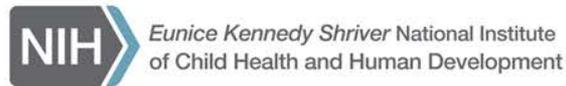


NICHD Director's Report June 8, 2017

Diana W. Bianchi, M.D.
Director, NICHD



Outline of My Talk Today

- **Budget Update**
- **Vision Update**
 - **Communicate the Message**
 - **Building Bridges**
 - **Training Scholars**
 - **Shared Data and Resources**
- **Other Items of Interest**
 - **Grant Support Index**
 - **Implementation of Cures Act**
 - **Pediatric Inclusion**
 - **RCDC**

Budget Update

- **FY 2017 Omnibus Budget \$1.38 billion (+40.5 million for NICHD)**
- **President's Proposed FY 2018 Budget**
 - **NIH congressional justification for FY 2018 requests a little over \$1 billion for NICHD**
 - **The proposed NICHD budget for FY 2018 is approximately \$345 million (or nearly 25 percent) less than NICHD's FY 2017 appropriation**
 - **NICHD leadership is working to soften the impact of *any* cut to our budget**



FY 2018: Case for Optimism

Rep. Cole
R., Oklahoma



Senator Blount
R., Missouri

May 2, 2017

“What we did once, and we did twice, we can surely do thrice.”

Staffing Update

- **Hiring freeze is still in effect, including special government employees (Council members)**



A Review of My Vision from January's Council Meeting



My Vision for NICHD-I

- **Define “our brand” (what is our focus?)**
 - **Communicate the message**
- **Listen to the Voice of the Patient**
- **Advocate for personalized medicine in pediatrics, obstetrics and rehabilitative medicine**
- **Build bridges between other NIH Institutes, external organizations**
- **Integrate obstetrics and pediatrics research at NICHD; take the long view (DoHaD)**



My Vision for NICHD-II

- **Analyze best way to identify and support trainees most likely to succeed**
- **Stress the importance of data science and sharing to leverage our investments**
- **Increase access to clinical trials for pediatric and obstetric patients, extramurally and intramurally**
- **Catalyze innovation**
- **Emphasize the “A” (for “Advice”) in the Advisory Council**



What Has Been Done Since January?

Communicate our Message



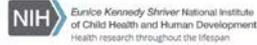
- **Website Update**
- **Advocacy**
 - **Friends of NICHD**
 - **Congressional Visits**
 - **Voice of the Patient**

Draft Web Site Design



US Department of Health and Human Services | National Institutes of Health

Directory | Follow     



 Browse A-Z

[Research](#) | [Health Topics](#) | [Grants & Contracts](#) | [Clinical Trials](#) | [Newsroom](#) | [About NICHD](#)

1 in every 33 infants born in the U.S. has a birth defect

[Learn about common types, risks, and treatments >](#)



Childhood brain injury linked to adult psychiatric illness, earlier death



FACT: A Flu Shot is more important for pregnant women



Research Resource: Check Out DASH, the NICHD Data and Specimen Hub

Featured



Safe to Sleep Campaign®

Learn from leading research of Sudden Infant Death Syndrome. Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat.



Rehabilitation Research at NIH

Moving the field forward. Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat.

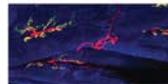
Director's Corner



Getting to Know the New NICHD Director

Diana W. Bianchi, M.D., Director

[BioSketch](#)



Funding Opportunities

[Active Funding Announcements](#)
[Small Business Programs](#)
[Lorem ipsum dolor](#)



Grant Information

[Peer Review](#)
[Sample Applications](#)
[Qui accusamus](#)

Divisions, Centers & Offices



[Contact Us](#)

[Publications](#)

[Sitemap](#)

[Español](#)



[NEWSROOM](#)

[News Releases](#)

[NICHD in the News](#)

[Videos](#)

[OUTREACH](#)

[Safe to Sleep®](#)

[The National Child & Maternal Health](#)

[Education Program](#)

[RELATED WEBSITES](#)

[NIH.gov](#)

[HHS.gov](#)

[USA.gov](#)

[ClinicalTrials.gov](#)

[WEBSITE POLICIES](#)

[Disclaimer](#)

[FOIA](#)

[Privacy Policy](#)

[Accessibility](#)



Friends of NICHD



Breakfast meeting on Capitol Hill



Congressional Visits





Listen to the Voice of the Patient



Welcome to Mrs. Kristine Ribas!

