Council of Councils Meeting

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Talk Outline

- NICHD Strategic Plan and Mission
- NICHD Science: the Human Placenta Project
- STrategies to EnRich Inclusion and AchieVe Equity (STRIVE) Initiative
- COVID-19 Research in Children and Pregnant Individuals
- Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative
- INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE) Project

NIH Pediatric Research Spending by Percent of IC Budget FY 2019





NIH Maternal Health Research Funding by IC, FY 2019







NICHD Strategic Plan

Mission Statement

The NICHD leads research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.





Scientific Research Themes

- Understanding the Molecular, Cellular, and Structural Basis of Development
- Promoting Gynecologic, Andrologic, and Reproductive Health
- Setting the Foundation for Healthy Pregnancies and Lifelong Wellness
- Improving Child and Adolescent Health and the Transition to Adulthood
- Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities

NICHD Science: Human Placenta Project



- The placenta is NICHD's organ
- NICHD has supported HPP with >\$91M over 7 years
- HPP investment is *in addition* to a large and continued investment in basic placenta research
- Advances in imaging the placenta and analyzing circulating factors
- Placenta is connected to cardiac disease, diabetes, and other conditions later in life
 - *"The placenta is the center of the chronic disease universe."* Kent Thornburg



Strategic Plan Cross-Cutting Themes (as of September 2019)

- Health Disparities
- Infectious Disease
- Global Health
- Nutrition
- Prevention



Credit: Guilak Lab, Washington University





STRIVE Initiative (STrategies to EnRich Inclusion and AchieVe Equity)

STRIVE Initiative Overview

NICHD must do more to address underlying causes of health disparities, including tackling structural racism. We are also committed to diversifying the scientific workforce, both within our institute and in the broader extramural community.

- NICHD effort is led by our Office of Health Equity (OHE)
 - OHE has been part of the NICHD OD since 2016
- Coordinated with NIH's UNITE initiative





STRIVE Committees and Goals

- I. Equity, Diversity and Inclusion in NICHD's Workforce: Recruit and retain the best talent across all career paths to more fully accomplish our mission
- II. Scientific Workforce: Train and support the scientific careers of diverse scientists in the extramural community
- III. Health Disparities Research: Encompasses research across intramural and extramural divisions







COVID-19 Research in our Populations

Gestational research assessments for covid-19 (GRAVID)

- Medical records analysis of up to 24,500 women who have given birth at a clinical center within NICHD's <u>Maternal-Fetal Medicine</u> <u>Units Networks</u> to examine maternal and neonatal outcomes for pregnant women with and without SARS-CoV-2 infection
- Early results analyzing data from 1,200 COVID+ pregnant women showed that pregnant women with severe symptoms of COVID-19 had a higher risk of complications during and after pregnancy.
 - Those with severe symptoms were at higher risk for cesarean delivery, postpartum hemorrhage, hypertensive disorders of pregnancy, and preterm birth.
- Pregnant people outside of the network inquired if they could participate



12 Centers; 39 individual hospital sites

Metz TD et al. *Obstet Gynecol*. 2021 Apr 1;137(4):571-580.



CARING for Children with COVID

(<u>C</u>ollaboration to <u>A</u>ssess <u>R</u>isk and <u>I</u>dentify Io<u>NG</u>-term outcomes for Children with COVID)



- <u>Two approaches</u>
- Leverages resources and networks from 3 NIH ICs to capture data from hospitalized patients with MIS-C
- Trans-NIH effort through RADxrad to enhance diagnostic and predictive efforts
- <u>CARING4KidswithCOVID.nih.gov</u>



CARING for Children with COVID

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- Leveraging networks from NICHD, NHLBI, NIAID to create a centralized cohort of children with MIS-C
 - Capitalizes on strengths of each network: immune profiling (NIAID); long-term cardiac effects (NHLBI); PK/PD of drugs used to treat COVID-19 but not labeled for children (NICHD)
 - Clinical data will be harmonized across MIS-C cohort studies
 - A large searchable data set with common data elements and widely available measures (including WGS) will be created for interoperable sharing across different platforms
 - Aim is to follow children with MIS-C for five years through longitudinal protocol



NIH Rapid Acceleration of Diagnostics (RADx)SM Initiative Overview



Project		Description
Ŷ	RADx Tech	Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19
	RADx-Advanced Testing Program (RADx-ATP)	Rapid scale-up of advanced POC technologies to accelerate and enhance and validate throughput – and support of ultra-high throughput machines and facilities
Q	RADx-Radical (RADx-rad)	Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing
	RADx-Underserved Populations (RADx-UP)	Interlinked community-engaged projects focused on implementation strategies to enable and enhance testing of COVID-19 in underserved and/or vulnerable populations

