



The American College of  
Obstetricians and Gynecologists  
WOMEN'S HEALTH CARE PHYSICIANS

**Office of the Vice President,  
Practice Activities**  
Christopher M. Zahn, MD  
Col (Ret), USAF, MC

December 10, 2020

José R. Romero, MD, FAAP  
Chair  
Advisory Committee on Immunization Practices  
Centers for Disease Control and Prevention  
1600 Clifton Road, N.E., Mailstop H24—8  
Atlanta, GA 30329-4027

**Re: Docket No. CDC-2020-0122; Advisory Committee on Immunization Practices; Notice of Meeting;  
Establishment of a Public Docket; Request for Comments**

Dear Dr. Romero:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing more than 60,000 physicians and partners dedicated to advancing women's health, thank you for the opportunity to submit written public comments on the upcoming meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). We appreciate ACIP's continued dedicated focus on development of a COVID-19 vaccine, and the opportunity to inform that work. Obstetrician-gynecologists, as trusted women's health physicians, are on the front lines of the response to the global COVID-19 pandemic.

According to the Centers for Disease Control and Prevention, pregnant individuals are at increased risk for severe illness and death from COVID-19 compared with non-pregnant individuals<sup>1</sup>. Yet pregnant and lactating individuals continue to be largely excluded from clinical trials related to the development of COVID-19 vaccines. ACOG is concerned that this lack of inclusion in clinical trials will result in the exclusion of pregnant and lactating individuals from the opportunity to receive a COVID-19 vaccine. Excluding pregnant and lactating individuals from COVID-19 vaccine allocation plans is concerning for the following reasons:

- 1) Pregnant individuals have been identified by the Centers for Disease Control and Prevention as an at-risk population for severe illness and death related to COVID-19<sup>2</sup>.
- 2) In addition to being identified as an at-risk population, upwards of half of pregnant individuals also fall into another priority category, including frontline workers and those with underlying conditions. Women make up more than 75 percent of the health care workforce, and it is estimated that there are 330,000 pregnant health care workers<sup>3,4,5</sup>.
- 3) In the absence of data, decision-making by pregnant and lactating individuals and their clinicians often focuses on fears about unknown risks of intervention during pregnancy and lactation rather than a

more balanced approach that also considers risks of failure to intervene. Further, historical data about risks posed to pregnant women and their fetuses by pandemic influenza establish the serious risks of failure to intervene<sup>6</sup>. If pregnant individuals are excluded from the opportunity to decide whether to be vaccinated, that not only violates their bodily autonomy, it also puts them at risk of severe outcomes and death related to COVID-19 illness. **Excluding this critical population at increased risk of severe illness and death related to COVID-19 would be unethical.**

Further, ACOG urges the ACIP to review and make recommendations related to pregnancy and lactation separately. While lactating individuals were not included in most clinical trials, ACOG recommends that COVID-19 vaccines should not be withheld from lactating individuals who otherwise meet criteria for vaccination. Given the components of the current COVID-19 vaccines and their mechanisms of action, theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine.

**As such, if the FDA approves an Emergency Use Authorization for a COVID-19 vaccine and remains silent on pregnancy, ACOG urges the ACIP to include pregnant and lactating individuals in its guidance, providing a permissive recommendation based on appropriate discussion of risks and benefits between clinicians and pregnant and lactating patients.**

Thank you for the opportunity to submit comments and inform the critical work of your Committee. ACOG commends the ACIP for continuing to consider these critical populations in discussions and recommendations. If we can provide any additional information or expertise, please contact me or Sarah Carroll at [scarroll@acog.org](mailto:scarroll@acog.org).

Sincerely,



Christopher M. Zahn, MD  
Col (Ret), USAF, MC  
Vice President, Practice Activities

cc: Sarah Carroll  
Megan McReynolds  
Rachel Tetlow  
Various ACOG staff

References:

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