Building Bridges



- **Internal**
 - NICHD and NHGRI
 - *All of Us*, various IC Directors
 - Integrate obstetric and pediatric research
 - Established lab at NHGRI
- **External**
 - Visits to area hospitals
 - Gates Foundation
 - Discovery and Translation Panel
 - G-CAPR
 - BMGF
 - Professional Societies
 - Academic Leaders



NHGRI-NICHD Bridge Building Meeting



Current Examples of Collaborations with NHGRI:

Newborn Sequencing In Genomic medicine and public Health (NSIGHT) program



Held a meeting on May 18 with NICHD and NHGRI to discuss additional collaboration opportunities



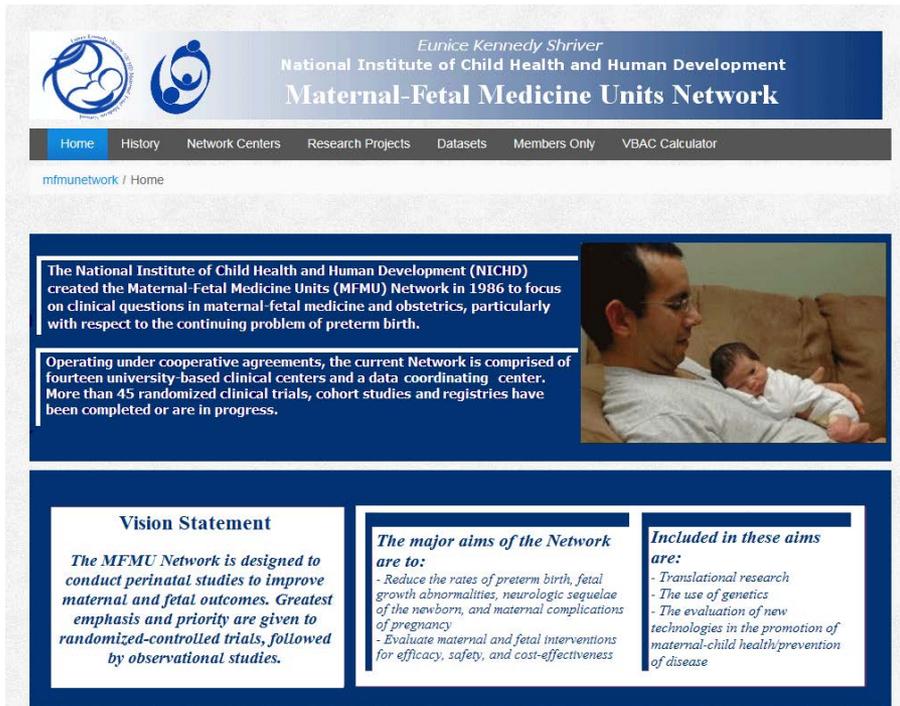
Ensure Representation of NICHD Populations in Trans-NIH Initiatives



- Meetings held with Eric Dishman, Director and former VP at Intel & Stephanie Devaney, PhD, Deputy Director
- NICHD's representatives include Alison Cernich, Germaine Buck Louis and Cathy Spong
- Tina Cheng, MD, Chair of Pediatrics at Hopkins is on Advisory Committee



Integrate Obstetrics and Pediatrics Research at NICHD



Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Maternal-Fetal Medicine Units Network

Home History Network Centers Research Projects Datasets Members Only VBC Calculator

mfmunetwork / Home

The National Institute of Child Health and Human Development (NICHD) created the Maternal-Fetal Medicine Units (MFMU) Network in 1986 to focus on clinical questions in maternal-fetal medicine and obstetrics, particularly with respect to the continuing problem of preterm birth.

Operating under cooperative agreements, the current Network is comprised of fourteen university-based clinical centers and a data coordinating center. More than 45 randomized clinical trials, cohort studies and registries have been completed or are in progress.



Vision Statement

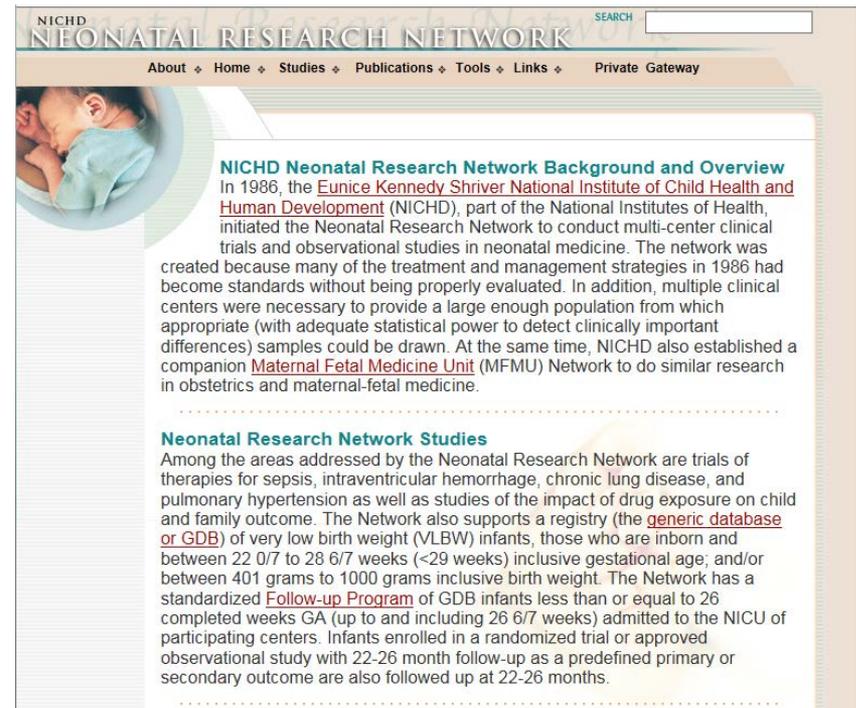
The MFMU Network is designed to conduct perinatal studies to improve maternal and fetal outcomes. Greatest emphasis and priority are given to randomized-controlled trials, followed by observational studies.

