PRGLAC
Summary of Responses to the Request for Information

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Request for Information
NOT-18-003

• Published February 15, 2018
• Comment period closed April 2, 2018
• 34 independent responses received
• Half represented multiple individuals or organizations
• Eight comments identical
Input Requested On…

• Pregnant women as a “vulnerable population” in regulations
• Who should consent to participation in research
• Inclusion of pregnant and lactating women in study designs
• Research on therapies used by pregnant and lactating women
• How to address reluctance to include pregnant or lactating women in research studies
• How to reach these populations, their partners, and health care providers with new information/clinical guidelines
Key Themes

• Study Design for Research on Therapies Used by Pregnant or Lactating Women
• Ethical Issues
• Issues Concerning Research on Lactation
• Communications Among Researchers, Health Care Providers, and Pregnant/Lactating Women
• Additional Issues
Study Design

• Adequate risk assessment prior to clinical research:
  • Pregnancy registries should be created/utilized
  • Predictive animal models developed
  • Breast milk repositories
  • Mathematical modeling

• Pharmacokinetic studies to confirm optimal dosing

• Presumption of exclusion should shift to inclusion

• Take advantage of opportunistic studies: gather data on pregnant and lactating women who are already taking drugs for their conditions

• Use existing studies as potential models (IMPAACT, VAMPSS)
Study Design: other suggestions

• Engage target populations in study design
• Bring trials to the participants (home health nurses)
• Incentives: childcare, transportation, prenatal vitamins, genetic testing and counseling
• Consider trimester-specific enrollment to measure physiologic changes
• Measure drug or metabolite in breast milk to determine infant exposure
• Post-market surveillance on drugs used and data sharing
Ethical Issues

- Vulnerable population
- Shift presumption to inclusion
- No greater than “minimal risk”
- Maternal consent only for research participation
Issues Related to Lactation

• Research needed on maternal milk supply/treatment of inadequate production

• Milk composition in minority populations
Communications Issues

• Telling pregnant and lactating women about the value of research/risks and benefits
• Professional societies and organizations - CMEs
• Strategies:
  • Websites and social media
  • Lactation consultants in hospitals
  • Support groups
Additional Issues Raised

• Study herbal supplements used by pregnant and lactating women
• Additional treatments needed for postpartum pain and mental health issues
• Alternative therapies evaluated in scientific manner
• Consider using BPCA/PREA model for drugs used by pregnant and lactating women; other incentives for research
• Research on underlying conditions: CAH, PCOS, diabetes, optimal weight gain
Summary
Most Common Comments

- Remove pregnant women from “vulnerable” category and shift to a presumption of inclusion in research
- Only consent of pregnant woman should be required for research participation
- Opportunistic studies of drugs used by pregnant/lactating women
- Little to no research on inadequate milk supply or treatment
- Research needed on safety/efficacy of herbal supplements
- Communicate with pregnant and lactating women about research
Thanks!

• To all respondents
Questions and Discussion