2026 MPRINT Prioritization Report on Therapeutic Research for Pregnant, Postpartum, and Lactating Women: A resource for practicing physicians

The Maternal and Pediatrics Precision in Therapeutics (MPRINT) Hub, funded by the NIH's *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), released the **Prioritization Report on Therapeutic Research for Pregnant, Postpartum, and Lactating Women** in September 2026 to document research gaps and priority research needs for drugs, vaccines, and dietary supplements used in pregnant, postpartum, and lactating (PPL) women. The project originated from the 2016 Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) and its 2018 recommendations to Congress, which called for dedicated processes to prioritize therapeutic research for this population. The NICHD gathered public input through a 2023 Request for Information, receiving 136 nominations across 24 therapeutic areas, then convened a 2024 stakeholder meeting and 2025-2026 expert working groups of researchers, clinicians, and patient advocates to refine research gaps and needs in eight areas: cardiovascular and hypertensive disorders, environmental exposures, hematology, infectious disease, mental health, obesity, preterm birth, and sleep/circadian disorders.
The report identifies research gaps and needs. However, it should not be interpreted as NIH clinical guidance or official research priorities. Importantly, the report distinguishes pregnancy from lactation, since the two involve different physiology and evidence needs.

Key Takeaways for Clinical Practice
For many medications commonly prescribed to reproductive-age women safety and dosing evidence for pregnant, postpartum and lactating (PPL) women is thin, uneven across drugs within the same class, or absent entirely. Prescribing decisions often rely on extrapolation, case reports, or small pharmacokinetic studies rather than controlled trials.

- **Cardiovascular/lipid disorders**: The FDA removed its strongest pregnancy contraindication for statins in 2021, and NICHD-sponsored pravastatin trials found neonatal outcomes similar to placebo along with lower rates of preeclampsia. Yet many patients still stop statins once pregnancy is recognized, and additional studies are needed to establish dosing in pregnancy and assess long-term outcomes to children. Newer cardiometabolic drugs, including SGLT2 inhibitors, sacubitril/valsartan, GLP-1 agonists, and PCSK9 inhibitors, have little to no pregnancy or lactation safety data despite rising use among reproductive-age women.
- **Mental health**: ACOG advises against discontinuing ongoing psychiatric medication solely because of pregnancy or breastfeeding. However, evidence quality varies widely by individual drug, and class-level data can mask meaningful differences between agents, so drug-specific counseling matters. Early data on newer postpartum depression treatments (brexanolone, zuranolone) show low infant exposure through breast milk.
- **Infectious disease**: For uncomplicated malaria, first-line treatment is quinine plus clindamycin, or chloroquine/hydroxychloroquine for sensitive strains, with atovaquone-proguanil reserved for when other options are unavailable due to limited pregnancy and lactation safety data. Standard tuberculosis (TB) therapy remains isoniazid, rifampin, and ethambutol with pyridoxine supplementation, while newer preventive regimens have more limited pregnancy and lactation data.

- **Hematology**: Because most pregnancy-associated venous thrombus embolism (VTE) occurs postpartum and most mothers initiate breastfeeding, anticoagulation and lactation timelines substantially overlap. Some DOACs like apixaban are actively transported into breast milk.
- **Obesity/metabolic**: GLP-1 agonists are approved to reduce cardiovascular risk in obesity, but their use during pregnancy and lactation is generally not recommended given limited safety data, even as use in reproductive-age women grows.
- **Environmental exposures**: Common chemical sunscreen ingredients such as oxybenzone show systemic absorption above the FDA's threshold for waiving further safety testing, yet pregnancy and lactation outcome data remain sparse.
- **Preterm birth**: Despite decades of tocolytic use (nifedipine, indomethacin, terbutaline, magnesium sulfate), no therapy has meaningfully reduced the overall preterm birth rate, reflecting a persistent gap in both prevention and management evidence. Improved understanding of the mechanisms governing preterm birth and improved clinical study designs are needed for therapeutics to treat and prevent preterm birth.
- **Sleep**: Poor sleep in the perinatal period is linked to gestational hypertensive disorders, gestational diabetes, postpartum depression, cesarean delivery, and NICU admission, yet the evidence base for sleep medications used by PPL women remains limited.

Clinical Application

These findings reflect research gaps and needs, not NIH clinical recommendations or formal NIH research priorities. The report is meant as a resource for people involved in maternal and lactation drug development, therapeutics research, and clinical care.

Pregnancy and lactation findings should not be treated as interchangeable. The two involve distinct physiology, health implications, and research needs. The 2024 PRGLAC Implementation Working Group noted that different trial designs are needed for pregnancy therapeutic studies and lactation therapeutic studies.

Individual therapeutic areas reinforce this individualized approach. Mental health treatment decisions are made on a case-by-case basis, and the working group calls for an individualized benefit-risk assessment that accounts for the risks of leaving a condition untreated alongside the risks of treatment.

The discussions behind this report largely reflect input gathered between July 2024 and January 2026. Additional information, guideline changes, or emerging topics since then were not considered, though the frameworks here are meant to remain useful even as that context shifts. The report can be accessed through the MPRINT Hub's website, which links to a GitHub discussion forum where researchers, clinicians, and other stakeholders can share emerging evidence and identify additional research gaps and needs.