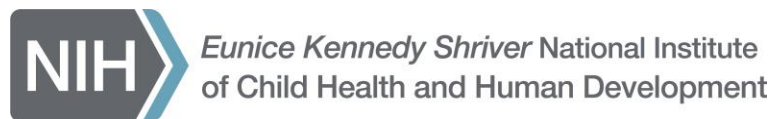


# **A Collaborative Approach to IMPROVE-ing Maternal Health**

***National Advisory Council for Nursing Research***

Diana W. Bianchi, M.D.

*September 12, 2023*

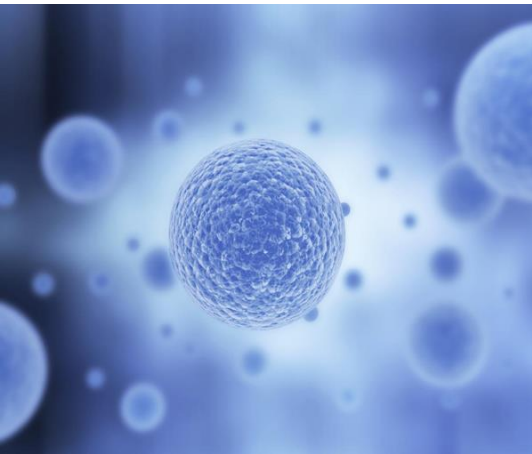


# Talk Outline

- NICHD Overview
- IMPROVE Initiative
- NICHD Research Program Highlights

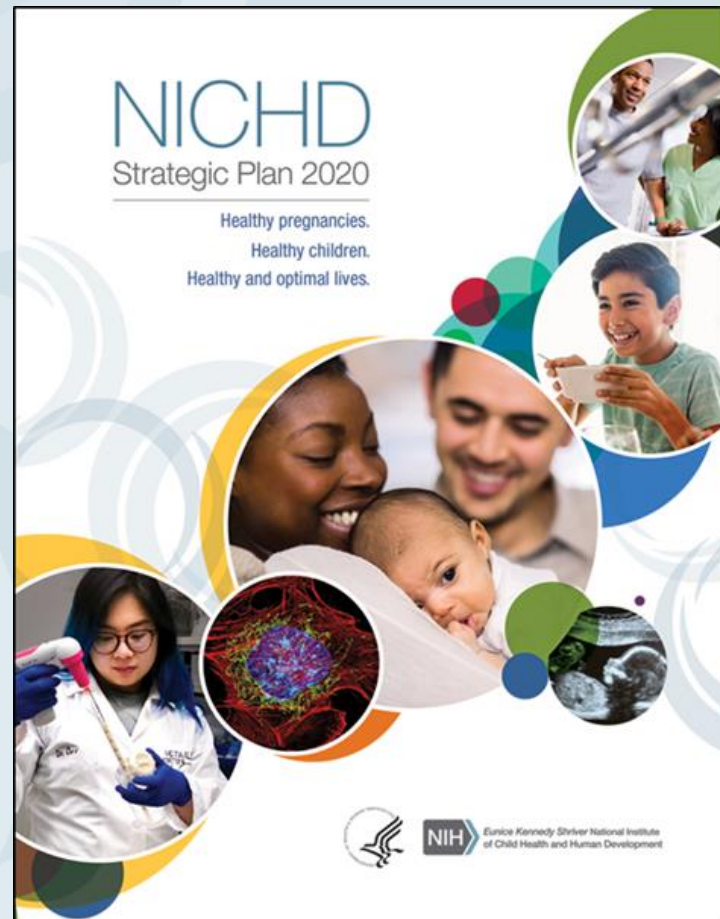
# Mission Statement

**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.**



# 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





# The IMPROVE Initiative

## Co-chaired by NICHD, NINR, and ORWH

# Maternal Morbidity and Mortality Crisis in the U.S.

- According to the CDC, **84%** of pregnancy-related deaths are **preventable**<sup>1</sup>
  - **93%** of AI/AN pregnancy-related deaths were determined to be preventable
- Causes of pregnancy-related deaths **vary across racial and ethnic categories.**
  - Hemorrhage (e.g., Asians), Cardiovascular complications (e.g., Black/AA), mental health, infection
- Analysis of CDC data by external investigators indicated that **maternal mortality increased by 29% from 2019 to 2020**<sup>2</sup>

