

PRGLAC Phase II Charge and Goals

August 22, 2019

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Talk Outline

- PRGLAC Activities in 2019
- PRGLAC Working Groups
- Questions
- Discussion



PRGLAC Activities in 2019

- Charter extended until March 2021
- Scheduled in-person meetings:
 - August 22-23, 2019
 - February 3-4, 2020
- Since the charge call in May:
 - Established four working groups to address subsets of the recommendations and develop plans for implementation
 - Existing members and additional *ad hoc* members included in the four working groups





Early Results: PregSource® Medication Tracker



Medication and Supplement Tracker

[Add](#)

[Drug list](#)

Select "Add" to list a prescription or over-the-counter medicine, vitamin, or herbal supplement. If you stopped taking an item or need to change information about it, select "Edit" next to that item.

Current Medications and Supplements

Add Medication or Supplement

Type the name of a medication, vitamin, or herbal supplement in the search field to add that item to your list.

What are you taking?

bactr

Search

bactracillin g

bactracillin g benzathine

bactrim

bactroban

Systemic Formulas Bio Command 3 Bactrex

Systemic Formulas T3 Bactrex Tincture

pregsource.nih.gov



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.



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

- 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.



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

- 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.
 - 13. Optimize registries for pregnancy and lactation



Working Group 3: Communication

- Co-chairs: Camille Fabiyi (AHRQ) and Kaveeta Vasisht (FDA)
- Members: Terry Adirim (DoD), Steven Foley (ob-gyn), 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

- Recommendations:
 - 9. Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to 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.
 - 12. Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women.



Working Group 4: Discovery

- Co-chairs: Elena Gorodetsky (ORWH) and Aaron Lopata (HRSA)
- Members: Susan Givens (March of Dimes), Linda Lipson (VA), Voula Osganian (NIDDK), Jennita Reefhuis (CDC), Lois Tschetter (SD State College of Nursing)
- *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



PRGLAC 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.
 - Decide on metrics to evaluate success of implementation



PRGLAC Working Groups (Cont.)

- Template of core questions have been shared with co-chairs of each group to help guide today's discussions
- As you go through the questions, think about what additional presentations you may need for subsequent meetings
- Tomorrow co-chairs will report on what was discussed in their groups

Questions?



Discussion Topic

- What lessons have been learned from developing other implementation plans for other organizations?



Thank you