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WOMEN'S HEALTH CARE PHYSICIANS

# COMMITTEE OPINION

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## Committee on Ethics

*This Committee Opinion was developed by the Committee on Ethics of the American College of Obstetricians and Gynecologists as a service to its members and other practicing clinicians. Although this document reflects the current viewpoint of the College, it is not intended to dictate an exclusive course of action in all cases. This Committee Opinion was approved by the Committee on Ethics and the Executive Board of the American College of Obstetricians and Gynecologists.*

## Ethical Issues in Pandemic Influenza Planning Concerning Pregnant Women

**ABSTRACT:** Pregnant women traditionally have been assigned priority in the allocation of prevention and treatment resources during outbreaks of influenza because of their increased risk of morbidity and mortality. The Committee on Ethics of the American College of Obstetricians and Gynecologists explores ethical justifications for assigning priority for prevention and treatment resources to pregnant women during an influenza pandemic, makes recommendations to incorporate ethical issues in pandemic influenza planning concerning pregnant women, and calls for pandemic preparedness efforts to include clinical research specifically designed to address safety and efficacy of treatment interventions or prevention strategies used by pregnant women.

Pregnant women are among those with significant interests at stake during an influenza pandemic. They traditionally have been assigned priority in the allocation of prevention and treatment resources during outbreaks of influenza because of their increased risk of morbidity and mortality. Generally, pregnant women are at higher risk than women who are not pregnant for both seasonal and pandemic influenza-related morbidity and mortality. Pregnant women in their second and third trimesters and those with chronic conditions are at especially high risk. The current rationale for assigning treatment priority during a pandemic to pregnant women is grounded in part in experience and data from the major influenza outbreaks of the 20th century (1–4).

During the 2009–2010 novel H1N1 influenza pandemic, the U.S. Centers for Disease Control and Prevention (CDC) continued this approach with its interim guidance on the allocation of antiviral medications during a pandemic, which advocates “considerations specific to pregnant women” (5). The American College of Obstetricians and Gynecologists (the College) and the CDC Advisory Committee on Immunization Practices (ACIP) recommended that all pregnant women receive both seasonal and H1N1 influenza vaccines (6, 7). Additional guidance spoke to the need for preventive strategies in acute-care settings to decrease exposure of pregnant

patients (and pregnant health care workers) to H1N1 influenza (8). This guidance was justified by surveillance data from the 2009–2010 influenza pandemic that showed increased morbidity and mortality among pregnant women (9–14) similar to that experienced during the three influenza pandemics of the 20th century (1–3). In this Committee Opinion, the College Committee on Ethics explores ethical justifications for assigning priority for prevention and treatment resources to pregnant women during an influenza pandemic. The Committee focuses on the influenza pandemic because the epidemiologic data on influenza clearly demonstrate that pregnant women are at significantly greater risk; one cannot necessarily make that claim about all pandemic illnesses.

The Committee makes the following recommendations to incorporate ethical issues in pandemic influenza planning concerning pregnant women:

- During a public health emergency, access to care and resources should be based on women’s clinical needs rather than the type of insurance, if any, that they have or their prior relationship to a clinic or health care institution.
- Because morbidity and mortality during an influenza pandemic are disproportionately high among pregnant women, the ethical consideration of protecting

the public's health justifies the objective of assigning priority to pregnant women.

- College Fellows should provide leadership by educating their patients, staff, and the public about appropriate interventions, such as vaccinations and antiviral therapy.
- To adequately protect pregnant women, pandemic preparedness efforts should include clinical research specifically designed to address the safety and efficacy of treatment interventions or prevention strategies used by pregnant women.
- Given that pregnant women and newborns are at increased risk of both seasonal and pandemic influenza-related morbidity and mortality and that a disproportionate number of them may die during these periods, issues related to death and dying for pregnant women and neonates, including formulation of advance directives, should be incorporated into pandemic planning.

## Ethical Considerations

Distributive justice involves problems that occur when resources are scarce and members of society must agree on how they should be allocated. Fairness is an explanation of justice that is concerned with what is due or owed to persons. Fairness requires that pandemic plans reduce barriers to access and avoid exacerbating health disparities (15, 16). Historical and recent experiences demonstrate that health disparities and barriers to access continue to effect disproportionate outcomes in pandemic influenza. These relate most directly to the effects of poverty and the maldistribution of resources (17, 18). In the face of systemic barriers to access to care, it is not enough to prioritize pregnant women in a formal manner for resources. To avoid creating or perpetuating health disparities, practices and health care systems should make every effort to provide access to care and resources to women during an influenza pandemic. During a public health emergency, access to care and resources should be based on women's clinical needs rather than the type of insurance, if any, that they have or their prior relationship to a clinic or health care institution. Scarce resources should not be hoarded by health care institutions but should be distributed according to national or professional society guidelines.

