Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

performed; a significant reduction of blood loss in the tranexamic acid group was observed when pooling studies using gravimetric blood loss quantification (mean difference, −175.75 mL; 95% confidence intervals [CI], −205.78 to −145.73) and estimated blood loss (mean difference, −217.69 mL; 95% CI, −295.24 to −140.15). No significant difference between subgroups was observed (P=.276). Therefore, the method for blood loss measurement was not identified as a source of bias in our meta-analysis.

We agree that the TRAAP2 trial represents the largest well-designed trial in the field, although ignoring smaller studies may lead to selective reporting and publication bias.[3] Further randomized controlled trials are needed to clarify the cost-effectiveness of prophylactic tranexamic acid administration and to define its efficacy in high-risk populations. ■

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Pregnancy is not a disability: including pregnant healthcare workers in COVID-19 vaccine mandates

TO THE EDITORS: We support consistent messaging by physicians, societies, and healthcare organizations that pregnancy is not a disability and that pregnancy should not be considered an accepted indication for time-limited exemption from COVID-19 vaccination for healthcare employment. That the question is even debated 2 years into the pandemic is an unfortunate—although not unexpected—consequence of excluding pregnant women from participating in the original clinical trials, delayed acquisition of safety and efficacy data, and the resultant lagging recommendations strongly supporting COVID-19 vaccination in pregnancy. The burden of weighing requests for time-limited deferral for pregnancy poses a moral dilemma for obstetricians given the benefits of vaccination and severity of COVID-19 in pregnancy.

In August 2021, the Centers for Disease Control and Prevention (CDC), the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal-Fetal Medicine (SMFM) recommend COVID-19 vaccination for all people who are pregnant, breastfeeding, trying to get pregnant now or might become pregnant in the future.[1] On September 29, 2021, a CDC health advisory alerted the public about the urgent need for the prevention of serious illness, death, and adverse pregnancy outcomes from COVID-19 by vaccinating pregnant patients. The health advisory noted that the highest number of COVID-19–related deaths in pregnant people in a single month was reported in August 2021, more than a year after the arrival of the pandemic to the United States. The highly transmissible Delta variant is associated with increased hospitalization for severe illness among pregnant patients,[2] and the Omicron variant has now arrived.

The evidence supporting the safety and efficacy of COVID-19 vaccination during pregnancy continues to accrue, and the benefits of vaccination overwhelmingly outweigh any potential risks. The Centers for Medicare and Medicaid Services (CMS) Omnibus Staff Vaccination Rule, effective November 5, 2021, requires that healthcare workers in all participating healthcare systems receive COVID-19 vaccination by January 4, 2022.[3] Although the mandate currently remains enjoined in the courts, some healthcare facilities have already begun implementing this requirement. As they do, leaders must weigh the acceptability of medical exemption requests in the context of pregnancy, an issue not explicitly addressed by the interim final rule. Alternatively, the CMS states that implementation must comply with applicable federal antidiscrimination laws and civil rights protections, including the Americans with Disabilities Act (ADA) and the Pregnancy Discrimination Act. The US Equal Employment Opportunity Commission clarifies: although pregnancy itself is not considered a disability, pregnancy-related medical conditions may be and thus should be considered under the usual ADA rules. With the language open to interpretation by employers and employees about what constitutes a "pregnancy-related disability," we risk excluding a key demographic of the healthcare workforce from the protection

of COVID-19 vaccination—young women of reproductive age. The CMS vaccination rule references a July 2020 consensus statement, authored by the Society for Healthcare Epidemiology of America and additional professional societies, including the Infectious Diseases Society of America, in which the societies recommend that COVID-19 vaccination be a condition of employment for all healthcare personnel in facilities in the United States.[4] However, the authors delineate medical contraindications and other exemptions specified by state or federal law and medical deferrals, which may be allowable by organizations, including pregnancy or other time-limited conditions. The exemption for pregnancy as a "time-limited" deferral could be seen as a reasonable accommodation but fail to acknowledge the most recent strong recommendations by the CDC for vaccination. We fear this is an unfortunate—but not unexpected—consequence of excluding pregnant patients from participating in the original clinical trials, delayed acquisition of safety and efficacy data, and lagging recommendations regarding COVID-19 vaccination in pregnancy. It would be helpful to correct the messaging and make it consistent: for societies to update their guidance concerning COVID-19 vaccination requirements for all pregnant healthcare workers based on the newest evidence available and the known risks of COVID-19 in pregnancy.