Predicting Viral-Associated Inflammatory Disease Severity in Children with Laboratory Diagnostics and Artificial Intelligence (PreVAIL klds)

PreVAIL klds AWARDEES





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RADx-UP Return To School Diagnostic Testing Approaches (OTA-21-004)

<u>Goal</u>

 Develop and test COVID-19 diagnostic testing approaches to safely return children and staff to the in-person school setting in underserved and vulnerable communities

Mechanism

 Other Transaction Authority to provide flexibility for changing circumstances and funding of non-traditional partners

Budget

• \$33 million awarded from the OD congressional appropriation for Phase I



Return to School

- Focus on children and adolescents below the age eligible for vaccination via Emergency Use Authorization (age 16) and all school personnel
- Advance methods to integrate testing in return to or maintenance of in-person instruction
- Identify effective, scalable, and sustainable testing implementation strategies, including in-school testing, in community pediatric primary care clinics, childcare centers, preschool, and school settings serving primarily underserved or disadvantaged children and their families.



Overview

- Awarded 8 projects in April FY21
- Strategies for school-based settings to combine frequent testing with proven safety measures to reduce the spread of COVID-19
- Phase I results will be available in summer of 2021, publicly presented in August
- Phase II Awards projected for the summer of FY21



Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)

- FY 21 COVID relief bill: \$1.15 billion to NIH to support research and clinical trials related to the long-term effects of COVID-19
- Trans-NIH effort: Improve understanding of and develop strategies to prevent and treat postacute manifestations of SARS-CoV-2 infection across the lifespan
 - Specific language in the Research Opportunity Announcement (ROA) included children
- Applications currently under review

The New York Times

At 12, She's a Covid 'Long Hauler'

Although most young people recover quickly, doctors are seeing some children and teens with lingering fatigue and other chronic problems.







IMPROVE Initiative (Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone)

Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative

- Encompasses both foundational biology as well as social and biobehavioral research
- Community partners will be key voices to assess needs and to implement interventions



Administrative Supplements for NIH Grants to Add or Expand Research Focused on Maternal Mortality

- \$7.2 million in grants awarded September 29, 2020 through a <u>Notice of Special Interest on Maternal Mortality</u>
- Supported by multiple NIH institutes and co-led by NICHD, the NIH Office of the Director, and the NIH Office of Research on Women's Health
- Areas of research include causes of death such as heart disease, hypertension, hemorrhage or bleeding, and infection
- Research on contributing conditions: diabetes, obesity, mental health disorders, substance use disorders, and structural factors that may contribute to delays or disruptions in maternal care







The INCLUDE Initiative (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome)

Total NIH Funding for Research on Down Syndrome 2008 – 2019





INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE)

3 components:

- 1. Conduct targeted, high-risk, highreward basic science studies on chromosome 21.
- 2. Assemble a large study population of individuals with Down syndrome across the lifespan.
- 3. Include individuals with Down syndrome in existing and future clinical trials.



NIH Down Syndrome Research Opportunities

- NICHD is supporting efforts to increase inclusion of people with DS in clinical trials through its Pediatric Trials Network
 - Pharmacokinetics of understudied drugs in those with DS
 - Developing a training program for clinical researchers
- Several new RFAs released in 2020 to focus on:
 - High-risk, high-reward basic science
 - Clinical trial readiness and full-fledged treatment trials
 - Primary and secondary data analysis
- NOSIs to encourage research on
 - Animal models of DS
 - DS and co-occurring conditions
 - Fellowship and career development awards
 - Supplements for investigators to expand research scope to include DS



New NIH DS/INCLUDE Research Plan will be released later this year

Summary

- NICHD's Strategic Plan guides our priorities and our investments, including research on maternal, child, and adolescent health as well as those with disabilities
- The placenta is "NICHD's organ" and a key to understanding chronic conditions throughout the lifespan
- NICHD is supporting COVID-19 research to understand the spectrum of SARS-CoV-2 infection in children and pregnant women, as well as other effects of the pandemic on child health and wellbeing
- NICHD is co-leading several NIH-wide projects such as IMPROVE and INCLUDE
- NICHD and NIH are committed to creating a diverse and inclusive culture and workforce, and to support health disparities research



NICHD Vision Statement



Healthy pregnancies. Healthy children. Healthy and optimal lives.