The major aims of the Network are to:

- Reduce the rates of preterm birth, fetal growth abnormalities, neurologic sequelae of the newborn, and maternal complications of pregnancy
- Evaluate maternal and fetal interventions for efficacy, safety, and cost-effectiveness

Included in these aims are:

- Translational research
- The use of genetics
- The evaluation of new technologies in the promotion of maternal-child health/prevention of disease



NICHD NEONATAL RESEARCH NETWORK

About Home Studies Publications Tools Links Private Gateway



NICHD Neonatal Research Network Background and Overview

In 1986, the [Eunice Kennedy Shriver National Institute of Child Health and Human Development](#) (NICHD), part of the National Institutes of Health, initiated the Neonatal Research Network to conduct multi-center clinical trials and observational studies in neonatal medicine. The network was created because many of the treatment and management strategies in 1986 had become standards without being properly evaluated. In addition, multiple clinical centers were necessary to provide a large enough population from which appropriate (with adequate statistical power to detect clinically important differences) samples could be drawn. At the same time, NICHD also established a companion [Maternal Fetal Medicine Unit](#) (MFMU) Network to do similar research in obstetrics and maternal-fetal medicine.

Neonatal Research Network Studies

Among the areas addressed by the Neonatal Research Network are trials of therapies for sepsis, intraventricular hemorrhage, chronic lung disease, and pulmonary hypertension as well as studies of the impact of drug exposure on child and family outcome. The Network also supports a registry (the [generic database or GDB](#)) of very low birth weight (VLBW) infants, those who are inborn and between 22 0/7 to 28 6/7 weeks (<29 weeks) inclusive gestational age; and/or between 401 grams to 1000 grams inclusive birth weight. The Network has a standardized [Follow-up Program](#) of GDB infants less than or equal to 26 completed weeks GA (up to and including 26 6/7 weeks) admitted to the NICU of participating centers. Infants enrolled in a randomized trial or approved observational study with 22-26 month follow-up as a predefined primary or secondary outcome are also followed up at 22-26 months.

Spoke at meetings of the NRN and the MFMU to encourage piloting approaches to integrating data



Established Prenatal Genomics and Therapy Section at NHGRI





Visiting Area Hospitals

- **Goal**: to identify opportunities for collaboration, including sub-specialists to help us with pediatric clinical research at NIH's Clinical Center
- **Visits to date:**
 - Walter Reed National Military Medical Center
 - Children's National Medical Center
 - Johns Hopkins visit is scheduled for June





NIH-Bill and Melinda Gates Foundation Partnership

Working groups with NICHD participation:

- **Maternal, newborn and child health**
- **Contraceptive research**
- **Met on June 2, 2017**