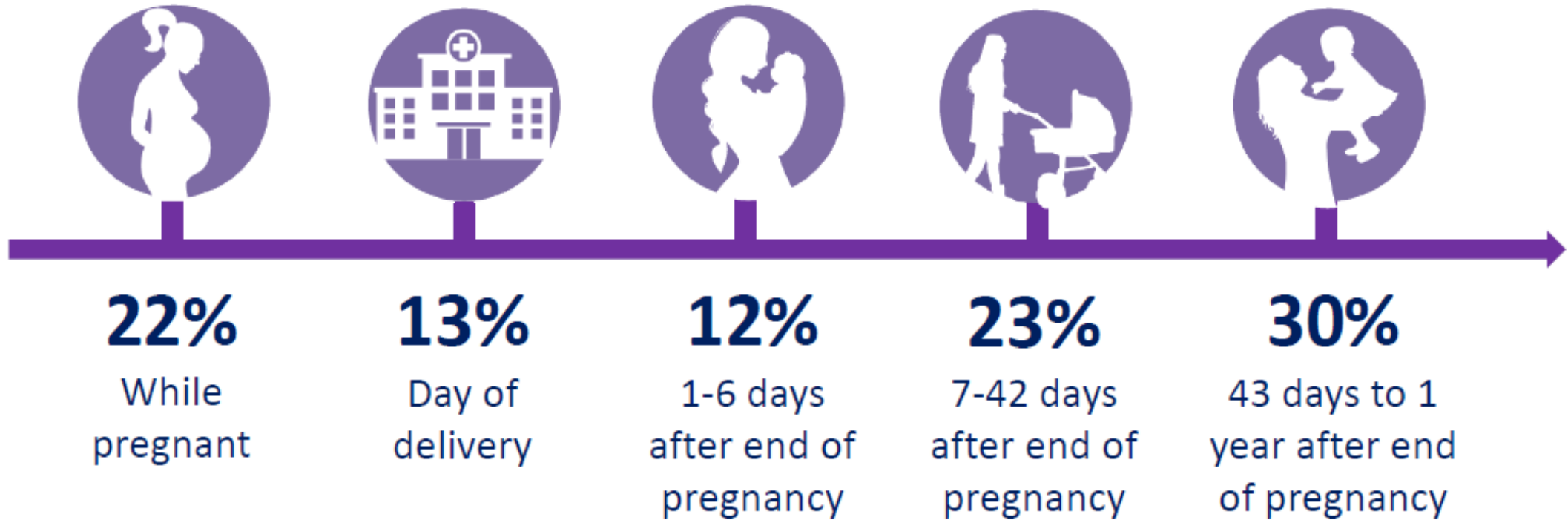
<sup>1</sup> Trost, S, Beauregard, J, Chandra, G, Njie, F, Berry, J, Harvey, A, Goodman, D. **Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees in 36 US States, 2017–2019.** [www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html](http://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html)

<sup>2</sup> Howard JT, Perrotte JK, Leong C, Grigsby TJ, Howard KJ. **Evaluation of All-Cause and Cause-Specific Mortality by Race and Ethnicity Among Pregnant and Recently Pregnant Women in the US, 2019 to 2020.** JAMA Netw Open. 2023;6(1):e2253280





# Timing of pregnancy-related deaths



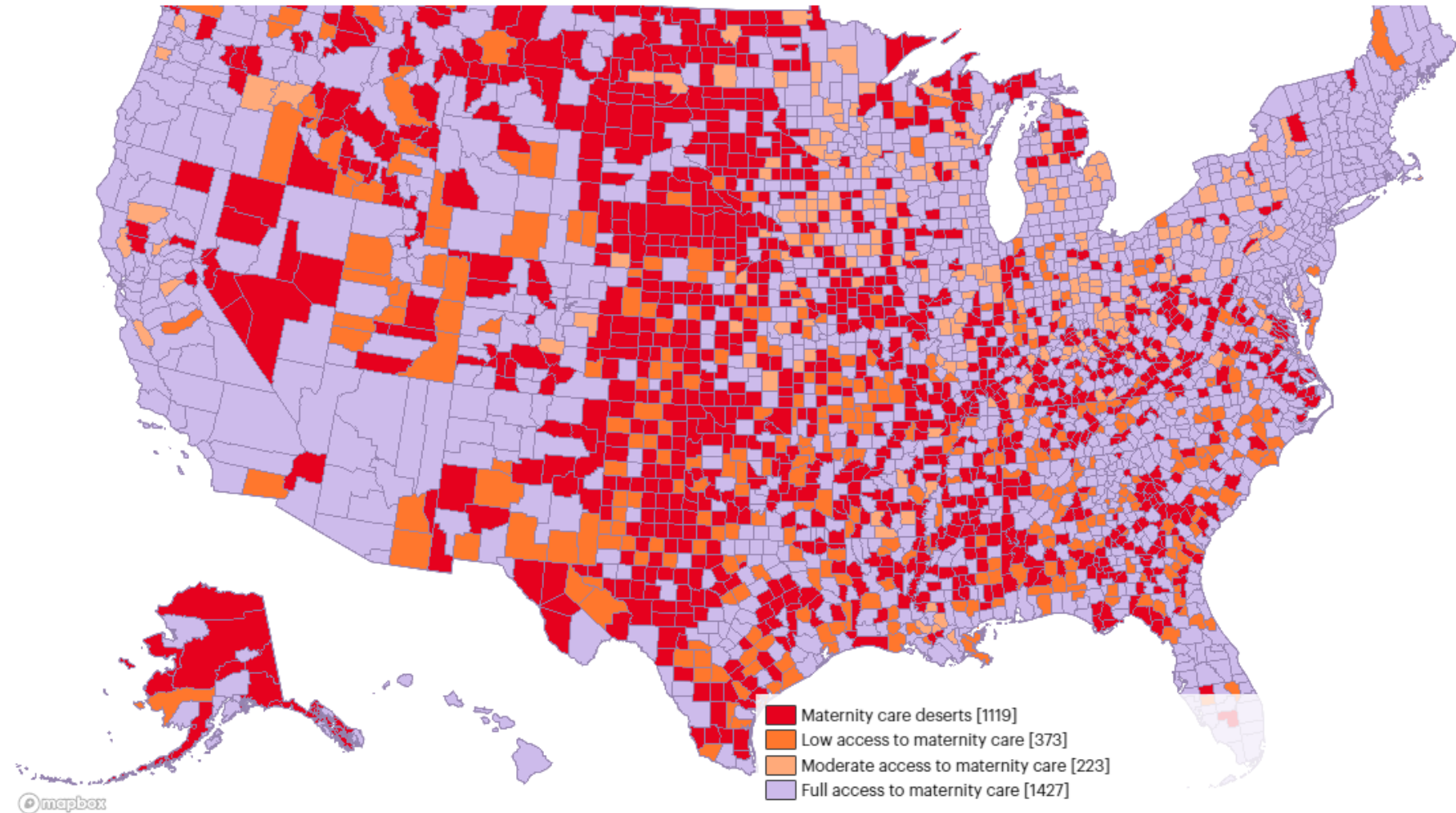
Timing was missing (n=2) or unknown (n=14) for 16 (1.6%) pregnancy-related deaths



