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Reversing physician hesitancy to recommend COVID-19 vaccination for pregnant patients



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Introduction

“Vaccine hesitancy” has been variously defined by the US Centers for Disease Control and Prevention (CDC) as persons indicating in surveys that they would “probably not” or “definitely not” receive a COVID-19 vaccine when available,¹ whereas the World Health Organization defines vaccine hesitancy as “... delay in acceptance or refusal of vaccines despite availability of vaccination services”² To reduce vaccine hesitancy, it is essential to build trust in COVID-19 vaccines, which is the confidence that patients, families, and providers have in recommending vaccines, administering vaccines, and establishing the processes and policies that lead to vaccine development, licensure or authorization, manufacturing, and recommendations for use.³ Vaccinations in general, and specifically COVID-19 vaccination, is considered to be one of the greatest achievements in medicine, saving millions of lives. To be successful in reducing the prevalence and incidence of COVID-19 disease, vaccination programs rely on a high uptake level.⁴

“Physician hesitancy” occurs when physicians or their professional organizations do not recommend COVID-19 vaccination. Physician hesitancy is a contributing factor of the presently low

Physician hesitancy is said to occur when physicians do not recommend COVID-19 vaccination, and it is a contributing factor for the low vaccination rate for COVID-19 in pregnant women. Physician hesitancy has become a major, unaddressed problem with regard to the quality and safety of obstetrical care. We identify 3 root causes of physician hesitancy and describe how professional ethics in obstetrics should guide in reversing these root causes. They are clinical misapplications of key components of professionally responsible obstetrical practice: therapeutic nihilism, shared decision-making, and respect for patient autonomy. Therapeutic nihilism directs the obstetrician to avoid any clinical interventions during pregnancy to prevent teratogenic effects that might be unknown. Therapeutic nihilism is misapplied when there is a documented net clinical benefit with no evidence of clinical harm. Shared decision directs the obstetrician to only offer but not recommend clinical management. Shared decision-making plays a major role when there is uncertainty in clinical judgment but is misapplied when it becomes a universal model. It does not apply when there is a net clinical benefit. When there is a net clinical benefit, clinical management should be recommended, not simply offered. The ethical principle of respect for patient autonomy plays an indispensable role in decision-making with patients. It is misapplied when it is assumed that respect for autonomy requires physicians not to make recommendations and to defer to and implement patients' decisions without exception. There is evidence that the obstetrician's recommendations about the management of pregnancy are the most important factor in a pregnant woman's decision-making. Simply deferring to the patient's decisions makes for misapplied respect for patient autonomy. Obstetricians must end physician hesitancy about COVID-19 vaccination of pregnant women by reversing these 3 root causes of physician hesitancy. Reversing the root causes of physician hesitancy is an urgent matter of patient safety. The longer physician hesitancy continues and the longer the low vaccine acceptance rate of pregnant women lasts, preventable serious diseases, deaths of pregnant women, intensive care unit admissions, stillbirths, and other maternal and fetal complications of unvaccinated women will continue to occur. Physician hesitancy should not be permitted to influence the response to future pandemics.

Key words: COVID-19 vaccine, diversity, maternal morbidity, maternal mortality, misinformation, neonatal morbidity, neonatal mortality, patient rights, preterm birth, respect for autonomy, shared decision-making, stillbirth, therapeutic nihilism, vaccine counseling, vaccine recommendations

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vaccine acceptance rate by pregnant women for COVID-19^{5,6} and other recommended vaccines.⁷ This should therefore be understood as a major, unaddressed problem for the quality and safety of obstetrical care.^{8,9} Unfortunately, physician hesitancy may have been encouraged by the reluctance, until very recently, of physicians' professional organizations and publications not to recommend COVID-19 vaccination to pregnant women, even though COVID-

19 vaccinations to most other risk groups had already been recommended.^{10–12}

Because pregnant women continue to become severely ill or die from COVID-19, overcoming physician hesitancy has become urgent. The purpose of this article is to identify the 3 root causes of physician hesitancy and describe how professional ethics in obstetrics should guide reversing these root causes.

