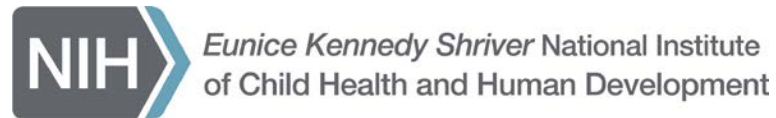


NICHD Director's Report

Diana W. Bianchi, M.D.

January 23, 2020



Talk Outline

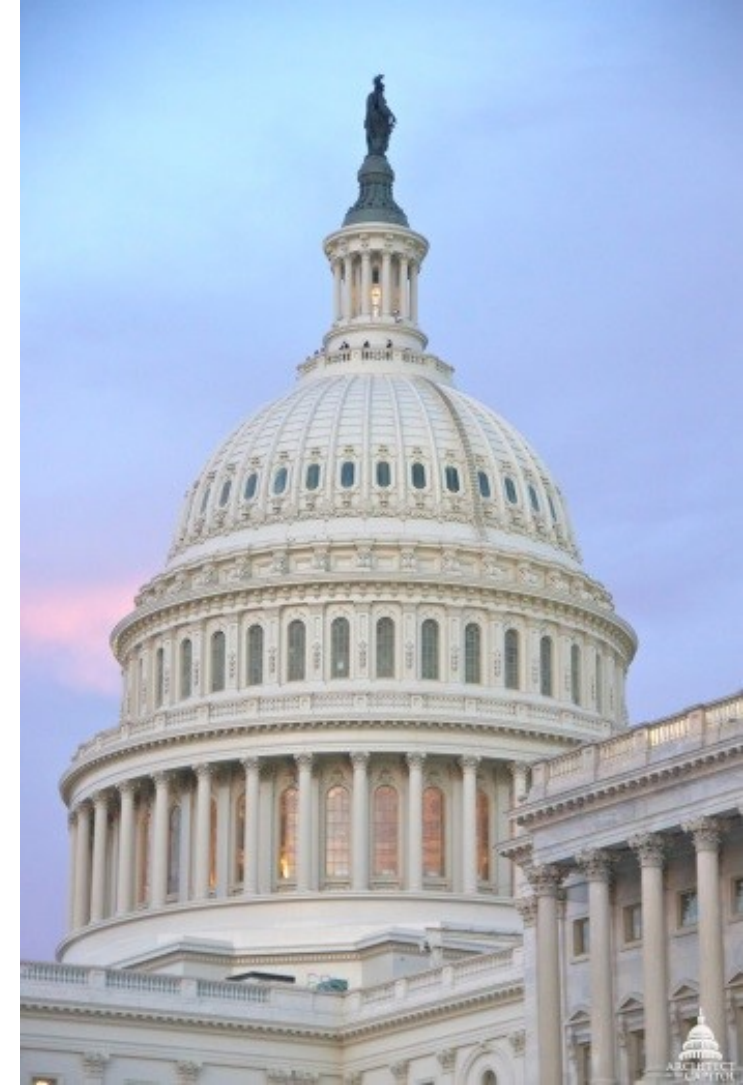
- Welcome to a new decade!
- NIH Budget
- NICHD Strategic Plan Implementation
- Maternal Mortality
- Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)
- Joint Consultative Meeting with Bill and Melinda Gates Foundation
- NICHD Staff Updates



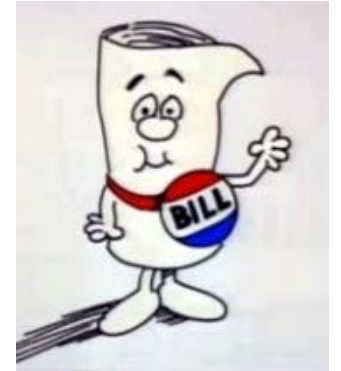
NIH Budget

FY 2020 and FY 2021 Appropriations

- Federal government is currently funded through September 30, 2020
 - \$41.7 billion to NIH
 - \$1.5 billion to NICHD
 - ~3% increase
 - Additional funding through Office of the Director for some projects (e.g., HEAL, INCLUDE)
 - FY 2021 President's Budget due to be released February 10, 2020



