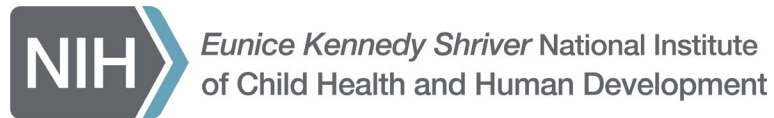


# Advisory Committee on Infant and Maternal Mortality (ACIMM): NICHD Updates

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

# IMPROVE Initiative

- NIH-wide effort supporting research focused on reducing preventable causes of maternal deaths and improving health for women before, during, and after delivery
  - Emphasizes health disparities and disproportionately affected populations
- Fiscal Year 2021 NIH awarded \$13 million across 22 projects
  - Included impacts of COVID-19 pandemic on maternal health and impact of structural racism and discrimination on maternal health outcomes in context of COVID-19
- New appropriation of \$30M in NICHD's base budget, beginning in FY22
  - Focus on initiatives and methods to promote evidence-based interventions in the community
  - Includes programs to accelerate technologies for maternity care deserts and improving health record methods to allow for real-world research



# Program Updates

- Connecting the Community for Maternal Health Challenge
  - 15 organizations were announced as winners of Gathering Phase (first phase of three-phase Challenge)
  - Each organization received \$10k and an invite to participate in the Proposal Phase
- Rapid Acceleration of Diagnostics Technology (RADx® Tech) for Maternal Health Challenge
  - 15 organizations were announced as winners of Viability Assessment Phase (first phase of three-phase Challenge)
  - Each organization received \$20k and an invite to participate in Deep Dive Assessment Phase
- Centers of Excellence, Dissemination & Implementation initiative, and Community Implementation received robust responses and are pending review





# **Stillbirth Working Group of Council**

# Progress

- NICHD formed the Stillbirth Working Group of Council in 2022 in response to an HHS request to lead a task force to examine stillbirth in the U.S.
- 4 Working Group (WG) meetings were held:
  - October 20, 2022 – Scope of the WG; NIH Portfolio Analysis; Fetal Deaths in the United States
  - November 22, 2022 – Current Barriers to Collecting Data on Stillbirths; Communities at Higher Risk
  - December 9, 2022 – Role of Federal Agencies; Psychological Impact and Treatment for Mothers Following Stillbirth; Known Risk Factors for Stillbirth
  - January 5, 2023 – Impact of Stillbirth on Families and Communities (presentations from members of the public)
- RFI was also published November 10, 2022; responses were due January 6, 2023
  - Received 11 distinct responses



# Summary of Recommendations

- Initial findings/recommendations were presented at January National Advisory Child Health and Human Development (NACHHD) Council meeting for feedback/discussion
- Final report was submitted on March 15 and included these overarching recommendations:
  - I. Improve the quality of vital statistics, surveillance, and epidemiologic data on stillbirth at the local, state, and national levels.
  - II. Use insights from improved epidemiologic and clinical data to explain and ultimately address disparities in stillbirth and identify prevention opportunities.
  - III. Conduct implementation research to help develop culturally sensitive interventions to support families that have experienced stillbirth.
  - IV. Create and support a full research agenda, including research on known and unknown risk factors and physiologic mechanisms, to support the development of interventions to prevent stillbirth.
- Spring-Summer 2023: Work begins on implementing recommendations





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



# Implementation and Progress

- **2016: Congress established PRGLAC** via the 21<sup>st</sup> Century Cures Act to identify and address gaps in knowledge regarding safe and effective therapies and vaccines for pregnant and lactating women.
- **Representation from all sectors:** multiple NIH institutes, CDC, FDA, AHRQ, HRSA, HHS, VA, professional societies, industry, academia, non-profit organizations. NICHD as lead.
- 2018: PRGLAC Report to Congress included **15 recommendations** to promote the inclusion of pregnant and lactating women in clinical trials.
- HHS Secretary extended PRGLAC charter, requesting guidance on implementation.



