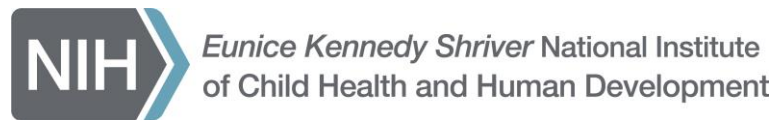


The NIH's Response to the Maternal Mortality Crisis

Diana W. Bianchi, M.D.

December 14, 2023



Preventable Tragedies

SPORTS

Tori Bowie, an elite Olympic athlete, died of complications from childbirth

June 13, 2023 · 3:58 PM ET

By Bill Chappell



Tori Bowie, who captured gold as a sprinter in the Olympics and the world championships, died at age 32 from complications of childbirth, according to an autopsy report.

Matthias Hangst/Getty Images



📷 Serena Williams poses with daughter Alexis in an image for the February issue of Vogue. Photograph: Mario Testino/Vogue

Serena Williams on her near-death experience after giving birth: 'No one was really listening'



Allyson Felix is a champion for maternal health

Olympic track star advocates for other women after preeclampsia



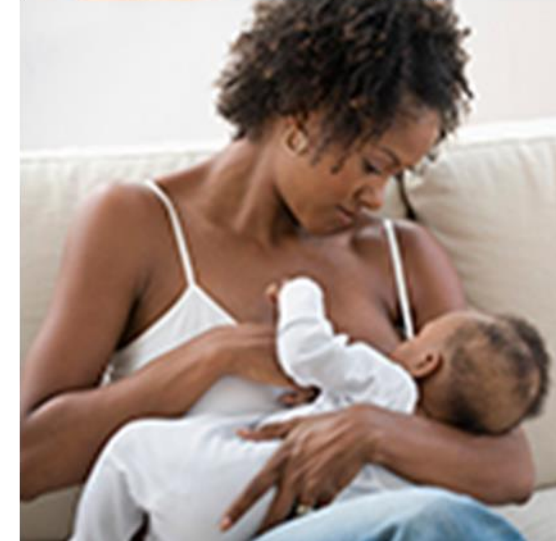
📷 Allyson Felix after winning the 400-meter Olympic bronze medal in Tokyo.

NIH MedlinePlus
MAGAZINE



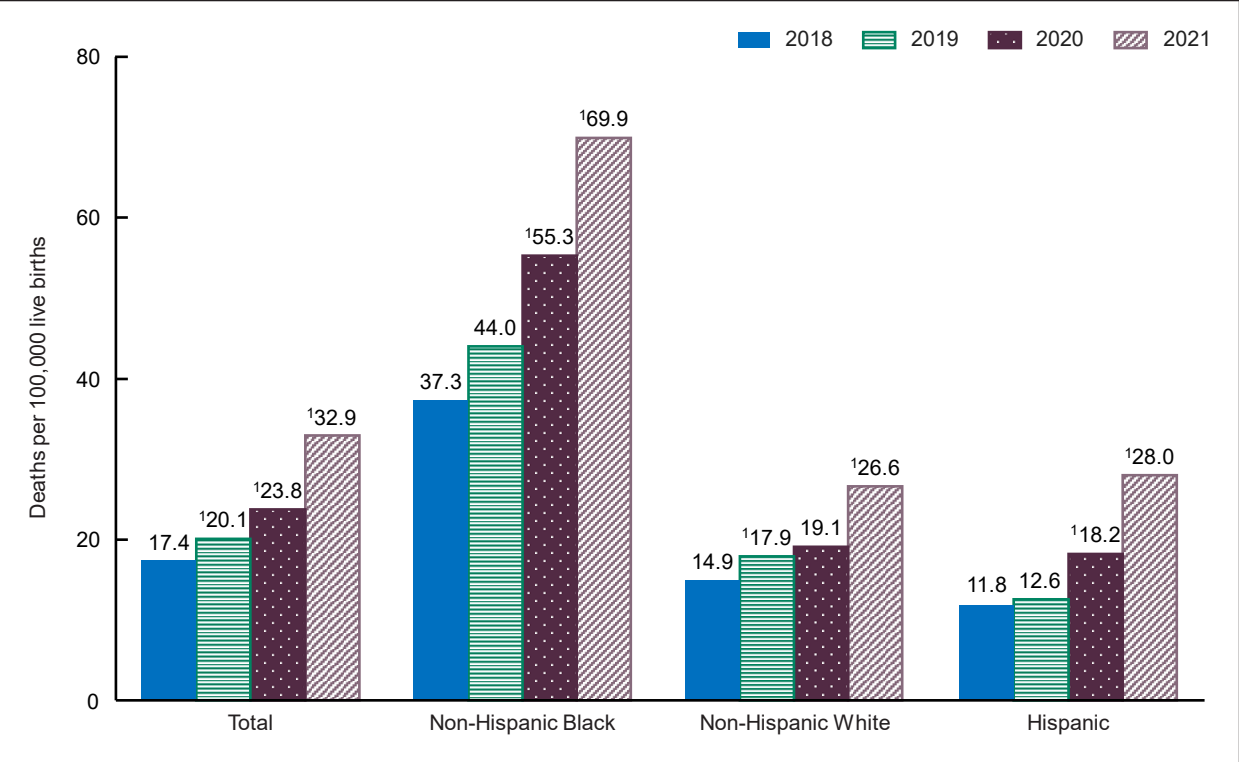
Talk Outline

- Maternal Mortality Crisis in Focus
- IMPROVE
- NIH-Wide Research Addressing Leading Causes of Pregnancy-Related Deaths
- Leveraging Networks and Infrastructure
- Prevention



