NICHD Clinical Network Update and the Unified Pediatric Research Consortium Proposal

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On Behalf of the Division of Extramural Research

October 2025 Council Presentation

September 9, 2025

Initiative Background

American Journal of Obstetrics and Gynecology

Founded in 1920

volume 172 *number* 2 *part* 1 FEBRUARY 1995

GENERAL OBSTETRICS AND GYNECOLOGY

Fetus-Placenta-Newborn

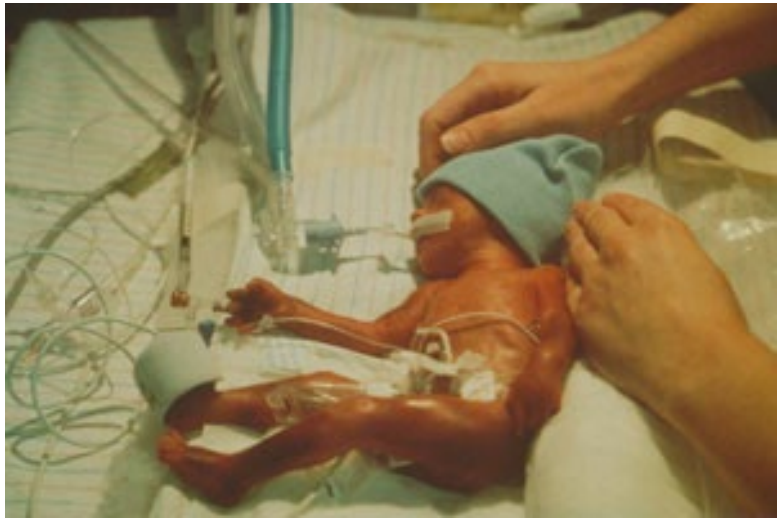
Very-low-birth-weight outcomes of the National Institute of Child Health and Human Development Neonatal Network, November 1989 to October 1990

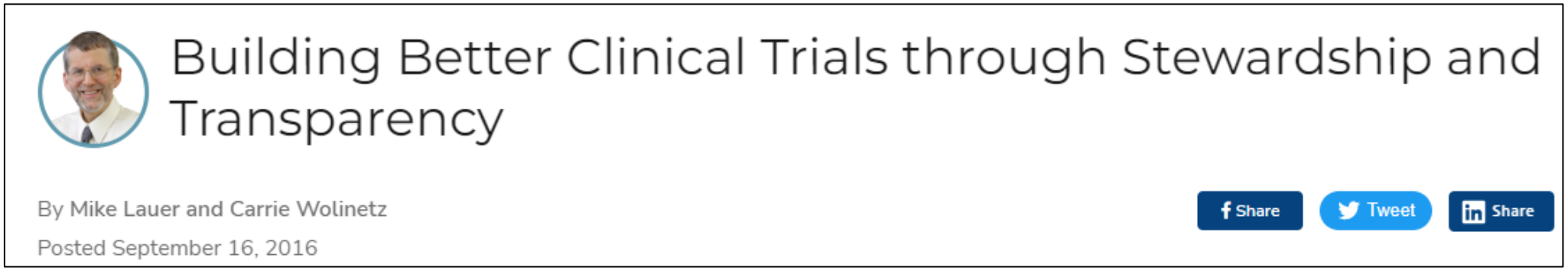
Maureen Hack, MB, ChB,[a] Linda L. Wright, MD,[b] Seetha Shankaran, MD,[c] Jon E. Tyson, MD,[d] Jeffrey D. Horbar, MD,[e] Charles R. Bauer, MD,[f] and Naji Younes, MA,[g] for the National Institute of Child Health and Human Development Neonatal Research Network

Cleveland, Ohio, Bethesda and Rockville, Maryland, Detroit, Michigan, Dallas, Texas, Burlington, Vermont, and Miami, Florida

OBJECTIVE: Our purpose was to describe the neonatal outcomes of 1804 very-low-birth-weight (≤1500 gm) infants delivered between November 1989 and October 1990 in the participating centers of the National Institute of Child Health and Human Development Neonatal Research Network.

NICHD has long and successful tradition of supporting pediatric-focused multisite clinical research dating back to the mid 1980s





NIH proposed to enhance clinical trial stewardship

- Individual Institutes/Centers asked to develop their own clinical trial FOAs
- **Four principles** for continued commitment of NICHD Network infrastructure for rigorous multisite clinical trials

  Notice (NOT-HD-19-034): *Infrastructure for NICHD Multisite Clinical Trials*
  https://grants.nih.gov/grants/guide/notice-files/NOT-HD-19-034.html

  Webinar: Strategic Plan 2020 Implementation: NICHD's vision for multi-site clinical trials infrastructure
  https://www.youtube.com/watch?v=kzgFRuH9rnE

Network Goals – Four Guiding Principles

Infrastructure for NICHD Multisite Clinical Trials

Notice Number: NOT-HD-19-034

Key Dates

Release Date: October 10, 2019

Related Announcements

None

Issued by

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Purpose

- *Enhance the rigor and reproducibility of clinical trial protocols*
- *Promote greater availability of multisite clinical trial infrastructure to support trials from a wider range of investigators*
- *Facilitate data sharing and access to biospecimens to efficiently expand research capacity for all investigators*
- *Facilitate greater involvement of diverse populations in multisite clinical trials*

