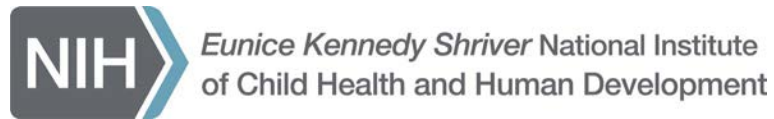


National Advisory Board on Medical Rehabilitation Research: NICHD Director's Report

Diana W. Bianchi

December 2, 2019



Outline

Today's Presentation

- NCMRR Director Search
- NICHD Strategic Plan Release and Implementation
- Trans-NIH Pediatric Research Consortium
- Maternal Morbidity and Mortality
- PregSource® and All of Us
- Draft NIH Data Sharing Policy
- NIH Budget Update

New NICHD Deputy Director

- Alison Cernich, Ph.D.
- NCMRR Director since 2015
- Played a major role in NICHD Strategic Plan
- Alison's skills and talents have been brought to the Office of the Director
- Our gain is not your loss!
 - Benefit to the rehabilitation research community to have someone in the Director's office with experience in your field



New NCMRR Director Search

- We are seeking candidates who have
 - A compelling vision for the future of the field
 - Experience managing and directing a scientific research program, including setting, planning, implementing and analyzing program objectives and priorities
 - Aptitude to lead a research program involving extensive internal and external collaborations
 - Well-honed administrative and interpersonal skills
 - A demonstrated ability to manage financial and human resources



NCMRR Director Search: Already Ongoing

- [Vacancy announcement](#) open Nov. 1, 2019 – January 3, 2020
- Search Committee was formally charged on Nov. 18
- List of qualified individuals will be forwarded to the Search Committee in early January for evaluation against established criteria
- Highly qualified candidates will interview with the Committee
- Search Committee will conduct reference checks
- Short list of best qualified candidates will be sent to NICHD Director for review
- Appointment recommendation will be sent forward to NIH Director for approval (projected for April 2020)



Acting NCMRR Director

- Theresa Cruz, Ph.D., health scientist administrator in NCMRR since 2009
- Co-Lead BRAIN Team B
- Manages grants in the Devices and Technology Development and Rehabilitation Diagnostics and Interventions Programs as well as SBIR grants for medical rehabilitation

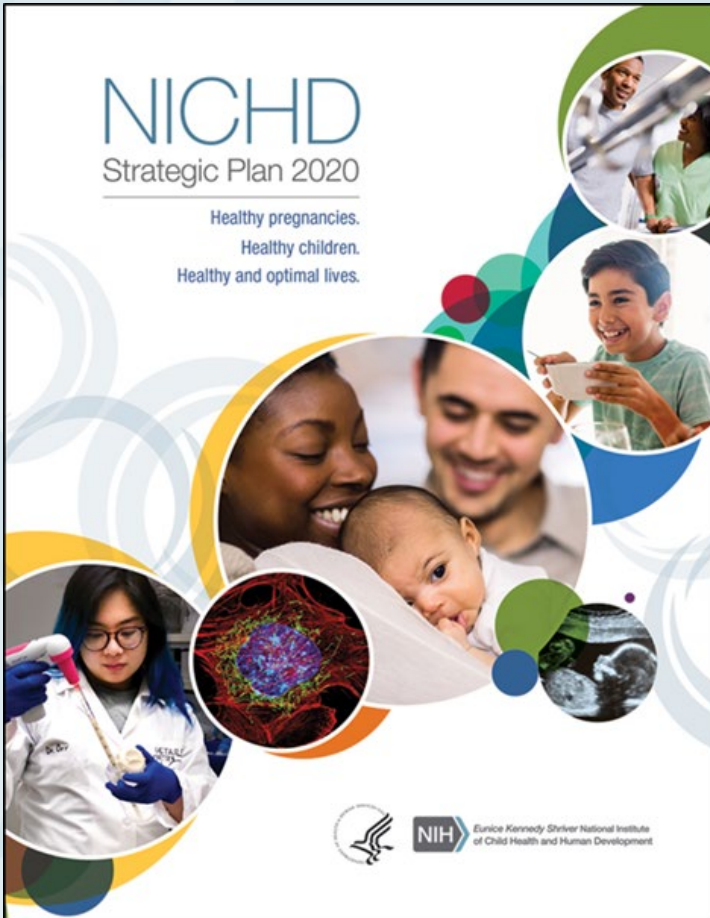
Thank you, Theresa!





