



# The American College of Obstetricians and Gynecologists

WOMEN'S HEALTH CARE PHYSICIANS

## ACOG Comments to PRGLAC Meeting August 22-23, 2019

My name is Tatiana Calderon. I am here on behalf of the American College of Obstetricians and Gynecologists (ACOG), representing over 58,000 physicians and partners dedicated to advancing women's health care. Thank you for the opportunity to comment today.

ACOG's members serve as frontline providers for women throughout their life course and are in a unique position as conduits of information for their patients. It is critical for physicians to have the ability to counsel their patients on safe medication use based on accurate, reliable data, especially during pregnancy and the postpartum period. During these periods, physicians are limited in treatment options for a multitude of conditions—including diabetes, heart conditions, pain management, and others— due to the paucity of human data that exists in studies of safe medication use for pregnant and lactating women.

We thank PRGLAC for its work to address these knowledge gaps. As the issue of maternal mortality garners increasing attention from policymakers, stakeholders, and the general public, we view the Task Force's work as crucial to our broader mission of improving maternal health. To improve maternal health outcomes, it is critical that we invest in studies that provide reliable, accurate data on safe medication use for pregnant and lactating women. Studies have estimated that more than 60% of pregnant women use at least one prescription medication during their pregnancies, most of which have not specifically been studied in pregnancy.<sup>1</sup> Because pregnancies are increasingly occurring in older women and in those with complex medical conditions, the use of prescription medications by pregnant women is likewise increasing. Physicians who care for pregnant women with complex medical conditions, and the pregnant women themselves, are faced with making health care decisions based on insufficient clinical evidence in an era when evidence-based medicine is standard practice.<sup>2</sup> The Task Force is critical to aiding America's physicians in addressing these issues through implementation of its recommendations and promoting innovative trial designs that include pregnant and lactating women.

Physicians and patients would also benefit from the implementation of improved evidence-based communication strategies to inform them of clinical trial opportunities and inclusion in research generally, as well as sharing research findings. As the Communication Working Group kicks off, we encourage you to focus your attention on the need to engage clinicians. Health care provider-initiated recruitment of patients is key to effective recruitment and retention of participants. We encourage the focus of additional resources on strengthening provider-initiated recruitment. We urge you to consider

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<sup>1</sup> Daw JR, Mintzes B, Law MR, Hanley GE, Morgan SG. Prescription drug use in pregnancy: a retrospective, population-based study in British Columbia, Canada (2001-2006). *Clin Ther* 2012;34:239–249.e2.

<sup>2</sup> Ethical considerations for including women as research participants. Committee Opinion No. 646. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;126:e100–7.

existing models of communication strategies for specifically targeting physicians. Additionally, proactive sharing of study results is key to retaining and maintaining relationships with participants.<sup>3</sup>

In addition, pregnancy registries are important tools for recording comprehensive safety information and studying the effects of medication in pregnant women and their fetuses. We urge the Communication Working Group to carefully consider the limitations of existing pregnancy registries, including patient recruitment and retention, access to information by health care providers, and difficulty accessing registry outcomes information, in order to improve their utility and enable us to realize their full potential.

We also stress the importance of addressing barriers to recruitment and retention of pregnant and lactating women in clinical studies. We encourage the Regulatory Working Group to consider how intimate partner consent may impose a barrier to recruitment of women and interfere with a woman's right to make independent decisions about her health care.<sup>4</sup> We support a woman's autonomy in making decisions during her pregnancy. As in other clinical situations, a pregnant woman's consent should be sufficient for research interventions that affect her or her fetus. In the absence of a few specific scenarios, requiring participation consent from a woman's intimate partner is neither warranted nor ethically justified.<sup>5</sup> Such consent is not required for general medical care and may pose a significant barrier to recruitment of study participants.

Lastly, liability concerns also create barriers for researchers and should be acknowledged and addressed up front. ACOG supports PRGLAC's recommendation that the FDA implement a liability-mitigation strategy for conducting research and evaluating therapeutic products in lactating women and urges the Regulatory Working Group to thoroughly evaluate implementation options for this recommendation.<sup>6</sup>

ACOG strongly supports the continuation of PRGLAC's invaluable work to improve the safety of maternal care through evidence-based approaches. Thank you again for the opportunity to comment. We look forward to continuing our support of PRGLAC's work to improve maternal and child health.

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<sup>3</sup> U.S. Food and Drug Administration. (2019). Postapproval Pregnancy Safety Studies; Draft Guidance for Industry; Availability (FDA-2018-D-4693). Rockville, MD. U.S. Food and Drug Administration.

<sup>4</sup> Ethical considerations for including women as research participants. Committee Opinion No. 646. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;126:e100–7.

<sup>5</sup> *Ibid.*

<sup>6</sup> Task Force on Research Specific to Pregnant Women and Lactating Women: report to Secretary, Health and Human Services, Congress. Washington, DC: National Institute of Child Health and Human Development, September 2018 ([https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC\\_Report.pdf](https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf)).