



Coalition to Advance Maternal Therapeutics

Who We Are

The Coalition to Advance Maternal Therapeutics (CAMT) was launched in 2014 with the goal of better understanding the safety and efficacy of prescription drugs, therapeutics, and vaccines used during pregnancy and breastfeeding. CAMT advocated for the creation of a federal task force (the [Task Force on Research Specific to Pregnant Women and Lactating Women](#), PRGLAC) to identify and address gaps in knowledge regarding safe and effective therapies and vaccines for pregnant and lactating women.

CAMT and its member organizations are committed to raising awareness among policy makers and industry about the need to include pregnant and lactating women in clinical trials, where appropriate, to close our gaps in knowledge, and ultimately improve the health of women and their families.

The Problem

Each year, nearly four million women in the U.S. give birth and more than three million breastfeed their infants.^{i,ii} Nearly all of these women will take a medication or receive a vaccine. **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.** For example, the rate at which certain drugs are excreted through the kidney may increase by 50% during pregnancy. 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.

Member Organizations

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 and Gynecology
Organization of Teratology Information Specialists
Society for Birth Defects Research and Prevention
Society for Obstetric Anesthesia and Perinatology
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

* Denotes Steering Committee Member

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 to the infant. Even when drug safety data are available, such data is usually limited, and often does not address how the changes of pregnancy and breastfeeding will affect dosage.

The lack of robust information on the safety and efficacy of many drugs across the continuum from pregnancy through breastfeeding is, in part, due to the fact that the Food and Drug Administration (FDA) has not historically required or otherwise incentivized drugs to be tested among pregnant or breastfeeding women.ⁱⁱⁱ In fact, the vast majority of trials have excluded this population. Efforts are

underway to revise and update how women are treated for the purposes of research, but we need special and immediate attention to this issue in the context of COVID-19 to move us forward toward innovation and cures.

COVID-19

As research related to COVID-19 moves forward at lightning speed, CAMT urges corporate and federally-funded researchers to include pregnant and lactating women in the development of vaccines and therapeutics.

There remain significant gaps in understanding the effects of COVID-19 on pregnant women and lactating women and their infants, and there are few recommendations specific to these populations regarding the virus. Based on available information, pregnant people seem to have the same risk of COVID-19 as adults who are not pregnant. However, much remains unknown and research from previous coronaviruses, such as SARS-coV and MERS-coV, identified pregnant women as particularly vulnerable relative to the general population. Accordingly, we urge you to ensure that pregnant women and lactating women are included in any clinical research related to vaccines and treatments for COVID-19. It is critical that they not be left behind the general population as we search for a vaccine.

We are disappointed that pregnant women and breastfeeding women are explicitly excluded from the Adaptive COVID-19 Treatment Trial currently underway at the National Institutes of Health. Failure to gather clinical trial data on these populations forces pregnant and lactating women diagnosed with COVID-19 and their health care providers to make care decisions based on incomplete evidence.

We are also concerned that new vaccine candidates will become available without sufficient data to recommend them for use in pregnant and lactating women. This would prevent millions of expecting and new mothers from participating in any future mass immunization campaigns, putting their health and the health of their infants, and the public at risk.

Rather than excluding pregnant and lactating women from research, we urge industry and federal agencies to ensure the development of vaccines and treatments suitable for this population by investing in early non-clinical studies to provide for the eventual enrollment of these women in late-stage clinical trials.

CAMT stands ready to work with you to remove any barriers and work with researchers to ensure that pregnant women and lactating women are included in this critical research. To draw on our assistance, please contact Kerri Wade at kwade@smfm.org.

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 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.