Initiative Background

- NICHD has adjusted its approach to Network research in many ways
  - Access to Network resources for all qualified extramural investigators
  - Network projects undergo NIH peer review

Multisite Clinical Research: Leveraging Network Infrastructure to Advance Research for Women, Children, Pregnant and Lactating Individuals, and Persons with Disabilities (U01 Clinical Trial Optional)

U01 Research Project – Cooperative Agreements

PAR-23-037

Pre-Application Process

Step 1: Researcher sends a letter of inquiry at least 4 to 8 months prior to application receipt date

Step 2: Researcher prepares and submits a concept proposal

Step 3: NICHD and the network(s) review the concept proposal. NICHD makes final decision on concept proposal

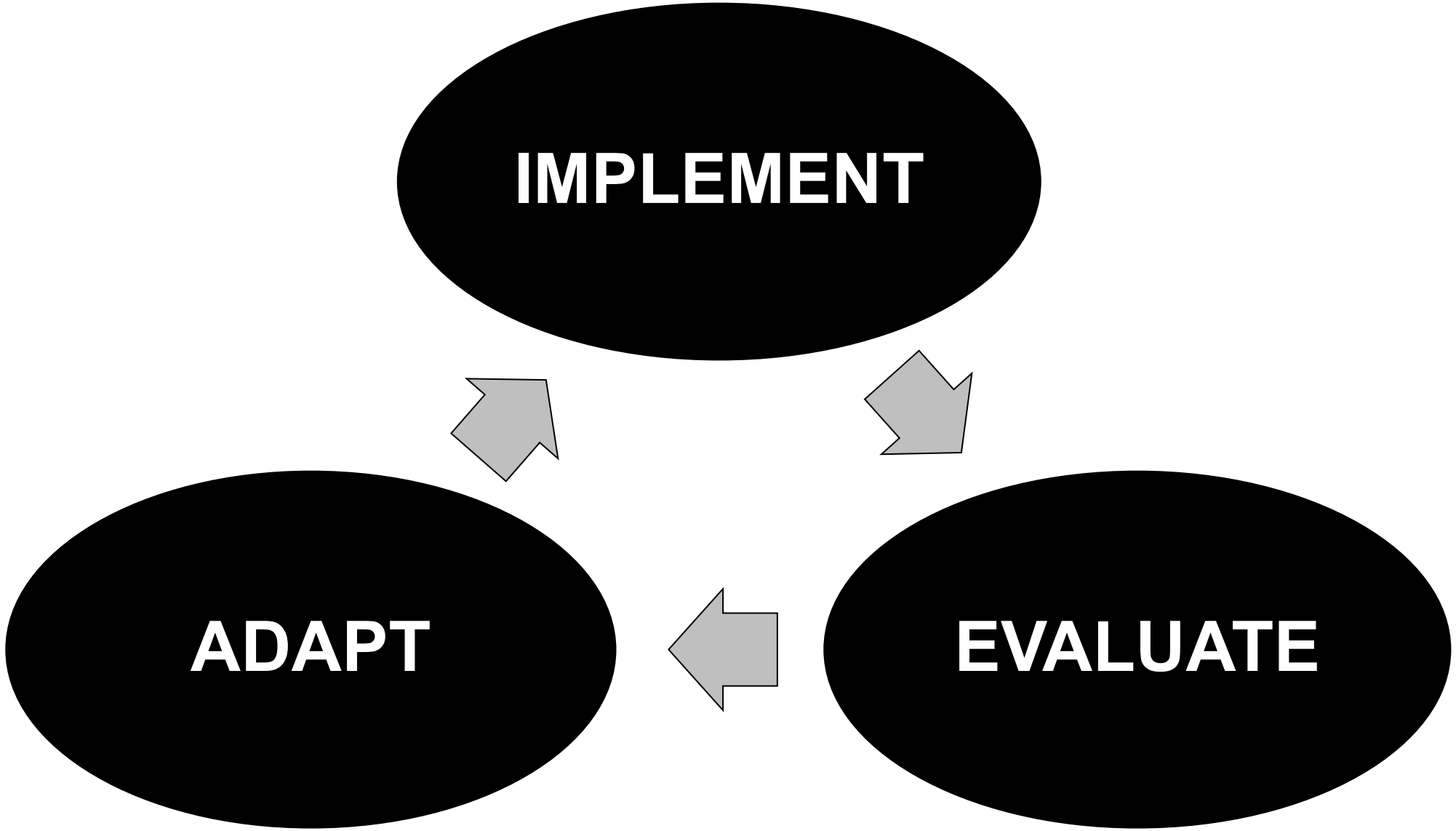
Step 4: Researcher, network(s), others develop the application (for approved concept proposals only)

Step 5: Researcher and network(s) submit the jointly developed application

https://www.nichd.nih.gov/health/clinical-research/clinical-trial-preapplication-process