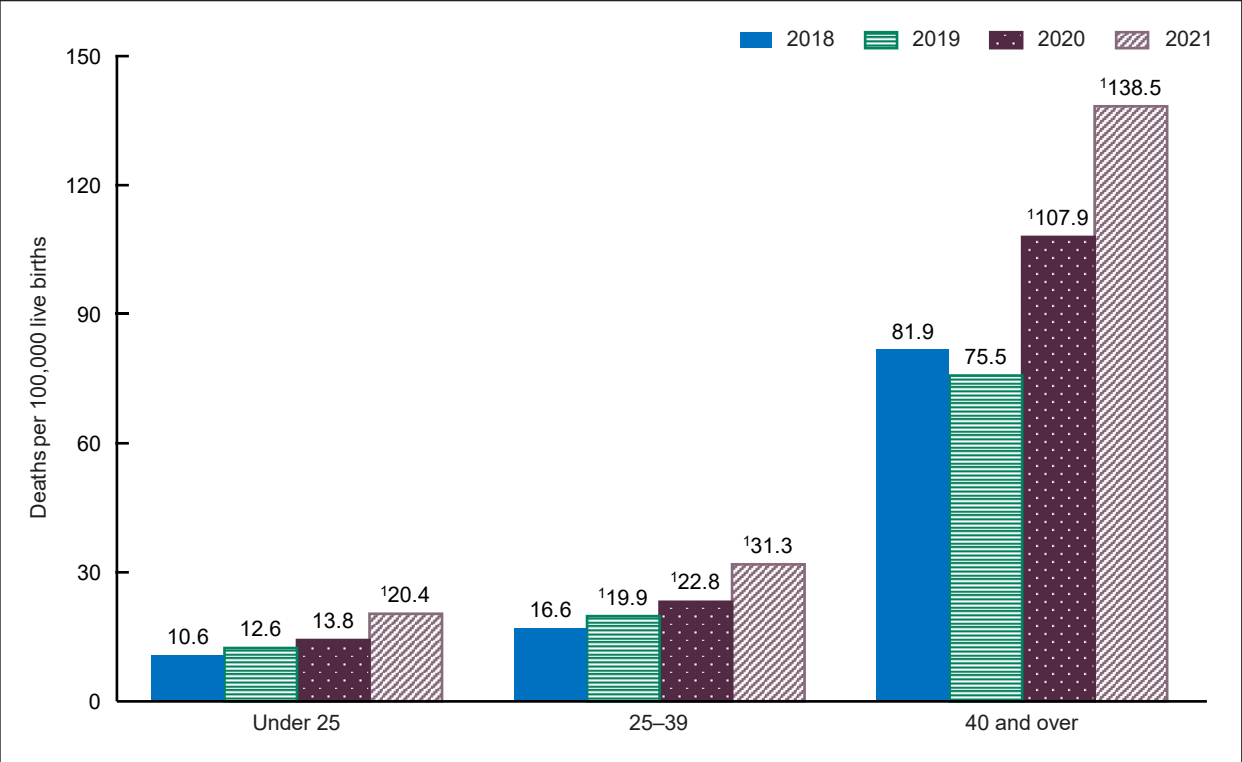
Maternal Mortality Rates in the U.S. Increased Between 2018-2021

Maternal mortality rates by race and Hispanic origin:
U.S. 2018-2021



¹Statistically significant increase from previous year ($p < 0.05$).
NOTE: Race groups are single race. SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality.

