Task Force on Research Specific to Pregnant and Lactating Women

Summary & Discussion

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(D) Identification of Federal activities, including-

- (i) the state of research on pregnancy and lactation;
- (ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;
- (iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and
- (iv) 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.

Discussion: Scope

Purpose: "to identify and make recommendations to address gaps in knowledge and research about safe and effective therapies used during pregnancy and for lactating women"

- Population: Pregnant women and lactating women
- Therapies: medications and vaccines
- Strategy
  - Overview
  - Highlight areas with unmet medical need – variety including critical, common, pregnancy specific
  - Review needs including information on medications (prescription and over the counter), vaccines, supplements, complimentary and alternative therapies, and non-drug interventions

(D) Identification of Federal activities, including-
(i) the 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;

- Current
  - Numerous collaborations ongoing
  - Network and multicenter trial infrastructures to tap
  - Industry collaborations, forums
  - Collaborations with industry NIH-NHLBI (cardiac networks), NCATS

(D) Identification of Federal activities, including-
(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

- Opportunities
  - Facilitate communication of ongoing efforts, ability to collaborate, think collaboration first
  - Enhance network type infrastructure and opportunities for trials
  - Facilitate ability to put in and get out data from registries
  - DoD and VA systems with strong infrastructure for collaboration of research
  - Collaboration with industry
    - Networks
  - Millennials, Gen X Gen Y are digital savvy and comfortable sharing things online, tap into this resource to engage in research
  - “substrate”: Research in lactating women is a huge opportunity; 4M births in the US is a huge population, willing engagement
  - Data availability – VA, DoD, Federally funded studies

(D) Identification of Federal activities, including-
(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

- Challenges
  - Legal and ethical challenges are a challenge for industry and researchers
  - Limited expertise for design of studies and trials in these populations in industry
  - Efficiency necessary/important for industry
  - Transparency
  - Cultural differences across agencies, industry
  - Registries
    - 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
  - New product development, not have women as the post-market evaluation every time

(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;

- Current
  - Websites, social media, presentations, publications, educational materials, pamphlets, Q&A, videos, YouTube
  - Providers provide much of the information
  - Information often obtained from internet – phone especially

(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;

- Opportunities
  - Provide access to evidence based treatment information
  - Scalable programs for evidence based therapies
  - Provider trainer / support to provide evidence based care
  - Database online for federal information on medication safety for pregnancy and lactation
  - Provide information on “what research means” for pregnant and lactating women
  - Evaluate the reach and use of communication materials
  - Leverage data from preclinical studies
  - Leveraging with google/parents magazine / etc to federal website
  - Partner with outside entities that have the reach – eg BabyCenter

(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;

- Challenges
  - Providers have limited information and time
  - Communicating uncertainty is difficult
  - How do women use information – do they change their behavior
  - Not a Yes/No answer – it is in a context of risk/benefit
  - Need to promote thinking of research is a progression, not a single study is endpoint
  - Important to have studies address the needed question – eg smoking vs nicotine replacement
  - Information obtained from internet
  - Need benchmark of where people are getting their information – a website would be great but would people use it as there are so many options
  - Generational differences “acceptance of information”
  - Limited evaluation of drugs in pregnancy and lactation for the evidence base
  - Health literacy – e.g. absolute risk vs relative risk, reading level of materials; “up to date” for patients is needed
  - Internet searches – WedMD, CDC, etc all say something slightly different – provider then asked to help patient discern
  - Industry regulations/restrictions

(D) Identification of Federal activities, including-
(iv) 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.

- Research activities
  - Grants, networks, registries, databases
- Clinical
  - Guidance: FDA, CDC, AHRQ (USPHTF), NVP
  - Care: DoD, VA
- Collaboration
  - Across federal and non federal agencies
- Communication
  - Websites: Resources and fact sheets
  - Public health campaigns
  - Twitter, text messaging, webinars

Details in word documents circulated prior to meeting

Summary recommendations

- State of research
  - Striking statistics, little data compared to rare diseases
    - 4M pregnant, 3M breastfeed (80%) and 30% are still breastfeeding at a year; over 90% of women are prescribed medications in the first year – do not forget the lactation part of the task force; 500K woman annually have difficulty making milk
  - Taking pregnancy as a case study to show the gaps
    - Personal voice compelling – walking through a case to illustrate the needs and impact
  - Have information on the physiologic changes in pregnancy
  - What is the quality of the information available; more information on registries, databases
  - Investigate why studies were not completed – 35 studies in the list, reviewing the information, Christina BR

Summary recommendations

- Coordination/collaboration
  - Infrastructure/pipeline to share techniques across federal agencies
  - Clinical trial networks needed to conduct the work, build on existing successful networks
  - Explore opportunistic studies, modeling/simulation designs
  - Data collaboration/warehouse publicly accessible for baseline information, generate safety signals, study design
  - Need incentives to engage industry, agencies; facilitate collaboration
  - Leverage real world information from clinical trials, registries
  - Industry is a willing partner – work through trade associations, in precompetitive space to eliminate barriers
  - Facilitate coordination across federal agencies, eliminate silos
  - Would be ideal to have a matrix across federal activities

Summary recommendations

- Dissemination
  - Need to incorporate new models of dissemination – internet, etc;
  - Need to collaborate with online sites
  - Health literacy needs to be considered, multilingual communication, include rural and minority communities
  - Lactation – lots get information from google
  - Communication strategy needs to be outlined, consistent across venues
  - Include peers in the dissemination process
  - Patient specific information

Summary recommendations

- General points:
  - Need to define what is success to the TF
  - Create a document that has items that are actionable
    - Comprehensive example of what a new drug looks like – for an aspirational goal
    - Propose specific studies
  - Focus on the unmet medical need, what does a patient need; common preexisting conditions, frequency/criticality
  - Tiered approach to therapies in the report; pathways for gaps based on therapies that have more evidence