Progress to date

- Letters of Inquiry
  - Over 70 Letters received
  - Approximately three quarters approved
  - Nearly 50% from non-Network investigators
- Concept Proposals
  - Over 40 Concept Proposals submitted
  - Approximately 40% approved
  - Approximately 40% from non-Network investigators
    - Lower approval rate than Network proposals, but improving
- Grant Applications
  - One third of Grant Applications received have been funded (PAR-23-037)
  - One submission from a non-Network investigator and another pending


IMPLEMENT
EVALUATE
ADAPT

Leveraging Network Infrastructure to Conduct Innovative Research for Women, Children, Pregnant and Lactating Individuals, and Persons with Disabilities (UG3/UH3 - Clinical Trial Optional)

UG3/UH3 Exploratory/Developmental Phased Award Cooperative Agreement

Reissue of PAR-23-037

See Notices of Special Interest associated with this funding opportunity

- **April 4, 2024** - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084.
- **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198.
- **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189.

PAR-25-311

Key Changes in PAR-25-311

- Bi-phasic (UG3/UH3) Mechanism
- Application Budgets
- Receipt Dates are now mid-March, mid-July, and mid-November
- Strong Preferences
- Junior Investigators

JAMA | Original Investigation

Trends in US Children's Mortality, Chronic Conditions, Obesity, Functional Status, and Symptoms

Christopher B. Forrest, MD, PhD; Lauren J. Koenigsberg, BA; Francis Eddy Harvey, BA; Mitchell G. Maltenfort, PhD; Neal Halfon, MD, MP

Original Articles

Relationship of Childhood Abuse and Household Dysfunction to Many of the Leading Causes of Death in Adults: The Adverse Childhood Experiences (ACE) Study

APS | European Society for Paediatric Research | spr Society for Pediatric Research

www.nature.com/pr

SPECIAL ARTICLE

Check for updates

The state and future of pediatric research—an introductory overview

The state and future of pediatric research series

Opportunities for Improvement

- More effective research represents one essential component of a multifaceted approach needed to best address evolving concerns of child health
  - **Collaborative** science
  - Clearly and consistently **defined pediatric outcome** parameters
  - **Longitudinal** research expanded and expedited
  - Successful **partnerships** with **non-traditional** stakeholders
  - Public-private **partnerships** free of “corporate capture”
    - **Rigor**, open data access and **transparency**
  - **Coordinated** Federal efforts
    - Prioritize result **reproducibility**
  - Broader approach with **multi- and interdisciplinary** components

Initiative Overview

- Purpose
  - Create one Unified Pediatric Research Consortium (UPRC) of networks to address the pediatric clinical priorities of NICHD and the extramural community
- Ultimate Goal
  - Unify efforts within the NICHD, across the Federal government and throughout the extramural community to address key pediatric health issues:
    - Accelerate advancements in science
    - Enhance scientific rigor
    - Improve outcomes for children
    - Reduce burden and costs

Initiative Overview

- Provide infrastructure to support and facilitate multisite pediatric research
  - Critical Care
  - Pharmacology
  - Medical devices

Pediatric Critical Care Research

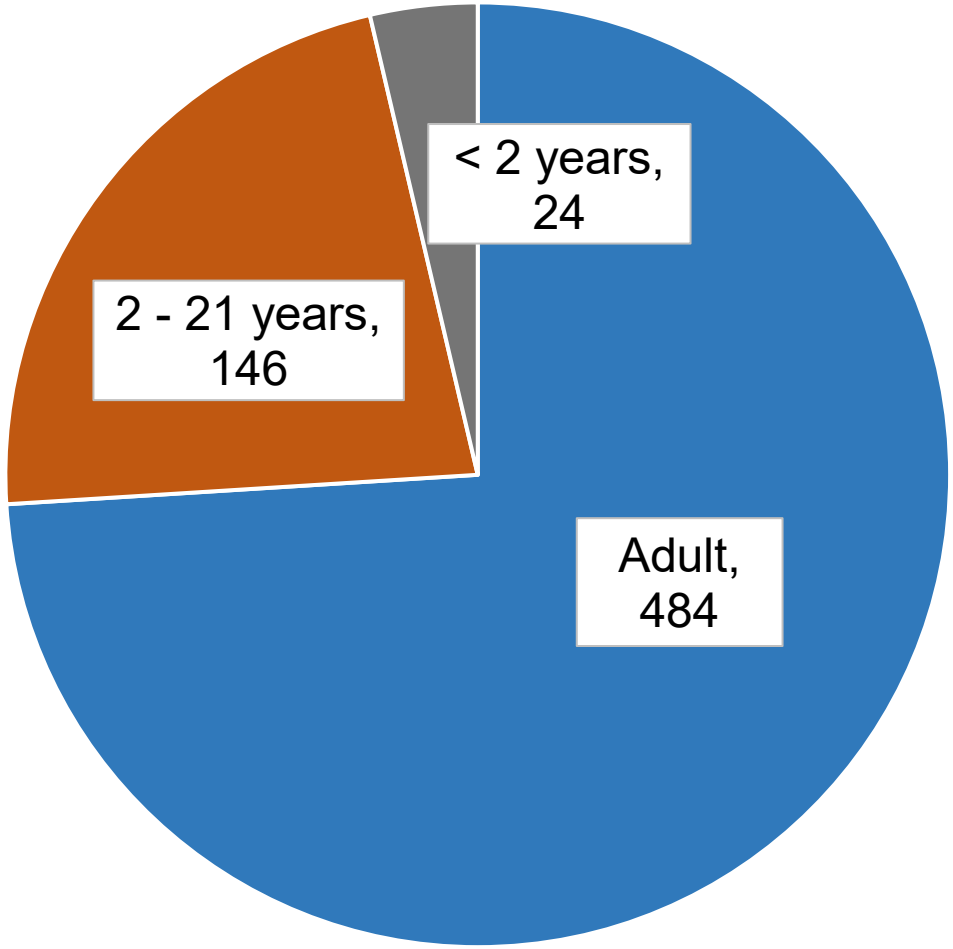
- Continuing and expanding that work is paramount to the mission of the NICHD
  - Injury leading cause of death
  - Multiple organ dysfunction proximate cause of death in children
- **Key Pediatric Critical Care Research Programs established in 2005**
  - Pediatric Critical Care and Trauma Scientist Development National K12 Program
  - Collaborative Pediatric Critical Care Research Network (CPCCRN)
    - Over 30 clinical projects - multisite trials and large-scale cohort studies
    - Approximately 175 publications and 18 public use datasets
- **Pediatric Trauma and Critical Illness Branch established in 2014**
- Development of validated tools to assess morbidity
- On-going precision medicine trial for sepsis induced multiple organ dysfunction
- Opportune time to further enhance and optimize investment in key area of research