# Maternal Health Crisis in the U.S.

*More than 2.2 million women live in maternity care deserts (1119 counties)*

- 5% increase in counties that have less maternity access since 2020





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

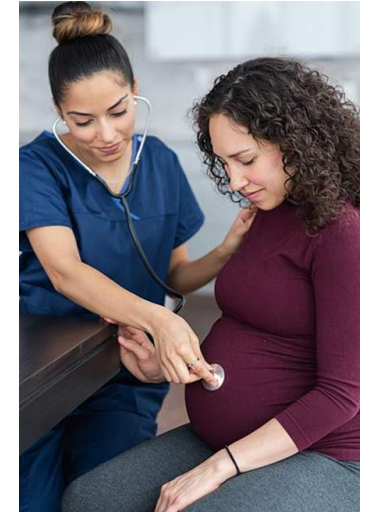


**IMPROVE is an NIH-wide effort, with representation of and collaboration with staff across the NIH Institutes, Centers, and Offices**

- Reduce preventable causes of maternal morbidity and mortality
- Address disparities in maternal health outcomes
- Expand implementation of evidence-based maternal health care practices before, during, and after pregnancy
- Build research capacity in community-based organizations
- Promote access to maternal health care with innovative technology
- Enable real-world research with electronic health record standards
- <https://www.nichd.nih.gov/IMPROVE>

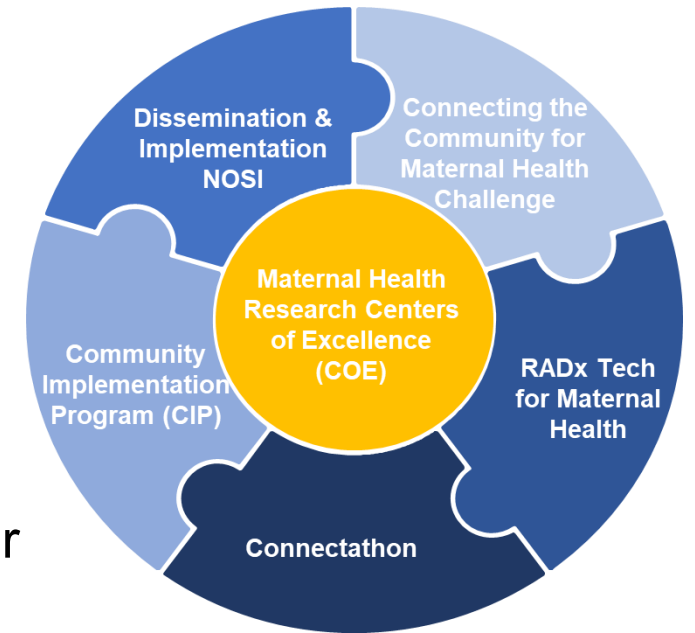
# FY20 and FY21 IMPROVE Awards

- Supplement programs in FY20 and FY21
  - FY20 focus on major drivers of mortality – cardiovascular issues, racism, mental health
    - Awarded >\$7 million to support 36 projects
  - FY21 focus on impacts of COVID-19 on maternal health; impact of structural racism and discrimination on maternal health outcomes in the context of COVID-19
    - Awarded >\$13 million for 22 projects
- New appropriation of \$30M beginning in FY22



