

Prioritizing and Investing in Pregnancy Research

An Official Position Statement of The Society For Maternal-Fetal Medicine

Position

To effectively address maternal mortality, severe maternal morbidity, and to make progress toward health equity for pregnant women and women at risk of pregnancy complications and mortality, it is critical that the federal government, industry, and philanthropic foundations prioritize investment in and expansion of research and clinical trials in pregnancy. Improving a woman's health before, during, and after pregnancy has the potential to benefit women, the developing child, and families through subsequent generations.

The Society for Maternal-Fetal Medicine (SMFM) urges the United States Congress to prioritize and invest specific resources for research in pregnant women, including additional funding to study, evaluate, disseminate, and implement interventions that optimize pregnancy outcomes. We also encourage industry and private funders to increase support for pregnancy-related research and work collaboratively with other stakeholders to optimize the health of women during pregnancy. Such research efforts are required in order to drive meaningful change in clinical practice, to provide an evidence base for practice, and to improve maternal and pregnancy related health outcomes.

Background

Pregnancy offers an important “window to future health” (Saade, 2009). Many disorders that extend well beyond pregnancy manifest first in pregnancy; as an example, women who experience depression in pregnancy are more likely to experience mood and anxiety disorders later in life. Furthermore, many maternal disorders that appear in pregnancy have long-term consequences for the woman and her offspring (Meltzer-Brody & Stuebe, 2013). Depression during pregnancy is associated with an increased risk of preterm birth and low birth weight, as well as an increased risk of developmental and cognitive delays and depression among the woman's children (Li, Liu & Odouli, 2009). Similarly, other conditions during pregnancy, such as gestational diabetes, gestational hypertension, and preterm birth, are associated with health complications later in life for both the woman and her children (Saade, 2009).

Historically, however, pregnant women have been underrepresented and even excluded from clinical research due to perceived ethical concerns regarding fetal harm, as well as regulatory barriers associated with studying pregnant women, who have been categorized as a “vulnerable population.” As a result, there is a critical lack of robust data about medications and other clinical interventions that may improve women's health and pregnancy outcomes (Blehar et al, 2013).

SMFM has adopted the use of the word “woman” (and the pronouns “she” and “her”) to apply to individuals who are assigned female sex at birth, including individuals who identify as men as well as non-binary individuals who identify as both genders or neither gender. As gender-neutral language continues to evolve in the scientific and medical communities, SMFM will reassess this usage and make appropriate adjustments as necessary.

A woman's physiology changes drastically during pregnancy, and the vast majority of physiologic functions are different than in non-pregnant individuals requiring research specific to pregnancy, both related to the medications a pregnant person might be prescribed or take during that time, as well as to determine appropriate clinical treatments and interventions.

The United States has the highest rate of maternal mortality among high-income countries with significant disparities among underrepresented minorities and underserved populations (CDC, 2019). While many factors that impact maternal health occur outside of the clinical setting (e.g. access to stable housing or clean water), other issues are fully within the health care setting (e.g. maternal sepsis or severe preeclampsia) and require specific clinical understanding. However, the exclusion of pregnant and postpartum women from research has left clinicians, scientists, and professional organizations with a dearth of reliable data on which to base recommendations regarding potentially life-saving interventions for this large and important population.

The funding that has been available for pregnancy-related research comes largely from the United States federal government. Unlike other medical fields such as oncology, cardiology, and psychiatry, which rely heavily on industry for research and clinical trials, much of the evidence that guides obstetric and postpartum practice is generated from studies that are funded by the National Institutes of Health (NIH). Historically, many fundamental clinical practices and recommendations regarding obstetrical care are based on NIH-supported research and, in addition to improving health outcomes, have been found to be either cost-effective or cost-reducing (MFMU, 2018).

In a 1994 report (Mastroianni, Faden & Federman), the Institute of Medicine recommended that pregnant women should be presumed to be eligible for participation in clinical studies. The Task Force on Research Specific to Pregnant Women and Lactating Women underscored the importance of this recommendation in its report (2018) to the Secretary of Health and Human Services and the United States Congress. SMFM strongly supports this recommendation and encourages an increased investment in research in pregnancy and the postpartum period as a primary strategy for reducing perinatal mortality/morbidity and advancing health equity.

**Approved by the SMFM Executive Committee
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References

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