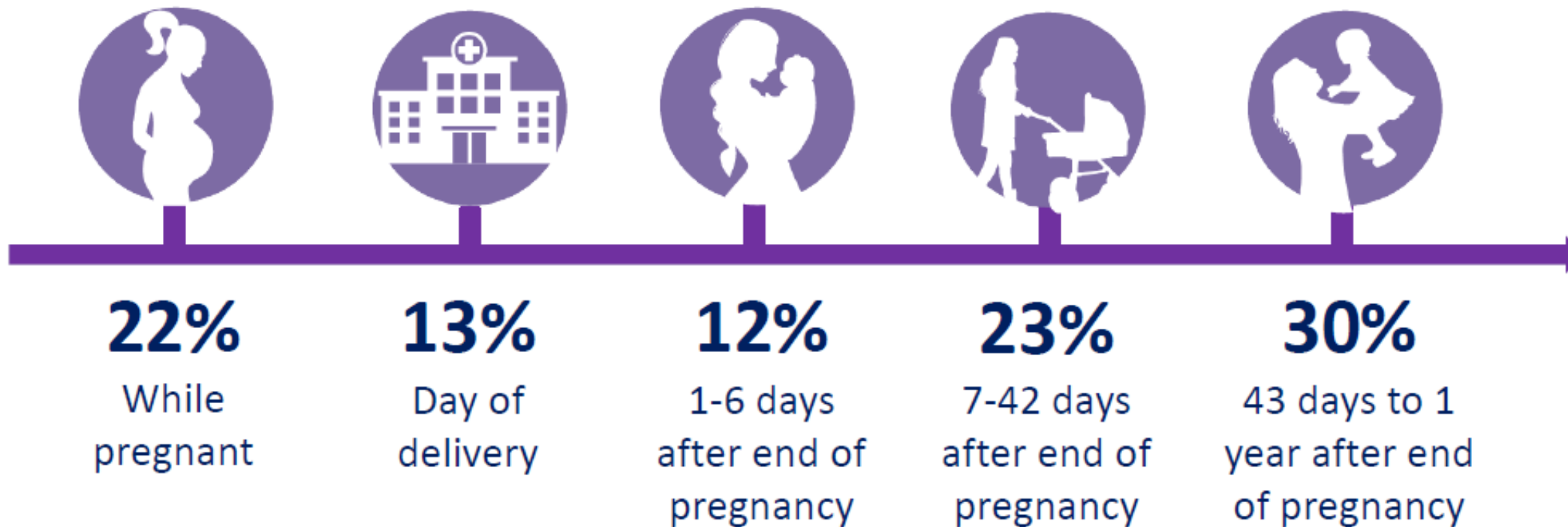
Maternal mortality rates by age: U.S. 2018-2021



¹Statistically significant increase from previous year ($p < 0.05$).
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality.



Timing of Pregnancy-Related Deaths



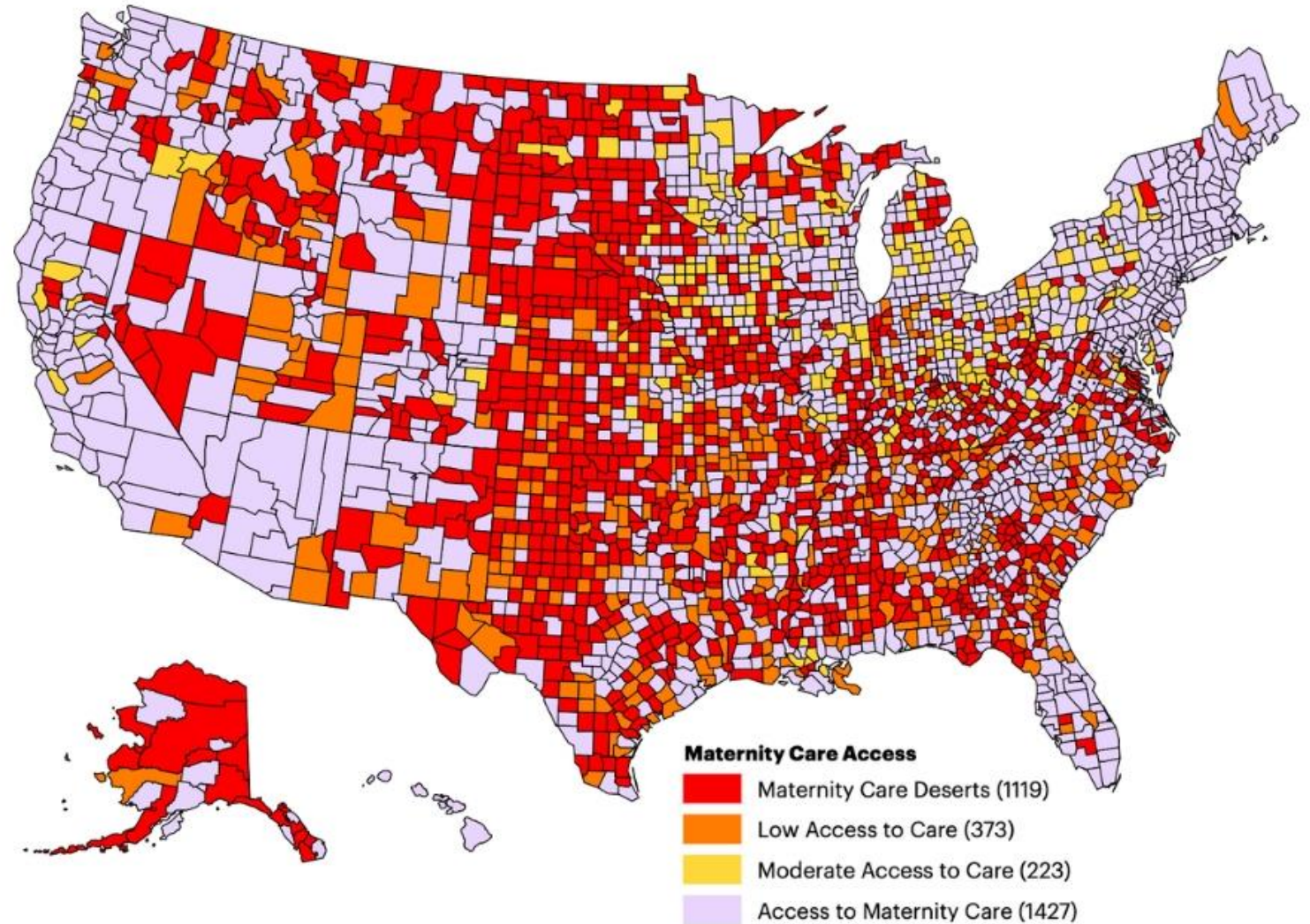
Timing was missing (n=2) or unknown (n=14) for 16 (1.6%) pregnancy-related deaths



