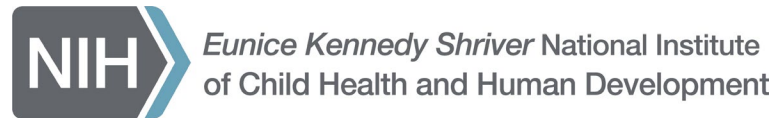


NICHD Director's Report ***NACHHD Meeting***

Diana W. Bianchi, M.D.

January 22, 2024



Talk Outline

- FY 2024 Budget Update and Congressional Interactions
- New NIH Director
- Looking Back on NICHD Research in 2023
- NICHD Strategic Planning: Aspirational Goals Update (Part 2)
- White House Women's Health Research Initiative
- Enhancing Accessibility and Disability Research at NIH
- ACD Working Group on Re-envisioning NIH-Supported Postdoctoral Training
- Kudos!
- NIH and NICHD Staff Updates



FY 2024 Budget Update and Congressional Interactions

FY24 Budget Update

- Congress has agreed to top line funding numbers for non-defense discretionary funding for FY24
- Continuing resolution passed last week
 - Extends funding for NIH from Feb 2 until March 8
- Goal is to give themselves more time to complete work on the final FY24 appropriations bills



Congressional Interactions

- Representative Yadira Caraveo, MD (CO) to discuss child health
- Senator John Boozman (AR) to discuss maternal health
- House and Senate appropriations staff to discuss the IMPROVE (Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone) initiative





New NIH Director

Monica M. Bertagnolli, MD, 17th NIH Director



Guiding Principles Articulated by the NIH Director

- Our work is not finished when we deliver scientific discoveries, our work is finished when all people are living long and healthy lives.
- NIH research encompasses the laboratory, the clinic, and the community. Patients are partners in discovery.
 - To tackle the most persistent and complex problems, NIH aims to bring more members of the public into the research enterprise as our partners in discovery.
 - Income, age, race, ethnicity, geographic location, and disability status should not be barriers to participating in research or to benefitting from research advances.



Guiding Principles Articulated by the NIH Director

- Progress is accelerated when advanced scientific methods, such as new data analytics, are applied to data that includes everyone, and when new discoveries are rapidly and equitably adopted in clinical care.
- NIH is committed to harnessing the power of AI/ML to advance research across diverse fields, diseases, and scientific communities.
 - Advanced scientific methods, new data analytics and technologies are unlocking possibilities to harness data in ways that achieve faster and more definitive results.
 - NIH has launched and will continue to launch innovative and ambitious initiatives to propel fusion of biomedicine and AI/ML.

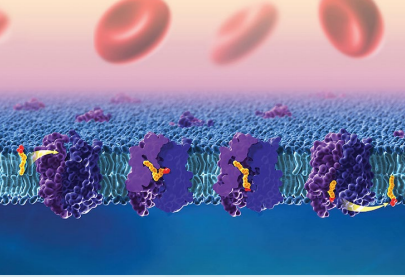
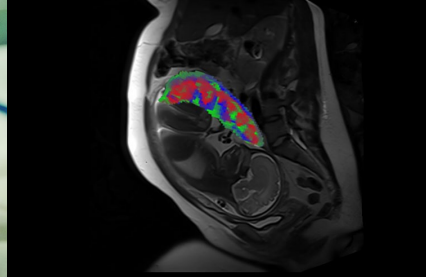
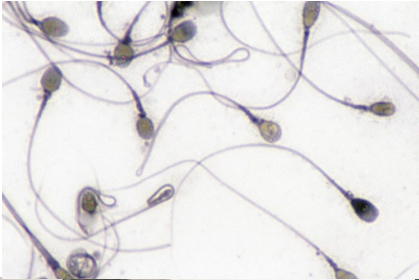