The Clinical Context

On September 29, 2021 the CDC published a health advisory recommending urgent action to increase COVID-19 vaccination among women who are pregnant, who were recently pregnant (including those who are lactating), who are trying to become pregnant now, or who might become pregnant in the future.⁶ As of October 4, 2021, more than 125,000 laboratory-confirmed COVID-19 cases have been reported in pregnant people, including more than 22,000 hospitalized cases and 171 deaths.⁶ The highest number of COVID-19-related deaths in pregnant people (n=22) in a single month of the pandemic was reported in August 2021. Data from the COVID-19-Associated Hospitalization Surveillance Network (COVID-NET) in 2021 indicate that approximately 97% of pregnant people hospitalized (either for illness or for labor and delivery) with confirmed SARS-CoV-2 infection were unvaccinated.⁶ Even though COVID-19 vaccines have been readily available in the United States since the end of 2020, as of September 25, 2021 about 3 in 4 of all pregnant women⁵ and about 7 in 8 of Black non-Hispanic pregnant women had not received any COVID-19 vaccine in pregnancy compared with <1 in 4 of those eligible in the general population.^{13,14} Vaccine acceptance by pregnant women is also low for the other 2 recommended vaccines in pregnancy (tetanus, diphtheria, and pertussis [TDAP] vaccine and influenza vaccine), with racial or ethnic disparities persisting and only 40.3% pregnant women in 2019–2020 women receiving both vaccines.⁷ The most common factor that influences women to get vaccinated is a healthcare provider's recommendation.^{15–21}

Pregnant and recently pregnant women infected with COVID-19, including their fetuses and newborns, are at a significantly increased risk of severe illness, death, stillbirths, preterm births, and neonatal admissions to an intensive care unit (ICU).^{22–48} As of October 4, 2021, 171 pregnant women in the United States have died of COVID-19 infection.¹³ COVID-19 vaccination

before and during pregnancy prevents maternal mortality and morbidity, and many of these died after the introduction of the COVID-19 vaccine; 97% of those who died were unvaccinated.

Vaccine availability and eligibility for pregnant women in the United States have been slower than other risk groups. At the end of January 2021, most states in the United States (36 of 51; 71%), encompassing 71% of the population of the country, did not include pregnant individuals among their priority populations.⁴⁹ Two months later, most states (36 of 51; 73%) classified pregnant individuals as a priority group for COVID-19 vaccination, but pregnant people were eligible for vaccination in <50% of the states (24 of 51).⁵⁰

Shortly after introduction of the COVID-19 vaccine, and for a long time, Israel was the first and only country to specifically recommend COVID-19 vaccines to all pregnant women.⁵¹ Although the CDC and most US states included pregnant women as a risk group, several professional groups and societies initially told to only “offer” but not “recommend” vaccination to pregnant women, therefore excluding the recommendation for COVID-19 vaccinations for pregnant women.^{10,52–55} That approach was further elaborated by several publications that called for “shared decision-making” between a patient and her provider for offering (presenting vaccination as an option without the physician expressing a view on whether the patient should be vaccinated), but not recommending (expressing the view that the patient should be vaccinated) COVID-19 vaccination to pregnant women.^{11,56–59}

Finally, COVID-19 vaccination was recommended to pregnant women in the United States and England by August 2021 and >8 months after vaccines were recommended to all other risk groups except pregnant women.^{60–63} Despite this recommendation, the American College of Obstetricians and Gynecologists (ACOG) sent out an email saying that, “...unequivocally, the vaccine should be offered or recommended during pregnancy,” from which it follows

that just offering vaccination and not recommending is appropriate clinical practice.⁶⁴ This position of conflating an offer with a recommendation will only encourage continuing physician hesitancy to recommend COVID-19 vaccination to pregnant women. Two months after professional organizations changed their stance from offering to recommending COVID-19 vaccinations to pregnant women, full vaccinations of pregnant women have barely changed (from 22.9% to 25.6%),⁵ showing the persistent vaccine hesitancy among pregnant women and physicians.

