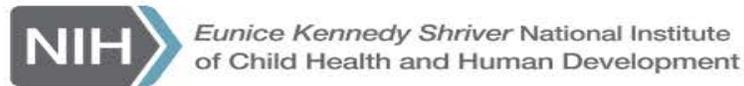


Task Force on Research Specific to Pregnant and Lactating Women



PRGLAC Recommendations



****Central focus of all recommendations is aimed at changing the culture****

15 Recommendations

Procedure:

1. Limited/focused discussion
2. Voting: PRGLAC Task Force members vote
Show of hands – Y/N
 - If majority approve: note concerns of negative votes





Include and integrate pregnant women and lactating women in the clinical research agenda

- Remove pregnant women as an example of a vulnerable population in the common rule
- FDA should harmonize with the common rule and remove pregnant women as a vulnerable population
- Develop HHS Guidance to facilitate the conduct of research in pregnant women and lactating women



Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women

- Provide additional resources and funding for research to obtain clinically meaningful and relevant data for both specific and co-existing conditions in pregnant women and lactating women
 - Including but not limited to:
 - Develop preclinical models
 - Expand basic science research to inform drug development
 - Develop new tools and methods to assay therapeutic products such as those that utilize small volumes and are sensitive to detect minute quantities including in human milk
 - Develop new tools to assess pharmacodynamic response in pregnant women, lactating women, and children
 - Fund clinically relevant research and studies to inform therapeutic product use in pregnant women and lactating women
 - Design trials to capture long term maternal, obstetric, and child outcome
 - Utilize longer award periods by government funders (beyond the typical 5 year award) when needed for study design and data collection



Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics.

- Develop and support training and career development opportunities in obstetric and lactation pharmacology and therapeutics for both clinical and basic science
- Develop mentors in obstetric and lactation pharmacology and therapeutics for both clinical and basic science
- Increase the knowledge and engagement of health care providers regarding obstetric and lactation pharmacology and therapeutics



Remove regulatory barriers to research in pregnant women

- **Modify subpart B**
 - Change 46.204(e) in subpart B to maternal consent alone
 - Given the recognized autonomy of a pregnant woman, the evolution of family structure, that for a child only one parental signature is required for research to benefit the child and to align with parental consent for pediatrics
 - Add in the option of “Minor increase over minimal risk” from subpart D to 36.046



Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women

- Highlight the importance of research on therapeutic products in pregnant women and lactating women including the impact of not taking the medication during pregnancy and lactation as well as the impact of not breastfeeding on mother and child
- Engage stakeholders such as HHS, professional societies, industry, advocacy, public and global partners



Develop and implement evidence based communication strategies with health care providers on information relevant to research on pregnant women and lactating women

- Increase the knowledge of health care providers regarding obstetric and lactation therapeutics and research needs
- Increase the engagement of health care providers to disseminate information from research findings to their patients
- Increase the engagement of health care providers to discuss participation in clinical trials, research, and registries
- Develop appropriate strategies for sharing and interpreting research findings and risk.



Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the National Institutes of Health Best Pharmaceuticals for Children Act as a model

- Provide specific funding
- Develop separate prioritization processes for therapies and/or conditions in pregnant women and lactating women



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

- Implement a liability-mitigation strategy for conducting research and evaluating new therapeutic products in pregnant women and lactating women
 - Using the Vaccine Injury Compensation Program (VICP) as a model, however include mitigation whether or not the therapeutic product achieves marketing approval
- If liability mitigation is insufficient, consider implementing a targeted incentive program and/or strengthening FDA authority to require clinically relevant data (such as pharmacologic and clinical data) on pregnant women and lactating women to inform dosing and safety



Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research

- Investigators/sponsors must specifically justify exclusion in study design
- Ensure studies are designed to capture the time dependency of physiologic changes in pregnancy and lactation
- Develop a systematic plan on how data for pregnant women and lactating women will be obtained in a timely fashion to include PK/PD, safety
- Develop guidance for institutional review boards and investigators about the inclusion of pregnant women and lactating women in research
- Develop a systematic plan for if a woman becomes pregnant in a study to include whether product should continue, if un-blinding is necessary, how to capture opportunistic information on pharmacology, clinical data, and pregnancy outcome information



Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women

- Create separate prioritization processes for pregnant women and lactating women
 - Unmet need examples in lactation: low milk supply, mastitis
 - Unmet need examples in pregnancy: preterm labor, hyperemesis
- Consider a BARDA-like model and the NIH vaccine model that takes clinical development up to phase II



Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women

- Design health record systems to link mother and infant records
- Leverage large studies and databases including health systems, health plans, surveillance systems, electronic medical records, registries
- Use novel data resources
- Use innovative methods of data analytics
- Require common data elements to facilitate collaboration and use



Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women

- Provide financial support and incentives to established and develop new multicenter infrastructures that capitalize on standard of care procedures (opportunistic studies), innovative designs, and methodologies.
- Broaden focus of ongoing research networks to include research on therapeutic products in pregnant women and lactating women
- Encourage networks/collaborations to engage in public-private partnerships to facilitate research



Optimize registries for pregnancy and lactation

- Create a user-friendly website for registry listing
- Develop registry standards and common data elements that facilitate input of pertinent data with easy, transparent access to obtain information in real time
 - Include maternal, obstetric, and child outcomes along with birth defects
- Facilitate access to data and transparency of information in registries
 - Use the ART registry as a model
- Develop disease / condition focused registries
 - Move toward a single registry for all therapeutic products with input from stakeholders



The Secretary should consider exercising the authority provided in law to extend the PRGLAC Task Force when its charter expires in March 2019.



Establish an Advisory Committee to monitor and report on implementation of recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research



Meeting 4 Summary

- Background of Task Force
- Review of report to date
 - Send in comments – be specific please – by Friday
- FDA updates
- Historical recommendations
- Incentives/Liability mitigation
- Recommendations



Important Deadlines

- May 18: send comments on draft report
- ~ May 29: revised full report sent to TF members for comments/review
- ~ June 4: send comments on executive summary
- June 30, 2018 finalized document to NIH Executive Secretary
 - September 2018 – Report sent to HHS Secretary and Congress
- December 2018 – Secretary required to act on Task Force recommendations
- March 2019 – Task Force will sunset unless extended





SEC. 2041. TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.

ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall establish a task force, in accordance with the Federal Advisory Committee Act...

(2) DUTIES.—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.



Report Requirements

(1) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies;

(2) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research;

(3) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women;

(4) Identification of Federal activities, including:

(a) The state of research on pregnancy and lactation;

(b) Recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

(c) Dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

(d) Existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities; and

(5) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.