Fortunately, there is mounting evidence in the past 5 months. On August 9, 2021, the CDC released a new report on the safety of COVID-19 vaccines in the preconception period or during early pregnancy from the v-safe pregnancy registry. They demonstrated that the cumulative risk of pregnancy loss from 6 to 19 weeks' gestation was 14.1% (95% confidence interval [CI], 12.1%−16.1%); after direct age standardization using a reference population, the cumulative risk of pregnancy loss decreased to 12.8% (95% CI, 10.8% −14.8%). This risk is consistent with reported rates in the general population. Local and systemic reactogenicity are similar following messenger RNA (mRNA) vaccination in pregnant and nonpregnant individuals, and there have been no concerning safety signals.

There is increasing evidence that binding, neutralizing, and functional nonneutralizing antibodies and CD4 and CD8 T-cell responses are detectable in maternal and infant cord blood and breast milk following mRNA vaccination. Furthermore, vaccine-induced immunoglobulin G titers in maternal serum are higher following maternal vaccination than natural infection. Although a debate on the timing of maternal vaccination to optimize transplacental antibody transfer before delivery is ongoing, the current focus remains on the immunization of all eligible candidates as soon as possible, to protect those most vulnerable to infection. Following a review of evolving evidence supporting the safety and efficacy of the COVID-19 vaccines in pregnancy, the CDC strengthened their position from "do not exclude" to "recommend."

The option of time-limited deferral of COVID-19 vaccination during pregnancy offered by healthcare employers otherwise requiring vaccination as a condition of employment would send a subtle but clear message that may be adopted by other non-healthcare employers. The message would convey that the safety of vaccination is questionable and that benefits may not outweigh the risks for this group. By failing to recognize the risks of COVID-19 in pregnancy and the not-as-robust-but-still-strong observational data on the safety and efficacy of vaccination in pregnancy, employers risk leaving pregnant workers unprotected. In addition, the authorizing physician—who may be an obstetrician-gynecologist—would be put in a difficult position. Pregnancy is not a medical indication for deferral of COVID-19 vaccination. For a physician to authorize a vaccine deferral for a pregnant patient without a life-threatening allergic reaction to the vaccine components would be to potentially put a patient's life—and thus the pregnancy—at risk and contradict the most recent CDC, ACOG, and SMFM recommendations.

In an analysis by the National Women's Law Center, 6.5% of registered nurses and nursing, psychiatric, and home health aides were pregnant in 2017, and the number of pregnant persons employed in healthcare-associated positions increased by approximately 70% between 2008 and 2017.[5] In their roles interacting with patients, pregnant healthcare workers will likely be exposed to COVID-19 during the ongoing pandemic. The availability of a highly efficacious and safe vaccine is one of several strategies—along with masking and social distancing—central to protecting patients and healthcare workers, maintaining a safe work environment, and preserving the healthcare workforce.

Implementing vaccination as a condition of employment requires trust in a system prepared to accommodate those unable to be vaccinated and clear criteria for reviewing exemption and deferral requests. Unfortunately, the very medical professionals asked to review these deferral requests may be the obstetricians currently experiencing the worst of the pandemic in their labor and delivery units and trying to educate patients on the importance of accepting COVID-19 and other indicated vaccines during pregnancy. This is the same battle fought each influenza season, when we educate pregnant patients about the morbidity of influenza in pregnancy, encourage them to be vaccinated, and are required as healthcare workers to be vaccinated ourselves.

Now as we enter the third year of this pandemic, each time a consensus recommendation carves out an exclusionary clause for pregnancy, public confidence in the vaccine weakens. Time is of the essence. Given the abundant evidence of high maternal morbidity from COVID-19 and the efficacy of vaccination in preventing hospitalization and severe illness, the urgency of vaccination during pregnancy cannot be understated. The message sent should be crystal clear and consistent from politicians, professional societies, physicians, and healthcare employers: COVID-19 vaccination is safe and required for all pregnant individuals, and vaccines save lives.

Patients should be able to trust that healthcare workers are vaccinated, including those who may be pregnant. ■

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