G-CAPR

Discovery and translation expert panel



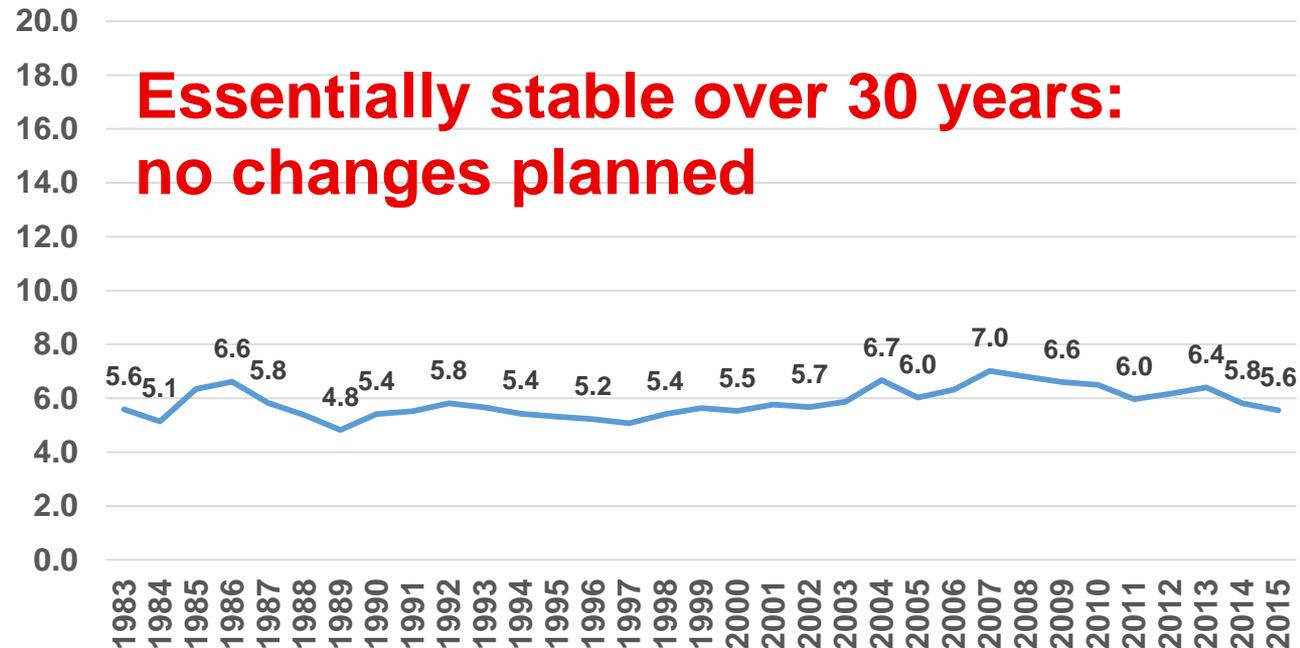
2016



June 2, 2017

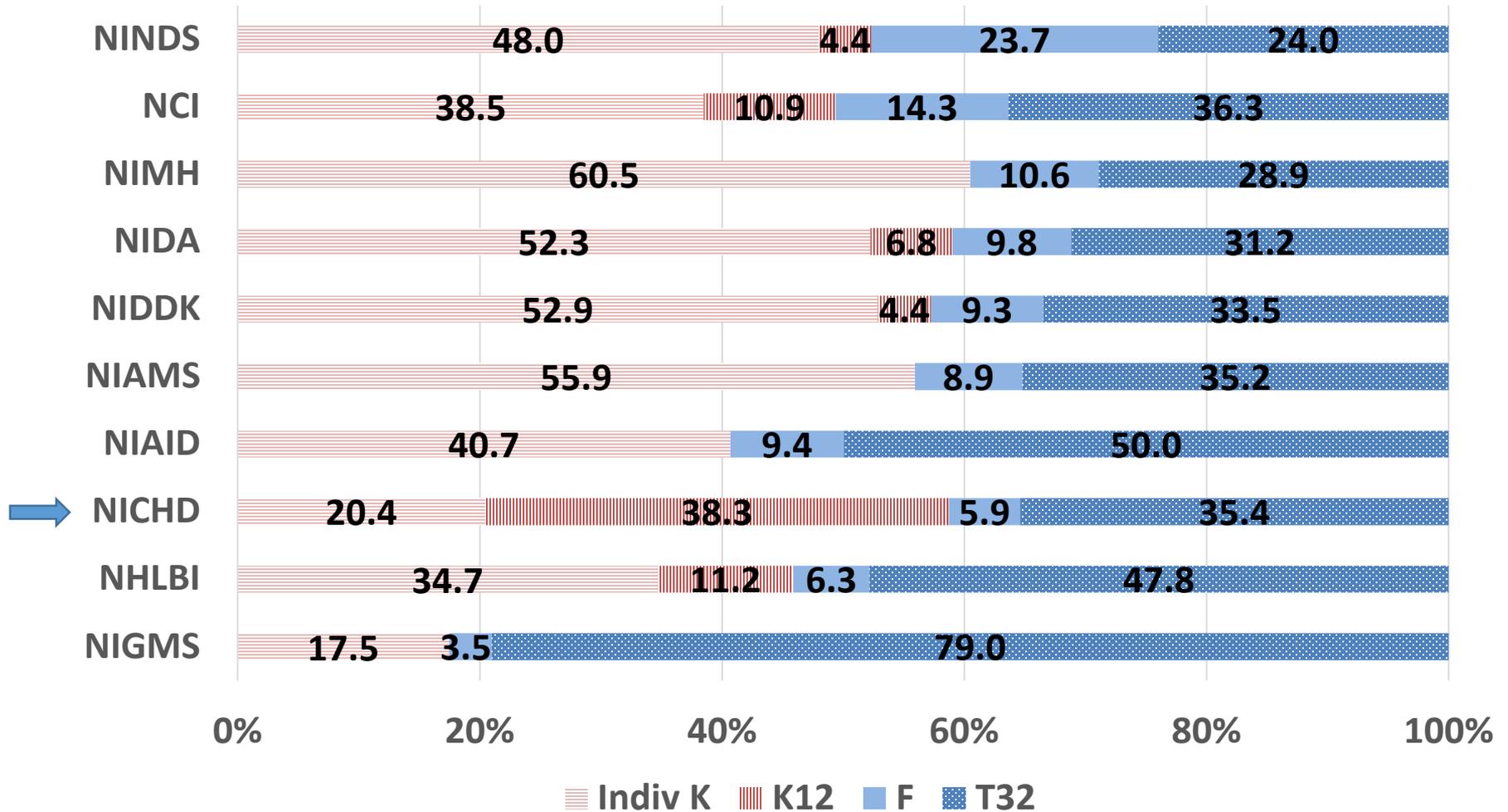
Training Scholars to Ensure Success

- Investing our training dollars in the people most likely to succeed
