

Task Force on Research Specific to Pregnant Women and Lactating Women

Meeting Summary

The Task Force on Research Specific to Pregnant Women and Lactating Women (Task Force or PRGLAC) convened for an online webinar on May 22, 2019. In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Interested individuals could attend online by registering in advance.

Task Force members present:

- Diana Bianchi, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), Chair
- Shelli Avenevoli, Ph.D., National Institute of Mental Health (NIMH)
- Karin Bok, Ph.D., M.S., National Institute of Allergy and Infectious Diseases (NIAID)
- Andrew Bremer, M.D., Ph.D., NICHD
- Christina Bucci-Rechtweg, M.D., Novartis Pharmaceuticals Corporation
- Camille Fabiyi, Ph.D., Agency of Healthcare Research and Quality (AHRQ)
- Steven Foley, M.D., FACOG, Prowers Medical Center
- Susan Givens, RN, March of Dimes
- Melissa Gorman, M.S.N., RN-BC, CCRN, Shriners Hospital for Children
- Elena Gorodetsky, M.D., Ph.D., Office of Research on Women's Health, NIH
- Bridgette Jones, M.D., University of Missouri-Kansas City
- Kristi Lengyel, M.B.A., UCB, Inc.
- Joan Nagel, M.D., M.P.H., National Center for Advancing Translational Sciences (NCATS)
- Victoria Pemberton, M.S., RNC, CCRC, National Heart, Lung, and Blood Institute (NHLBI)
- Jeanna Piper, M.D., NIAID
- Jeanne Sheffield, M.D., Johns Hopkins University
- Diane Spatz, Ph.D., University of Pennsylvania
- Robert Ternik, Ph.D., Eli Lilly and Company

Executive Secretary Lisa Kaeser, J.D., NICHD, was present.

Ad hoc Task Force members present:

- Voula Osganian, M.D., Sc.D., M.P.H., National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- Jennita Reefhuis, Ph.D., Centers for Disease Control and Prevention (CDC)

Task Force members absent:

- Terry A. Adirim, M.D., MPH, Department of Defense (DoD)
- Linda Lipson, M.A., Department of Veterans Affairs (VA)
- Lois Tschetter, Ed.D., RN, IBCLC
- Lee Andrew Wilson, M.S., Health Resources and Services Administration (HRSA)

Ad hoc Task Force members absent:

- Dorothy Fink, M.D., Office of Women's Health, Department of Health and Human Services (HHS)
- Wendy Weber, N.D., Ph.D., M.P.H., National Center for Complementary and Integrative Health (NCCIH)
- Kaveeta P. Vasisht, M.D., Pharm.D., U.S. Food and Drug Administration (FDA)

Others present:

- NICHD Staff members
- Members of the public

Welcome and Opening Remarks

Dr. Bianchi welcomed everyone to the public webinar and explained that closed captioning was available. She also explained that the telephone lines were muted and if participants had questions, to use the chat feature on the screen, and they would be answered at the end of the presentation.

Changes to the PRGLAC Membership

Dr. Bianchi explained that a few changes were made to the Task Force membership because some federal members who were on the Task Force, either left government service or changed federal positions. Dr. Bianchi introduced the ad hoc members who will now represent the federal organizations that had vacancies. Those nominations are pending approval. Dr. Osganian and Reefhuis were on the call and introduced themselves to the meeting participants.

There were four federal members who retired from the Task Force. Dr. Catherine Spong left government service, as did Dr. Marjorie Jenkins. Both Dr. Athena Kourtis and Dr. Sayeedha Uddin are still employed by the federal government; however, they have changed positions. Dr. Bianchi stated that she was very appreciative of their service on the Task Force.

Plan for Phase II of PRGLAC

Before explaining the specific plan for Phase II of PRGLAC, Dr. Bianchi briefly reviewed the work that had been completed in Phase I of PRGLAC. She described the report that was submitted to the HHS Secretary and Congress in September 2018. The full report is available online at <https://www.nichd.nih.gov/About/Advisory/PRGLAC>. She outlined the key themes from the recommendations. They 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 the workforce of clinicians and researchers with expertise in obstetric and lactation pharmacology and therapeutics; and
- Remove regulatory barriers.

In March 2019, NIH received notification that the charter for PRGLAC has been extended to March 2021. Two public PRGLAC meetings will be held each year. For 2019, this includes the charge call on May 22, 2019, and an in-person meeting on August 22-23, 2019.