Pediatric Pharmacology Research

- Many advances in the care of children with acute and chronic health conditions
- Clinical Pharmacology Training Network including K12 and F32/T32 Programs
- Best Pharmaceuticals for Children Act (BPCA)
  - Pediatric Trials Network and its affiliated BPCA DCC
  - Prioritize and sponsor clinical trials of therapeutics for children
  - Over 13,000 participants across 301 sites and 51 studies
  - 200 publications and 25 age specific FDA medication label changes
- Development of resources for researchers, healthcare providers, and the public
  - BPCA Framework to Enable Pediatric Drug Development
- Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub
  - Medication use in pregnancy as well as its impact on breast milk
- Opportune time and natural fit with pediatric critical care studies (e.g. nitroprusside)

Pediatric Medical Device Research

- Tremendous potential for detection and treatment of pediatric conditions
- Successful NICHD and NIH-wide pediatric medical device research efforts
- Nascent Public-Private Pediatric Medical Device Partnership
  - Launched by the NIH, FDA and BARDA through the FNIH
  - Self-sustaining pediatric medical device public-private partnership infrastructure
  - De-risk the entire lifecycle of pediatric medical product development
  - Identify centers capable of conducting multisite device clinical research

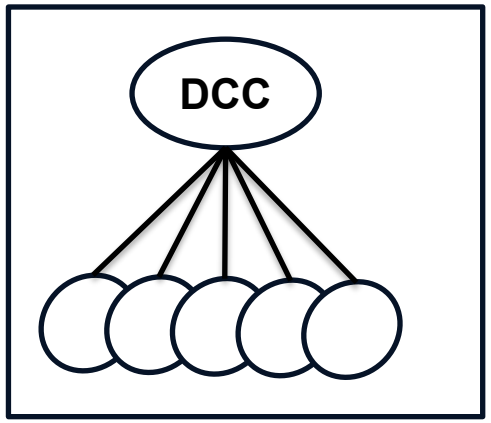


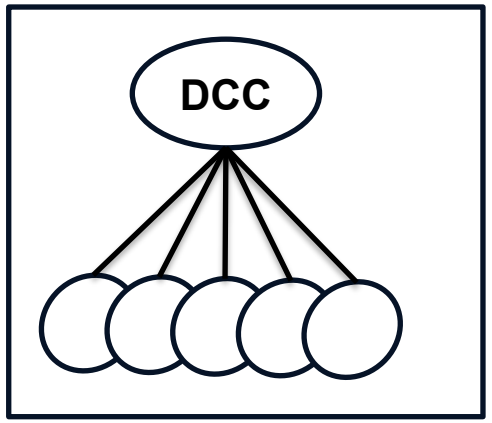
CDRH Premarket Approval and Humanitarian Device Exemption FY 2008-2020