- Training and Career Development as a % of Extramural Budget 1983-2015



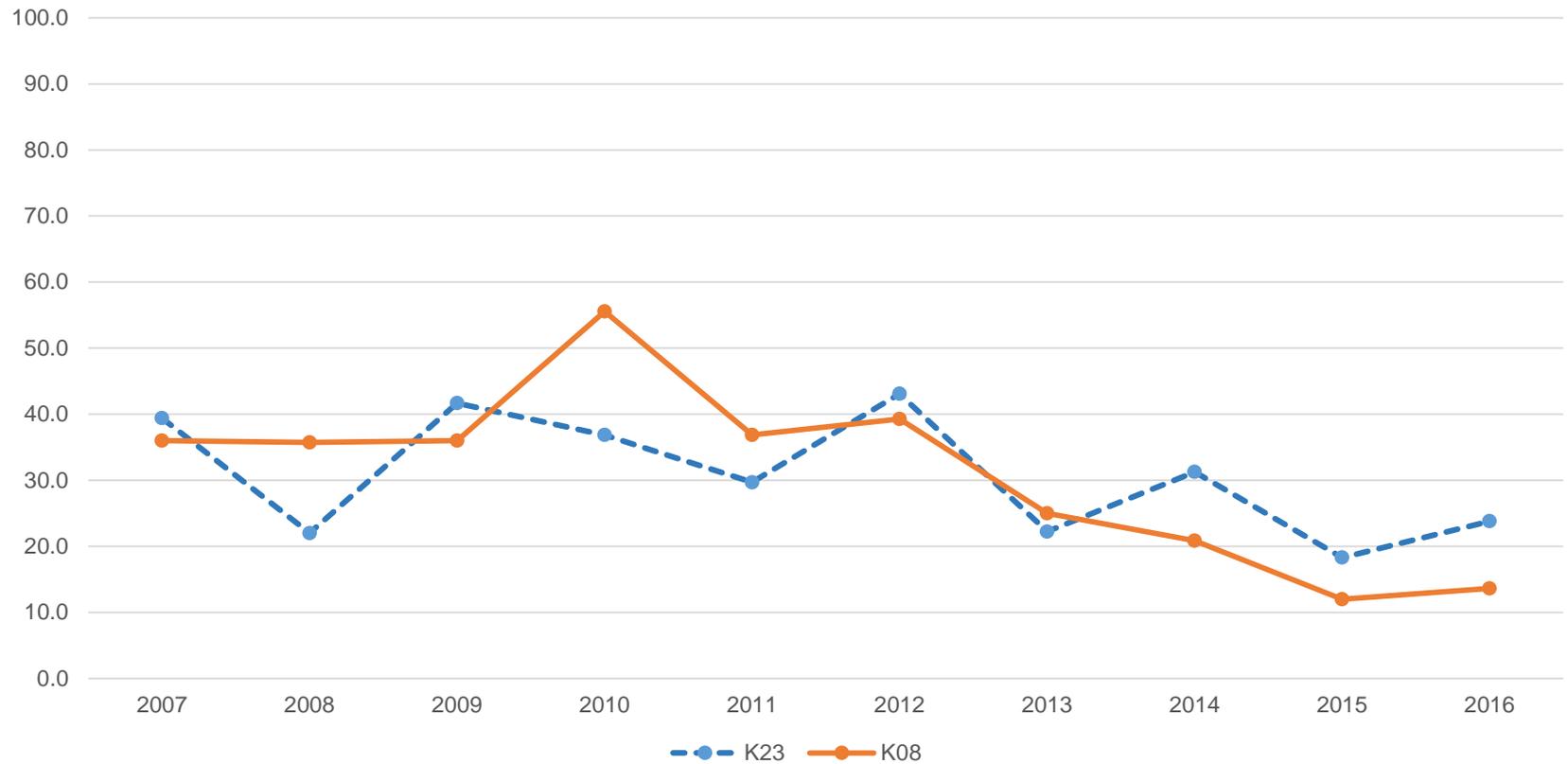


Relative % of Funds Committed to Individual vs. Institutional Training by NIH Institute (FY2014)



