

Coalition to Advance Maternal Therapeutics Guiding Principles

INTRODUCTION

Each year, almost four million women in the United States give birth and 75% of them breastfeed their infantsⁱⁱⁱ. There are 73.7 million women of childbearing age in the U.Sⁱⁱⁱ. Nearly all of these women will take a medication or receive a vaccine during pregnancy. Yet not enough is known about the effect of most drugs on a woman and her pregnancy, or the ways in which pregnancy may alter the uptake, metabolism and effect of medication. As more women with chronic diseases, such as diabetes, hypertension, depression and asthma are becoming pregnant, safe and effective medications to manage these ongoing conditions throughout their pregnancy and beyond are needed. While the federal LactMed database collects and distributes the available information on drug levels in human milk, significant gaps still remain on the impact of drugs on breastfeeding women and their children.

The lack of robust information on the safety and efficacy of many drugs across the continuum from pregnancy through breastfeeding is due in part to the fact that the Food and Drug Administration (FDA) does not require drugs to be tested among pregnant or breastfeeding mothers^{iv}. In fact, the vast majority of drug trials exclude this population. Without reliable data, women who are pregnant or nursing may decide to stop taking necessary medications, increasing risk for both mother and child. In other cases, women may choose not to initiate breastfeeding or may wean earlier than desired because they lack information about the extent of drug transfer into human milk, the potential impacts of the drug on milk production, and the impact of exposure on the infant. Even when drug safety data is available, such data is usually limited, and do not address how the changes of pregnancy and breastfeeding affect dosage.

Additionally, pregnant women and their newborns are uniquely susceptible to the negative effects of various vaccine-preventable infectious diseases^v. However, immunization rates for life-saving vaccines among pregnant and breastfeeding women remain low despite longstanding recommendations from the Centers for Disease Control and Prevention (CDC).^{viii} In part, this is due to patient and provider reluctance because vaccine safety data is generated only after vaccine exposures, rather than during initial vaccine trials.

Overall, better information is needed regarding drug metabolism and safety, including possible longer-term effects, among women who are pregnant or breastfeeding their infants. Such information would allow mothers and health care providers to choose the safest drug for a given health problem in the appropriate dose to improve health and minimize risk for mother and child. Armed with high-quality data, providers would be more likely to recommend appropriate use of medications during pregnancy and lactation, and women would no longer be advised erroneously to stop breastfeeding due to medication exposure. Data are also needed on the extent to which medications during pregnancy and lactation affect breast development and lactation physiology and impact a mother's ability to achieve her breastfeeding goals. High-quality information on drug safety would enable women to manage their health problems in the safest possible manner during pregnancy, make informed decisions about the use of medications in the perinatal period, and meet their breastfeeding intentions, thereby improving health outcomes for mother and child.

Guiding Principles

We support the following guiding principles in moving forward on health policy related to the issue of pharmacologic trials in pregnancy and lactation:

- I. Women and their newborns have the right to expect quality care and treatment options.
- II. Studies have shown the use of prescription medications for the management of chronic conditions has increased over time in the pregnant and breastfeeding population.^{viii} Many health care providers and women lack sufficient information on the safety and efficacy of prescription drugs, therapeutics, and vaccines used during pregnancy and breastfeeding to make shared decisions informed by high-quality evidence. It is essential to disseminate current, evidence-based information about the safety and efficacy of these drugs, so that the best course of treatment can be determined.
- III. Appropriate research must be conducted in both the pregnant and breastfeeding populations on the safety and efficacy of existing and new drugs, therapeutics and vaccines. Many published studies have concluded that more research is needed, noting that physiological changes may alter drug pharmacokinetics during pregnancy through lactation, and that infant maturity may affect drug transfer in lactation.^{ix}
- IV. The federal government must prioritize clinical research and the generation and dissemination of data on a drug's effects on underlying medical conditions across the entire period from pregnancy through lactation on the mother and her infant to better inform clinical decision-making.

Coalition Members (in alphabetical order *denotes steering committee):

Academy of Breastfeeding Medicine

American Academy of Pediatrics *

American Academy of Allergy, Asthma & Immunology's Vaccines and Medications in Pregnancy Surveillance System

American College of Nurse-Midwives

American Association of Colleges of Pharmacy

American College of Obstetricians and Gynecologists *

American Heart Association

Association of Maternal & Child Health Programs

Association of Women's Health, Obstetric, and Neonatal Nurses

Elizabeth Glaser Pediatric AIDS Foundation

Endocrine Society

Epilepsy Foundation

Genetic Alliance

March of Dimes *

Maternal Mental Health Leadership Alliance

National Association of Nurse Practitioners in Women's Health

North American Society for Psychosocial Obstetrics & Gynecology

Organization of Teratology Information Specialists

Society for Obstetric Anesthesia and Perinatology

Society for Birth Defects Research & Prevention

Society for Maternal-Fetal Medicine*

Society for Women's Health Research

Treatment Action Group

United States Breastfeeding Committee

WomenHeart: National Coalition for Women with Heart Disease

ⁱ Martin JA, et al. "Births: Final data for 2013." *National vital statistics reports*; 64 .1. (2015).

ⁱⁱ McDowell, et al. "Breastfeeding in the United States: findings from the national health and nutrition examination surveys, 1999-2006". *US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics*, 2008.

ⁱⁱⁱ Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States, States, Counties, and Puerto Rico Commonwealth and Municipios: April 1, 2010 to July 1, 2013 Source: U.S. Census Bureau, Population Division. Release Date: June 2014

^{iv} U.S. Food and Drug Administration, "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling," 2014

^v Center for Disease Control. ACIP Guidelines for Vaccinating Pregnant Women. Atlanta, GA. 2014.

^{vi} American College of Obstetricians and Gynecologists. "Influenza vaccination during pregnancy. ACOG Committee Opinion No. 608". *Obstet Gynecol* 124 (2014):648-51.

^{vii} American College of Obstetricians and Gynecologists. "Update on immunization and pregnancy: tetanus, diphtheria, and pertussis vaccination. ACOG Committee Opinion No. 566." *Obstet Gynecol* 121 (2013):1411-4.

^{viii} Mitchell, Allen A., et al. "Medication use during pregnancy, with particular focus on prescription drugs: 1976-2008." *American journal of obstetrics and gynecology* 205.1 (2011): 51-e1.

^{ix} Costantine, Maged M. "Physiologic and pharmacokinetic changes in pregnancy." *Frontiers in pharmacology* 5 (2014).

^x Blehar, Mary C., et al. "Enrolling pregnant women: issues in clinical research." *Women's Health Issues* 23.1 (2013): e39-e45.