Looking Back on NICHD Research in 2023

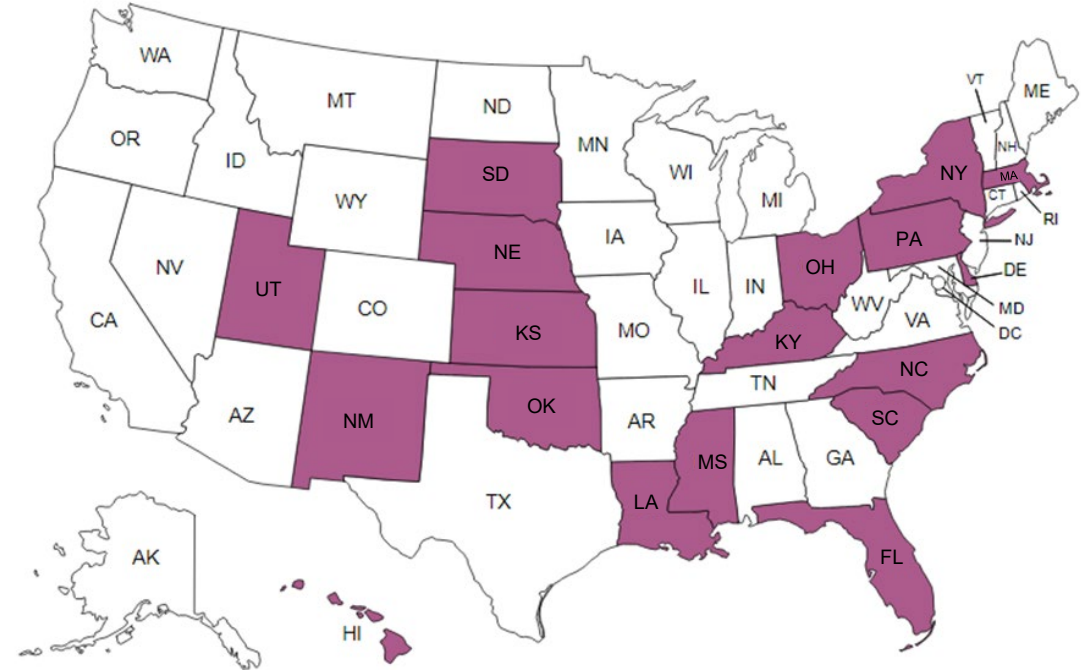
NICHD Annual Research Advances

- *Promoting Healthy Pregnancy, Labor, and Delivery*
- *Improving Outcomes for Newborns with Opioid Withdrawal*
- *Advancing Treatments for Gynecological Conditions*
- *Creating New Technologies*
- *Developing New Contraceptives*
- *Reducing Disparities for Children with Intellectual and Developmental Disabilities*
- *Enhancing Safety in Contact Sports*
- *Improving Care for Pediatric Injury and Illness*
- *Advancing Outcomes for Children with a COVID-19 Complication*
- *Boosting Basic Science Research*



HEAL Initiative: Eating, Sleeping, and Consoling for Neonatal Opioid Withdrawal

- Collaboration combined two NIH pediatric clinical trial networks
 - NICHD's Neonatal Research Network
 - ECHO's IDeA States Pediatric Clinical Trials Network (ISPCTN)
- Results: Reduced hospital stay and need for medication among opioid-exposed infants
- Changed standard of care for NOWs



Washington State Requires ESC Implementation by January 2025

State agencies announce changes in policy and best practices for infants and parents affected by substance use at birth

For immediate release: June 26, 2023 (23-087)

Contact: [DOH Communications](#)

Change incorporates “Eat, Sleep, Console” model of care for substance-exposed infants

OLYMPIA – The Washington State Department of Children, Youth, and Families (DCYF), in conjunction with the Department of Health (DOH), the Health Care Authority, and the Washington State Hospital Association, have updated state requirements and best practices that aim to improve the health of infants and parents affected by substance use at birth.

If there are no safety concerns, state policy now allows substance-exposed infants to receive voluntary wrap-around services without being reported to Child Protective Services. All hospitals should update policies to align with [state policy](#) and train staff no later than Jan. 1, 2025, to comply with federal requirements.

“While hospitals are still required to report cases where there is a safety concern for the child, not all families that have a child with prenatal substance exposure require child welfare intervention. We still want to connect these families with community-based services and resources that will support the family’s needs, reduce risks, and increase protective factors,” said DCYF Secretary Ross Hunter.

Updated requirements also include best practices for the clinical care of mothers/birth parents who need withdrawal/stabilization care at birth, as well as for infants being monitored or treated for withdrawal.

For years, the Finnegan Neonatal Abstinence Scoring Tool was the primary model of care for treating substance-exposed infants. However, a growing body of research shows infants treated using the Eat, Sleep, Console (ESC) model of care experience shorter hospital stays and are less likely to receive medication to treat neonatal opioid withdrawal symptoms. Eat, Sleep, Console prioritizes parental involvement and non-pharmacological care such as cuddling, swaddling, rooming-in with parents, chest/breastfeeding, and a quiet, dark room. The announced change formally recognizes Eat, Sleep, Console as the new best practice for birthing hospitals, and states medications and NICU admissions should no longer be the first line of treatment for infants exhibiting withdrawal symptoms.

“The opioid and overdose epidemic is disrupting the lives of a growing number of families in our state,” said Tao Sheng Kwan-Gett, MD, MPH, Chief Science Officer at DOH. “These changes will help every baby born in Washington get the healthiest start possible.”

The [DOH website](#) is your source for a healthy dose of information. [Find us on Facebook](#) and [follow us on Twitter](#). Sign up for the DOH blog, [Public Health Connection](#).