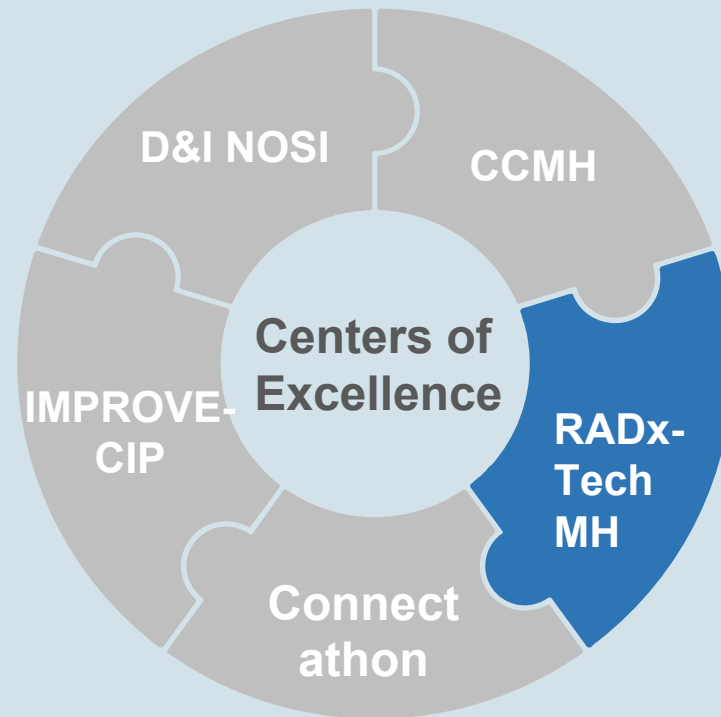
# FY22 and FY23 IMPROVE Programs

- **Connectathon:** Focused on developing electronic health record standards for pregnancy to enable real-world research
- **Dissemination & Implementation NOSI:** Dissemination & implementation science to inform policy and practice interventions across pre-pregnancy, pregnancy, and postpartum care
- **RADx Tech for Maternal Health:** Tech funnel to develop home-based or point-of-care diagnostics to extend care to maternal care deserts
- **Connecting the Community for Maternal Health Challenge:** Program to build effective research infrastructure and capacity in communities
- **Community Implementation Program:** Community partnered program enabling adoption and integration of interventions that are effective into community settings
- **Centers of Excellence:** National network to develop, implement, and evaluate community-tailored interventions to address health disparities in maternal health



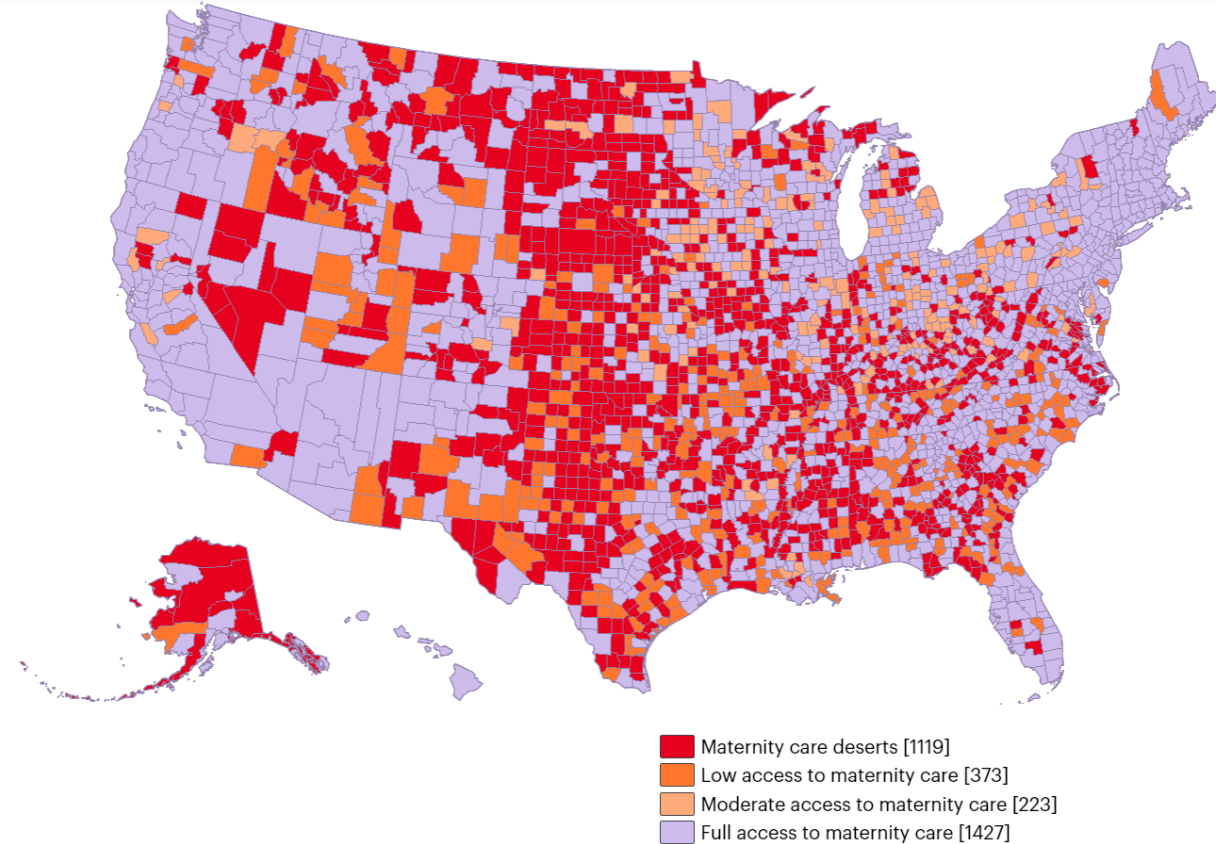


# RADx Tech for Maternal Health Challenge



# IMPROVE- Strategic Focus on Maternal Care Deserts

- **RADx® Tech for Maternal Health Challenge**
  - Prioritizes home-based or point-of-care diagnostic devices, wearables, and other remote sensing technologies to extend postpartum care in regions lacking access to maternity care
  - Up to \$8M in prizes awarded through several phases