NICHD Strategic Plan Release and Implementation

NICHD Strategic Plan 2020

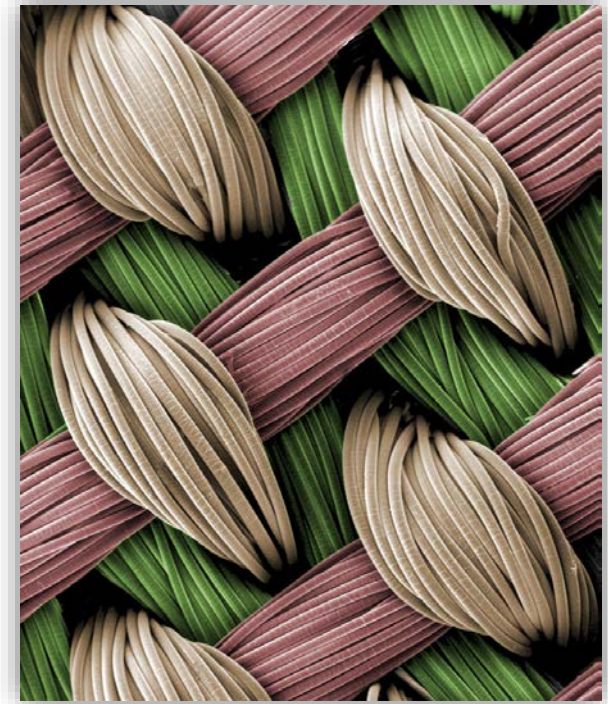


Research Themes

- 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

Cross-Cutting Themes

- **Global Health:** Improve pre-pregnancy health globally using new interventions to benefit pregnancy outcomes, and prevent prematurity, malnutrition, childhood stunting, disease, and developmental delays.
- **Health Disparities:** Understand how social, economic, structural, and regional factors are vital to the advancement of preventive, diagnostic, and intervention efforts.
- **Prevention:** Prevent adverse health outcomes, improve early detection, and understand the optimal timing of prevention efforts.
- **Nutrition:** Improve our understanding of the lifetime impact of nutrition on reproductive health, fertility, pregnancy, and fetal, child, and adolescent growth and development.
- **Infectious Disease:** Improve the basic understanding of how infectious pathogens affect pregnant women and young children, address the impact of infections on reproductive and overall health in children and adolescents, and advance safe and effective treatments for pregnant and lactating women, children, and people with disabilities.

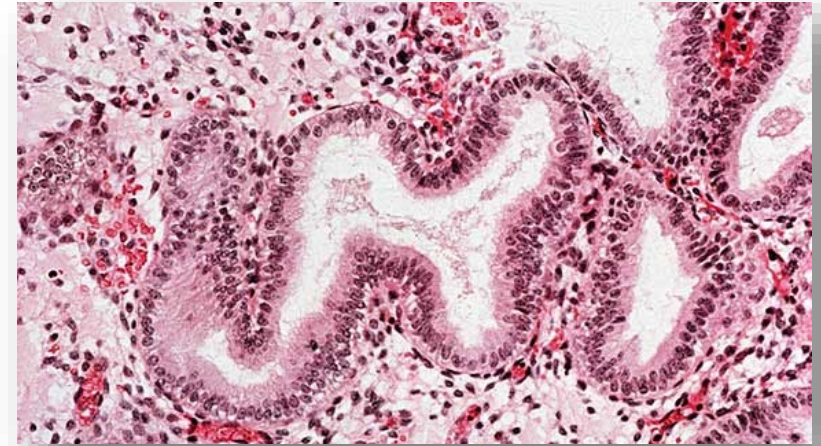


Credit: Guilak Lab, Washington University



Aspirational Goals

- **Goal 1: Limb Regrowth**
- **Goal 2:** Personalized Medicine for Children
- **Goal 3:** Diagnose, Treat, and Cure Endometriosis
- **Goal 4:** Predict Pregnancies at Risk for Fetal Loss
- **Goal 5:** Advance and Apply Knowledge of the Fetomaternal Immune Relationship
- **Goal 6:** Improve Care of Premature Infants
- **Goal 7:** Explore Risks of Technology and Media Exposure in the Developing Brain
- **Goal 8:** Synthesize and Personalize Human Milk
- **Goal 9: Build Connections Between Atypical Neurodevelopment and Risk of Neurodegeneration**
- **Goal 10: Train Investigators in Artificial Intelligence**