###



NICHD Data and Specimen Hub (DASH)



DASH Content

Top Study Topics

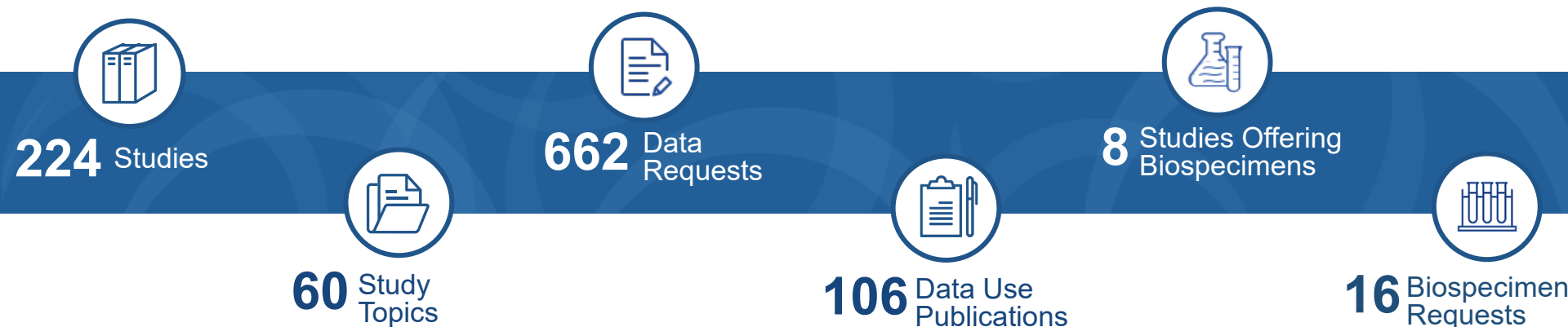
Breastfeeding & Breast Milk*	Labor & Delivery
Cerebral Palsy	Newborn
Child Health*	Screening
Early Learning	Obesity & Overweight
Early Labor and Birth	Pelvic Floor Disorders
Fertility Problems	Pharmacology
High-Risk Pregnancy	Pregnancy*
HIV/AIDS*	Preterm Labor & Birth*
Infant Care & Health*	Stillbirth
Infant Mortality	Women's Health*
Infertility & Fertility	

*biospecimens available

Biospecimens Available

Amniotic fluid	Hair
Blood	Lymphocytes
Breast Milk	Meconium
Buffy Coat	Nail
Cord Blood (Buffy Coat, RBC, Plasma, Serum)	Saliva
DNA/RNA/Proteins	Serum/Plasma
Environmental Samples	Tissue samples
Erythrocytes (RBC)	Urine
	Vaginal Fluid

- Centralized resource for researchers to share de-identified data from studies funded by NICHD
- Serves as a portal for requesting biospecimens from selected studies in DASH
- Aims to accelerate scientific findings to ultimately improve human health



