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.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.
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Professionally responsible COVID-19 vaccination counseling—response to Chervenak et al

TO THE EDITORS: In their article, Chervenak et al1 designated their favored approach to counseling pregnant women for COVID-19 vaccination as “professionally responsible.” However, their stance diverges in important aspects from product licenses and guidance issued by professional bodies. Their approach aims to increase vaccine uptake. Their view is rooted in willingness to view caution as necessarily or primarily a legalistic concern, coupled with their readiness to substitute experiment-based scientific evidence with inferences or suppositions.

The seriousness of COVID-19 is not in doubt. Remarkable scientific progress enabled vaccine development and emergency use authorization in record time. The technology used in most COVID-19 vaccines is novel. There is cause for optimism, but vaccines have not been tested in pregnant women. Emerging information emphasizes the value of surveillance and monitoring, which should include long-term fetal outcomes. The authors built their argument based on extrapolations from short-term data derived from research on nonpregnant adults. They need to provide an account of how this lower standard of proof can be adopted without undermining medicine’s claim to be rooted in scientific rigor.

Doctors have considerable influence on patients’ choices. This stems from the trust patients bestow on doctors. Chervenak et al1 view this trust as an opportunity to channel patients’ choices. However, they need to address the concern that their approach risks undermining the fiduciary relationship and the essence of trust. In addition, they need to provide an account as to how to reconcile “respect” for autonomy with advocating persistent efforts to sway women toward a particular choice or to reverse expressed preferences. Counseling for consent ought not to be grounded in a conviction that particular choices are irrational or irresponsible. Thus, Chervenak and colleagues need to describe how to reconcile the tension inherent in providing care with the standpoint that pregnant women who hesitate about vaccination are free riders and, as such, morally reprehensible.

At the core, Chervenak et al1 seek to influence value judgments. Pregnant women and care providers face a dilemma when balancing the risks to public health, the individual woman, and the unborn baby. It is difficult to see how labeling a particular stance as “responsible” can be helpful. Alternatively, Chervenak and colleagues should clarify why they believe pregnant women need to provide a reason or justify their choice.

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Reply to professionally responsible COVID-19 vaccination counseling

We thank Dr Habiba for his interest in our article.1 Dr Habiba claims that our article failed to be “rooted in scientific rigor” because “vaccines have not been tested in pregnant women” in a randomized controlled clinical trial. In February 2021, Pfizer and BioNTech embarked on studying the effects of COVID-19 vaccination on pregnant women. Before the results of trial data, it was necessary to protect pregnant and lactating patients through emergency access and advocate for their participation in research. Recently, the US Centers for Disease Control and Prevention has endorsed recommending COVID-19 vaccination to pregnant women, relying on the best available evidence.2 When we submitted our article and to date, the best
available evidence supports the judgment that, because of the significantly higher COVID-19 morbidity and mortality rates among pregnant women, vaccines will save lives.

Implicit in Dr Habiba’s criticism is the view that in professional ethics in obstetrics and gynecology (and in all other specialties), making definitive recommendations shows disrespect for patients, even when the best available evidence is clear. His concern is that making recommendations aims to “influence value judgments” and “sway women toward a particular choice.” For this criticism to become persuasive, Dr Habiba should have shown that making recommendations is incompatible with the ethical principle of respect for patient autonomy.

Making evidence-based recommendations is an accepted professional standard, such as smoking cessation, wearing seat belts, using baby car seats, and abstaining from alcohol in pregnancy. Such recommendations are standard components of the informed consent process. There is an ethical point to such standards: it would be negligent to not make a recommendation for fear that a patient’s value judgments about the health risks for herself and her fetus may be influenced or that she might be swayed toward a particular choice. If the patient disagrees with a recommendation, the professional standard of informed consent is clear: repeated, directive counseling aimed at respectfully providing knowledge for the patient to reconsider. These standards are beneficence based, reflecting the professional commitment to protecting the health of pregnant and fetal patients. Furthermore, Dr Habiba should have shown that respect for autonomy overrides such beneficence-based considerations.

There is a justice-based justification for directive counseling of patients who refuse COVID-19 vaccination, whether they are pregnant or not: their refusal to be vaccinated puts others at risk of morbidity and mortality without their consent. We proposed that such patients be asked if their refusal is fair, a strategy designed deliberately to avoid passing moral judgment on the patient. In addition, Dr Habiba should have shown why asking this ethically appropriate question entails passing such moral judgment.

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