Annual Budget Process



*Late fall/
early winter*

February

*March or
April*

*Late spring/
summer*

September 30



*NIH staff prepare
Congressional
Justification (CJ)*

*President's
Budget
released*

*House and Senate
appropriations
hearings*

Bill mark-up

*Budget signed!
Or Continuing
Resolution (CR)*

Fiscal year runs from Oct 1-Sept 30





NICHD Strategic Plan Implementation

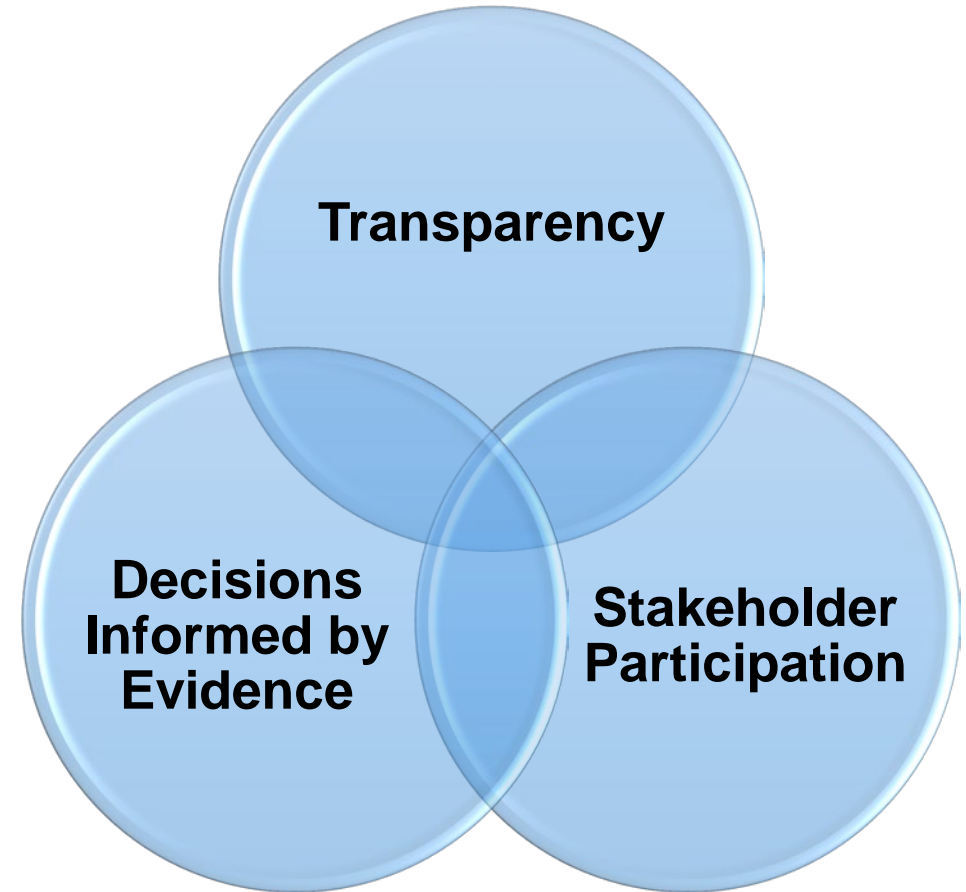
NICHD Strategic Plan 2020

Goals

1. Identify where NICHD should lead (priorities)
2. Identify where NICHD should partner and collaborate
3. Inform future investments in research, training, and infrastructure



Core Principles



Strategic Plan Implementation and Metrics

- Working with NICHD staff to consider how to make progress towards each objective within these themes and goals
 - Extramural branch priorities
- 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
 - 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, national health priorities, etc.
- Transparency – will regularly report progress to Council