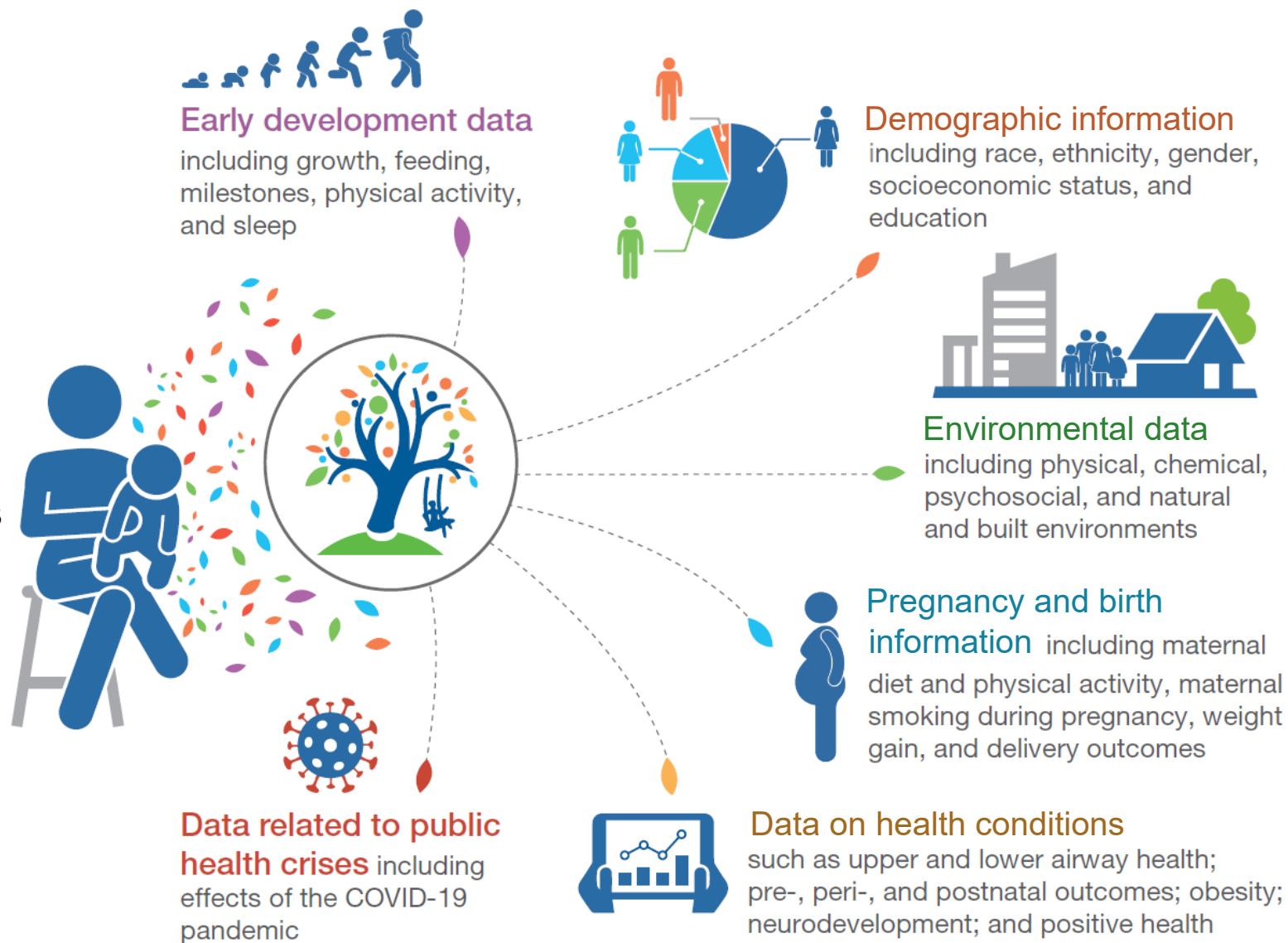
<https://dash.nichd.nih.gov>



Last updated 01/02/2024

ECHO Cohort Data Now Available on DASH

- Controlled-Access Public Use Database
 - De-identified data in DASH
 - Cohorts: Deposited at regular intervals
 - ISPCTN: Deposited after each trial
 - Funding opportunities incentivize us
- Data from >60,000 participants
- >40 user requests to date
- Sharing protocols across NIH studies
 - Common data elements

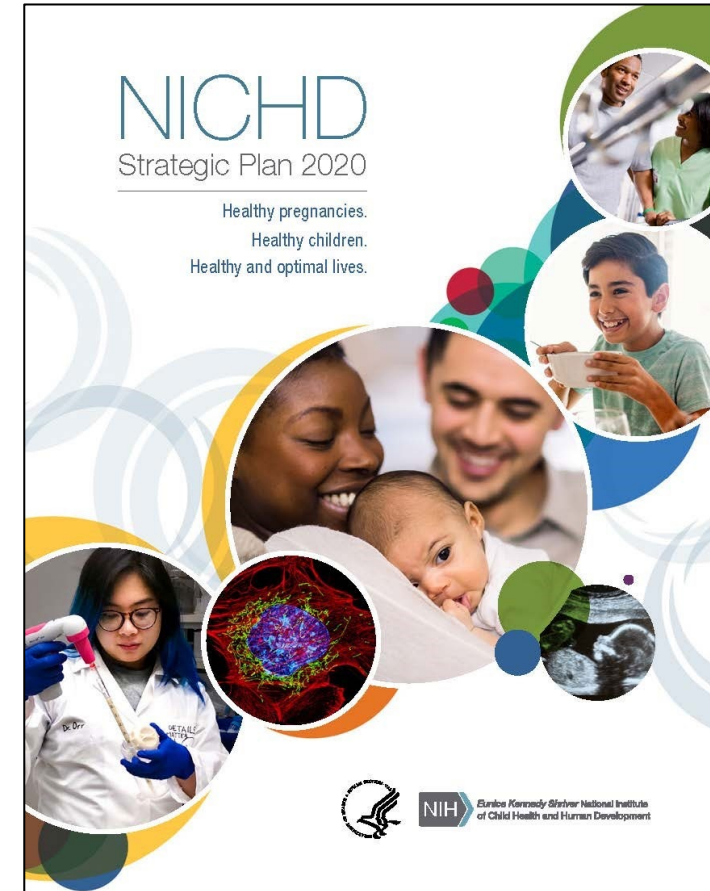




NICHD Strategic Planning: Aspirational Goals Update (Part 2)

Update: NICHD Strategic Plan 2025

- Refreshing the NICHD Strategic Plan
 - **Nov 2023:** Strategic Plan Refresh process began
 - **April/May 2024:** Virtual listening sessions
 - **Aug/Sept 2024:** Engage external stakeholders (FACA advisory groups + RFI)
 - **Mar 2025:** Release of updated Strategic Plan
- NICHD has been documenting and tracking activities and achievements towards current objectives
 - Aspirational Goals (part 2)



Aspirational Goals

- Identify biomarkers of atypical neurodevelopment that can establish the likelihood of neurodegenerative disorders later in life.
- Identify genomic changes and exposure risks that explain or predict fetal loss, using advanced technological approaches and population-based study methods.
- Use the growing understanding of immune factors in pregnancy and placental development to determine reasons for pregnancy rejection, mechanisms to prolong at-risk pregnancies, and ways to transfer this knowledge to other medical needs, such as organ transplantation.
- Optimize infant survival by synthesizing human milk, capturing all its components and properties, and individualizing it to the characteristics of the infant's mother.
- Discover how technology exposure and media use affect developmental trajectories, health outcomes, and parent-child interactions in early childhood.



