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 (UPenn 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).
Thank You and Questions