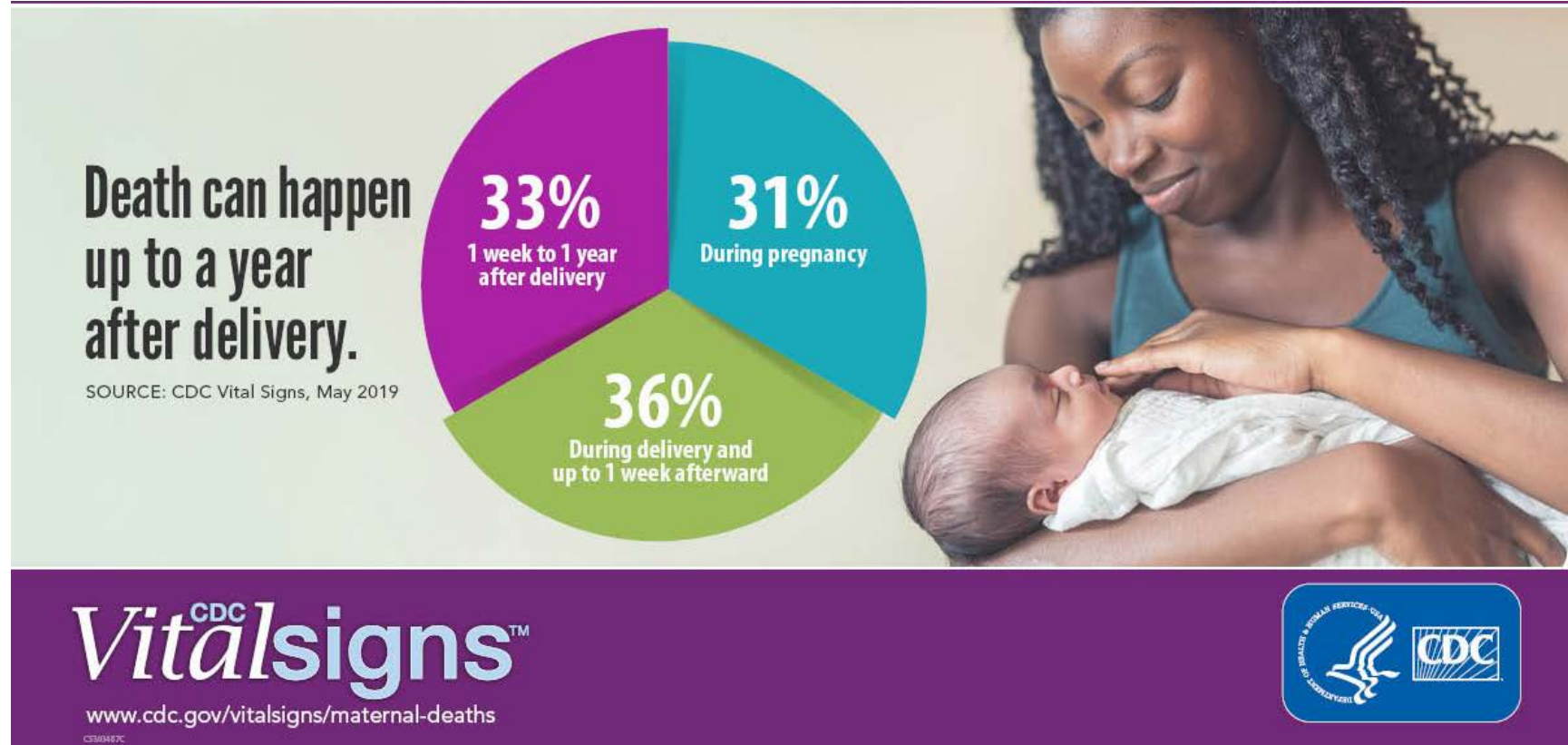


Maternal Mortality



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