Aspirational Goals: Neurodevelopment and Long-term Risk

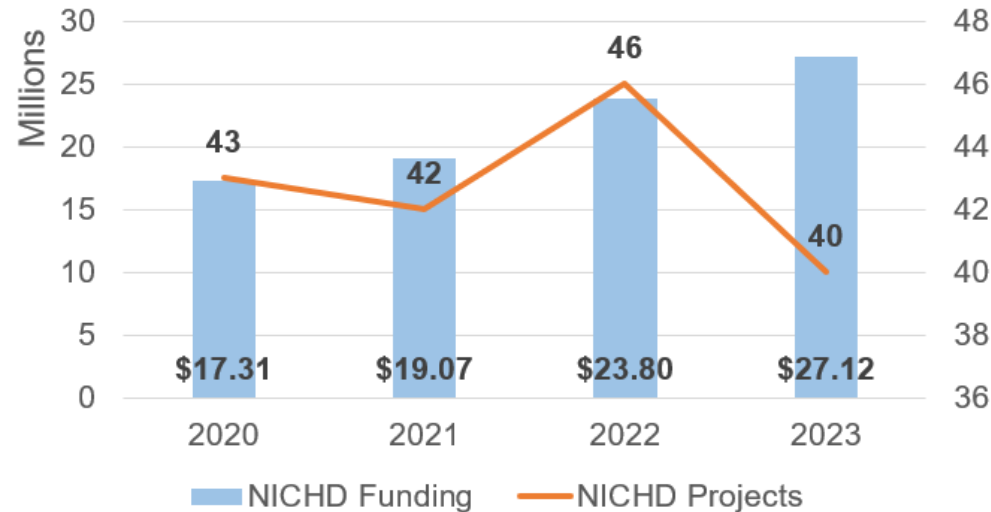
Baseline

17.8 % of US children age 3-17 have been diagnosed with 1 or more developmental disabilities (NCHS, 2020)

Potential lifelong limitations, ↑ risk of neurodegenerative diseases

Zero early neurodevelopmental biomarkers with independent evidence and specificity and sensitivity of at least 80%
2023 systematic review, PMID 36640395)

Actions



Source: NIH RCDC Categorical Spending (official data): Neurodegenerative diseases and Pediatrics

Findings

- **Alzheimer's risk associated with specific cognitive phenotypes in Down syndrome** ([PMID 37855447](#))
- DNA methylation profiles are correlated with functional differences in genetic neurodevelopmental disorders ([PMID 35904121](#))
- Differential DNA methylation from cord blood and increased neonatal caudate volumes were independently associated with severe neurodevelopmental delay at 2 years of age ([PMID 34895032](#))



Aspirational Goals: Genomics and Fetal Loss

Baseline

>20,000

Families affected by stillbirth each year in US (CDC)

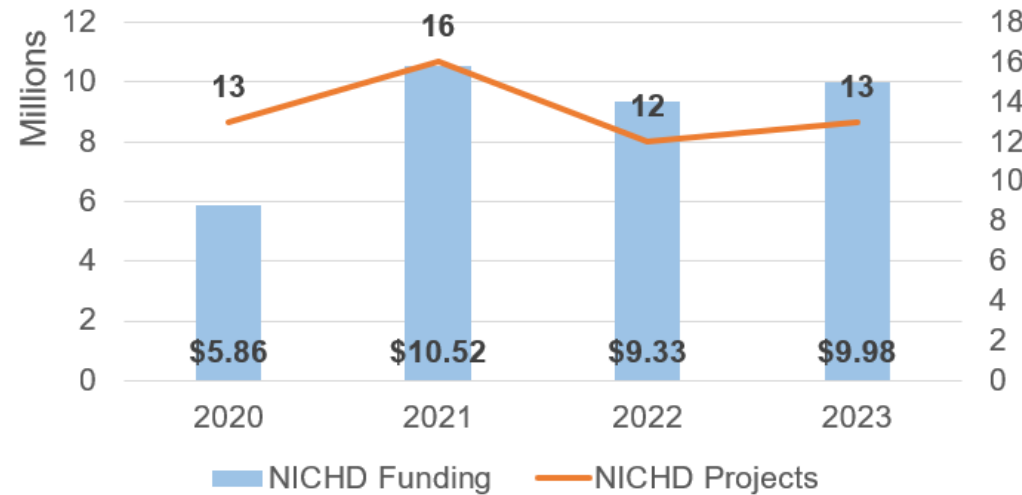
10-20%

Of pregnancies end in miscarriage / fetal loss (CDC)

Painful loss for families, risk of complications

60% of tissue samples from early pregnancy loss showed evidence of chromosomal anomalies ([PMID 27287007](#))

Actions



Source: NICHD Child Health Information Retrieval Program (unofficial data)

Includes but not limited to:

- RFA: HD21-005

Other activities include Stillbirth Working Group of NICHD Council, data sharing of data from NICHD projects and networks, and others.

