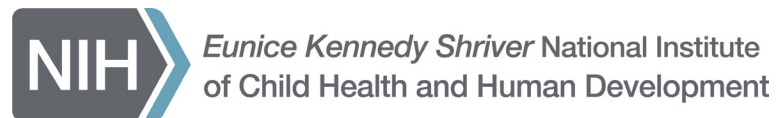


NIH Efforts to Improve Maternal Health

Alison N. Cernich, Ph.D.

January 25, 2021



Talk Outline

- IMPROVE (Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone)
- Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)
- Severe Maternal Morbidity and Mortality EHR Data Infrastructure (PCOR-TF Initiative)

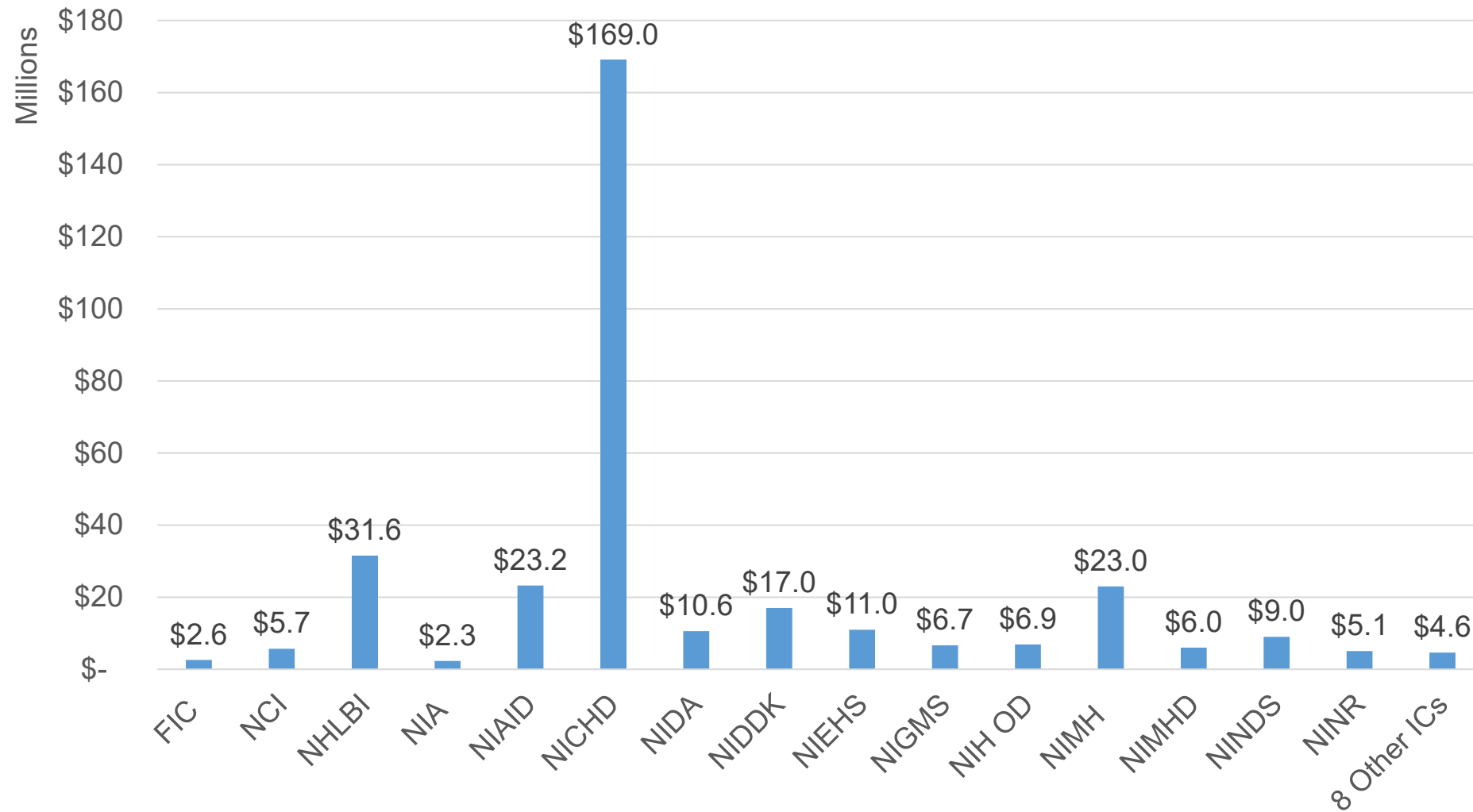
Increased Congressional Interest in Maternal Health