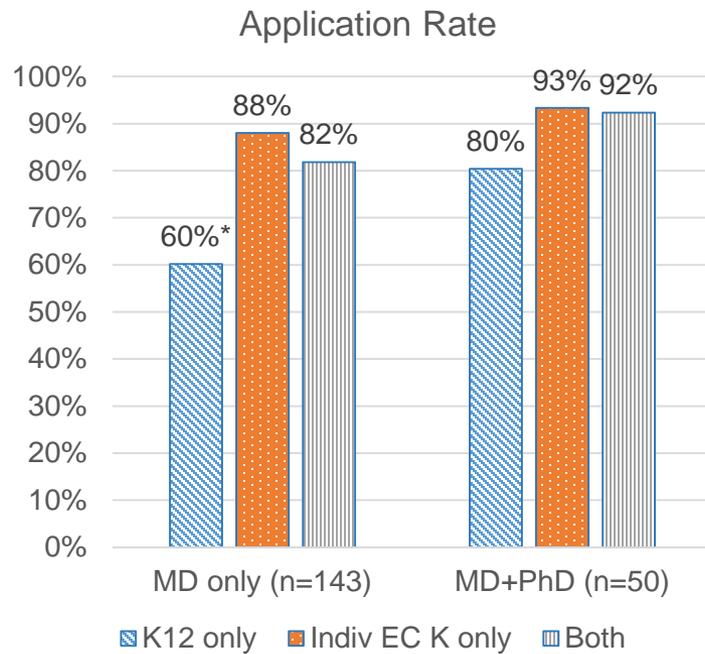


Funding Rates for NICHD K08 and K23 Awards

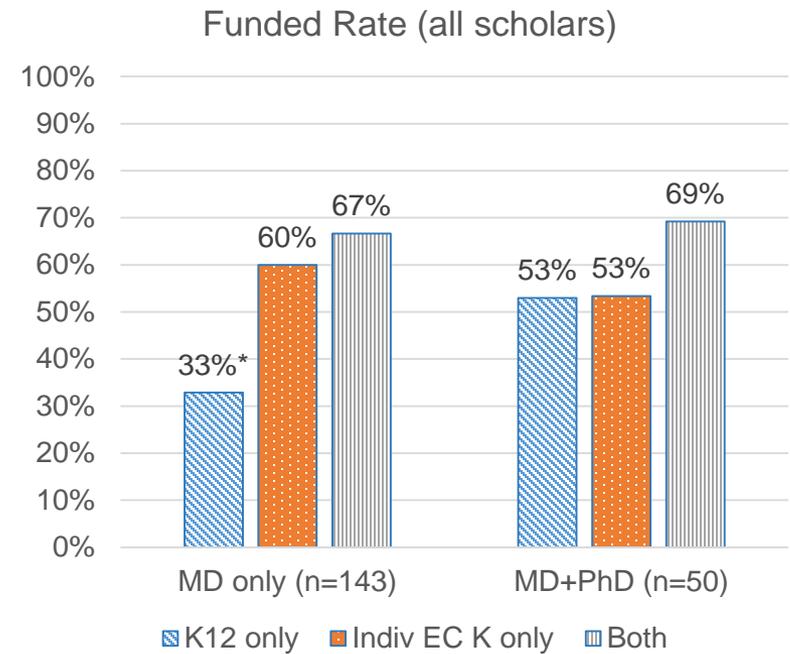




Application and Funding Rates for K and K12 Scholars Supported in 1999-2001 and applying for subsequent NIH grants