21st Century Cures Act – Legislative Requirements

In 2016 the 21st Century Cures Act, SEC. 2031. ‘National Institutes of Health (NIH) Strategic Plan’ outlined requirements for the NIH Strategic Plan.

Specifically, Section 402(m) of the PHS Act stipulated that Strategic plans developed and updated by the national research institutes and national centers of NIH...shall have a common template

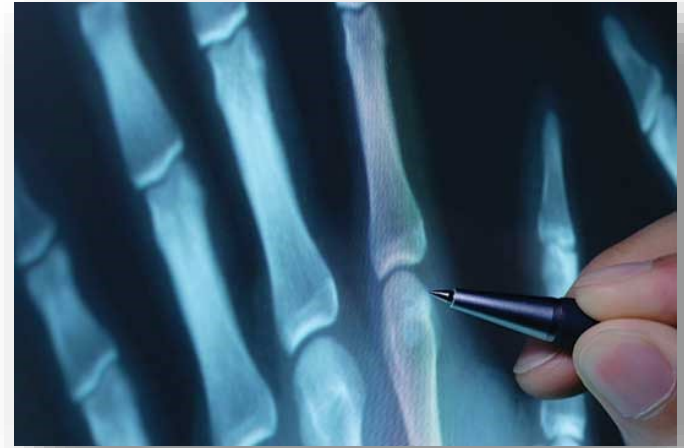
NIH Template for IC Strategic Plans:

- Overview and Introduction
- Scientific Goals/Objectives/Priorities
- Serving as an Efficient and Effective Steward of Public Resources
 - Priority Setting
 - *Scientific Stewardship*
 - *Management & Accountability*
- Description of the Strategic Planning Process



Scientific Stewardship Goals

- Goal 1: Promote an Inclusive Scientific Workforce that Fosters Research Training
- Goal 2: Facilitate Data Sharing and Access to Biospecimens
- Goal 3: Partner to Enhance Science
- Goal 4: Setting Research Priorities
- Goal 5: Align Resources to Support Science
- Goal 6: Improve Clinical Trial Oversight and Management
- Goal 7: Monitoring and Evaluating Programs
- Goal 8: Facilitating Transparency and Communication



Management and Accountability Goals

- Goal 1: Promote Workforce Development and Balance
- Goal 2: Ensure Infrastructure Innovation
- Goal 3: Improve Administrative Efficiency
- Goal 4: Advance Enterprise Risk Management