December 11, 2019

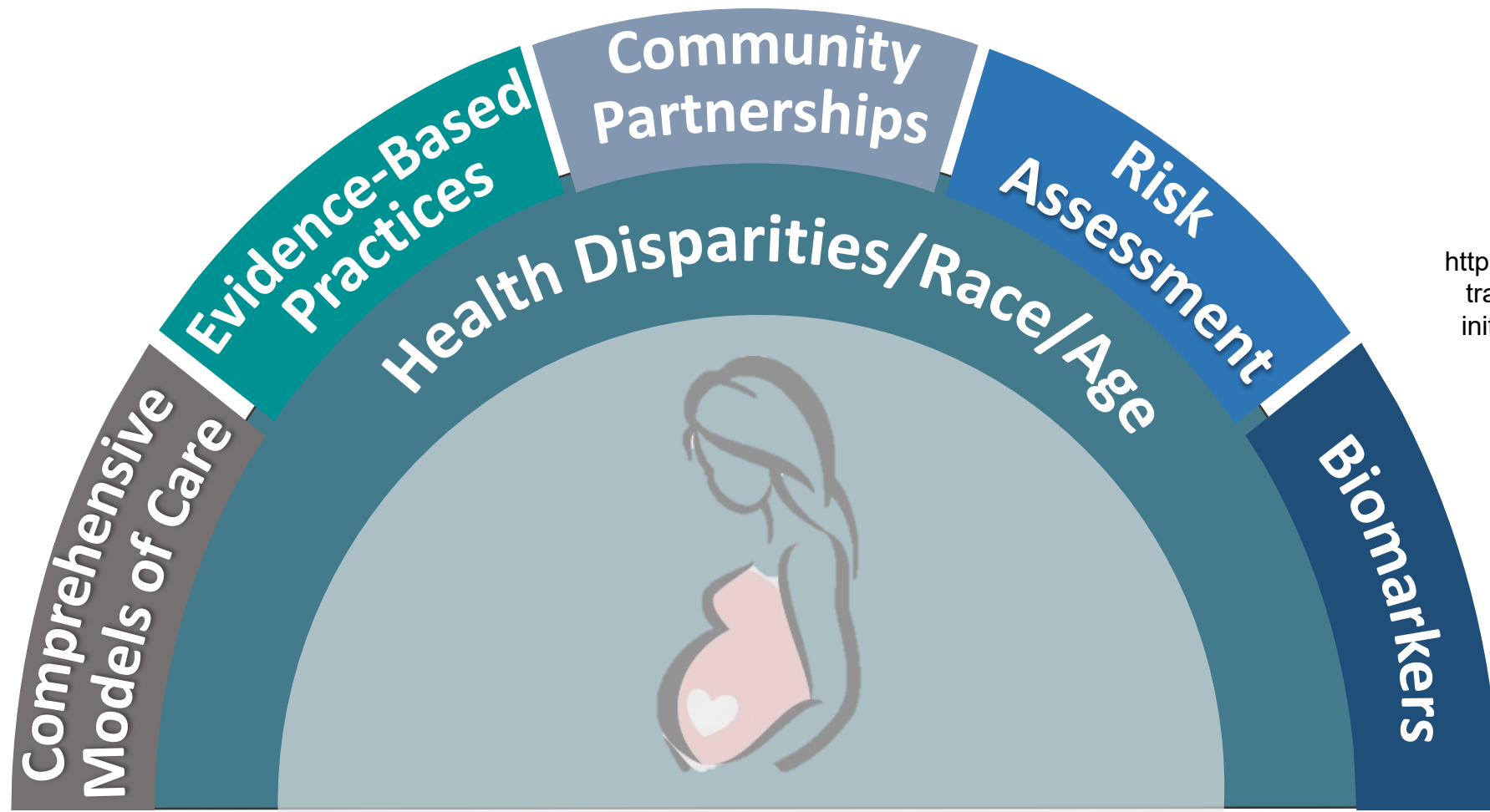


NIH Maternal Health Research Funding by IC, FY 2019



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

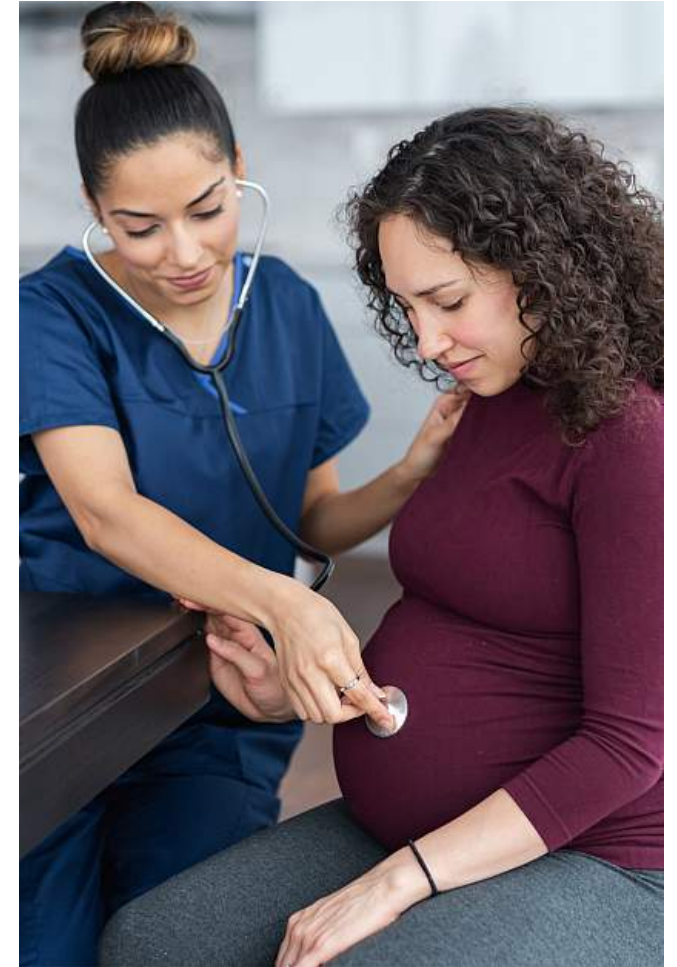
- Encompasses both foundational biology as well as social and biobehavioral research
- Community partners will be key voices to assess needs and to implement interventions