Findings

- No Evidence of Association Between Maternal Alcohol Metabolism Genetics and Miscarriage ([PMID 35597276](#))
- Copy Number Variations and Placental Anomalies Associated with Stillbirth ([PMID 35876766](#))
- Novel Bacterial Pathogens Associated with Stillbirth and Early Preterm Birth ([PMID 35993728](#))
- A Fetal Growth Factor Protein Level in Maternal Blood Could Predict Placental Insufficiency ([PMID 35709732](#))



Aspirational Goals: Infection and Immune Factors in Pregnancy

Baseline

At full term, about 20 ounces of blood passes through the placenta every minute ([PMID 26333191](#))

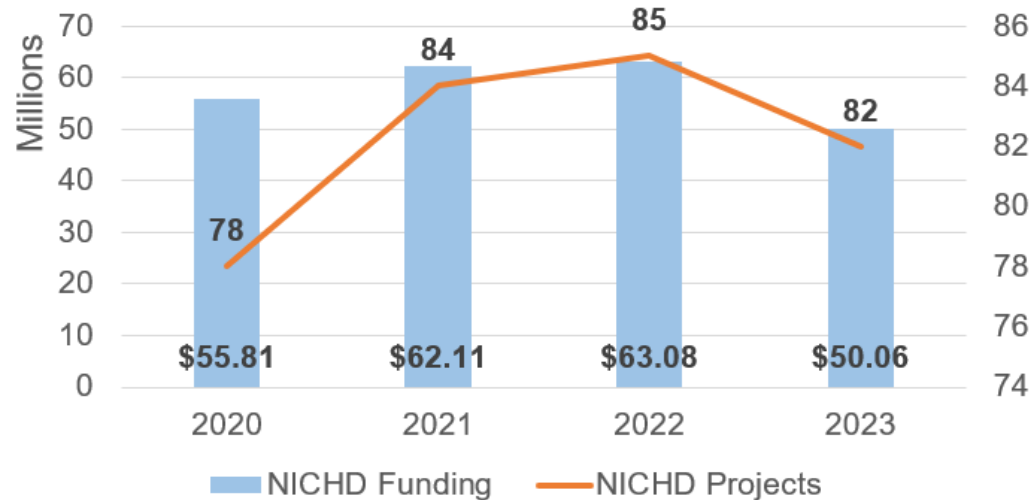
Infections are a leading cause of maternal, fetal, and neonatal deaths (CDC)

Uptake of recommended vaccines among pregnant women, 2022 (CDC):

48.4 %: flu
45.8 %: Tdap
60.5%: COVID



Actions



Source: NIH RCDC Categorical Spending (official and unofficial data): Pregnancy and Infection

Other activities include Stillbirth Working Group of NICHD Council, data sharing of data from NICHD projects and networks, and others.

Findings

- Sepsis screening tools perform best from 20 weeks of pregnancy through 3 days postpartum (PMID 38086055)
- A series of malformations in stillborn infants linked to copy number variants (PMID 37264725)
- Widespread COVID-19 vaccination likely halted spike in preterm birth (PMID 38011548)
- Antibody treatment for CMV appears to offer no longer-term benefit to children by age 2 (PMID 37937785)