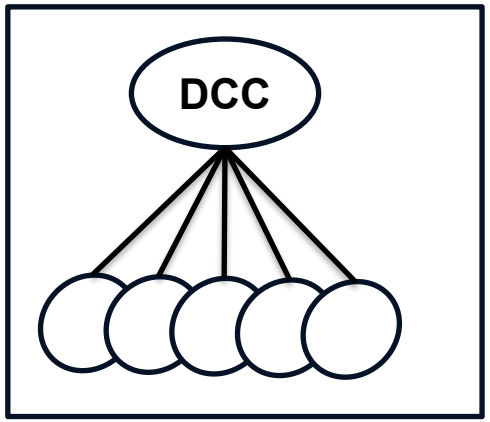
Initiative Overview

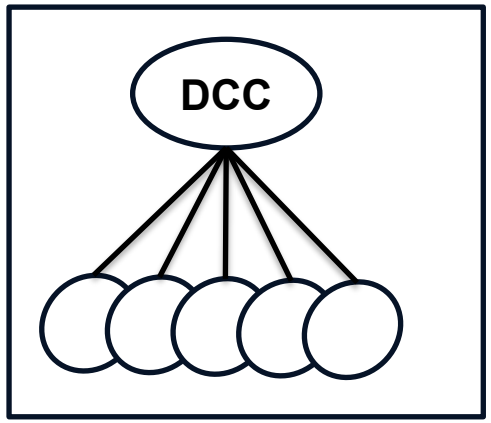
- Create framework to which existing Pediatric Networks can be added:
  - Leverage resources
  - Increase efficiency
  - Expand capacity
- Establish interactions among NICHD and non-NICHD Pediatric Networks
  - Enable a more timely and cohesive emergency response
- Facilitate long-term, longitudinal assessments using data linkage and sharing
  - Maternal and infant data