Lack of Access to Obstetric Care is a Major Problem

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

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



“You Need to Do More...” 2019 Meeting with Black Maternal Health Caucus

Led to formation of NIH-wide
Maternal Mortality Task Force
and eventually, the IMPROVE
Initiative



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

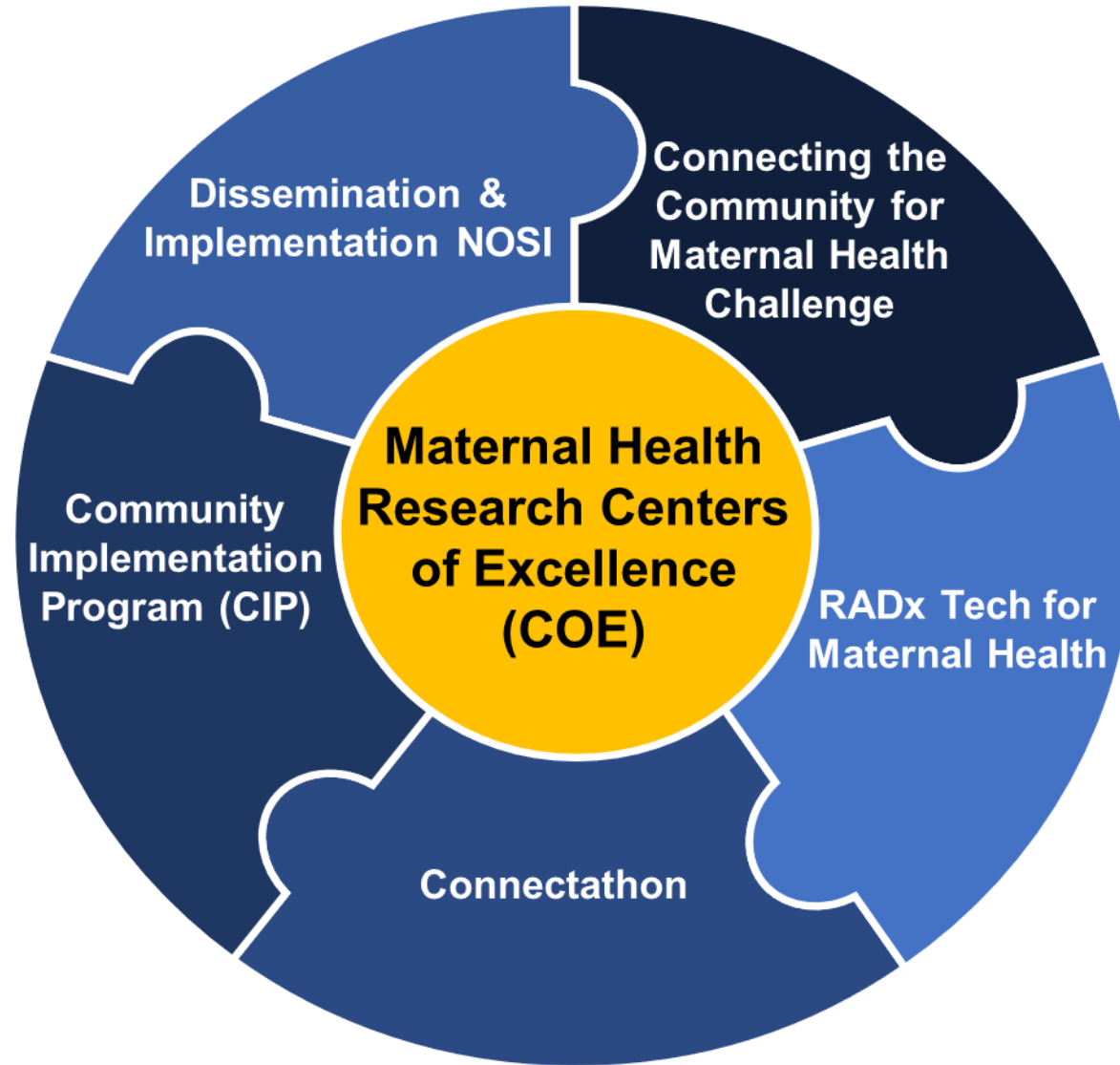
<https://www.nichd.nih.gov/IMPROVE>



IMPROVE Goals

- NIH-wide initiative co-led by NICHD, NINR, and ORWH
- **Core Principles:**
 - **Reduce preventable causes of MMM**
 - **Community involvement**
 - **Implementation research**
 - **Addressing disparities**
- Initially supported by ICO budgets; appropriated funds in FY22 and FY23