COVID-19 vaccine acceptance and equity will require multifaceted policies and programming that respect diverse communities, and it is essential not only to increase vaccinations overall but also to reduce the overall disparities in ethnic and racial communities.²¹ Consequently, Carson et al²¹ concluded that among the important considerations for vaccine acceptance is the desire for practitioner recommendation: “Culturally centered care and practitioner recommendations may help promote vaccine acceptability, trust, and combat misinformation,” which is a view that is supported by others.^{65,66} Strong provider recommendations are essential for accepting vaccines, because there is a consensus that receiving a recommendation for vaccination from a healthcare provider is among the most important factors in maternal decision-making.^{15–21}

Besides the recent additions of COVID-19 vaccines, the CDC and the Advisory Committee on Immunization Practices (ACIP) also recommend for pregnant women to receive the influenza and the TDAP vaccine.⁶⁷ In their “Standards for Practice: Vaccine Recommendation”⁶⁷ the CDC said to “... strongly recommend vaccines that your patients need, whether your office stocks them or not. Your recommendation can make a difference.” And “... clinicians are the most valued and trusted source of health information for adults.”^{67,68}

In February 2021, we published an article suggesting that COVID-19 vaccination should be strongly recommended to pregnant women to prevent maternal

mortality and morbidity.⁶⁹ It took another 6 months for others to support that recommendation in a way similar to what we used 6 months previously. The ACOG stated that "...misinformation has proliferated when it comes to COVID-19 and women's health, especially specific to the COVID-19 vaccines..."⁷⁰, and a recent study about COVID-19 misinformation in national samples across 5 countries showed that misinformation negatively affected respondents' self-reported compliance with public health recommendations and reduced respondents' willingness to get vaccinated and recommend the vaccine to others.⁷¹

Our clinically-grounded, ethical justification for recommending COVID-19 vaccination to pregnant women concluded that "Physicians should recommend coronavirus disease 2019 vaccination to patients who are pregnant, planning to become pregnant, and breastfeeding or planning to breastfeed."⁶⁹ We believe that early adoption of this position in 2021, in a way not dissimilar from Israel's implementation of recommending COVID-19 vaccination for pregnant women, would have subsequently prevented the ensuing months of physician hesitancy, and with it, many unnecessary maternal deaths and injuries in unvaccinated pregnant women.

Three Root Causes of Physician Hesitancy

Reversing the root causes of physician hesitancy remains an urgent matter of patient safety, not just during the COVID-19 pandemic but also for future outbreaks. The 3 root causes have their origin in the clinical misapplications of important components of professionally responsible obstetrical clinical judgment and practice: therapeutic nihilism, shared decision-making, and the ethical principle of respect for autonomy.

Clinical misapplication of therapeutic nihilism

The first root cause of physician hesitancy is the misapplication of therapeutic nihilism in the clinical management of pregnancy. Therapeutic nihilism is defined as "scepticism regarding the

worth of therapeutic agents especially in a particular disease."⁷² Therapeutic nihilism is a powerful antidote to enthusiasm, which is a belief in clinical benefit in the absence of evidence.

Therapeutic nihilism was reinforced when a small number of catastrophes, including those involving thalidomide and diethylstilbestrol, made practitioners and the public realize that the placenta did not always prevent medications from reaching or harming the fetus. Thus, the new philosophy in obstetrics became "...akin to therapeutic nihilism," in which obstetricians were taught to believe that "...we live in a sea of teratogens."⁷³ Therapeutic nihilism as it relates to COVID-19 vaccines is partially exemplified in a letter to the authors in response to our COVID-19 vaccination counseling publication.⁷⁴

Therapeutic nihilism was 1 reason why pregnant women were excluded from COVID-19 vaccine trials. This exclusion, even though there were no theoretical concerns and no evidence of adverse outcomes after thousands of pregnant women had already been vaccinated, reinforced therapeutic nihilism in clinical practice and helped to explain the hesitancy of professional associations to recommend COVID-19 vaccination before the results of clinical trials became available. In our view, this misapplication of therapeutic hesitancy by professional associations likely encouraged continuing physician hesitancy to recommend vaccination.

Clinicians' therapeutic nihilism can be further reinforced by fear of exposure to professional liability. The logic here is that if a physician recommends a form of clinical management in the absence of a statement from professional associations that such a recommendation should be made, and if the patient experiences an adverse outcome, the physician may increase exposure to professional liability. Understandable prudence creates strong physician hesitancy to recommend COVID-19 vaccination.

Clinical misapplication of shared decision-making

The second root cause of physician hesitancy is the clinical misapplication of

shared decision-making (in shared decision-making, the physician should not be directive, by only offering but not recommending a specific management).⁷⁵ Shared decision-making has an important role in decision-making with patients when evidence is uncertain.⁷⁵ It is misapplied when it is taken to be the sole model for decision-making with patients.