- 2020: PRGLAC issued an **Implementation Plan.**
- On March 13, 2021, PRGLAC's charter expired, ***but implementation continues!***



# The MPRINT Hub: Advancing Frontiers in Health through Maternal and Pediatric PRecision In Therapeutics

- **National resource for expertise in maternal and pediatric therapeutics**
- **Conducts and fosters therapeutics-focused research in obstetrics, lactation, and pediatrics, while enhancing the inclusion of people with disabilities**
- **Addresses underrepresentation of women and children in clinical trials**
- **MPRINT Hub is both a service center and science catalyst:**
  - Enhances the availability of knowledge, regulatory science, and drug development tools
  - Catalyzes and accelerates maternal and pediatric therapeutics towards precision medicine
  - Synergizes with other resources and networks
  - Facilitates safer, more inclusive, and more cost-effective trials

**MPRINT Hub:  
Knowledge Core  
and Centers of  
Excellence**



# A-PLUS (Azithromycin-Prevention in Labor Use Study) Trial

- Research supported 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



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



# Advisory Committee



*Image credit: Architect of the Capitol*

“The Committee includes \$200,000 for the creation of an Advisory Committee to monitor and report on the implementation of the recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). PRGLAC’s 2020 Implementation Plan called for the creation of an Advisory Committee to monitor and report on implementing recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical trials. Additionally, the Committee directs the Secretary to submit a report to Congress within 180 days of the date of enactment of this Act outlining the Department’s progress on implementing each of PRGLAC’s 15 recommendations from the Implementation Plan it submitted to the Secretary in August 2020.”



## **Other Updates**



# Maternal-Fetal Medicine Units (MFMU) and Neonatal Research Network (NRN) Renewal

- Applicants were reviewed at January Council meeting; new awardees will be announced soon
- Structure is changing to be more open to researchers outside of current network
  - Hope is to broaden and diversify group of investigators who propose projects and use the network
- New structure enhances review and approval process
  - Protocol review process will be implemented with goal of further enhancing rigor and reproducibility
  - Proposals from both network investigators and those outside of networks will undergo NIH scientific review





**Thank you!**

# Electromyometrial Imaging (EMMI)

- New imaging tool, EMMI, creates real-time, 3D images and maps of contractions during labor
  - Non-invasive technique
  - Integrates two types of scans: anatomical MRI to obtain image of uterus and surface scanning electromyogram that uses sensors placed on belly to measure contractions during labor
  - Data is combined and processed into 3D uterine maps
- Provides knowledge to improve labor management, especially for preterm births
- Research supported in part by NICHD through its Human Placenta Project and other programs

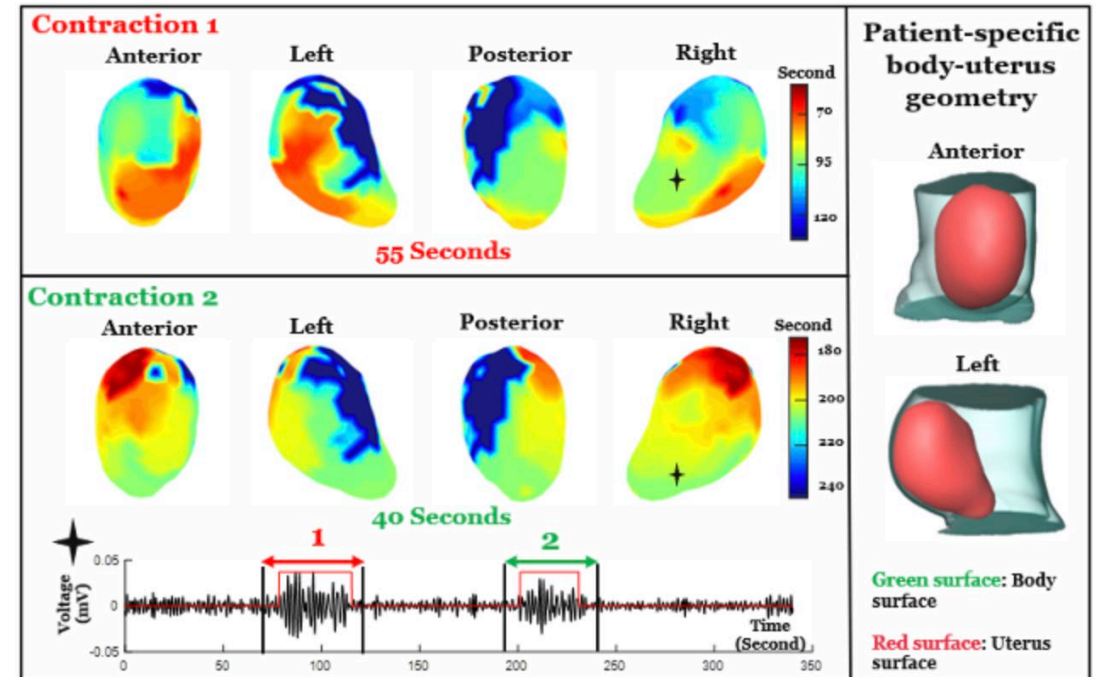


Image credit: Washington University in St. Louis

Wang, H., Wen, Z., et al. *Nature Communications*. (2023)