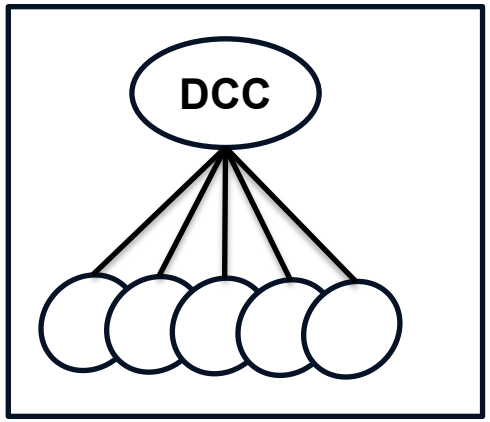
CURRENT STRUCTURE





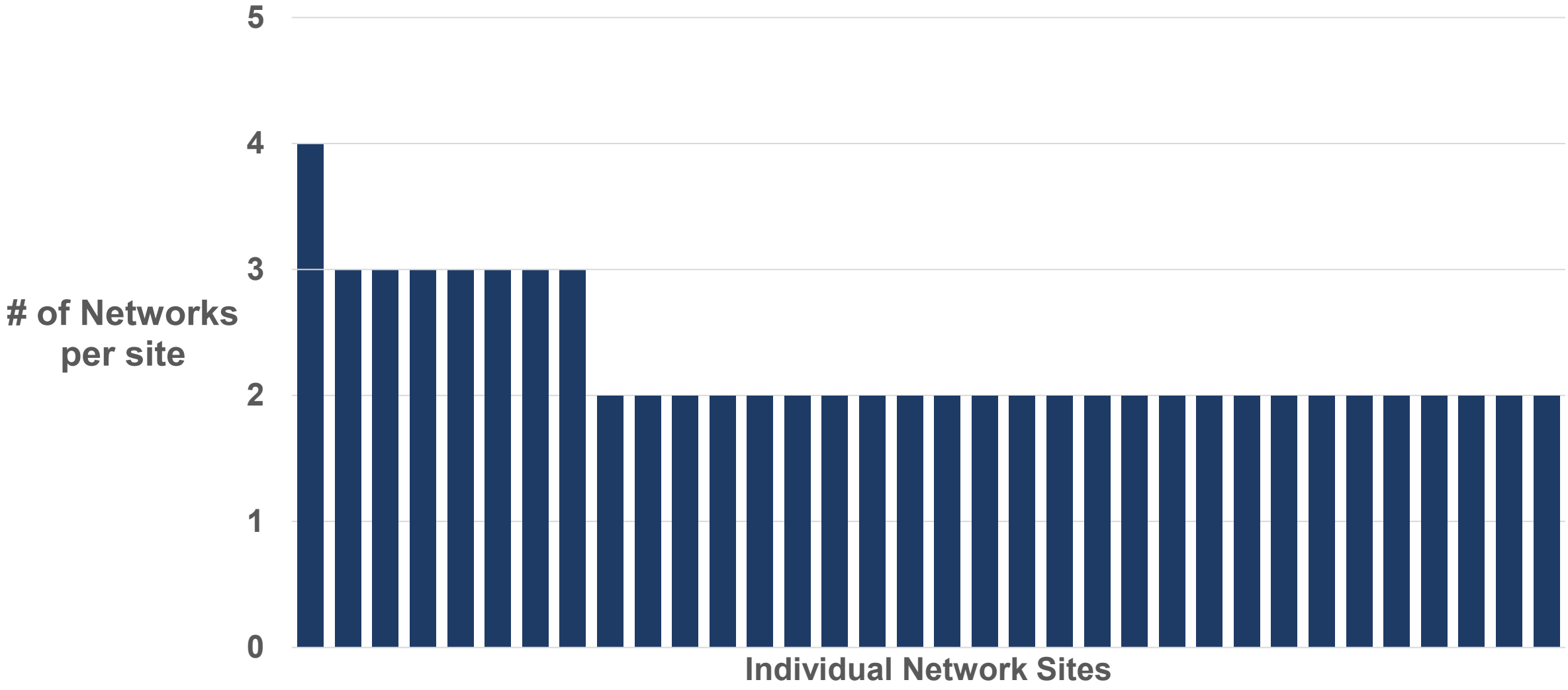




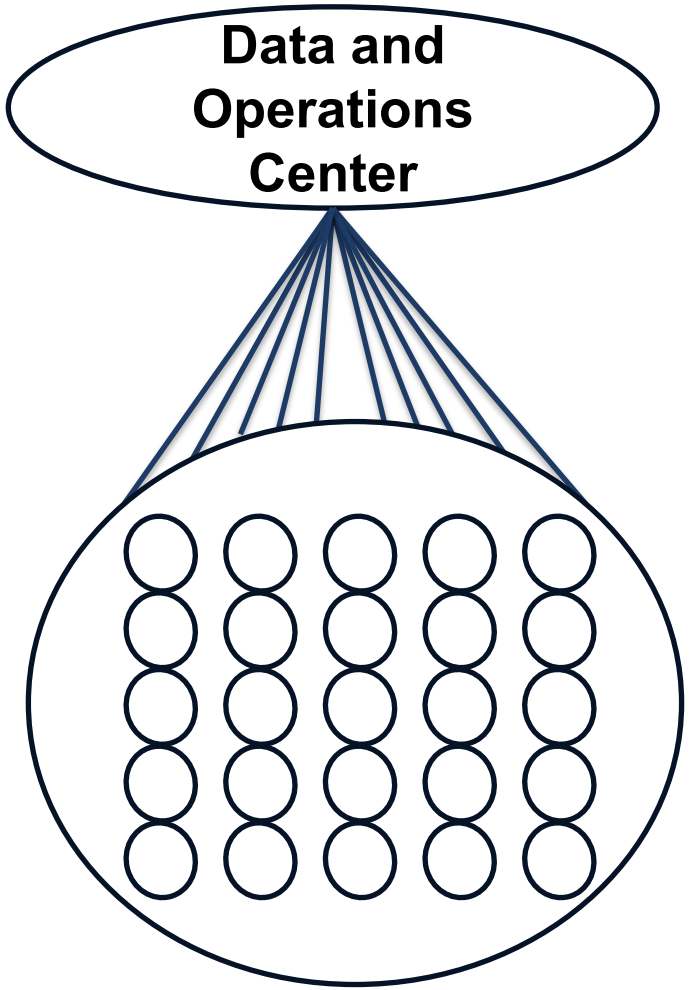


DCC: Data Coordinating Center

Pediatric Network Ecosystem Analysis



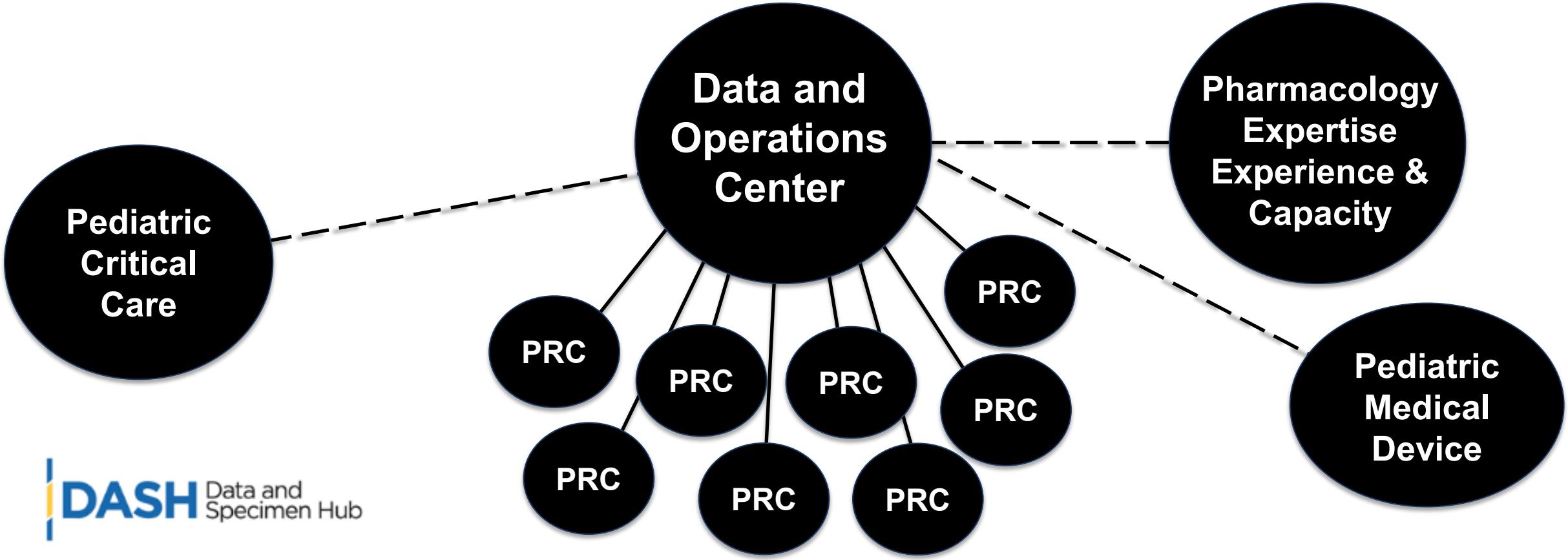
PROPOSED STRUCTURE



- Break down barriers
- Mitigate duplication
- Many more eligible centers = faster trials
- Wider spectrum of interventions and outcomes
- Enhanced communication and collaboration
- Leverage strengths and resources

