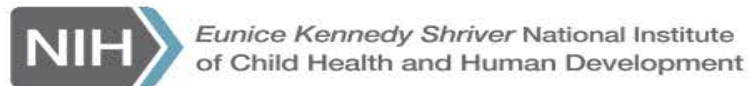


Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) Charge Call – Phase II May 22, 2019

Diana W. Bianchi, M.D.
Chair, PRGLAC



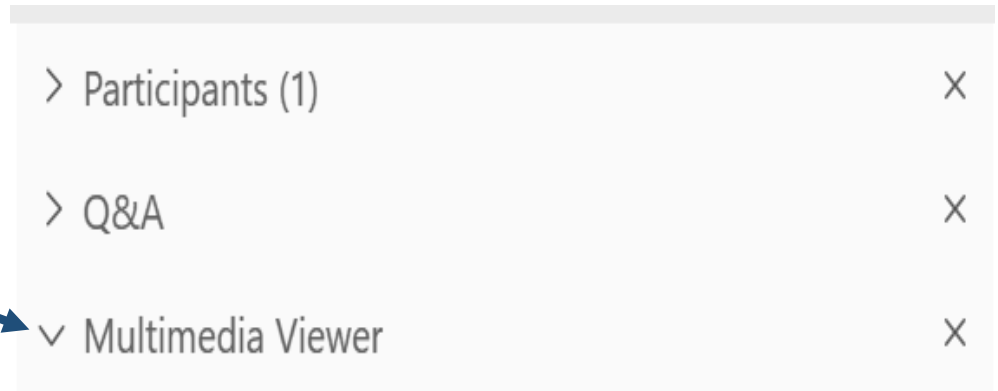
Talk Outline

- Welcome Remarks
- Changes to the PRGLAC Membership
- Plan for Phase II of PRGLAC
- Charge for Phase II of PRGLAC
- Next Steps
- Q&A



Closed-Captioning

- Closed-Captioning is being provided today.
- To view the captioning, click on the drop-down arrow in front of, “Multimedia Viewer, which is located on the right-hand side of your screen.
- Live captioning will then appear in the Multimedia Viewer panel.





Changes to the PRGLAC Membership

- New Task Force Members (Nominations Pending Approval)
 - Dorothy Fink, MD, Office of Women's Health, Department of Health and Human Services
 - Voula Osganian, MD, ScD, MPH, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health
 - Jennita Reefhuis, PhD, Centers for Disease Control and Prevention
 - Wendy Weber, ND, PhD, MPH, National Center for Complementary and Integrative Health, National Institutes of Health
 - Kaveeta Vasisht, MD, Pharm D, U.S. Food and Drug Administration



Changes to the PRGLAC Membership

- Former Federal Members Who Have Changed Positions
 - Catherine Spong, MD (Represented NICHD)
 - Marjorie Jenkins, MD (Represented FDA)
 - Athena Kourtis, MD (Represented CDC)
 - Sayeedha Uddin, MD, MPH (Represented OWH/HHS)

Brief Review of PRGLAC Recommendations



- Report submitted to HHS Secretary and Congress in September 2018
- Key recommendations include:
 - 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>

Plan for Phase II of PRGLAC



- Charter extended until March 2021
- Will hold 2 meetings of the full Task Force per year (required in legislation)
 - Today's charge call
 - August 22-23, 2019
- Establish four working groups to address subsets of the recommendations and develop plans for implementation
- Divide existing members into the four working groups
- Add additional *ad hoc* members as needed to fill in the missing expertise





Group Assignments: Rationale

- Mix of expertise/knowledge within each group
- Prior participation in PRGLAC I mixed with members new to the Task Force



Working Group 1: Research/Training

- Recommendations:
 - 2. Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women.
 - 3. Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics.
 - 8. Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model.
 - 11. Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women.
- Co-chairs: Bremer (NICHD) and Pemberton (NHLBI)
- Members: Bucci-Rechtweg (Novartis), Jones (KC School of Medicine), Piper (NIAID), Sheffield (JHU), Weber (NCCIH)



Working Group 2: Regulatory

- Recommendations:
 - 1. Include and integrate pregnant women and lactating women in the clinical research agenda.
 - 4. Remove regulatory barriers to research in pregnant women.
 - 7. Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women.
- Co-chairs: Bok (NIAID/VRC) and Avenevoli (NIMH)
- Members: Gorman (Shriners Hospital), Ternik (Eli Lilly), Fink (OWH/HHS)



Working Group 3: Communication

- Recommendations:
 - 5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women.
 - 6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant women and lactating women.
 - 10. Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research.
 - 13. Optimize registries for pregnancy and lactation
- Co-chairs: Vasisht (FDA) and Fabiyi (AHRQ)
- Members: Adirim (DoD), Foley (ob-gyn), Nagel (NCATS), Spatz (U Penn School of Nursing)



Working Group 4: Discovery

- Recommendations:
 - 9. Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women.
 - 12. Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women.
- Co-chairs: Gorodetsky (ORWH), and Wilson (HRSA)
- Members: Givens (March of Dimes), Lipson (VA), Lengyel (UCB, Inc.), Tschetter (SD State College of Nursing), Reefhuis (CDC), Osganian (NIDDK)



Charge to the Working Groups

- Compile a written report that includes:
 - Steps needed to address each recommendation (including the sub-bullets),
 - Whether any of those steps have started
 - What agencies and stakeholders should be involved, and
 - A plan for implementing them, including potential costs and timelines.
 - If any existing programs should be established or expanded, those should be noted.
- NICHD staff will assist Working Groups to set up additional meetings by conference call/webinar
- The Working Groups will report back to the full Task Force next year with the information they include in the written report



Next Steps

- Send Lisa Kaeser, Executive Secretary, PRGLAC, (kaeserl@mail.nih.gov) nominations of subject matter experts to fill in the missing expertise on the working groups by June 7, 2019
- Plan to attend the August 22-23, 2019 meeting to hold your first working group meeting
- Hold additional Working Group meetings to finalize the plan to implement the recommendations
- Reconvene in winter (February 2020) to present final outlines
- Finalize Working Group reports by August 2020



Question and Answer Session

- Phones will remain muted. ***Please do not unmute your phone line.***
- Please use the Q&A Panel at the right-hand side of your screen to type in your questions.
- Click on the drop down arrow that appears before 'Q&A'.
- The Q&A Panel will expand.
- Type your question into the blank box and click "send" (circled to your right).

> Participants (1) ×

∨ Q&A ×

All (0)

Select a question, and then type your answer here,
There is a 256-charactors limit.

Send Send Privately

∨ Multimedia Viewer ×



Thank You and
Questions