<https://www.nih.gov/research-training/medical-research-initiatives/improve-initiative>

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

- \$7.2 million in grants awarded September 29 through a [Notice of Special Interest on Maternal Mortality](#)
- 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



IMPROVE: Additional Efforts Across NIH



Ongoing

- Addressing Racial Disparities in Maternal Mortality and Morbidity (Lead Institute: NIMHD)
- Notice of Special Interest (NOSI): Administrative Supplements for Research on Women's Health in the IDeA States (Lead Institute: NIGMS)

Upcoming

- Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) Multisite (UG3/UH3 Clinical Trial Required (Lead Institute: NHLBI; planned for winter 2021)
- Challenge opportunities related to technology, secondary use of existing data, and ideas to address disparities in care



Research Highlight: Maternity Care Deserts and Pregnancy-associated Mortality

- Recent publication by NICHD-funded researcher examined maternal mortality in Louisiana
- Risk of death during pregnancy and up to 1 year postpartum due to any cause and in particular death due to obstetric causes was significantly elevated among women residing in maternity care deserts compared to women in areas with greater access
- A large racial inequity in risk (2.2 X greater) persisted above and beyond differences in geographic access to maternity care





Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

Pregnancy and Lactation

- 6.3 M women per year in the US become pregnant
 - >90% take medications and 70% are prescribed medications
 - 500,000 woman have difficulty making milk
- Concerns re: liability
- Complexity of pregnancy
 - Fetus and placenta change over gestation, timing of exposure
 - Physiologic changes of pregnancy
 - Impact of external factors: obesity, environment
 - Co-existing chronic or acute conditions
- Lactation
 - Benefits of breastfeeding vs. medications for woman
 - Limited assays for assessment of medications in breastmilk



Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

- Established by the 21st Century Cures Act in 2016
- 2018 report recommendations included:
 - Change existing culture that has limited scientific knowledge of therapeutic product safety, effectiveness, and dosing for pregnant and lactating women
 - Protect pregnant women *through* research instead of *from* research
 - Remove pregnant women as a vulnerable population through U.S. Common Rule
 - Expand workforce of clinicians and researchers with expertise in obstetric and lactation pharmacology and therapeutics
- Remove regulatory barriers
- All 15 recommendations and full Task Force report are available online:
<https://www.nichd.nih.gov/About/Advisory/PRGLAC>



PRGLAC Implementation Plan

- Submitted to HHS Secretary in September 2020
 - https://www.nichd.nih.gov/sites/default/files/inline-files/PRGLAC_Implement_Plan_083120.pdf
- Overarching themes include
 - Leverage or expand existing federal programs or networks
 - Develop new research tools and strategies
 - Consider alternative trial designs
 - Establish a prioritization process for studying therapeutics used during pregnancy and lactation
 - Address ethical considerations, liability concerns, and potential research incentives to pursue research
 - Foster education and awareness among health care providers and pregnant and lactating women
 - Create partnerships to accomplish the steps
- **Everyone** has a role in the implementation plan
 - Cross-sector engagement – NIH, FDA, other HHS Operational Divisions, private non-profits, industry, etc.





Severe Maternal Morbidity and Mortality EHR Data Infrastructure

Patient Centered Outcomes Research – Trust Fund

Severe Maternal Morbidity and Mortality EHR Data Infrastructure (NIH/ONC/CDC)

- **Purpose:** to strengthen both maternal and infant health data needed to examine the effect of medical conditions and/or interventions on pregnant, postpartum or lactating women and their infants
- **Project Goals:**
 - Develop an HL7® FHIR® Implementation Guide/Guidance (IG) for research that includes pregnancy, pregnancy outcomes, and pregnancy-related conditions, comorbidities, and procedures
 - Conduct pilot studies to assess the feasibility
 - In two existing NIH data systems (1) All of US and (2) Gabriella Miller Kids First Pediatric Research Programs
 - In health departments in 1-2 states and the District of Columbia To link EHR data with maternal mortality vital records data
 - Produce a report that includes the IG and related material





Thank You!