. The first webinar, “Understanding the New NIH Data Management and Sharing Policy” will be held August 11, 2022, 1:30 – 3:20 pm. [Sign up to be notified when registration opens.](#)
- The Network of the National Library of Medicine has made recordings of five webinars available from their “NIH Data Management and Sharing Requirements Series”. This series introduces the basics of data management and the new requirements for data management and sharing that will be in place beginning in 2023. The goal of this series is for attendees to be able to: 1.) Describe basic best practices in data management, 2.) Advise researchers on steps to adhere to the NIH DMSP requirement, and 3.) Create a plan for outreach at their own institution. [View webinars here...](#)

Upcoming Events

- 07-19-2022 [Towards Authenticity: Critical Appraisal of Data Management Plans](#)
- 08-11-2022 [Understanding the New NIH Data Management and Sharing Policy](#)

NICHD and NIH Funding Opportunities and Notices

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-22-131 NOSI: [Request for Public Comments on DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data](#)
- NOT-OD-22-104 NOSI: [Notice of Extension of the Public Comment Period for NOT-OD-22-064 “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)

NIH has launched a new [Scientific Data Sharing](#) site. At this site, you can stay up to date on NIH data sharing policy-related statements, news, and events, and look for training opportunities. To learn more about the NIH Data Management and Sharing Policy, select the **Policy Information Materials** in this list:

- 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](#)

Questions? Please contact the DASH Administrator at SupportDASH@mail.nih.gov.
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of Child Health and Human Development