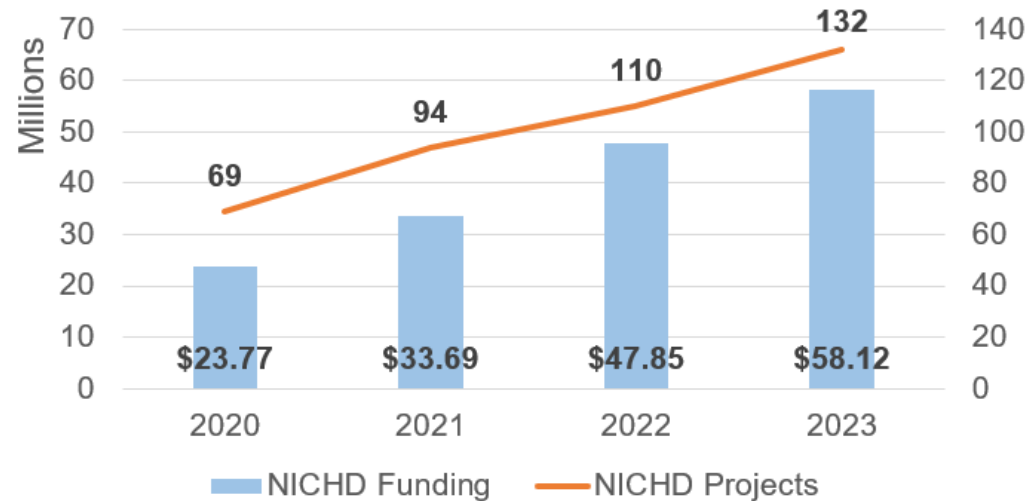
Aspirational Goals: Human Milk

Baseline

- 83 % US infants born in 2019 who started out receiving some breast milk (CDC)
- 58 % US infants born in 2019 receiving some breast milk at 6 months (CDC)

Mechanisms behind the benefits of breast milk are not well understood

Actions



Source: NIH RCDC Categorical Spending (official data): Breastfeeding, Lactation, and Breast Milk

Includes but not limited to:

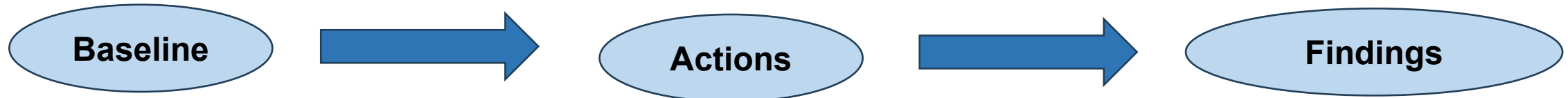
- RFA: HD22-020

Findings

- Lactoferrin in human milk has antimicrobial properties against group B strep ([PMID 33755306](#))
- C reactive protein, glucose, and insulin in breast milk differ for women who had gestational diabetes ([PMID 35277026](#))
- For most oligosaccharides, concentrations in breast milk decreased over time, but there were several exceptions ([PMID 33693851](#))
- Researchers identify six unique lactocyte subpopulations in human milk ([PMID 35767604](#))



Aspirational Goals: Media and Child Development

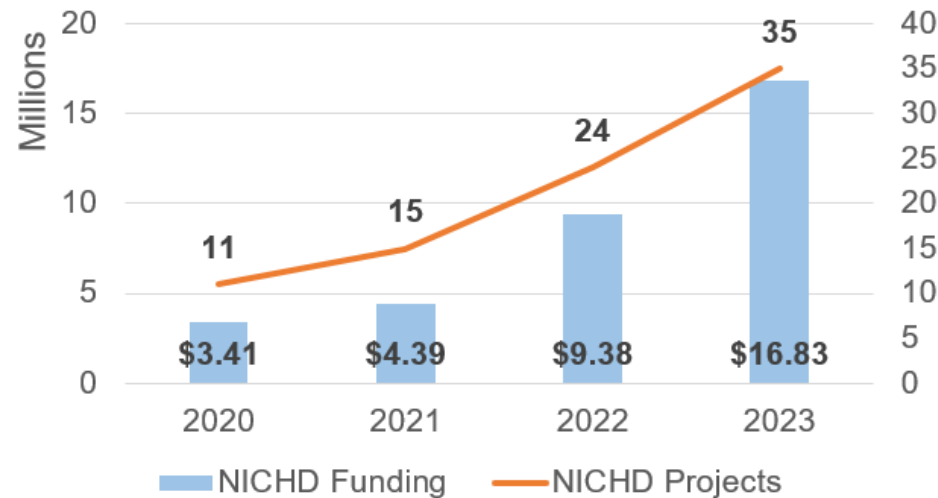


↑ in daily screen time, children age 6-10, during pandemic
[\(PMID 35615691\)](#)

Physical Activity, Learning Loss, Mental Health

May 20, 2023

Surgeon General's advisory on excessive social media use



Source: NICHD Child Health Information Retrieval Program (unofficial data)

Includes but not limited to:

- Program Projects RFA: HD22-009

Other activities included a Director's Blog and other communications, and NIH-wide and HHS coordination.