FY22 and FY23 IMPROVE Programs



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
- 10 Research Centers supported by a Data and Innovation Hub and an Implementation Science Hub
- **Key benefits:**
 - Community partnership from inception of research projects
 - Robust training component to grow future workforce
- Awarded in August 2023



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



RADx® Tech for Maternal Health Challenge

Strategic Focus on Maternal Care Deserts

- Home-based or point-of-care diagnostic devices, wearables, and other remote sensing technologies to extend postpartum care in regions lacking maternity care access
- Up to \$8M in prizes awarded through several phases
- Ten innovator teams in final Technology Assessment Phase
 - Devices undergoing independent testing and validation of performance and usability
- **Teams developing solutions related to blood pressure monitoring, mental health, hemorrhage, UTIs, anemia**
- Final prizes awarded in Spring 2024



RADx® Tech for Maternal Health Challenge

Caretaker Medical®, Charlottesville, VA

- The VitalStream™
 - FDA-cleared, ICU grade wearable device
 - Provides continuous measurement of heart rate, blood pressure, respiration, cardiac output/stroke volume, left ventricular ejection time, and heart rate variability
 - For in-hospital and at-home remote monitoring
- Testing usability and utility in postpartum populations
- Developing AI frameworks to use the vital sign outputs to predict and detect hemorrhage and sepsis



Connecting the Community for Maternal Health Challenge

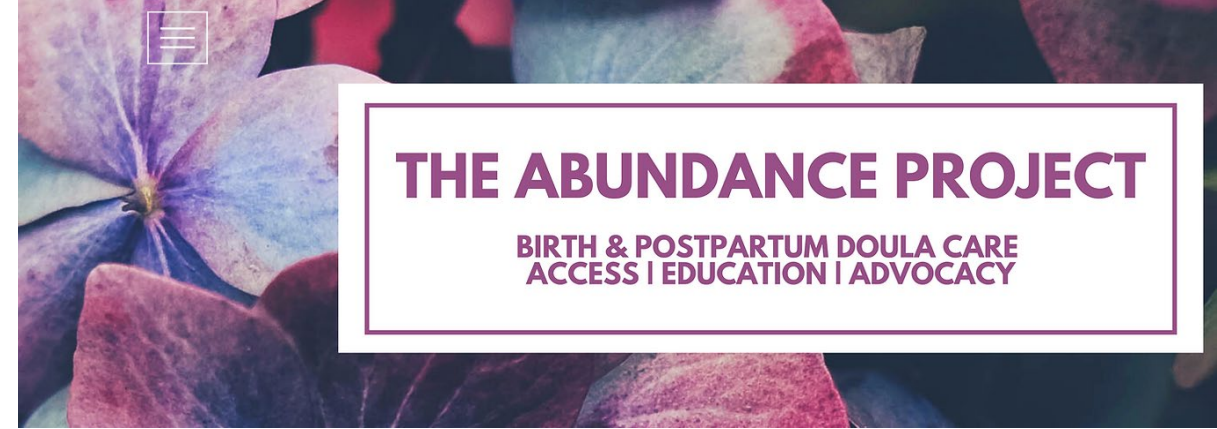
Capacity Building in the Community

- 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
- Final Research Phase: Organizations will have ~1 year to implement project plans, conduct proposed research, and report results
 - Projects include mental health interventions (7 of 9 teams); culturally congruent doula care; hypertension monitoring; nutrition care
- Final winners announced September 2024



The Abundance Project *Colorado*

- Evaluates impact of **postpartum doula care** on **reducing hypertension, depression, and anxiety** among Black, Indigenous, and People of Color **(BIPOC) postpartum mothers**
 - Community referral partners
 - Postpartum doulas provide six 4-hour visits to the research study's intervention group
- Assess feasibility and acceptability of postpartum doula care
- Some participants will also participate in pilot testing of Caretaker Medical's® VitalStream™ technology



*"As a mom who identifies as BIPOC and struggles with hypertension, I'm grateful that me and my family can benefit from being in this study."
- Study Participant*