Goals of Initiative

- Informed, alternative, and fungible option
  - Maintains advantages of current system / potential for enhanced efficiency
- Aligns well with components of the *Make America Healthy Again* initiative
- Facilitates interactions with non-traditional partners
- NIH Implementation Plan for *Restoring Gold Standard Science*
- Immediate goals of current Proposal are to establish and support:
  - Data and Operations Center (DOC) capable of supporting multisite research on any number of areas related to pediatric health
    - Pediatric Critical Care Medicine
    - Pediatric Pharmacology Research and Drug Development
    - Pediatric Medical Device Research and Development

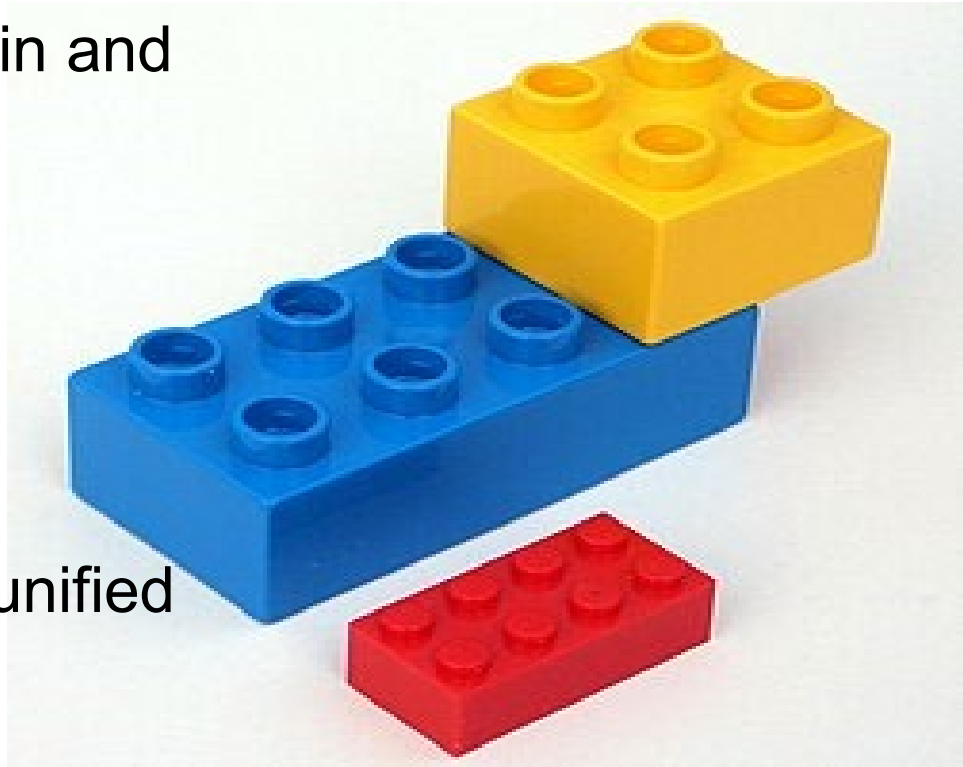


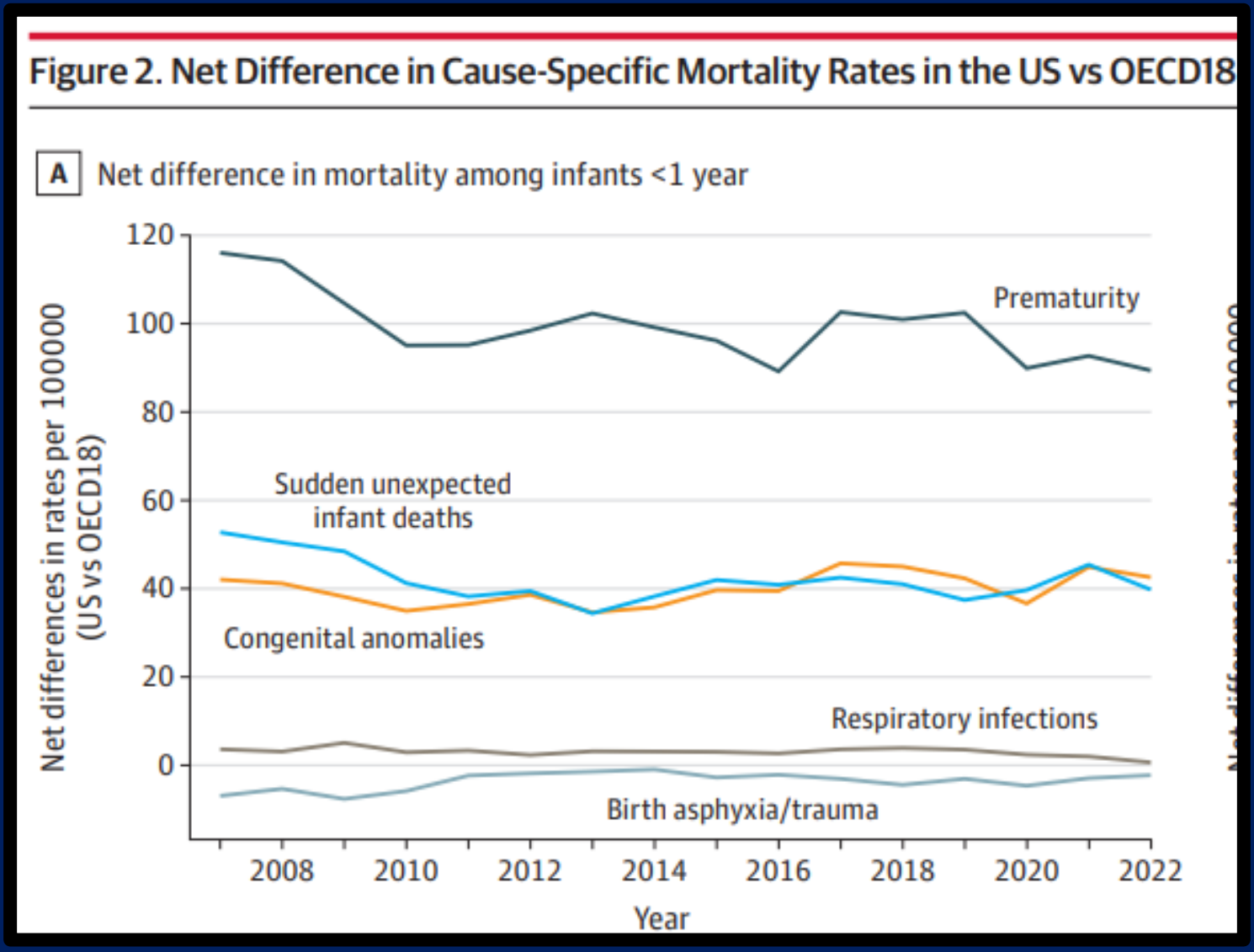
The Initial Plan

- Data and Operations Center
- Primary Research Centers (PRC)
- Capable of conducting Pediatric Critical Care, Pharmacology and Device Research

Establish Foundation

- Framework and infrastructure within which other areas of science can be added
- Facilitate collaboration with other Networks both within and beyond the NICHD
- Data sharing and linkage
  - Maternal and infant data
- Biosample collection
  - Inform and enhance further research
- If successful, a huge first step toward establishing a unified pediatric research consortium





Forrest CB. Trends in US Children's Mortality, Chronic Conditions, Obesity, Functional Status, and Symptoms. JAMA. 2025;334(6):509-516. doi: 10.1001/jama.2025.9855. PMID: 40622733; PMCID: PMC12235530.

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems…

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…and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Thank you!

Core Group

- Rohan Hazra
- Caroline Signore
- David Clark
- Aaron Pawlyk
- Valerie Maholmes

Non-NICHD Colleagues

- Bill Kapogiannis
- Michael Anderson
- Sara Kinsman
- Tee Morrison-Quinata
- Marrah Lachowicz-Scroggins
- Adam Hartman
- Wendy Weber
- Kristin Burns
- Gail Pearson
- Beena Sood
- Sara Van Driest
- Sanae ElShourbagy
- ECHO Program
- Damiya Whitaker

NICHD DER Colleagues

- Perdita Taylor-Zapata
- Antonello Pileggi
- Lesly Samedy-Bates
- Zhaoxia Ren
- Camille Fabiyi
- Gabi Piatkowski
- Katie Vance
- Tammara Jenkins
- Cinnamon Dixon
- Abisola Tepede
- Marjorie Vandy
- Nahida Chakhtoura
- Gus Santos Schmidt
- Melissa Parisi
- Sonia Lee
- Tracy King
- David Weinberg
- Kristin Newton
- Marcia Fournier
- Andrea Marques Horvath
- Kathryn Adams
- Katherine Todman
- Theresa Cruz

NICHD DEA Colleagues

- Rebekah Rasooly
- April Edwards
- Lisa Jatta
- Joe Gindhart
- Alexis Clark
- Nichole Zivuku
- Dennis Twombley

Office of Data Science/Sharing

- Rebecca Rosen
- Valerie Cotton
- Stephanie Tison
- Elizabeth Clerkin
- Tarsheka Thompson
- Liz Umberfield

Data Linkage

- Brett Miller
- Rebecca Clark
- Randy Capps
- Susan Jekielek

Project Management Support

- Marissa Drell
- Ashley Barnes