Strategic Plan Implementation and Metrics

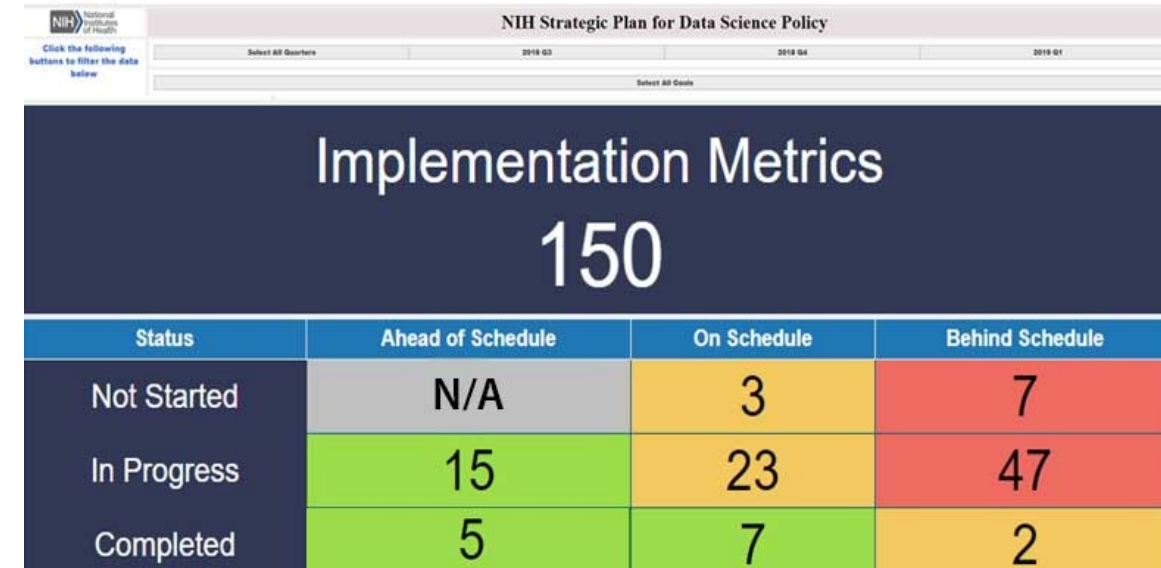
- Carefully considering how to make progress towards each objective within these themes
- Cannot focus on everything simultaneously
 - Some objectives are longer-term by nature
 - Phased approach enables flexibility and incorporates resource limitations
- Developing measures to mark progress
 - For broader goals (e.g., improve survival of infants born preterm or of low birthweight), proximal measures with help mark advances
 - Measures could include: number of new investigators in a field; increasing diversity of the workforce; publications; patents; inclusion of findings in clinical guidelines
- Implementation process will remain flexible to accommodate advances in technology, pivots in a field of research, national health priorities, etc.



Dashboard to Track Metrics (Example)

NIH's Division of Program Coordination, Planning, and Strategic Initiative's Office of Evaluation, Performance, and Reporting is developing a Strategic Plan Tracking System that can:

- Showcase visualizations of the ongoing status and performance of plan elements
- Produce reports on qualitative progress against plan elements, milestone achievement, and metric targets
- Provide transparency to leadership and advisory boards



The screenshot shows a web interface for the NIH Strategic Plan for Data Science Policy. At the top, there is a header with the NIH logo and the title 'NIH Strategic Plan for Data Science Policy'. Below the header, there are filters for 'Select All Quarters' and 'Select All Goals'. The main content area features a large dark blue box with the text 'Implementation Metrics' and a large white number '150'. Below this, there is a table with four columns: 'Status', 'Ahead of Schedule', 'On Schedule', and 'Behind Schedule'. The table has three rows: 'Not Started', 'In Progress', and 'Completed'.

Status	Ahead of Schedule	On Schedule	Behind Schedule
Not Started	N/A	3	7
In Progress	15	23	47
Completed	5	7	2





Trans-NIH Pediatric Research Consortium (N-PeRC)

N-PeRC Details

- Harmonize efforts in child health research across 27 Institutes and Centers
- Major activities
 - Transition to adult health care work group
 - Expanding the pediatric research workforce
 - Creation of shared pediatric data resources
 - Increase study section reviewers with child health expertise
 - Regular review/discussion of existing trans-NIH pediatric programs and upcoming workshops (e.g., BPCA, ABCD, HEAL)