Another fundamental ethical consideration that should be reflected in a pandemic plan is protecting the public's health (15, 16, 19). Because morbidity and mortality during an influenza pandemic are disproportionately high among pregnant women, the ethical consideration of protecting the public's health justifies the objective of assigning priority to pregnant women. Prioritizing pregnant women protects the population's health by reducing serious morbidity as well as mortality and by decreasing vertical transmission to infants.

Protecting the public's health should be balanced with the ethical objective of striving for fairness and avoiding unfairness. Given that pregnant women are at increased risk of influenza, fairness justifies prioritizing pregnant women in an effort to reduce significant group differences in morbidity and mortality (16).

In a true pandemic, College Fellows should respect public health decisions regarding fair allocation of resources. "First come, first served," is not a fair distribution strategy, for example, because it perpetuates existing social inequities (16). In addition, strategies such as prioritizing based on patients' birth dates or social security numbers are not truly random and can introduce bias (20). Allocation strategies among equally prioritized individuals must be random to be fair.

Disruption of critical services can pose as much of a threat to the public's health as influenza itself. This threat justifies prioritizing key workers in an effort to protect critical services (15, 16, 19). Key workers can be defined by state or government organizations as "those whose functions are critical to limiting flu-related deaths and degradation of the health care, public health, public safety and other critical infrastructures, including volunteers" (16). Although preservation of critical services protects the public's health, a balance should be struck between allocation of scarce resources to key workers and allocation to other individuals who are at particular risk of influenza (eg, pregnant women) (16, 17).

## Impediments to Effective Vaccination and Treatment

Pregnant women and clinicians may face unprecedented challenges during influenza pandemic planning and implementation. Impediments to effective vaccination and treatment include the following (4):

- Availability and cost of vaccine and antiviral medication and cost to administer
- Patients' reluctance to be vaccinated or use antiviral medications during pregnancy
- Clinicians' reluctance to offer vaccination or antiviral medication to pregnant women
- Time constraints that limit clinicians' opportunities to educate each patient about the benefits and risks of vaccination
- Health care professionals' reluctance to be vaccinated themselves

## Patient Vaccination and Treatment

Data from 1989–2005 indicate that pregnant women had the lowest rates of influenza vaccination of all recommended adult target groups (21). Data from the 2003–2004 influenza season show that the majority of obstetrician–gynecologists surveyed would recommend the influenza vaccine for both healthy and chronically ill pregnant women. However, during this period, 36–38%

of obstetrician–gynecologists did not offer the vaccine in their practices (22). The physician barriers identified were inadequate reimbursement, a lack of vaccine information for patients (who may be reluctant to be vaccinated), liability concerns (23), and clinicians’ beliefs that vaccine should be provided elsewhere (23).

Recent data “support previous findings that receipt of influenza vaccination can be influenced greatly by health-care providers offering or recommending influenza vaccination” (24). Vaccination rates for pregnant women improved during the 2009 H1N1 pandemic (24). Given that the time from identification of a novel virus to bulk manufacturing and clinical trials of a vaccine is generally 5–6 months (25), there will be a delay in the availability of a vaccine. However, once vaccines become available, clinicians’ behavior significantly influences vaccination rates among pregnant women.

Concerns about patient reluctance to be treated and clinician reluctance to treat must be considered given that data from the 2009 H1N1 influenza pandemic indicate that the lack of treatment and treatment delays were associated with significantly greater morbidity and mortality among pregnant women, even when antiviral supplies met the demand for treatment (9, 10, 12, 24).

In situations that involve decision making concerning treatment of pregnant women, pregnant women’s autonomous decisions should be respected. Concerns about the effect of maternal decisions on the fetus should be discussed in light of relevant medical evidence and understood within the context of each woman’s broad social network, cultural beliefs, and values (26). Pregnant patients who decline vaccination or antiviral medications should continue to be supported with appropriate care options that honor their autonomous choices. Clinicians have a special obligation to educate women who decline vaccination or antiviral medications about nonpharmaceutical interventions.

Patient reluctance to be vaccinated or use antiviral or other medications and clinician reluctance to administer such treatment during pregnancy may be alleviated by providing information about the risks of influenza and the safety and efficacy of vaccines and antiviral medications. For example, the CDC notes that the seasonal influenza vaccine has been safely given to millions of pregnant women over many years (27). Clinicians may need to rely on early results from clinical vaccine trials rather than waiting for final data, which can lag for some time (4, 23, 28). In describing the safety of the H1N1 vaccine, the CDC indicated that the H1N1 vaccine was being made in the same way and at the same facilities as the seasonal influenza vaccine. Studies in pregnant women were ongoing, but preliminary data on safety in women who were not pregnant were very similar to those seen with the seasonal influenza vaccine (29). The CDC reports that no evidence exists of risk to the fetus from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids (30). Thus, College Fellows

should provide leadership by educating their patients, staff, and the public about appropriate interventions, such as vaccinations and antiviral therapy (4).

