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Reply to: Coronavirus disease 2019 vaccine in pregnant women: not so far! The importance of counseling and the need for evidence-based data



We appreciate your interest in our manuscript and your letter to the editor. We agree that vaccine development is a stepwise process and acknowledge the time needed to thoroughly assess efficacy and safety. As you stated, pregnant women have been historically excluded from most clinical trials of investigational products, including vaccine trials. Thus, pregnant women and their providers are left to rely on limited data to make. However, we do believe there is sufficient (United States population–based) data, as cited in our review and further substantiated by Jering et al¹ in a recent publication, to show that pregnant women are at an increased risk of severe maternal morbidity and mortality owing to coronavirus disease 2019 (COVID-19) infection.

As stated in our review, we fully agree that pregnant women should be included in clinical trials of COVID-19 vaccines and that social distancing and appropriate masking and vaccination of the general public will help reduce the overall risk to the population, including pregnant women. However, we feel strongly that despite a lack of data regarding the use of current Food and Drug Administration–authorized COVID-19 vaccines in pregnant individuals, the risks of acquiring COVID-19 along with the risks of COVID-19 in pregnancy (ie, increased rates of mechanical ventilation, intensive care unit admission, venous thromboembolism, thrombotic events, myocardial infarction, and mortality) must be weighed against the potential theoretical risks of the vaccines. It is for these reasons we feel strongly that pregnant women

should be given the choice to receive the vaccine if they are otherwise eligible. ■

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G.K.S. serves as a coinvestigator for the Pfizer coronavirus disease 2019 (COVID-19) vaccine trial, as chair of the Independent Data Monitoring Committee (IDMC) for GlaxoSmithKline trials involving novel respiratory syncytial virus vaccine in pregnant women, and chair of IDMC for Pfizer trials involving novel Guillain-Barré syndrome vaccine in pregnant women. She is also the principal investigator for a Centers for Disease Control and Prevention (CDC)–funded planned observational study of COVID-19 vaccine in pregnant women (CDC 200-2012-53663). The remaining authors report no conflict of interest.

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1. Jering KS, Claggett BL, Cunningham JW, et al. Clinical characteristics and outcomes of hospitalized women giving birth with and without COVID-19. *JAMA Intern Med* 2021. [Epub ahead of print].

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