<https://www.nichd.nih.gov/research/supported/nperc>



Transition to Adult Health Care Working Group

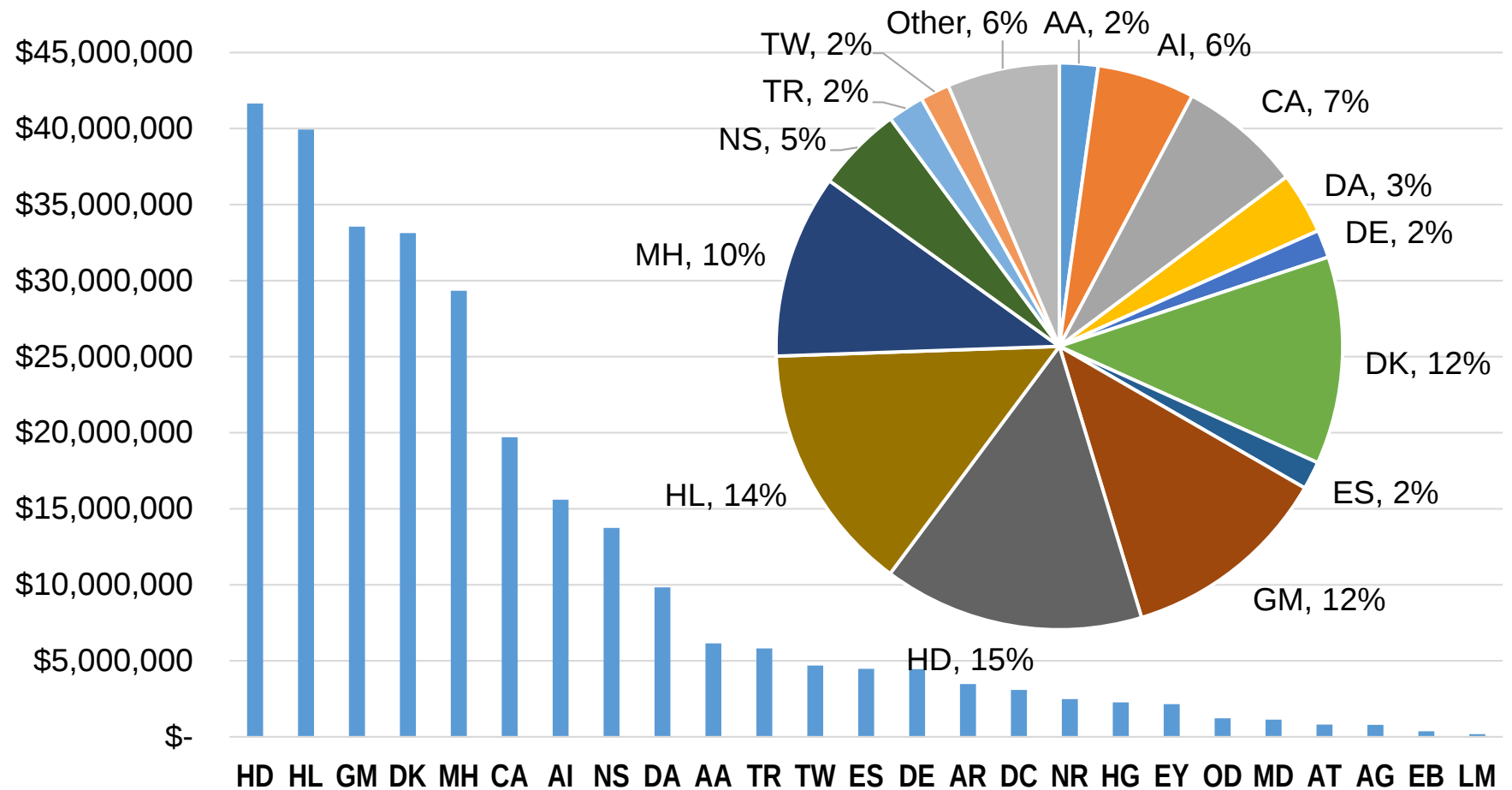
- Adolescents with chronic conditions or disabilities face increased challenges
- N-PeRC working group conducted a portfolio analysis of current research in this area
- Planning a workshop to address transition across conditions and look for synergies (likely fall 2020)
- Research gaps include:
 - Developing measures of “successful” transitions
 - Evaluating interventions



Expanding the Pediatric Workforce: Training Opportunities

- Working group is analyzing where and how pediatric training is supported at NIH
- Aim is to make researchers aware of opportunities across NIH
- These data likely underrepresent the amount of pediatric training support (e.g., NCATS' CTSA's not included)

Est. Total Awarded: \$280,003,407



Shared Pediatric Data Resources

- Exploring options to connect pediatric datasets generated by IC-supported research projects:
 - Gabriella Miller Kids First Pediatric Research Program (<https://commonfund.nih.gov/kidsfirst>)
 - NCI Childhood Cancer Data Initiative (CCDI) (<https://www.cancer.gov/research/areas/childhood/childhood-cancer-data-initiative/symposium>)
 - Investigating Co-Occurring Conditions Across the Lifespan to Understand Down syndrome (INCLUDE)
- Key issues include:
 - Harmonization and interoperability
 - Participant assent and other ethical issues
 - Data security