<https://www.marchofdimes.org/maternity-care-deserts-report>



# RADx Tech Maternal Health Challenge Innovator Teams

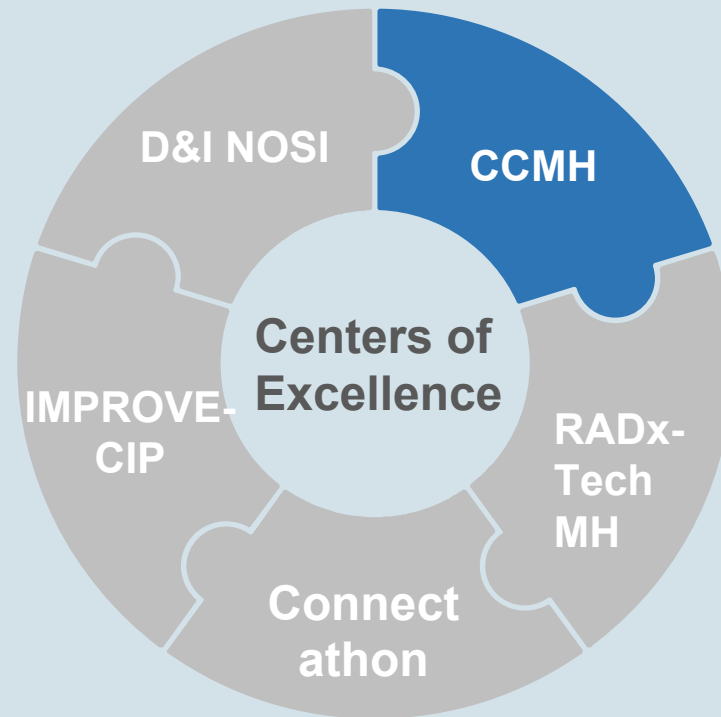
Entity/Team Name	Submission
<b>CardieX</b>	Expand care and reduce cardiovascular morbidity for post-partum women through non-invasive monitoring of central blood pressure using a novel dual blood pressure home monitor and wearable.
<b>Caretaker Medical LLC</b>	Maternal Health Monitoring with the Vitalstream
<b>Dionysus Digital Health Inc</b>	Prognosis PPD: Navigation of Maternal Mental Health Risk in the Postpartum Period using a Modular Antenatal Passive Digital Screening Tool and Combined Epigenetic Blood Test
<b>HemoSonics, LLC</b>	Rapid Point-Of-Care Diagnostic Device to Aid in the Management of Postpartum Hemorrhage
<b>Mologic Inc/GADx</b>	At home urinary tract infection diagnostic
<b>MyLUA Health</b>	An Artificially Intelligent Care Coordination Software System for Pregnancy and Postpartum Care Management
<b>PyrAmes Inc</b>	Non-invasive, continuous blood pressure monitoring for postpartum maternal health
<b>Sanguina, Inc</b>	AnemoCheck MyMobile for Maternal Health Anemia Management
<b>Sibel Health</b>	Comprehensive Postpartum Vital Sign Monitoring with Novel, Bio-integrated Wearable Technologies
<b>Washington University</b>	Maternal aRMOR: protection through early hemorrhage detection







# Connecting the Community for Maternal Health Challenge



# Connecting the Community for Maternal Health Challenge

## *Capacity Building*

- Encourages community-based and advocacy organizations to develop research infrastructure and capabilities
- Total prize of ~\$3M distributed across multiple phases
- Non-monetary incentives such as mentoring and proposal writing assistance also provided
- Proposal Phase winners announced in June
- Final Research Phase: Organizations will have ~1 year to implement project plans, conduct proposed research, and report results
- Final winners announced September 2024