The term "shared decision-making" has been increasingly used in the medical literature, with an over 5000% increase in PubMed mentions between 2000 and 2020 (from 42 to 2120).⁷⁶ According to the ACOG, shared decision-making is "...a patient-centered, individualized approach to the informed consent process that involves discussion of the benefits and risks of available treatment options in the context of a patient's values and priorities."⁷⁷ The National Institute for Health and Clinical Excellence (NICE), United Kingdom, says that "Shared decision-making is a joint process in which a healthcare professional works together with a person to reach a decision about care."⁷⁸

Several authors and the Society for Maternal-Fetal Medicine have recommended using shared decision-making for COVID-19 vaccinations in pregnant women,^{11,56–59} even though the CDC has never supported it for COVID-19 vaccinations in pregnant women. The CDC only supports shared decision-making for some vaccines where, contrary to COVID-19 vaccinations, the current evidence does not support making a recommendation.^{79,80} The CDC ACIP calls for shared decision-making for the following 4 vaccines only: meningococcal B vaccination for adolescents and young adults aged 16 to 23 years, hepatitis B vaccination for adults with diabetes mellitus aged ≥ 60 years, human papillomavirus vaccination for adults aged 27 to 45 years, and pneumococcal conjugate vaccination for adults aged ≥ 65 years who are not immunocompromised, cerebrospinal fluid leak, or cochlear implants. In these clinical circumstances, there is no "default decision" to vaccinate.^{79,80}

On the contrary, according to the CDC, there are clinical circumstances in

which the “default decision” is to vaccinate. In these circumstances, and that includes COVID-19 vaccination, shared decision-making does not apply, because counseling about COVID-19 vaccination should be directive. Directive counseling requires making a recommendation to communicate to the patient that the physician’s clinical judgment is that she should be vaccinated.^{81,82} Given that COVID-19 vaccination should be recommended to pregnant people, as we have argued and as the CDC and professional associations now state, it is a mistake in clinical practice to continue to implement a shared decision-making approach to COVID-19 vaccination for pregnant women. A recommendation by physicians for COVID-19 vaccination for pregnant women, should now be the standard of care.⁶⁹

Vaccine hesitancy is an international problem,^{83,84} and Durand et al believe that when tackling COVID-19 vaccine hesitancy, “... there is good evidence that the combination of trusted evidence sources in the hands of competent professionals provides the best chance of dealing with vaccine hesitancy.”⁸⁵ This applies first and foremost to physicians, whose own hesitancy to recommend COVID-19 vaccines to pregnant women can inadvertently contribute to patients’ vaccine hesitancy.

Clinical misapplication of the ethical principle of respect for autonomy

The third root cause of physician hesitancy is the misapplication of the ethical principle of respect for autonomy. This ethical principle plays an indispensable role in decision-making with patients. It is misapplied when it is assumed that respect for autonomy requires physicians not to make recommendations and to defer to and implement patients’ decisions without exception.⁸⁶

An example of the former is the view that “advocating persistent efforts to sway women toward a particular choice or to reverse expressed preferences” is incompatible with respect for patient autonomy.⁷⁴ An example of the latter is the obstetrician who accommodates every preference of pregnant women

about the clinical management of pregnancy, even when that choice of management is associated with unacceptably high risks. The underlying false assumption is that respect for patient autonomy requires such accommodation.

This assumption can be reinforced by the belief that respecting patients’ decisions without exception may improve patient satisfaction. In an era in which Press-Gainey and other measurement tools have come to considerable prominence, the potential for synergy between the misapplication of respect for autonomy and the legitimate self-interest in good patient-satisfaction scores is considerable and becomes a powerful root cause of physician hesitancy. The result is that some physicians may believe that making a recommendation for COVID-19 vaccination risks creating a dissatisfied patient, especially if she herself has expressed vaccine hesitancy. The logic of this misapplication concludes that offering but not recommending vaccination avoids this risk.