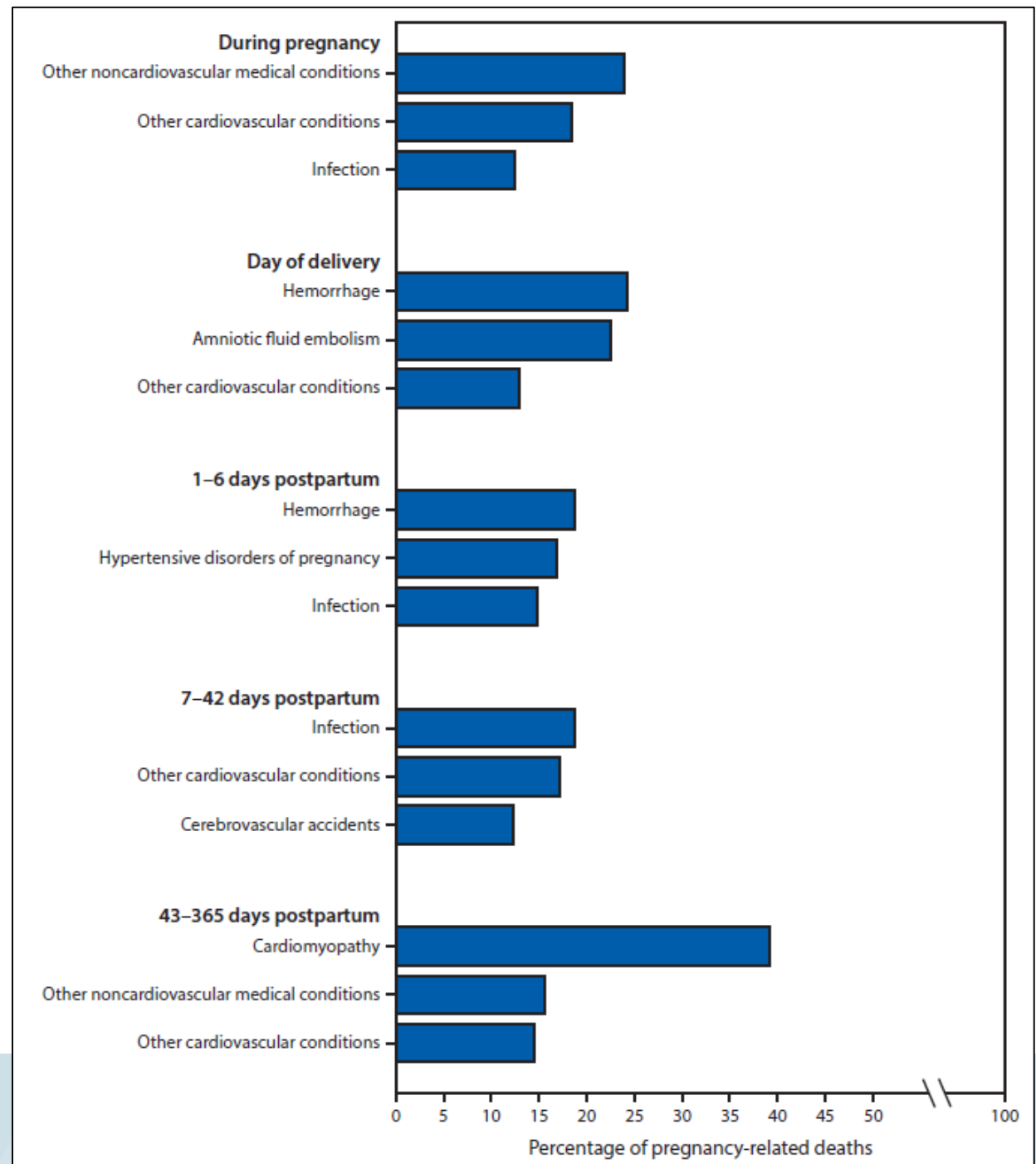
Increased Congressional Interest in Maternal Health