Clinical research often excludes pregnant women, who are historically at high risk of morbidity and mortality related to influenza. In the absence of data, decision making by pregnant women and their clinicians often focuses on fears about unknown risks of intervention during pregnancy rather than a more balanced approach that also considers risks of failure to intervene (31). Historical data about risks posed to pregnant women and their fetuses by pandemic influenza establish the serious risks of failure to intervene. To adequately protect pregnant women, pandemic preparedness efforts should include clinical research specifically designed to address the safety and efficacy of treatment interventions or prevention strategies used by pregnant women.

### **Physician Vaccination and Absenteeism**

A related issue concerns clinicians’ own failure to get vaccinated. The College recommends influenza vaccination for health care workers (32). College Fellows have a personal, professional, and ethical responsibility to protect their patients’ health and best interests by following national guidance regarding vaccination of health care professionals (4). Vaccination of health care professionals not only protects them from infection but also protects patients by decreasing the transmission of influenza in health care settings and by maintaining the health care workforce. Clinicians have a primary ethical obligation not to impose harm on their patients (the principle of nonmaleficence). This principle argues for reasonably prioritizing their patients’ well-being over their own. This principle informs the dynamic tension between the physician’s own role as a patient and his or her ethical responsibility to advocate for his or her patients and for the health of the public. As advocates and stewards of public health, obstetrician–gynecologists have an ethical responsibility to be vaccinated (when appropriate to their clinical circumstances) (4).

To meet the ethical objectives of promoting public health, especially during a pandemic, strategies should be implemented to increase vaccination rates among clinicians and prevent contact between symptomatic clinicians and patients (4). This is particularly urgent given that 1) pandemic influenza progresses so rapidly in pregnant women and carries a disproportionately high rate of morbidity and mortality relative to the general population, and 2) few options are available for protecting these vulnerable patients. Strategies to consider include educational campaigns (concerning, for example, the importance of vaccination of health care professionals and other approaches to reduce transmission in the work environment), priority in access to care for health professionals to reciprocate for risk undertaken in the service of others, and mandates.

### **Nonpharmaceutical Interventions**

Pandemic preparedness initiatives should include non-pharmaceutical interventions, such as isolation of the ill

when they present for delivery, social distancing through use of home monitoring, and increased capacities for telephone triage. Nonpharmaceutical interventions can be targeted to protect pregnant women and women in the postpartum period and their infants. Provisions should be made to separate well women from those who are infected with influenza when they present for delivery. In some locations, this might dictate separate birthing centers for well women. However, this will not always be feasible; where it is not, provisions for isolation of ill patients may be needed. Consideration also should be given to possible alterations in routine prenatal care to reduce exposure of healthy pregnant women to persons who may be infected with influenza. For example, reductions in the number of routine prenatal visits, reliance on home monitoring, and increased capacities for telephone triage may be implemented, especially for low-risk pregnancies (3, 33). Ethical considerations require that these nonpharmaceutical interventions be applied fairly across populations; discriminatory strategies must be rejected.

### Issues Related to Death and Dying

Given that pregnant women and newborns are at increased risk of both seasonal and pandemic influenza-related morbidity and mortality and that a disproportionate number of them may die during these periods, issues related to death and dying for pregnant women and neonates, including formulation of advance directives, should be incorporated into pandemic planning. Strategies related to death and dying should include the formulation of advance directives by pregnant women, the role of government or institutional stockpiling of supplies for palliative care, and education for alternative caregivers in the provision of palliative and hospice care services and grief counseling. Prospective planning and the allocation of sufficient resources for compassionate care for the terminally ill are of moral significance that equals the just allocation of health-preserving and life-saving resources (17). This dynamic is reflected in the primary objectives of mass casualty medicine: maximizing survival, minimizing morbidity, and, when possible, minimizing pain (34). Officials charged with pandemic planning and preparedness should strive to meet each of these ends, not just those concerned with preserving and protecting life. Such planning should occur in concert with professional organizations such as the National Hospice and Palliative Care Organization and the Academy of Hospice and Palliative Medicine.

Executing an advance directive in the obstetric context allows a pregnant woman to state her preferences relative to end-of-life care for herself and to speak to the issue of fetal outcome. Like all physicians, obstetricians are responsible for discussing whether or not their patients have an advance directive and what their patients' preferences are (35). Although the 1991 Patient Self-Determination Act mandates that patients be asked about the existence of advance directives upon hospital

admission, many states do not honor such directives should a woman become pregnant (36). All women's autonomous decision making regarding treatment preferences at the end of life should be respected regardless of pregnancy status.

### Conclusion

Prospective planning efforts for pandemic influenza are ethically imperative given the high risks facing pregnant women and their newborns. A lack of planning, or failure to rapidly implement an appropriate plan, constitutes a violation of moral and professional obligations to these high-risk patients. Professional associations such as the College, federal organizations such as the CDC and the ACIP, and international organizations such as the World Health Organization have provided guidance that institutions can use in developing and implementing pandemic planning. Such plans are generally best built upon existing professional norms and guidance, include community engagement activities, and are developed with the advice of relevant professional organizations such as the National Hospice and Palliative Care Organization and the Academy of Hospice and Palliative Medicine.

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