- Video games and watching videos prospectively associated with new-onset cases of OCD in early adolescents. [\(PMID 36517380\)](#)
- High screen time (≥ 2 hr/ day) associated with \uparrow risk of problems at early school age [\(PMID 34251406\)](#)
- When toddlers were energetic before using media, less difficulty transitioning away. But when parents used media to calm down toddlers, harder to transition to the next activity. [\(PMID 37053409\)](#)
- Parent estimates of children's screen time and media use were inaccurate more often than they were on target [\(PMID 32482771\)](#)





White House Women's Health Research Initiative

Presidential Memorandum: Women's Health Research Initiative

- November 13, 2023: President Biden announced first-ever White House Initiative on Women's Health Research, led by First Lady Dr. Jill Biden and the White House Gender Policy Council
- The Initiative will:
 - Deliver concrete recommendations to advance women's health research
 - Take a targeted, high-impact approach in focus areas where additional investments could be transformative
 - Engage the scientific, private sector, and philanthropic communities, exploring new public-private partnerships
- NICHD contributed to government-wide recommendations submitted on Dec. 28, 2023



Photo credit: Erin Scott, White House Photographer





Enhancing Accessibility and Disability Research at NIH

Advisory Committee to the Director Working Group on Diversity

- Subgroup on Individuals with Disabilities
- Report recommendation:
 - One immediate action to support disability inclusion is to remove the language of “reducing disability” from the NIH mission statement. The current mission statement could be interpreted as perpetuating ableist beliefs that disabled people are flawed and need to be ‘fixed’.
 - https://www.acd.od.nih.gov/documents/presentations/12092022_WGD_Disabilities_Subgroup_Report.pdf



Updating the NIH Mission Statement

- **Current Mission Statement:** “To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, *and reduce illness and disability.*”
- **Proposed Mission Statement:** “To seek fundamental knowledge about the nature and behavior of living systems *and to apply that knowledge to optimize health and prevent or reduce illness for all people.*”
- Public feedback via Request For Information:
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-163.html>
- Responses were due Nov. 24



Health Disparities Populations

- **NIH designated people with disabilities as a health disparity population (October 2023)**
- Supports NICHD's mission area of including people with disabilities in research
- New funding opportunity for innovative approaches and interventions that address the intersecting impact of disability, race and ethnicity, and socioeconomic status on healthcare access and health outcomes.
 - <https://grants.nih.gov/grants/guide/pa-files/PAR-23-309.html>





ACD Working Group on Re-envisioning NIH- Supported Postdoctoral Training

Working Group Charge and External Input

- Charge:
 - Evaluate evidence on perceived shortage in PhDs seeking U.S. postdocs
 - Assess and consider factors influencing the scope and persistence of the issue
 - Review and compare other approaches to postdoctoral training
 - Consider ways to support postdocs' quality of life and work-life balance, increase retention
 - Engage key internal and external parties
- 4 public listening sessions
- Request for Information – 3,252 comments



Recommendations

- Increase pay and benefits for all NIH-supported postdoctoral scholars.
- Create and expand mechanisms to support the full talent pool of postdoctoral scholars.
- Facilitate transition of postdoctoral scholars into their next career stage, including roles beyond academic faculty.
- Promote training and professional development of postdoctoral scholars and their mentors.
- Support safe and diverse perspectives and research environments within institutional research programs.
- Improve means to measure and share postdoctoral scholars' career progression.



https://acd.od.nih.gov/documents/presentations/12152023_Postdoc_Working_Group_Report.pdf



NICHD Extramural Research Training Programs

- Today's Discussion
 - NICHD Extramural Training Working Group will present
 - Council Members: will discuss recruitment and retention of junior faculty
 - Colleagues from professional organizations, research organizations, and funded researchers will respond





Kudos!

Elected to the National Academy of Medicine



Bonnie Maldonado, MD



Ursula Kaiser, MD



Catherine Spong, MD



CLIO Award - Innovation and Creative Excellence in Advertising, Design, and Communication

- NICHD's Population Dynamics Branch iPOP coordinating center won a [Clio Health Award](#)
- The Population Reference Bureau (working with the population research centers) collaborated with TANK Worldwide and Dr. Shalon's Maternal Action Project on a national campaign to raise awareness of the Black maternal health crisis in America.
- The award-winning video includes findings from NICHD research.



Recognition from the Foundation for NIH (FNIH)

NICHD was awarded the 2023 Charles A. Sanders, M.D., Partnership Award by FNIH, recognizing significant contributions to FNIH's work in support of the mission of NIH.

Collaborations centered on **two maternal health clinical trials**:

1) A-PLUS Trial

- Single dose of low-cost oral antibiotic azithromycin, given during labor, reduced maternal sepsis and death by about one-third.
- NICHD's Global Network for Women's and Children's Health Research
- Additional sub-studies and secondary analysis ongoing

2) PRIORITY Trial

- Ongoing trial assessing impact of postpartum intravenous iron therapy to treat anemia





NIH and NICHD Staff Updates

New NIH Leaders

- W. Kimryn Rathmell, MD, PhD,
New Director of the National Cancer Institute
- Tara A. Schwetz, PhD, Deputy Director for Program
Coordination, Planning, and Strategic Initiatives
- Andrew A. Bremer, MD, PhD,
Director, Office of Nutrition Research



We're Hiring!

- Extramural Branch Chiefs, Program Officers, Extramural Policy Officers
- Intramural Labs (postdocs, fellows, trainees)

<https://www.nichd.nih.gov/about/jobs>





Thank You!
Questions?