U.S. Department of Health and Human Services
Task Force on Research Specific to Pregnant and Lactating Women

Agency Activities: Food and Drug Administration (FDA)

Research

FDA designs and performs research to advance knowledge related to drugs, devices, biologics, cosmetics, foods, and tobacco used by pregnant and lactating women. FDA supported science includes basic research into the mechanisms of therapies in pregnancy and lactation; preclinical studies, especially in toxicity; utilization of medication by pregnant and lactating women; safety and effectiveness of therapies and medications during pregnancy and lactation; pharmacokinetics and pharmacodynamics; effects of exposure to medical devices; and the impact of tobacco product use during pregnancy and lactation. Multiple FDA organizational units support intramural and extramural research portfolios applicable to the work of the Task Force.

- The FDA's Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP) is a multi-site collaborative research program developed to enable the conduct of studies of medication use and outcomes in pregnancy. Collaborators include the U.S. Food and Drug Administration and researchers at the HMO Research Network, Kaiser Permanente Northern and Southern California, and Vanderbilt University. Datasets have been created at each site linking healthcare data for women delivering an infant from 2001-2008 and infants born to these women.
- The FDA Office of Women's Health (OWH) promotes and conducts research related to sex differences and conditions unique to women, including pregnancy.
- The Tobacco Regulatory Science Program (TSRP) works with other FDA organizations and with the NIH to fund research supporting regulatory activities over tobacco products. For example, TSRP funds studies that investigate the impact of health warnings on tobacco use, ultrasound markers of maternal smoking, how design and flavors affect waterpipe use, and response to reduced nicotine content in pregnant smokers compared to non-pregnant smokers. FDA has described the likelihood of electronic nicotine delivery systems among pregnant smokers.
- The CDRH funds studies of prenatal exposures to medical devices. For example, researchers used a computational modeling approach to evaluate exposure to hand-held metal detectors and MRIs.
- The FDA's NCTR worked with NIH's National Institute for Environmental Health Sciences (NIEHS) on a preclinical toxicology study of exposure to oxybenzone, a UV filter that is often incorporated into consumer products. NCTR has also worked with a number of other FDA groups and NIEHS on a group of studies to address exposure to BPA, including in pregnant and lactating women.
- CBER conducts animal and human studies related to the safety and efficacy of vaccines in a variety of populations, including pregnant women.

FDA has supported research on the utilization of medication among pregnant and/or lactating women for a wide variety of health conditions. These studies primarily describe how many women with a particular condition use medication, and what types of medications they use. FDA researchers have assessed medication use among pregnant women with asthma; convulsive disorders; and mental health disorders; bacterial and viral infections.

Clinical Practice Information and Recommendations

FDA generally does not provide direct clinical care. However, the information produced and analyzed by the FDA forms the foundation for the regulation of prescription drugs, biologics, and medical devices. FDA's role as a regulatory agency also includes development of guidance, policies, and information to ensure the safety and effectiveness of therapies for pregnant and lactating women.

FDA's Pregnancy and Lactation Labeling Rule requires industry to provide standardized information on prescription drug labels to help health care providers in assessing benefit and risk, and in subsequent discussions with pregnant and lactating women who need medication.

Other examples of relevant regulation and/or guidance include:

- FDA regulates human donor milk as food and for donor banks.
- FDA's CDRH is working to provide more information and possibly more detailed guidance on MRI exposure in pregnancy.
- FDA is working to develop guidance to address and inform industry of the required format and content of Pregnancy and Lactation information in prescription drug and biologic labeling (https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/labeling/ucm093307.htm; https://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/actsrulesregulations/ucm445102.htm ; https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/labeling/ucm093311.htm).

FDA also participates in provider training activities to help inform clinical practitioners about the safety and effectiveness of drugs in pregnancy. FDA webinars or briefing materials are available on a wide range of medications and related topics, including:

- vaccines in pregnancy (https://www.fda.gov/aboutfda/transparency/basics/ucm508553.htm);
- pain medication in pregnancy (https://www.fda.gov/drugs/drugsafety/ucm429117.htm) ;
- use of amoxicillin in pregnancy (https://www.fda.gov/drugs/emergencypreparedness/bioterrorismanddrugpreparedness/ucm072124.htm)
- flu treatment in pregnancy (https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm184917.htm)
- valporate (https://www.fda.gov/Drugs/DrugSafety/ucm350684.htm)
- doxycycline (https://www.fda.gov/drugs/emergencypreparedness/bioterrorismanddrugpreparedness/ucm131011.htm)
- cipro (https://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm130712.htm) and
- magnesium sulfate (https://www.fda.gov/drugs/drugsafety/ucm353333.htm).