Listening Session with Maternal Health Community Organizations



# Connecting the Community for Maternal Health Challenge

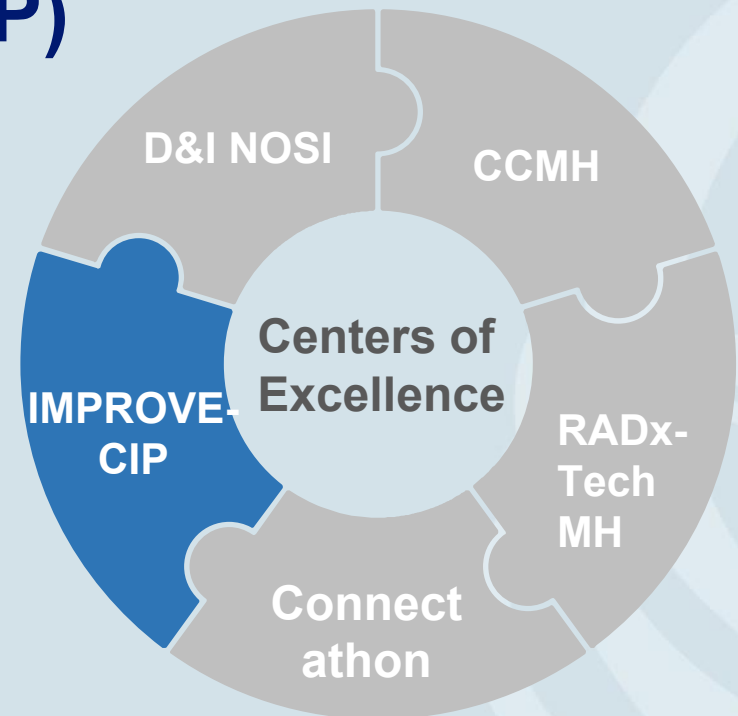
## *Proposal Phase Winners*

Submission Proposal Title	Organization/Institution	State
Carrying for the Culture: An Infant Carrying Intervention for Health Equity	Nurturely	Oregon
Can it Happen to Me? Developing a Maternal Morbidity Risk Prediction Tool	Central Jersey Family Health Consortium	New Jersey
Increasing Resiliency in the Perinatal Period	Atlanta Birth Center	Georgia
Leveraging Community-Rooted Peer Support to Improve Maternal Mental Health	HealthConnect One	Illinois
Maternal Health Literacy for Nutrition Care Equity	AHIMA Foundation	Illinois
Postpartum Doula Care Reduces BIPOC Mothers' Hypertension, Depression & Anxiety	The Abundance Project	Colorado
Culturally Congruent Doula Care; The Missing Lens Into Maternal Mental Health	Doula CO-OP	Nevada
Survivor Moms' Companion: A Perinatal PTSD Program	Buffalo Prenatal Perinatal Network, Inc	New York
The IMAGINE Project (Iowa MAternal Group INitiativeE): Optimizing Mental Health	Postpartum Support International	Iowa





# IMPROVE Community Implementation Program (IMPROVE-CIP)



# Implementation Science to Improve Maternal Health

- **Purpose:** Investigate community-informed and community-engaged implementation strategies focused on prevention and reduction of disparities in maternal morbidity and mortality.
- **Goal:** Use Implementation Science and community engagement to bring known effective maternal health interventions into communities hardest hit by maternal health disparities.
- **Focus:** Community-based implementation strategies to increase adoption, uptake, scale up and scale out of evidence-based interventions to improve maternal health and maternal health equity in underserved communities.





# IMPROVE-CIP Awardees

Research Coalition	Location	Evidence Based Intervention
Arizona State University	Indigenous, Black, and Latinx communities in AZ	<b>Doulas</b> to improve outcomes including <b>mental health</b> and <b>substance use disorders</b>
University of Nebraska Medical Center	Winnebago tribe, northern NE	<b>Kinship involvement</b> to improve <b>maternal health outcomes</b> , including maternal mental health in the Winnebago Tribe
Texas Tech University Health Sciences Center	Underserved women in rural and urban counties in the Panhandle region	<b>Low-dose aspirin, blood pressure measurements</b> and/or treatment with <b>antihypertensive therapy</b>







# Maternal Health Research Centers of Excellence



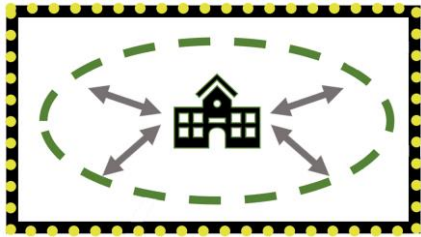
# IMPROVE Maternal Health Research Centers of Excellence

- **Goal:** Reduce maternal morbidity and decrease preventable mortality by partnering with communities affected and incorporating their needs and perspectives in the research performed by the Centers of Excellence
- **Key benefits:**
  - Community partnership from inception of research projects
  - Robust training component to grow future workforce
- Awarded in August 2023