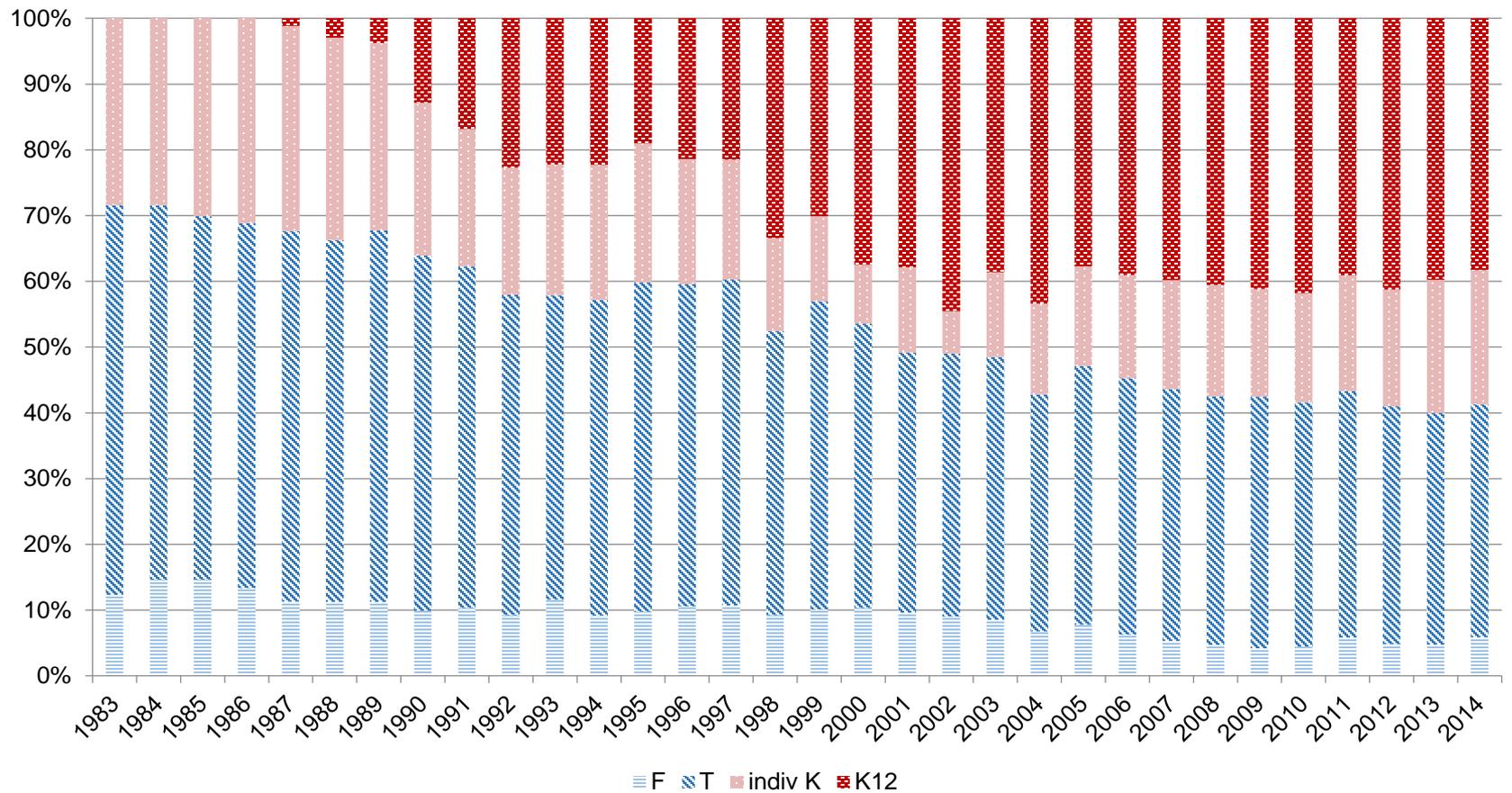
*Significantly different from Indiv EC K only
OR: 4.9, 95% CI: 1.8-13.6; Fisher's exact test: $p < .001$.



*Significantly different from Indiv EC K only
OR: 3.1, 95% CI: 1.5-6.3; Fisher's exact test: $p = .001$.



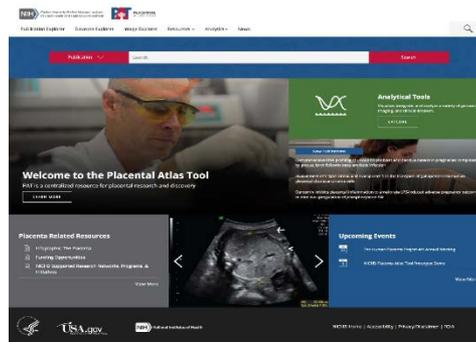
Proportion of NICHD Expenditures by Fiscal Year and Grant Type



Shared Data and Resources

NICHD's Commitment to Shared Resources

- Data and Specimen Hub (DASH)
- Placenta Atlas Tool
- Bio Specimen Repository and Clinical Data Task Force



Study Topics Represented in DASH

(Number of studies in parentheses; some studies with overlapping topics)

Autism Spectrum Disorder (1)
Children's Bone Health and Calcium (1)
High Risk Pregnancy (2)
HIV/AIDS (21)
Infant Care and Infant Health (3)
Infant Mortality (1)
Labor and Delivery (2)
Necrotizing Enterocolitis (1)
Pharmacology (2)
Preconception Care and Prenatal Care (1)
Preeclampsia and Eclampsia (2)
Pregnancy (9)
Preterm Labor and Birth (6)
Rehabilitation Medicine (1)
Stroke (1)
Sudden Infant Death Syndrome (1)
Women's Health (1)

- Centralized resource for researchers to store and access de-identified data from studies supported by NICHD
- Can help investigators meet NIH's data sharing requirements for their own studies and find others' study data for secondary analyses
- Aims to accelerate scientific findings and improve human health
- Launched in August 2015 and governed by the NICHD DASH Committee



41 Studies Available



17 Study Topics



8,300+ Users



47 Data Requests

Questions? Contact supportdash@mail.nih.gov.