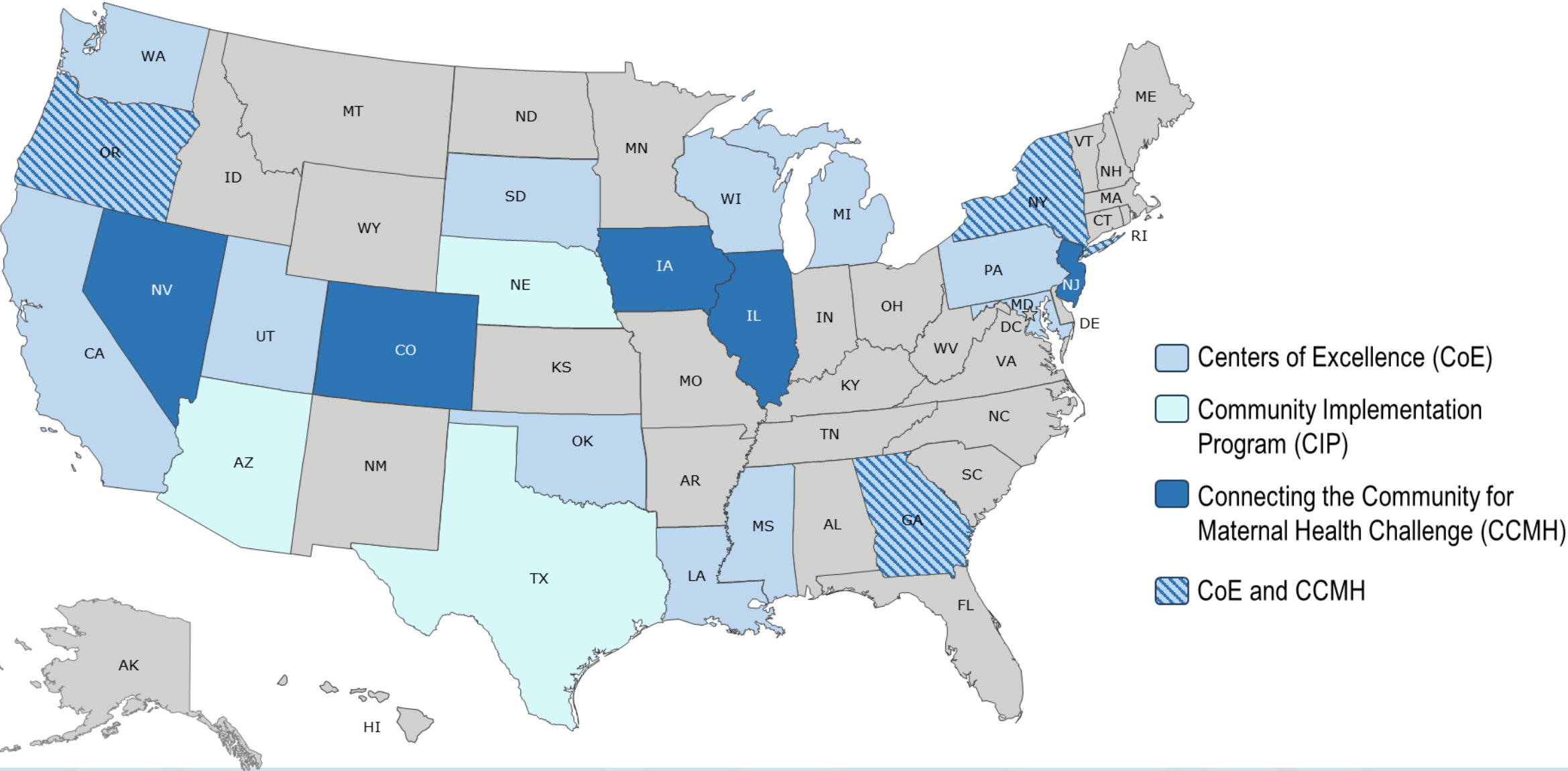
IMPROVE Community Implementation Program (CIP)



- **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**.
- Builds on successful **Maternal Health CIP** model
 - <https://maternalhealthcip.org/> (NHLBI)
- Three research coalitions will focus on:
 - **Doulas** to improve outcomes including **mental health** and **substance use disorders**
 - **Kinship involvement** to improve maternal health outcomes (including mental health) in Tribes
 - **Hypertension interventions** in underserved populations



Geographic Distribution of IMPROVE Initiative Programs





NIH-Wide Research Addressing Leading Causes of Pregnancy-Related Deaths

Leading Causes of Pregnancy-Related Deaths

- Mental health conditions (including deaths to suicide and overdose/SUD) (23%)
- Excessive bleeding (hemorrhage) (14%)
- Cardiac and coronary conditions (13%)
- Infection (9%)
- Thrombotic embolism (blood clot) (9%)
- Cardiomyopathy (9%)
- Hypertensive disorders of pregnancy (7%)

Research efforts across NIH address all leading causes of maternal mortality



A-PLUS (Azithromycin-Prevention in Labor Use Study) Trial: *Reduce Maternal Infection*