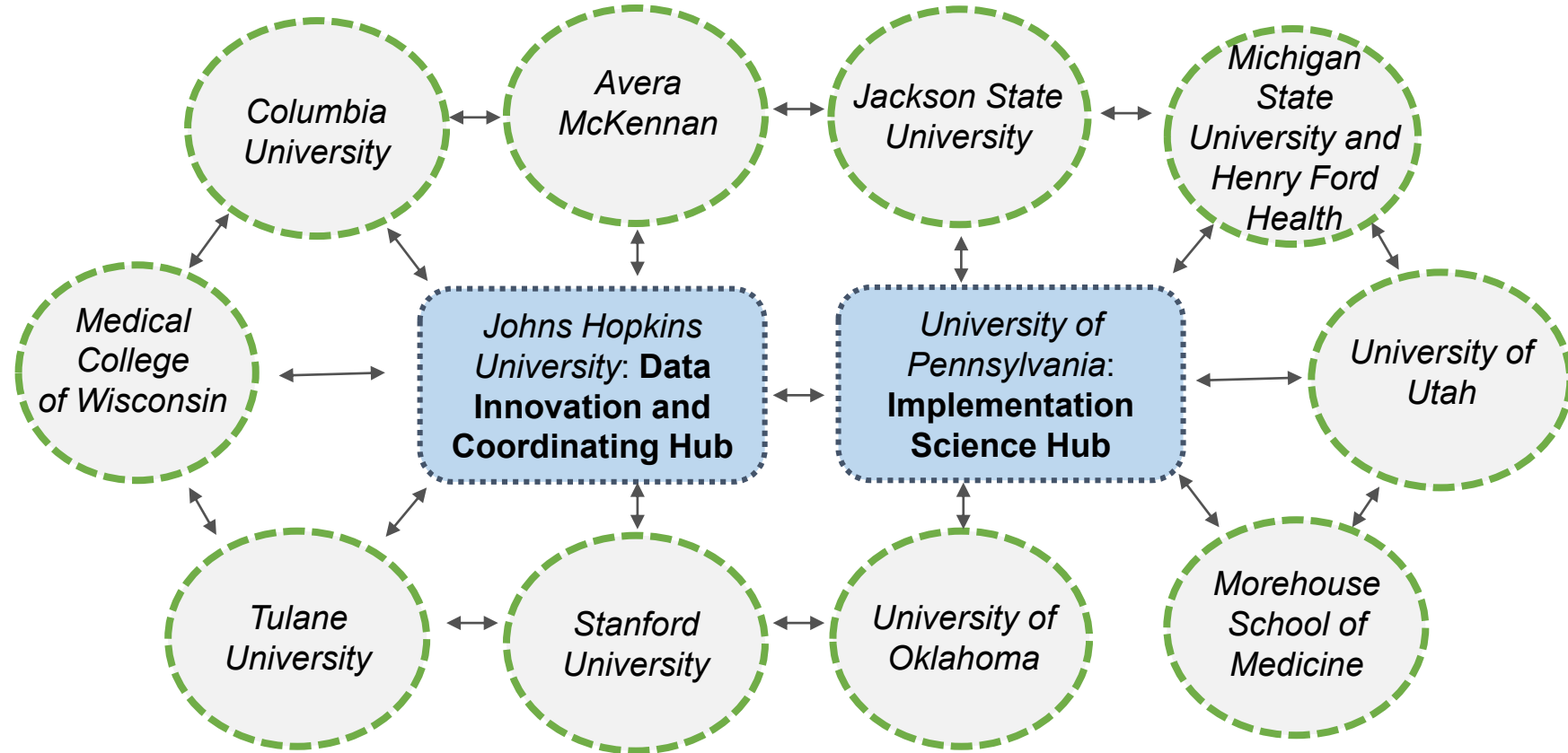


# Maternal Health Research Centers of Excellence: Research, Community Partnerships, and Training

Research Center



Community      Hub      Communication



# CoE Research Centers: Breadth of Science

## Conditions

- Anemia
- Preeclampsia
- Hypertensive Disorders of Pregnancy
- Gestational Diabetes
- Postpartum Hemorrhage
- Substance Use Disorder
- Perinatal Mood and Anxiety Disorders

## Gestational Timepoints

- Prenatal/ Perinatal
- Labor/ Delivery
- Postpartum

## Populations

- American Indian/ Alaska Native
- Asian
- Black
- Hispanic
- Low Socioeconomic Status
- Rural

## Novel Approaches

- Community health workers- including doulas
- Home visiting programs
- Applying artificial intelligence and machine learning to electronic medical records
- Integrated care models

## Healthcare

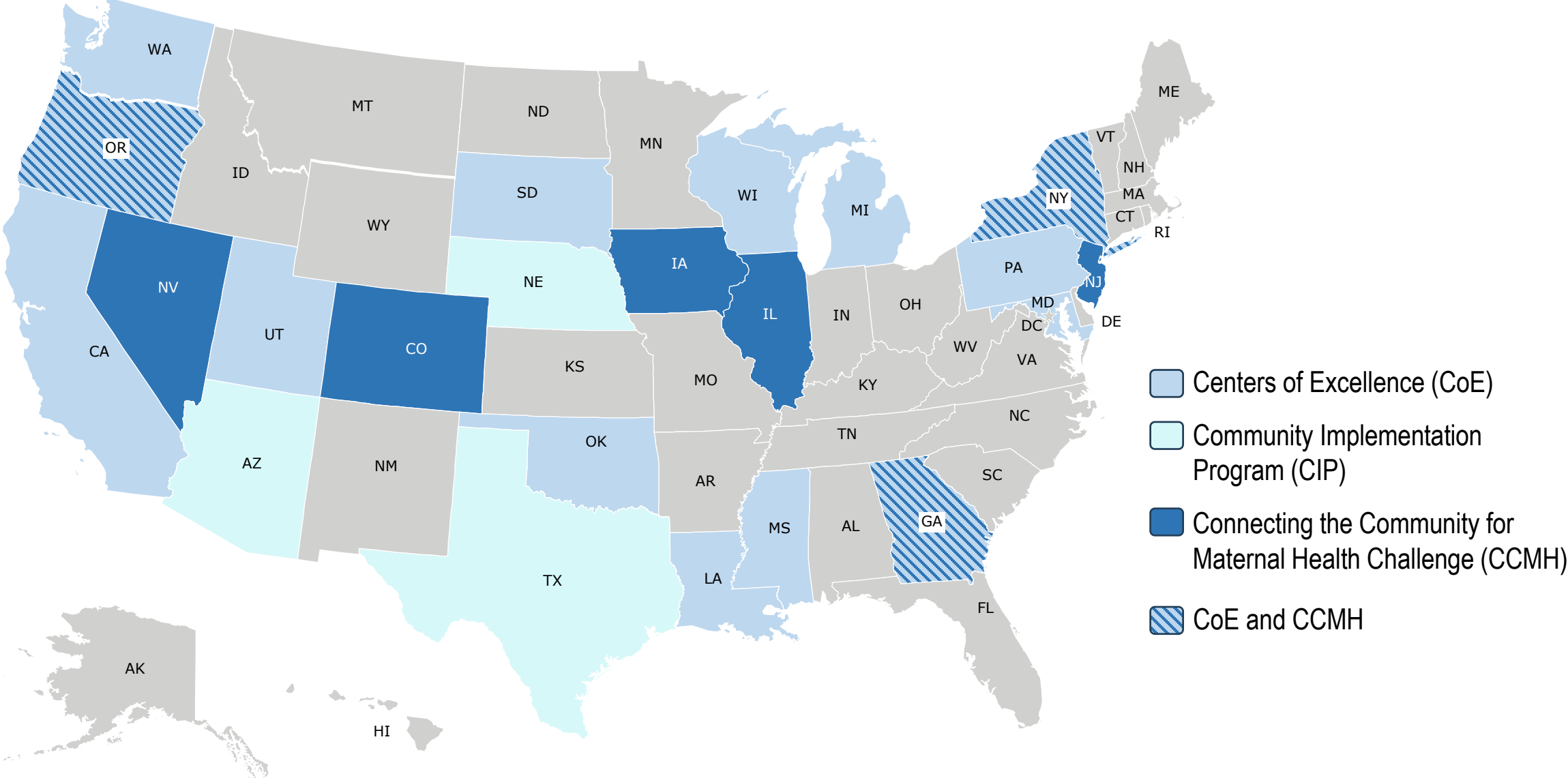
- Implicit provider biases
- Creation of predictive models
- Clinical interventions