The COVID-19 pandemic should result in a greater prominence for public health in undergraduate, graduate, and continuing medical education. Obstetricians currently in practice typically have received only minimum exposure to the principles of public health, inviting physicians to conclude that the public health dimensions of a pandemic will be addressed by public health officials, such as the US Surgeon General and state and local officials. The result is sometimes an overt and sometimes a subtle root cause of physician hesitancy, manifesting as an absence of the public health dimensions in counseling pregnant patients about vaccination as the means to protect not only themselves but others.

Reversing the 3 Root Causes of Physician Hesitancy

Reversing the clinical misapplication of therapeutic nihilism

The response to the clinical misapplication of therapeutic nihilism should be deliberative, beneficence-based clinical judgment. Therapeutic nihilism is justified when an intervention during

pregnancy should be considered to result in significant net clinical harm. However, this did not apply to COVID-19 vaccination at the time of our February 1, 2021, publication in the *American Journal of Obstetrics & Gynecology*.⁶⁹ The increased risks of maternal severe illness; ICU admission; and maternal, fetal, and neonatal death were already well-documented early in 2021.^{22,25,27,30,32,35,36} There were no “red flags” according to Dr Fauci⁸⁷ and no increased serious adverse events for women who were or became pregnant in the clinical trials of COVID-19 vaccines pregnant women that would have warranted suspension of these trials. There was no documented theoretical risk of maternal, fetal, or neonatal harm, and there were no documented increased adverse outcomes in vaccinated pregnant women. Because the harms of COVID-19 disease in pregnancy were severe and immediate and there were no documented safety concerns, deliberative beneficence-based clinical judgment supported the conclusion that vaccination should be recommended, and it was clear as early as January 2021.

The conclusion that COVID-19 vaccines should be recommended to pregnant women, did not require completion of the clinical trials, US Food and Drug Association approval, or sanction by professional association. It is important to keep in mind that although randomized clinical trials (RCTs) are considered as the “gold standard,” they should not be considered the only standard. We emphasize that the final guideline of professional groups to change from “offer” to “recommend” was made without an RCT. Many therapeutic and clinical recommendations are made without the benefit of RCTs. Therapeutic nihilism may be misinterpreted to mean that RCTs are the only standard, but this is an error in deliberative, beneficence-based clinical judgment. Pregnant women worldwide are understandably concerned and decline the vaccines, because they are worried that they could harm the baby, and they needed more information about the safety of the COVID-19 vaccine.^{83,84} Instead of therapeutic nihilism, the information that

COVID-19 vaccines are safe should be emphasized,⁸⁸ and vaccination should be emphatically recommended to all pregnant women.

Women and their healthcare providers need to shift away from the "therapeutic nihilism" paradigm. All clinical decisions must be made cautiously and thoughtfully, with the understanding that meeting the health needs of pregnant women is in their best interests and those of the fetus,⁷³ as was the case already in February 2021 when we first recommended COVID-19 vaccines in pregnancy and elaborated on a counseling process.⁶⁹

Reversing the clinical misapplication of shared decision-making

As the CDC has explained, shared decision-making has an important place when there are competing medically reasonable alternatives for, and therefore uncertainty about, the management of the patient's condition or diagnosis. For example, the obstetrician should offer both trial of labor and planned cesarean delivery after a low transverse cesarean delivery. Their clinical benefits and risks should be explained. The patient should be supported in understanding and evaluating each alternative. The patient's values should be decisive about the preferred course of clinical management.

On the contrary, making a recommendation is required when there is 1 medically reasonable alternative, for example, repeat cesarean delivery after classical cesarean delivery. Deliberative clinical judgment, not the patient's values and beliefs, establishes the preferred course of clinical management. This clinical judgment should be recommended and should be explained to the patient. She should be supported in her evaluation of it. For example, if a patient had a previous classical cesarean delivery incision, a repeat cesarean delivery should be recommended, and she should then be asked to consent to a cesarean delivery.