- Co-funded by NICHD's Global Network for Women's and Children's Health Research and Bill and Melinda Gates Foundation
- Tested whether single oral 2-gram dose of the inexpensive antibiotic azithromycin could reduce postpartum sepsis and death
- Enrolled more than 29,000 women in seven low- and middle-income countries
- Study stopped early due to clear maternal benefit
- **Results: Single dose azithromycin can reduce by one-third the risk of postpartum sepsis and death**
 - Did not reduce the risk of stillbirth, newborn sepsis or newborn death
 - May also be applicable in U.S. settings with limited access to care

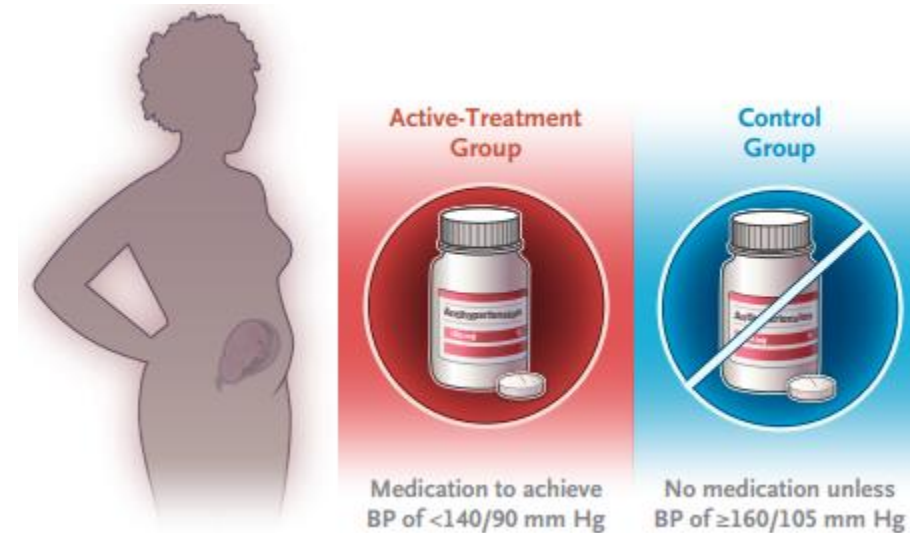


Tita ATN, Carlo WA, et al. NEJM. (2023)



Chronic Hypertension and Pregnancy Trial (CHAP): *Focus on Cardiac Conditions*

- **Test:** Is treating to BP <140/90 better than <160/105 during pregnancy?
- **Conclusion:** Treating mild chronic hypertension in pregnancy reduced adverse pregnancy outcomes (severe preeclampsia, preterm birth <35 wks, abruption, fetal or neonatal death).
- **Safety:** The percentage of infants who were small for gestational age (<10th percentile) was similar in the active treatment and control groups.
- **Implementation:** The result rapidly **changed practice guidelines** to recommend the threshold of 140/90 mm Hg for treatment of chronic hypertension in pregnancy



NHLBI-supported study
N Engl J Med; 386:1781-1792 (2022)



IMPROVE Center of Excellence at Stanford University: *Hemorrhage-Related Maternal Complications*

- **COE goal: Address disparities in two precursors to postpartum hemorrhage**
 - Prenatal iron deficiency anemia
 - Rates up to 2 to 4 times higher in Latinx and Black people, respectively
 - Cesarean birth
 - Highest prevalence of cesarean birth among low-risk pregnancies in Black and Asian people
- **Partners** include community organizations, state and county health departments



Effective Treatment Options and Recovery-Oriented Care: *Substance Use Disorders*

- Increases in pregnancy-associated overdose mortality (2018-2021) reflect persistent U.S. overdose crisis
- [Medication Treatment for Opioid-dependent Expecting Mothers \(MOMs\) study](#) to determine most effective delivery of an OUD medication to increase adherence
- New [NOSI](#) to support recovery-oriented, family-centered care across service sectors for pregnant and postpartum people with OUD
- Research supported by NIDA and HEAL initiative

Original Investigation

ONLINE FIRST

November 22, 2023

Pregnancy and Postpartum Drug Overdose Deaths in the US Before and During the COVID-19 Pandemic

Beth Han, MD, PhD, MPH¹; Wilson M. Compton, MD, MPE¹; Emily B. Einstein, PhD¹; [et al](#)

[» Author Affiliations](#) | [Article Information](#)

JAMA Psychiatry. Published online November 22, 2023.

doi:10.1001/jamapsychiatry.2023.4523



Preventing Perinatal Depression: *Improving Maternal Mental Health*

- Research to prevent perinatal depression by improving intervention delivery to individuals experiencing mental health disparities
- [NIMH supported awards](#) beginning in FY22
- Awarded projects will test:
 - Scale-up of an effective preventive intervention
 - Text message-based screening and intervention
 - Virtual vs. in-person preventive intervention
 - Depression risk using algorithmic identification and digital solutions using EHRs
 - An intervention adapted for individuals who had Adverse Childhood Experiences



New FY24 IMPROVE Funding Opportunities

- New opportunities address additional areas of increased maternal mortality and health disparities
- FY24 funding focus areas for MMM research
 - Intimate Partner Violence (OBSSR)
 - Healthcare access and quality (NIMHD)
 - Address overdose mortality (NIDA)