For NICHD studies not archived in DASH, visit: <https://dash.nichd.nih.gov/Resource/LinksToOtherArchives>.



First Publication That Used the DASH Resource

Journal of Perinatology (2017) 00, 1–5

© 2017 Nature America, Inc., part of Springer Nature. All rights reserved 0743-8346/17

www.nature.com/jp

ORIGINAL ARTICLE

Racial and social predictors of longitudinal cervical measures: the Cervical Ultrasound Study

EW Harville¹, KS Miller² and LR Knoepp³

OBJECTIVE: To evaluate whether the racial and socioeconomic disparities are present in adverse cervical parameters, and, if so, when such disparities develop.

STUDY DESIGN: A prospective cohort study was conducted. 175 women with a prior preterm birth had up to four endovaginal ultrasounds between gestational weeks 16 and 24 (Cervical Ultrasound Trial of the MFMU). Each sociodemographic factor (race/ethnicity, marital status, insurance funding and education) was examined as a predictor of short cervix or U/funnel shape, using multiple logistic and linear regression. Changes in the cervical length and shape across pregnancy and after pressure were also examined.

RESULTS: The strongest associations were seen between race and government-funded insurance and short cervix and U shape per funneling (race and length < 25 mm per funnel: adjusted odds ratio (OR) 5.52, 2.24 to 13.63; government-funded insurance and length < 30 mm per funnel: adjusted OR 3.10, 1.34 to 7.15). Changes in cervical length were not associated with sociodemographics.

CONCLUSION: African-American race and, to a lesser extent, insurance funder, are associated with cervical length and shapes that have been associated with preterm birth, and those properties are present largely early in pregnancy.

Journal of Perinatology advance online publication, 12 January 2017; doi:10.1038/jp.2016.240



Other Items of Interest

Grant Support Index

Principal NIH Deputy Director Dr. Larry Tabak will present detailed information later today



The screenshot shows the bioRxiv preprint server interface. At the top left is the Cold Spring Harbor Laboratory (CSH) logo. The bioRxiv logo is prominently displayed in the center, with the tagline 'THE PREPRINT SERVER FOR BIOLOGY'. In the top right corner, there are navigation links for 'HOME' and 'ABOUT', and a search bar. Below the navigation, the text 'Confirmatory Results' is visible. The main title of the preprint is 'Marginal Returns And Levels Of Research Grant Support Among Scientists Supported By The National Institutes Of Health'. Below the title, the authors are listed: Michael S. Lauer, Deepshikha Roychowdhury, Katie Patel, Rachael Walsh, and Katrina Pearson. A DOI link is provided: <https://doi.org/10.1101/142554>. A note states: 'This article is a preprint and has not been peer-reviewed [what does this mean?]'.

Navigation tabs are located below the note: 'Abstract' (selected), 'Info/History', 'Metrics', 'Supplementary material', and 'Preview PDF'.

Abstract

The current era of worsening hypercompetition in biomedical research has drawn attention to the possibility of decreasing marginal returns from research funding. Recent work has described decreasing marginal returns as a function of annual dollars granted to individual scientists. However, different fields of research incur varying cost structures. Therefore, we developed a Grant Support Index (GSI) that focuses on grant activity code, as opposed to field of study or cost. In a cohort of over 71,000 scientists funded by NIH between 1996 and 2014, we analyzed the associations between grant support and 3 bibliometric outcomes based on the Relative Citation Ratio (RCR), namely maximum RCR, median RCR, and annual weighted RCR. We found that for all 3 measures marginal returns decline as annual GSI increases. Thus, we confirm prior findings of decreasing marginal returns with higher levels of research funding support.

Lauer et al.

BioRxiv. <http://biorxiv.org/content/early/2017/05/26/142554>

Cures Act Relevant to NICHD

Lisa Kaeser will
discuss later
today

- **Inclusion of Children in Clinical Research**
- **Task Force on Research Specific to Pregnant and Lactating Women**
- **National Pediatric Research Network**
- **Global Pediatric Research**
- **Medical Rehabilitation Research**

**Summary
of
Pediatric
Inclusion
Data at
NIH**

**Presented at Inclusion
Across the Lifespan
Workshop on June 1, 2017**

- **Analysis of What Researchers Originally Planned to Do (Grants)**
- **Review of a Major Publication as Indication of Actual Participant Cohort**





Summary of Key Results

- **Inclusion**: ~65% of all NIH grants plan to include children <21; about half of those plan to include children <18.
- **Analysis**: In 60% of NIH phase III clinical trial grants that planned to include children, researchers **did not plan** to analyze results by age.
- Over 80% of NIH phase III clinical trial grants published results within 5-7 years of the start of funding.
- **Inclusion**: ~25% of grants stated they intended to include subjects <18, but did not include children <18 in published results.
- **Analysis**: 36% of grantees differed from their original analysis plan in their published results.



Questions?