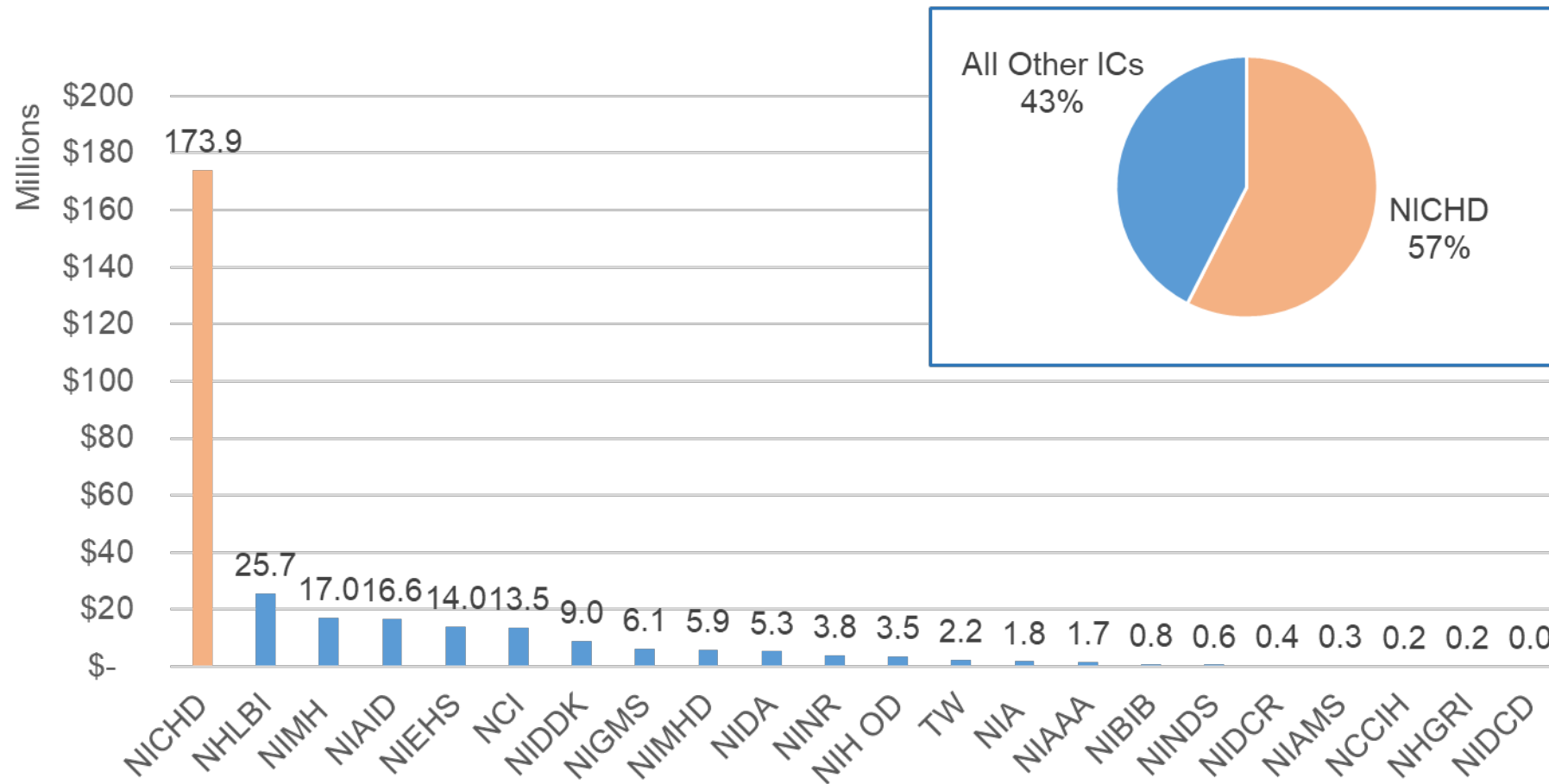
December 11, 2019



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



NIH Maternal Health Spending by IC, FY 2018



Note: NICHD funds almost 7 times the amount of maternal health research as the next highest IC.



Coordinated Efforts Focused on Maternal Mortality

- HHS is coordinating all operational divisions (CDC, HRSA, AHRQ, FDA, IHS, NIH) to develop an action plan - *March 2020*
- NICHD is co-leading a trans-NIH Task Force to outline a “bold and innovative” research agenda - *March 2020*
- Surgeon General action plan for communities – *May 2020*
- HHS working to fund a maternal health project through the Patient-Centered Outcomes Research Trust Fund
- Patient-Centered Outcomes Research Institute workshop – *March 16, 2020*
- NICHD-ORWH comorbidities workshop – *May 19-20, 2020*





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

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

- Report submitted to HHS Secretary and Congress in September 2018
- Key recommendations included:
 - Change existing culture that has limited scientific knowledge of therapeutic product safety, effectiveness, and dosing for pregnant and lactating women
 - Protect *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>



Implementation of PRGLAC Recommendations

- Established four working groups to address subsets of the recommendations and develop plans for implementation
 - Research and Training
 - Regulatory
 - Communications
 - Discovery
- **Working groups report out at PRGLAC meeting on Feb. 3, 2020**
- Implementation plan will include
 - Steps to address each recommendation, including potential costs and timelines
 - Whether any recommendations have already been implemented
 - What agencies and stakeholders should be involved
 - If any existing programs should be established or expanded
 - Metrics to evaluate success of implementation



International Efforts



conCEPTION
SAFETY EVIDENCE ECOSYSTEM



innovative
medicines
initiative

- Goal: create a trusted biomedical ecosystem capable of providing evidence-based information on the safety of medications during pregnancy and breastfeeding in an efficient, systematic and ethically responsible way
- 5-year initiative; public-private partnership involving 88 organizations from 22 countries
- \$28.6 million € project
- Key activities:
 - Use existing de-identified data generated during routine patient care to improve and unify data collection
 - Develop procedure and tools to collect digital data and samples from pregnant women
 - Create the first Europe-wide human milk biobank for research purposes
 - Develop tools to predict which drugs are likely to be transferred to human milk