Shared Pediatric Data Resources

- Exploring options to connect pediatric datasets generated by IC-supported research projects:
 - Gabriella Miller Kids First Pediatric Research Program (<https://commonfund.nih.gov/kidsfirst>)
 - NCI Childhood Cancer Data Initiative (CCDI) (<https://www.cancer.gov/research/areas/childhood/childhood-cancer-data-initiative/symposium>)
 - Investigating Co-Occurring Conditions Across the Lifespan to Understand Down syndrome (INCLUDE)
- Key issues include:
 - Harmonization and interoperability
 - Participant assent and other ethical issues
 - Data security

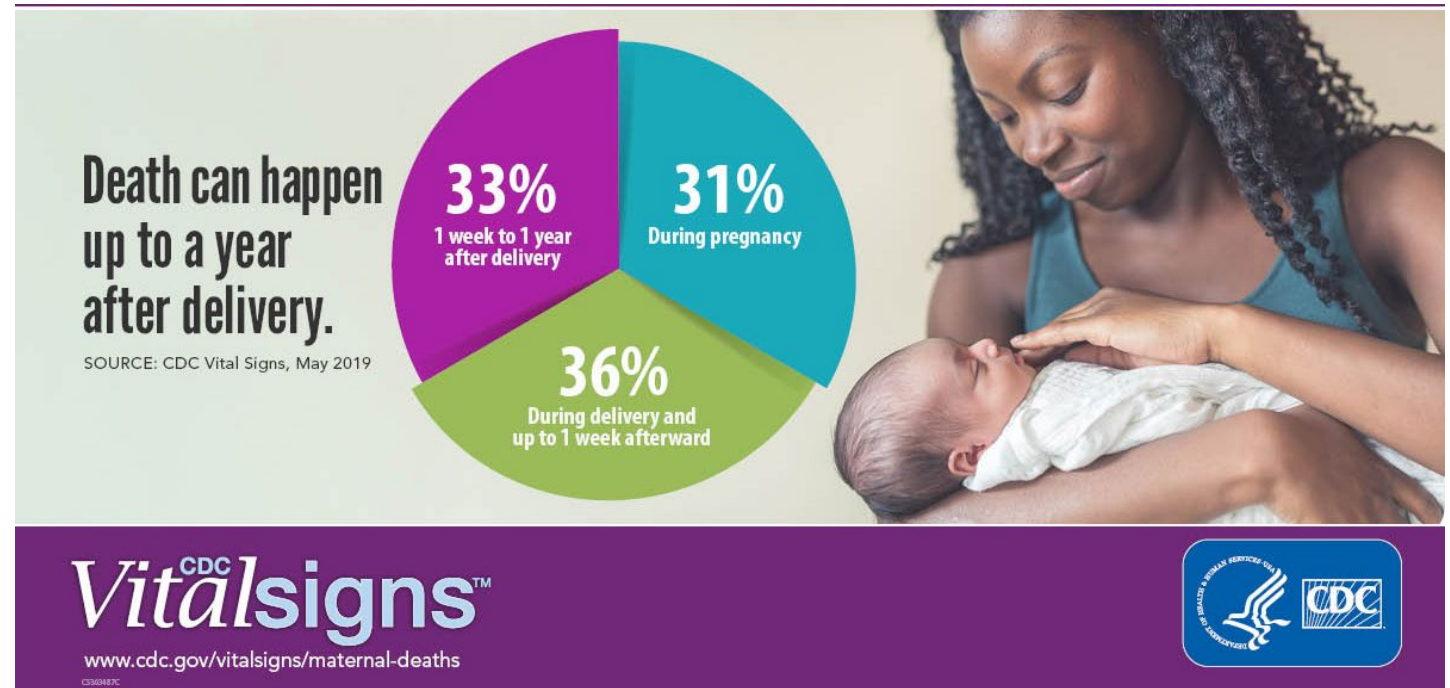




Maternal Morbidity and Mortality

Maternal Mortality

- Every 12 hours a woman dies in the US as a complication of childbirth
- ~60% of maternal deaths deemed preventable
- Data confirm persistent racial and age disparities