To address subsets of the recommendations and develop more detailed plans for implementation, four working groups will be established. Task Force members will be divided into the four working groups. Additional ad hoc members may be added as needed to fill in the missing expertise for each group.

Working Group 1: Research/Training will be co-chaired by Dr. Bremer and Ms. Pemberton. Members include: Drs. Bucci-Rechtweg, Jones, Piper, Sheffield, and Weber.

They will address 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 program as a model.
- 11. Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women.

Working Group 2: Regulatory will be co-chaired by Drs. Bok and Avenevoli. Members include: Ms. Gorman and Drs. Ternik and Fink. This group will address 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 3: Communication will be co-chaired by Drs. Vasisht and Fabiyi. Members include: Drs. Adirim, Foley, Nagel, and Spatz. This group will address 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.

Working Group 4: Discovery will be co-chaired by Dr. Gorodetsky and Mr. Wilson. Members include: Ms. Givens, Ms. Lipson, Ms. Lengyel and Drs. Tschetter, Reefhuis and Osganian. They will address 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.

Charge for Phase II of PRGLAC

The main goal of each working group will be to 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 implementation, 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 in February 2020 with the information they plan to include in the written report. Members of the public will also have an opportunity to comment on the proposed plans.

Next Steps

Dr. Bianchi requested that meeting participants send Ms. Kaeser nominations of subject matter experts to fill in any missing expertise in the Working Groups. The deadline to send information is June 7, 2019. Dr. Bianchi also announced that the first Working Group meetings will be held at the Task Force meeting in August 22-23, 2019. Additional meetings can be held as needed. The Task Force will reconvene in February 2020 for the Working Groups to present their findings. Working Group reports will be finalized by August 2020.

Q&A

The following questions were asked and answered.

Q: Will the slides from the presentation today be available?

A: Yes, once the slides are made 508 compliant they will be posted on NICHD's website at: <https://www.nichd.nih.gov/About/Advisory/PRGLAC>

Q: Who may submit nominations for the Task Force?

A: Both Task Force members and the public may submit nominations suggesting ad hoc members of the Task Force who would be able to provide expertise currently missing from the Working Groups. The deadline is June 7, 2019.

Q: How large will the Working Groups be?

A: The exact number is not known, but the Working Groups need to be small enough to hold dedicated discussions, yet they also need to have the appropriate expertise.

Q: Other than sending in names, is there anything else that the working groups should be doing right now?

A: We will be contacting each of the co-chairs for the Working Groups before the August 22-23, 2019 meeting to outline the framework more extensively.

Q: What information should be included in the nominations for the Task Force?

A: At a minimum, nominations should include name, title and affiliation, and what expertise they bring to the working group for which they are being considered. NICHD will reserve the right to determine where a nominee should be placed based on the expertise that is needed.

Q: Will the August meeting be public?

A: Yes, the August 2019 meeting will be open to the public and will allow for a public comment period. Additionally, during the presentations of the Working Groups, the public will have an opportunity to make comments, similar to what has been done in the past in other Task Force meetings. The first day is expected to be a public comment period, then the members and ad hoc members will break into their Working Groups. During the second day, the Working Groups will present their initial findings in a public session.

Q: Can the details of the Working Groups be shared with other organizations to request recommendations for additional ad hoc members?

A: Yes, we encourage everyone to share the information presented at this meeting with others and submit your recommendations by June 7.

Q: What are the plans of PRGLAC to involve non-clinical scientists?

A: Because the question wasn't clear, it was suggested that the person asking the question email the Executive Secretary, Ms. Kaeser, to find a time to talk in more detail.

Q: Can the public participate in the Working Group meetings?

A: If a member of the public wants to know what was discussed during the Working Group meetings, he or she should plan to attend the committee meetings of the Task Force, which are open to the public. The public, along with Task Force members, will be able to comment after the Working Group presentations.

Adjournment

Dr. Bianchi reminded everyone of the date to submit nominations to Ms. Kaeser, Executive Secretary, PRGLAC. She also reinforced that Ms. Kaeser would be in touch with the co-chairs prior to the August meeting with additional instructions about the Working Groups. Dr. Bianchi stated that she looks forward to seeing everyone in person in August and adjourned the meeting.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Lisa Kaeser, J.D.

Executive Secretary, Task Force on Research Specific to Pregnant Women and Lactating Women