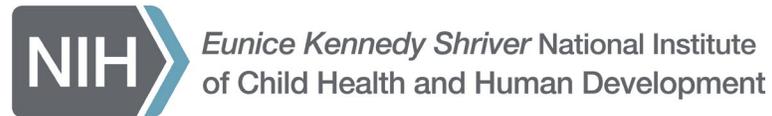


Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

Diana W. Bianchi, M.D., Chair

February 3, 2020



Recap of PRGLAC Activities Since August 2019

- Each working group met 5 times from September 2019 to January 2020 via webinar
- Additional discussion:
 - The Office for Human Research Protections
 - NIH's All of Us Communications
 - Best Pharmaceuticals for Children Act program representatives from NIH and FDA
 - NCATS's Clinical and Translational Science Awards program
- Main goal: Complete template of core questions for Recommendations 1-13



Today's Presentations

- For each recommendation, working groups will summarize the following:
 - Bullet points reflecting steps from worksheets,
 - Steps needed to implement this recommendation, and whether any have been started
 - Which stakeholders/federal agencies should be involved in carrying out this recommendation, and which should have the lead
 - Potential costs to carry out the recommendation
 - Potential timeframes for each step
 - Major takeaways



Working Group 1: Research/Training

- Co-chairs: Andrew Bremer (NICHD) and Victoria Pemberton (NHLBI)
- Members: Christina Bucci-Rechtweg (Novartis), Bridgette Jones (KC School of Medicine), Jeanna Piper (NIAID), Jeanne Sheffield (JHU), Wendy Weber (NCCIH)
- Ad hoc Members: Brookie Best (UCSD), Christina Chambers (UCSD), Ahize Eke (JHU), George Saade (UTMB), Lynne Yao (FDA)
- NICHD Staff: Sarah Glavin and Elizabeth Wehr



Working Group 2: Regulatory

- Co-chairs: Shelli Avenevoli (NIMH) and Karin Bok (NIAID/VRC)
- Members: Dorothy Fink (OWH/HHS), Melissa Gorman (Shriners Hospital), Robert Ternik (Eli Lilly)
- Ad hoc Members: Michael Greene (Harvard), Rahul Gupta (March of Dimes), Susan McCune (FDA), Melissa Tassinari (Mother-to-Baby), Susan Wood (GWU), Anne Zajicek (NIH)
- NICHD Staff: Lisa Kaeser



Working Group 3: Communication

- Co-chairs: Camille Fabiyi (AHRQ) and Kaveeta Vasisht (FDA)
- Members: Kristi Lengyel (UCB, Inc.), Joan Nagel (NCATS), Diane Spatz (U Penn School of Nursing)
- *Ad hoc* Members: Alicia Forinash (St. Louis College of Pharmacy), Tamara Johnson (FDA), Belinda Pettiford (NC Dept of HHS), Melissa Simon (Northwestern University), Douglas Storey (JHU), Sarah Taylor (Yale)
- NICHD Staff: Lorena Kaplan



Working Group 4: Discovery

- Co-chairs: Elena Gorodetsky (ORWH) and Aaron Lopata (HRSA)
- Members: Susan Givens (March of Dimes), Linda Lipson (Retire-VA), Voula Osganian (NIDDK), Jennita Reefhuis (CDC)
- *Ad hoc* Members: Susan Kindig (Eli Lilly), Kelle Moley (March of Dimes), Sonja Rasmussen (Univ of Florida), Sarah Reece-Stremtan (Children's National/Academy of Breastfeeding Medicine), Leyla Sahin (FDA)
- NICHD Staff: Christie Rogers





International Efforts Related to PRGLAC

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





Questions?