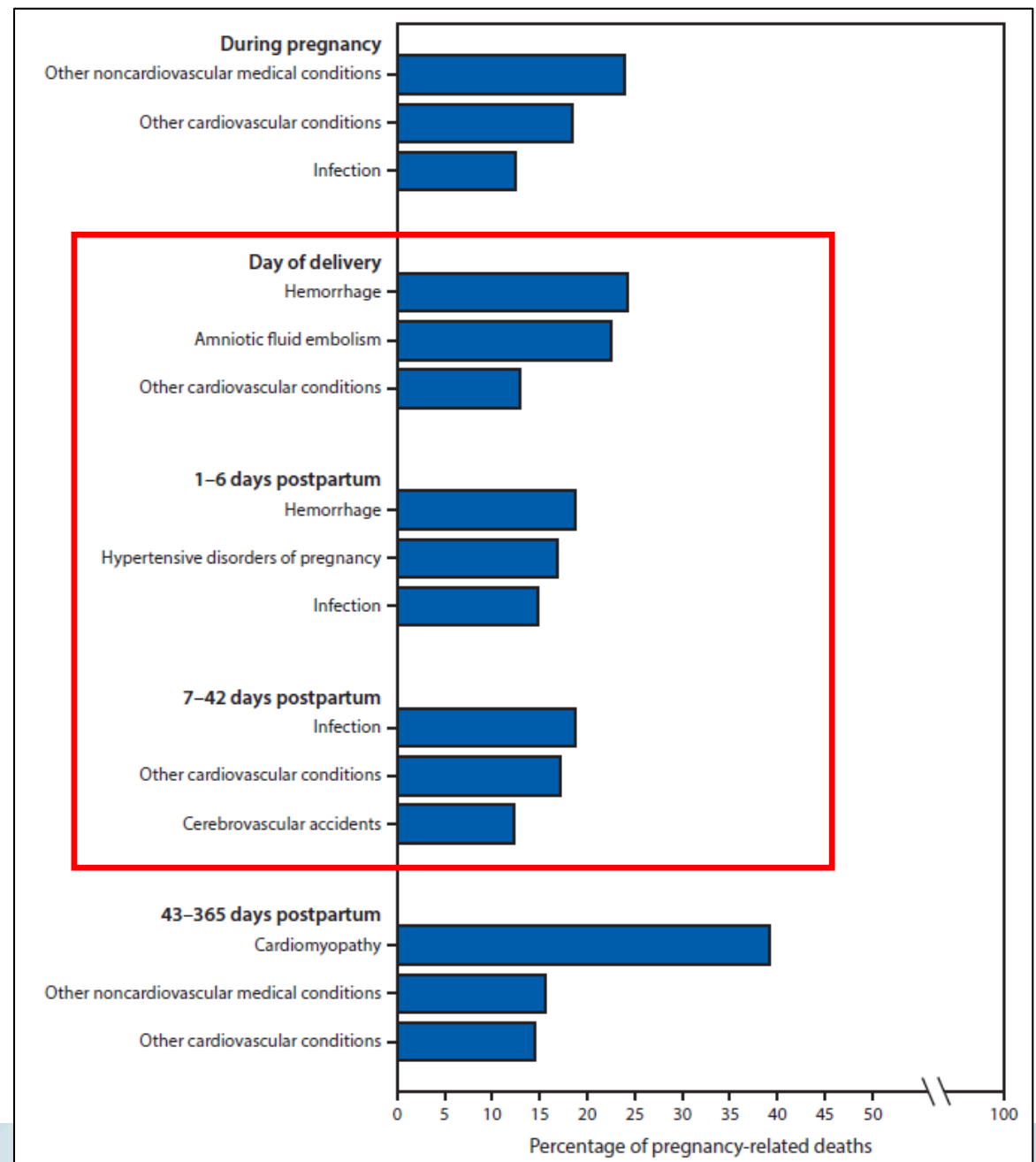
Data from 2011-2015 national pregnancy-related death data and 2013-2017 data from maternal mortality review committees in 13 states.



