Task Force on Research Specific to Pregnant and Lactating Women
Summary and Discussion of Work Products from Meeting 1
Background
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.
Important Deadlines

• September 2018 – Send report to HHS Secretary and Congress
• December 2018 – Secretary required to act on Task Force recommendations
• March 2019 – Task Force will sunset after two years unless extended
Report to Include

(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;
Report to Include (continued)

(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.
## Strategy for Report

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<tr>
<th>TF 1</th>
<th>(4) Identification of Federal activities, including:</th>
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Task Force Report
Draft of Federal Activities Section
(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;
(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;
Report – Draft Sections

• Current state of research
• Federal activities
• Appendices
  • Research on Therapies in Pregnant and Lactating Women
  • Federal Activities Related to Pregnancy and Lactation
  • Pregnancy Registries
Current Research on Therapies for Pregnant and Lactating Women

Literature Analysis

Results

Key Research Gaps

Funding Sources
• Research Activities
  • Prenatal Exposures
  • Safety and Efficacy of Medicinal Therapies in Pregnant and Lactating Women
  • Utilization and Quality of Care for Pregnant and Lactating Women
  • Health Care and Clinical Practice

• Communications

• Trans-Federal Collaborative Efforts

Summary Document
Appendices

Appendix VIII: Research on Therapies in Pregnant and Lactating Women

• Literature review: overall therapies
• Funding sources
• Specific conditions:
  • Literature
  • Current research activities
  • Research gaps

Categories for Analysis (Selected Conditions)

- Asthma
- Autoimmune diseases (excl diabetes)
- Cancer
- Central nervous system disorders
- Diabetes (all types)
- Endocrine disorders (excl diabetes)
- Hypertensive disorders
- Infectious diseases
- Low milk supply
- Mental health
- Pain
- Preterm birth
- Substance abuse
- Vaccines
Appendix VII: Federal Activities Related to Pregnancy and Lactation, by Agency

- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Department of Agriculture (USDA)
- Department of Defense (DoD)
- Department of Veterans' Affairs (VA)
- Environmental Protection Agency (EPA)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- National Institutes of Health (NIH)
- National Vaccine Program Office (NVPO)
- Office of the Assistant Secretary for Health (OASH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
Appendix XII: Pregnancy Registries

• Summary
  • 45 registries: 2/3 industry, ¼ non-profit
  • Majority by condition or medication
  • 46% Europe, 40% USA/Canada
  • Enrollment varies, most at 101-500

• Table of Registries
  • Name
  • Medicine(s)
  • Medical condition(s)
  • Organization/sponsor
  • Enrollment
  • Date established
  • website
Feedback & Input

• Format
• Corrections / additions / suggestions?
• Anything missing?

Work in progress – finalized document ~September 2018
Summary Recommendations from Federal Activities Discussion
Striking Statistics

- 4M pregnant, 3M breastfeed (80%) and 30% are breastfeeding at a year
- >90% of women are prescribed medications in the first year
- 500K woman annually have difficulty making milk
State of Research on Pregnancy and Lactation

• Literature
  • Limited basic science, population database, PK/PD, clinical trials of medications and vaccines in pregnancy
  • Extremely limited literature in lactating women

• Complexity of pregnancy
  • Fetus and placenta change over gestation, timing of exposure
  • Physiologic changes of pregnancy
  • Impact of external factors: obesity, environment

• Lactation
  • Benefits of breastfeeding vs medications in woman
  • Limited assays for assessment of medications in breastmilk
  • Pharmacogenomics: baby & mom

• Limited pipeline even compared to rare diseases
(D) Identification of Federal Activities, Including-
(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

- Clinical trial networks needed, build on existing successful networks
- Explore opportunistic studies, modeling/simulation designs
- Need incentives to engage industry, agencies; facilitate collaboration
- Facilitate registries to provide needed data
  - Data collaboration/warehouse publicly accessible for baseline information, generate safety signals, study design
  - Drug centric registry design is limiting – disease focused registry provides more information
  - Registries are not owned by FDA, sponsor
  - Not uniform in design, quality, or reporting
- Encourage new product development, women should not be the post-market evaluation
(D) Identification of Federal Activities, Including-
(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public;

- Incorporate new models of dissemination
  - Collaborate with online sites
- Millennials, Gen X Gen Y are digital savvy and comfortable sharing things online, tap into this resource to engage in research
- Health literacy needs to be considered, multilingual communication, include rural and minority communities
- Provide access to evidence based treatment information
- Database online for federal information on medication safety for pregnancy and lactation
- Provide information on “what research means” for pregnant and lactating women
Feedback & Input

• Format
• Corrections / additions / suggestions?
• Anything missing?

Work in progress – finalized document ~September 2018
Discussion