In 2016, FDA issued guidance documents addressing blood safety in response to the Zika virus. Although these recommendations were not specific to pregnant women, they were important as a preventive measure to reduce pregnant women's potential exposure to the virus.

Communications

FDA uses a wide range of forms of print, digital, and web-based communications related to pregnancy and lactation. FDA's websites provide detailed information to pregnant and lactating women and their health care providers about medications in pregnancy and lactation generally, and about specific therapies as well. FDA seeks to inform a wide range of audiences about use and safety for medications, biologics, and medical devices among pregnant and lactating women. Some examples include:

- FDA's Pregnancy web page includes consumer-oriented information on medication in pregnancy, breast pumps, food safety, and X ray and ultrasound (https://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117976.htm).
- FDA's CDRH provides information on the availability, safety, and use of breast pumps (https://www.fda.gov/forconsumers/consumerupdates/ucm335261.htm)
- FDA's Drug Safety Communications provide up to date information about drug safety issues, including those of special interest to pregnant and lactating women (https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm413118.htm; https://www.fda.gov/Drugs/DrugSafety/ucm199082.htm). For example, a recent communication recommended against the use of prescription codeine pain and cough medicines and tramadol pain medicines in breastfeeding women (https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm).
- FDA's OWH created a web portal to help connect pregnant women and health professionals with medical product and disease-based registries that collect information on drug exposures during pregnancy (https://www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm134848.htm).

Other Collaborative Efforts

In addition to those noted above, FDA is involved in a wide range of collaborative efforts with other federal agencies to promote scientific and communications efforts to benefit pregnant and lactating women. For example, FDA is a collaborating agency in the Treating for Two initiative, to review medication safety data in pregnancy to develop treatment guidelines (https://www.cdc.gov/pregnancy/meds/treatingfortwo/index.html).

FDA often collaborates with professional groups and other federal agencies on scientific workshops:

- In 2016, FDA partnered with NIH, DoD, CDC, and SAMHSA to sponsor a workshop addressing critical gaps in research on opioid misuse and pregnancy. Topics included (1) Screening for opioid use in pregnancy (2) Complications of pregnancy associated with opioid use (3) Most appropriate treatment of pregnant women with opioid use disorders given risks and benefits (4) Treatment and management of infants with neonatal abstinence syndrome; and (5) long-term effects of prenatal opioid exposure on children and the role of preventive interventions to improve childhood outcomes for this high-risk population.
- In 2016, FDA also collaborated with NIH, other HHS divisions, EPA, and USAID to hold a scientific workshop to identify optimal approaches for treating and caring for the generation of children exposed to ZIKV in the womb.

- FDA and CDC collaborated on a conference on Zika Virus in the Americas in March 2016; FDA presented material on regulatory considerations in the development of drugs for use in pregnant women (www.cdc.gov/zap/).
- In November 2014, FDA and CDC held a workshop, in collaboration with the American College of Obstetricians and Gynecologists, to discuss new and emerging tobacco product use in pregnant and reproductive age women (https://www.fda.gov/downloads/tobaccoproducts/newsevents/ucm542886)
- In 2016, FDA representatives participated in the Academy of Breastfeeding Medicine's 8th annual summit on breastfeeding (http://www.bfmed.org/)
- FDA collaborated with NIH on an expert panel to advance inclusion of pregnant and postpartum women in tuberculosis drug trials (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4772846/pdf/civ991.pdf).
- FDA and NIH collaborated on a scientific review conference on phenylketonuria (PKU), including PKU and pregnancy (http://www.sciencedirect.com/science/article/pii/S1096719214000857).

FDA's CDRH and CDER participate as liaisons to the ACOG OB Practice Committee.

FDA collaborates with CDC on the National Health and Nutrition Examination Survey (NHANES), which includes medical, diet, dental, and physiologic measurements that may contribute to understanding of medical and nutritional issues in pregnant and lactating women (https://www.cdc.gov/nchs/nhanes/index.htm). FDA also collaborates with CDC on the Pregnancy Risk Assessment Monitoring System (PRAMS) (https://www.cdc.gov/prams/index.htm).