Most frequent causes of pregnancy-related deaths, by time relative to the end of pregnancy (2011-2015)

- Incidence of peripartum and postpartum maternal stroke is increasing

*CDC MMWR. May 10, 2019.
Vol. 68 No. 18*



Maternal Stroke

- A 47% increase in stroke during hospitalization for delivery in the US (1994-95 to 2006-07)
- An 83% increase in postpartum stroke admissions (1994-95 to 2006-07)
- In New York State, 1 in 5 strokes in women aged 18-35 was associated with pregnancy (2003-2012)
- Physiologic changes during pregnancy likely contribute to increased stroke risk
- Risk factors include advanced maternal age; race/ethnicity; hypertensive disorders (e.g., preeclampsia); preexisting heart disease; cesarean section; infections; migraine

Zambrano & Miller. Curr Atheroscler
Rep. 2019 Jun 22;21(9):33



NICHD Strategic Plan Theme 3: Setting the Foundation for Healthy Pregnancies and Lifelong Wellness

- Objectives Most Relevant to Maternal Stroke
 - *Characterize pre-pregnancy and pregnancy factors that can raise the risk of adverse maternal conditions.* Use emerging technologies and big data analytic methods, such as artificial intelligence, to integrate genomic, nutritional, social and behavioral, and exposure data to inform prevention efforts and address health disparities.
 - *Develop targeted strategies to improve the prevention of and response to labor and delivery complications that lead to maternal morbidity and mortality. Extend studies of key adverse events to the postpartum period (“the fourth trimester”) to include hemorrhage, mental health conditions, and cardiovascular events,* emphasizing populations affected by health disparities.





PregSource[®] and All of Us

PregSource® – Using Crowdsourcing to Define Typical Pregnancy



Why join PregSource®?

- Free expert health information
- Pregnancy tracking
- The chance to help future moms-to-be

pregsource.nih.gov



- Pregnant women provide information about their experiences in real-time:
 - Sleep
 - Nausea
 - Exercise
 - Weight
 - Medications
- Answers to these topics will help researchers build a more complete picture of typical pregnancy and develop strategies for improving maternal care



All of Us Research Program

- Creating a research community of one million people who will share their unique health data.
 - Survey questions and sharing EHRs; some will provide blood and urine samples
- 3,800 pregnant women currently enrolled
 - About 3 new pregnant women are enrolled each day
- Enrollment of children anticipated in 2020



PregSource® and *All of Us* Partnership

All of Us will promote joining PregSource® as an option for participants who are pregnant



<https://www.joinallofus.org/en/pregsource>





Draft NIH Data Sharing Policy

Feedback Requested: DRAFT NIH Data Sharing Policy

- Goal: Promote effective and efficient data management and sharing to further NIH's commitment to making the results and accomplishments of the research it funds and conducts available to the public.
- Draft policy follows RFIs in 2016 and 2018
- Comment on:
 - Draft NIH Policy for Data Management and Sharing
 - Supplemental Draft Guidance: Allowable Costs
 - Supplemental Draft Guidance: Elements of a Data Management and Sharing Plan
- Submit responses by January 10, 2020 to <https://osp.od.nih.gov/draft-data-sharing-and-management/>
- Upcoming webinar on the draft policy – date TBD





NIH Budget Update

Budget Update

- FY 2020 Appropriations
 - Continuing Resolution through Dec. 20 to operate at FY 2019 levels
 - Some additional funds for the Census
 - 3.1% pay raise for the military
 - Additional short-term CRs create uncertainty for grantees and challenges for distributing funds late in the fiscal year
 - CRs maintain flat budgets for everyone
- FY 2021 Appropriations
 - Expected release of President's Budget - Feb. 2020





Join Our Team!

We're Hiring!

- Branch Chiefs
 - Pregnancy and Perinatology Branch
- Program Officers
 - Child Development and Behavior Branch
 - Intellectual and Developmental Disabilities Branch
 - Obstetric and Pediatric Pharmacology and Therapeutics Branch
 - Pediatric Trauma and Critical Illness Branch
 - Pregnancy and Perinatology Branch
- More info at <https://www.nichd.nih.gov/about/jobs>





Thank You!