In deliberative clinical judgment, not being vaccinated for COVID-19 was not a medically reasonable option for pregnant women in February 2021, and it is not today. Recent statements of

professional societies only reinforce this position. Unfortunately, for a long time, professional societies previously took the view that vaccination should be offered only but not recommended as a clinical misapplication of shared decision-making. Consequently, according to the CDC, as of October 4, 2021, there were 171 maternal deaths.¹³ Many died after vaccines became available; most of them (97%) were unvaccinated, and many maternal and perinatal deaths and complications including stillbirths were preventable.^{6,89}

Reversing the clinical misapplication of ethical principle of respect for autonomy

The clinical misapplication of the ethical principle of respect for autonomy results from a failure to recognize that making recommendations is compatible with respect for patient autonomy. The important ethical principle is that patient autonomy and making strong recommendations guides decision-making with patients by creating the ethical obligation to empower pregnant women to make informed decisions about COVID-19 vaccination. Pregnant women report that their physician's recommendations were the most important factor in their decision-making,⁹⁰ especially as it relates to the recommendations to get COVID-19 vaccines. It follows that making recommendations empowers pregnant women to make informed decisions, belying the view that making recommendations is not compatible with respect for autonomy. Furthermore, the view that making recommendations is incompatible with respect for autonomy makes 2 unacceptable assumptions. The first is that pregnant women are somehow helpless pawns of physicians, an assumption that is plainly false, not to mention insulting, to female patients. The second is that physicians are simply automatons alienated from their patients.⁹¹

Another misapplication of respect for autonomy relates to the public health obligations of patients. The misapplication occurs when it is assumed that individuals have only those ethical obligations that they freely assume, and

that therefore, vaccination is a "personal choice." This makes sense only on the assumption that one is not accountable for the predictable, harmful consequences of one's choices for others, who have not consented to experience those consequences. Very young children are allowed by their parents to think and act this way only once before correction. Respect for autonomy does not create a license for creating the preventable risk of harm to others. As John Stuart Mill pointed out, none of us have the freedom to cause unconsented-to harm to others.⁹²

All of us have an ethical obligation to prevent becoming a vector of the transmission of a communicable disease with a documented risk of serious morbidity and mortality. Pregnant women have such an ethical obligation, known more precisely as the public health responsibility that everyone has in a pandemic. Fulfilling this ethical obligation also protects the health and life not only of the pregnant woman but also of her fetus and newborn. Recent studies confirm that the fetus receives maternal antibodies after vaccinations, which further protect the newborn after birth.^{93–96} When an ethical obligation enters synergy with legitimate self-interest, the ethical obligation cannot reasonably be considered burdensome. Refusal of clinical management that fulfills one's public health responsibilities and is unequivocally in one's health-related interests should be considered to lack moral authority for the patient and therefore, for the physician.

COVID-19 vaccination for pregnant women should be considered as standard of care, and refusal of vaccination by a pregnant woman should not be simply accepted by her physician. The legal requirement of informed refusal should be satisfied and documented, supplemented by the ethical requirement of respectful persuasion.⁹⁷ Respect for autonomy, properly understood, creates the ethical obligation of the physician to engage the patient with repeated recommendations and targeted follow-up, with the goal of securing authorization of vaccination. Because COVID-19

vaccinations are recommended in pregnant women and those recommendations are considered standard of care, to meet the standard of care, physicians are required to document their recommendation in the patient's chart in addition to documenting the patient acceptance and refusal, which is similar to other recommendations (eg, group B *Streptococcus* testing, flu vaccinations, HIV testing, etc.) or government or organizational policies that mandate that vaccination is ethically well-justified because they justifiably enforce an ethical obligation, the fulfillment of which poses no unreasonable burden on those subject to such policies.

Conclusion

We have identified 3 previously undefined root causes of physician hesitancy to recommend COVID-19 vaccinations for pregnant women: the clinical misapplications of therapeutic nihilism, shared decision-making, and the ethical principle of respect for autonomy. The pregnant woman's rights reductionism model is fallacious because it leads obstetrical ethics to conceptual and clinical failure and therefore should be abandoned.⁹⁷ Obstetricians and those in leadership positions must end physician hesitancy about COVID-19 vaccination of pregnant women by reversing these 3 root causes of physician hesitancy and focus on the mission of perinatal medicine to put women and children first.⁹⁸

Reversing the root causes of physician hesitancy is an urgent matter of patient safety, not only for COVID-19 vaccinations but for other recommended vaccines. The longer physician hesitancy continues and the longer the low vaccine acceptance rate of pregnant women lasts, preventable serious diseases, deaths of pregnant women, ICU admissions, stillbirths, and other complications of unvaccinated women will continue to occur. Physician hesitancy should not be permitted to influence the response to future pandemics. ■

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