

Lactating Women and Research

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Task Force on Research for Pregnant and Lactating Women
(PRGLAC)

November 6-7, 2017



Lactation Landscape

The American Academy of Pediatrics (AAP) recommends breast feeding until 1 year of age



Women take an average of four medications during lactation

Mitchell AA. Am J Obstet Gynecol. 2011



47.9% of drugs had no data on breastfeeding, 42.7% had some animal data, and only 4.7% had human data.

Mazer-Amirshahi M. Am J Obstet Gynecol. 2014



Importance of Research in Lactating Women

Accelerating scientific understanding of differences in lactating women can advance understanding of:

The degree of drug transfer into breast milk

The effects of drugs on milk production and composition

The exposure of breast-fed infants to drugs in breast milk

The impact of a woman's physiological state due to hormonal changes, body fat proportion and changes in weight during lactation

The effects due to changes in composition of breast milk over time (colostrum) and during a single session (foremilk vs hindmilk)

Regulations

45CFR46 Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research



- Regulations are focused on minimizing risks to the mother and fetus
- Addresses prospect of benefit and no benefit to the mother, fetus or both
- Includes language on research related to the placenta and fetal material

But there is no language addressing research with lactating women



Guidance

FDA Guidance for Industry

Clinical Lactation Studies – Study Design, Data Analysis, and Recommendations for Labeling

Issued Feb 2005 for public comment and provided nonbinding recommendations

Goals were to (1) provide the basic framework for designing, conducting, and analyzing clinical lactation studies and (2) stimulate further research to assist in therapeutics for lactating patients.

FDA Workshop

“Evaluation of the Safety of Drugs and Biological Products Used During Lactation”

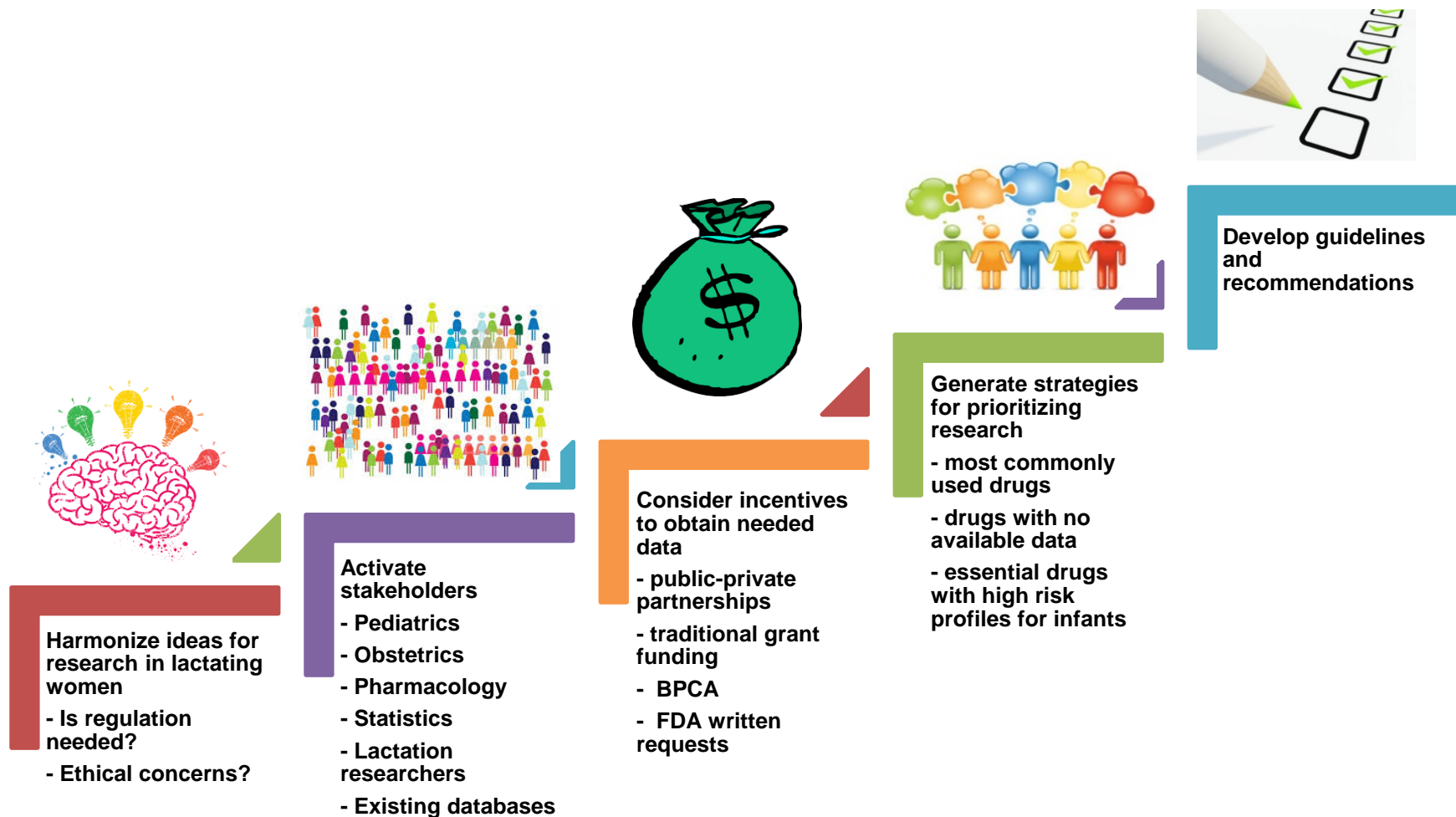
Goals:

- to review current safety data collection approaches
- to discuss and consider novel approaches
- to inform the public of the potential risks of medication use during lactation
- to create strategies to raise awareness and communicate safety information about medication use during lactation

National Cancer Institute

“Breast-feeding women may not be arbitrarily excluded from participation in clinical cancer treatment trials. Exclusion of breast-feeding women from a particular trial must be based on a clear and compelling rationale or justification that shows that inclusion is inappropriate.”

Steps Towards a Collaborative Plan



Our Charge For Today

Input and Feedback

- What are your thoughts about regulations governing lactating women in research?
- What do you see as the most pressing priorities in this area?
- What are the best strategies for gathering safety data on lactating women?
- Are there existing resources that could guide our thinking?





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