## Social Determinants of Health

- Housing instability
- Interpersonal violence
- Access to care
- Nutrition disparities
- Food insecurity
- Resource access



# Geographic Distribution of IMPROVE Initiative Programs





# **NICHD Research Program Highlights**



# NICHD's Research Portfolio

*Eunice Kennedy Shriver*

National Institute of Child Health and  
Human Development

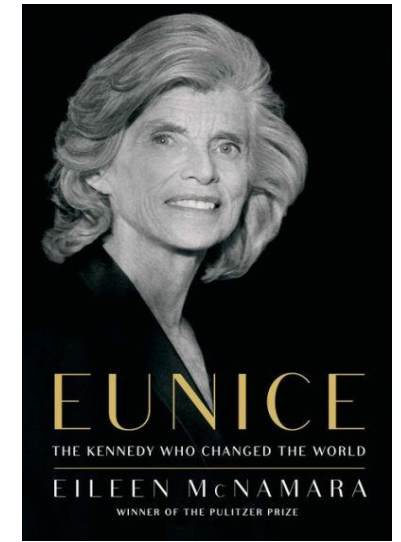
**55% Pediatrics**



**30%  
Reproductive  
Health**



**18% Intellectual and Developmental  
Disabilities and Rehabilitation**



# NIH HEAL Initiative: Opioid-Exposed Neonates *Eat, Sleep, Console (ESC) Study Results*

- ESC approach developed about 8 years ago, but not previously tested rigorously in a large population
  - Approach keeps mother and baby together
- Collaboration combined two NIH pediatric clinical trial networks (NRN and ECHO)
- Stepped wedge cluster randomized trial
- Whole of practice change
  - Trained ~5000 care providers
- Results: Reduced hospital stay and need for medication among opioid-exposed infants



# Maternal Fetal Medicine Units (MFMU) Network

- Founded in 1986, the MFMU conducts collaborative, multi-site clinical trials and observational studies involving newborns and lactating people, providing information to guide maternal health care practice
- Research includes
  - Diseases and conditions related to pregnancy, labor, and recovery after birth
  - Reducing preterm birth, low-birth weight, infant death, and other diseases and conditions
- Examples: tranexamic acid to prevent hemorrhage; induction of labor at 39 weeks; CPAP for sleep apnea in pregnancy
- 14 network sites awarded for the 2023-2030 cycle
- Non-network investigators able to propose studies and use network resources



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

- Congress established PRGLAC in 2016
- Tasked with identifying and addressing gaps in knowledge regarding safe and effective therapies and vaccines for pregnant and lactating women
- Representation from all sectors: NIH institutes, CDC, FDA, AHRQ, HRSA, HHS, VA, professional societies, industry, academia, non-profit organizations
- Recommendations issued in 2018
- Implementation plan issued in 2020



# Brief Overview of PRGLAC Recommendations

- Key recommendations included:
  - Change the existing culture that has limited scientific knowledge of therapeutic product safety, effectiveness, and dosing for pregnant and lactating women.
  - Protect pregnant people through research instead of from research.
  - Remove pregnant women as a vulnerable population through 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>





# Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub



- National resource to aggregate, present, and expand the available knowledge, tools, and expertise in maternal and pediatric therapeutics to the broader research, regulatory science, and drug development communities
- Knowledge Core and Centers of Excellence
- For more information: [mprint.org](http://mprint.org)





**Thank You!**  
**Questions?**