Leveraging Networks and Infrastructure

Leveraging Networks and Data Infrastructure to Advance MMM Research

- Infrastructure investment enables rapid response to public health crises
- Many ICs support trial networks or other resources that could pivot or scale up
 - Data repositories: Data and Specimen Hub (DASH), BioData Catalyst, ImmPort
 - NICHD's Maternal Fetal Medicine Units (MFMU) Network conducts clinical trials to assess interventions to improve maternal and infant health
 - MFMU scientists assessed the impact of COVID-19 infection during pregnancy and found that SARS-CoV-2 infection was associated with an increased risk for MMM



Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-Be (nuMoM2b)



- NICHD-funded study established in 2010
- Enrolled more than 10,000 pregnant people
- Purpose: Understand potential predictors of adverse pregnancy outcomes (e.g., preterm birth, preeclampsia, fetal growth restriction, stillbirth)
 - Maternal characteristics, biomarkers, and environmental factors
 - Specific aspects of placental development and function
 - Genetic, growth, and developmental parameters of the fetus
- Secondary analyses examined gestational weight gain, acculturation



NuMoM2b Heart Health Study



- NHLBI-funded study established in 2013 to follow participants from original nuMoM2b study
 - 6000+ participants with diverse backgrounds
- **Key Question:** Do individuals with adverse pregnancy outcomes (APO) have **preexisting** subclinical vascular conditions that are unmasked during pregnancy OR do APOs produce **de novo damage** that predisposes to cardiovascular issues later in life?
- **Major findings:**
 - Women with APOs at higher risk for hypertension as early as 2-7 years after delivery
 - Significant association of maternal obesity with APOs and cardiovascular health
 - APOs more likely to be a marker of **pre-pregnancy** CVD risk
- **Vital role of pre-pregnancy health for optimal pregnancy and postpartum outcomes**





Prevention

According to the CDC, 84% of pregnancy-related deaths are preventable


Studies That Focus on Prevention

- Early Intervention to Promote Cardiovascular Health of mothers and children ([ENRICH](#)) by addressing social and behavioral determinants (NHLBI)
 - Tests an implementation-ready intervention leveraging HRSA's Maternal and Child Health Home Visiting Programs and community engaged resources
- Glycemic Observation and Metabolic Outcomes in Mothers and Offspring ([GO MOMS](#)) study (NIDDK)
 - Aims to develop a better way to detect gestational diabetes early in pregnancy to intervene sooner and promote better health outcomes
- Maternal and Pediatric Precision in Therapeutics ([MPRINT](#)) Hub (NICHD)
 - Expand research on safe and effective therapies for pregnant and lactating people
- Commonly Used Drugs During Lactating and infant Exposure ([CUDDLE](#)) Study (NICHD)
 - Inform safe medication dosing levels that are safe for mother and infant while breastfeeding



NIH Pathways to Prevention Program: Identifying Risks and Interventions to Optimize Postpartum Health

- [Evidence-based process to identify research gaps](#)
 - Systematic Evidence Review
 - Independent Panel Report
 - Federal Partners Meeting to develop action plan
- Final reports due in a few months
- Sponsoring institutes: ODP, ORWH, NHLBI, NICHD, NIMHD




NIH Pathways to Prevention
Workshop: **Identifying Risks
and Interventions to Optimize
Postpartum Health**

November 30, 2022

Sponsoring Institutes:

- NIH Office of Research on Women's Health
- National Heart, Lung, and Blood Institute
- *Eunice Kennedy Shriver* National Institute of Child Health and Human Development
- National Institute on Minority Health and Health Disparities
- NIH Office of Disease Prevention

SEE VIDEOS

 National Institutes of Health
Office of Disease Prevention



Additional Maternal Health Research at NIH

- **These highlights are not comprehensive; NIH has a broad maternal health research portfolio supported across the agency.**
- [Advancing integrated models \(AIM\)](#) of care to address healthcare access or quality, together with structural or social inequities, to prevent adverse pregnancy outcomes among racial and ethnic minority women (NINR)
- Testing efficacy and/or effectiveness of [interventions to reduce racial disparities](#) in MMM (NIMHD)
- [Centers of Excellence on Environmental Health Disparities Research](#) supports some projects that aim to understand the effects of environmental exposures on pregnant people and their infants (NIEHS, NICHD, NIMHD)
- Funding opportunities from NIH and other federal agencies, along with additional information, can be found on **ORWH's Maternal Morbidity and Mortality Web Portal**:
<https://orwh.od.nih.gov/mmm-portal>



Summary

- Maternal mortality rates continue to rise in the U.S.
- Most pregnancy-related deaths are preventable
- NIH has a broad maternal health research portfolio supported across many ICOs
- NIH research is addressing all major causes of maternal morbidity and mortality
- IMPROVE focuses on community involvement, implementation research, and addressing disparities





Thank You!
Questions?