Joint Consultative Meeting with Bill and Melinda Gates Foundation (BMGF)

Annual Meeting with BMGF Colleagues

- 6th annual NIH-BMGF meeting on global health
 - Held on December 20, 2019
- Several topics of mutual interest, especially within NICHD's Global Network for Women's & Children's Health Research
- Most relevant working groups
 - Maternal, Neonatal, and Child Health
 - Pregnancy Outcomes
 - Nutrition and Growth
 - Neurodevelopment
 - Contraception
- Goal: Develop milestone-driven collaborations



<http://clipart-library.com/clipart/1858994.htm>



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

Proposed Partnership with NICHD Global Network, BMGF and FNIH

- Maternal and neonatal infections among the most frequent causes of death in mothers and infants
- Multicenter RCT will assess whether a prophylactic oral dose of azithromycin given during labor will reduce
 - Maternal death or sepsis within 6 weeks
 - Intrapartum/neonatal death or sepsis within 28 days
- Potential partnership with Bill and Melinda Gates Foundation to expand the study to enroll 34,000 women at 8 research sites
- Actively engaged in partnership discussions with BMGF and the Foundation for NIH





NICHD Staff Updates

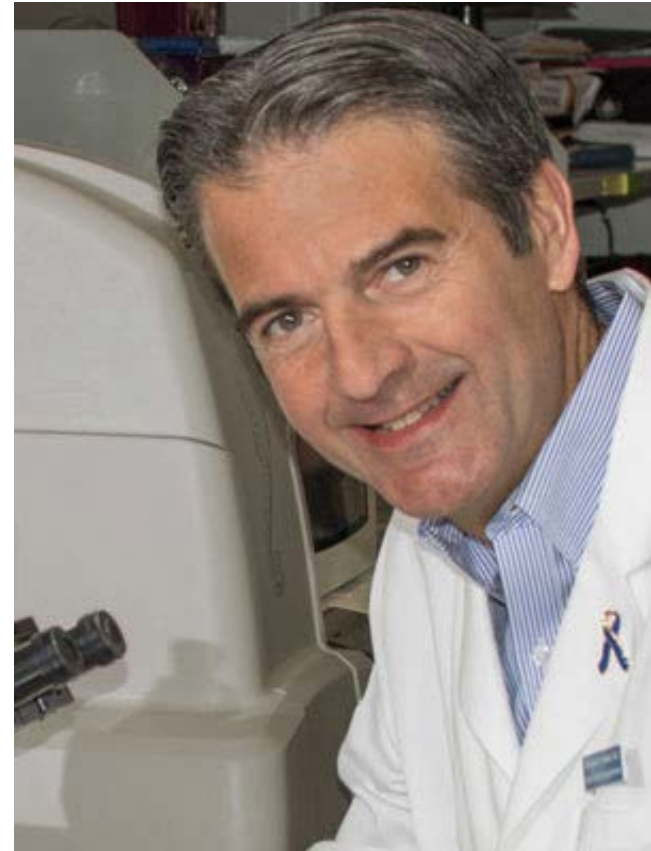
Welcome!

- Niteace Whittington, AAAS Science & Technology Policy Fellow
 - Ph.D. in Biology, with a focus on developmental biology, from Georgetown University
 - Previously a post-doctoral fellow with NINDS intramural lab
 - NICHD Office of Science Policy, Reporting and Program Analysis



Farewell and Best Wishes!

- NICHD Scientific Director since 2011
- As of June 1 2020, will become Executive Director/Chief Scientific Officer of the Research Institute of the McGill University Health Centre (MUHC) in Montréal and Director of Research for the MUHC system



Dr. Constantine Stratakis



Leadership Positions: Searches Underway

- **Director, National Center for Medical Rehabilitation Research (NCMRR)**
 - Search Committee has reviewed applicant packages
 - Invited applicants will interview with the Committee; best candidates presented to NICHD Director for review
 - Appointment recommendation sent forward to NIH Director for approval (projected for April 2020)
- **Director, Division of Population Health Research (DIPHR)**
 - Forming Search Committee
 - Formal job advertisement likely out in February; will be advertised for 60 days
 - Search Committee will interview highly qualified applicants and check references – early spring 2020
 - List of best candidates presented to NICHD Director for interview and selection
- **NICHD Scientific Director**
 - Similar process and timeline as the search for Scientific Director





Questions?