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WOMEN'S HEALTH CARE PHYSICIANS

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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 With Vaccination for the Obstetrician–Gynecologist

ABSTRACT: Because of the growing importance of infectious disease prevention in the individual patient and the larger community, it is vital that Fellows of the American College of Obstetricians and Gynecologists be prepared to navigate the practical and ethical challenges that come with vaccination. Health care professionals have an ethical obligation to keep their patients' best interests in mind by following evidence-based guidelines to encourage patients to be vaccinated and to be vaccinated themselves. College Fellows should counsel their patients about vaccination in an evidence-based manner that allows patients to make an informed decision about the use of these agents in their health care. The Centers for Disease Control and Prevention reports that no evidence exists of risk to the fetus from vaccinating pregnant women with noninfectious virus or bacterial vaccines or toxoids. Mandatory vaccination of health care professionals may be an ethically justified strategy in cases in which the harm to patients and the general population is believed to outweigh the autonomy of individual physicians.

Fellows of the American College of Obstetricians and Gynecologists (the College) have assumed an important role in the successful vaccination of women, both in the course of well-woman and prenatal care. Because vaccine-preventable infectious diseases cause morbidity and mortality that sometimes affects the fetus as well as the pregnant woman, the timely and effective vaccination of women has become a clinical priority for College Fellows. Given the scope of obstetrics and gynecology, these efforts help address the health of women across the full spectrum of their lives.

In their role as providers of well-woman care, obstetrician–gynecologists are in a position to advocate vaccination of the general adolescent and adult female patient population against infectious disease as part of routine care. Vaccinations are appropriately part of routine periodic assessments, underscoring the continuing role obstetrician–gynecologists play in the maintenance of women's health (1). Tetanus vaccinations serve as a leading example of the routine vaccines that women of reproductive age receive in the course of well-woman care.

The preconception and postpartum periods are other prime opportunities for vaccination against potentially dangerous or teratogenic infectious agents, such as rubella, that could affect future pregnancies (2). Vaccinations also play a central role in the prevention and control of acute outbreaks, as in the case of seasonal influenza or pandemics.

Recent attention has focused on potentially preventable human papillomavirus (HPV) infections among adolescent girls, and safety concerns about the vaccination of pregnant women during pandemic events have highlighted a number of ethical issues inherent in the allocation and administration of vaccinations among the patient population receiving care from obstetrician–gynecologists (3). At the same time, issues also have arisen about the role of physicians (obstetricians and gynecologists) in the mitigation of pandemics through compliance with stringent vaccination guidelines and allocation schemes for patients and health care workers. Given the growing importance of vaccination in clinical practice, it is vital that College Fellows be familiar with the

leading issues that attend the use of vaccines. Therefore, the Committee on Ethics makes the following recommendations:

- It is important for College Fellows to recognize that they have responsibilities to both the individual patient and the general population.
- It is a physician's responsibility to be knowledgeable about current standards of practice regarding vaccines, including their indications, benefits, and risks.
- College Fellows should counsel their patients about vaccination in an evidence-based manner that allows patients to make an informed decision about the use of these agents in their health care. Withholding vaccination or information about vaccinations is unacceptable because it violates the ethical obligations to respect patient autonomy and promote patient safety.
- Health care professionals are obligated to serve their patients' best interests by following authoritative guidance on vaccination for patients and clinicians, where medically appropriate and based on the best available evidence.
- The vaccination of adolescents poses unique ethical challenges for obstetrician-gynecologists related to privacy, confidentiality, and informed consent. College Fellows should respect the importance of protecting adolescents' access to reproductive health care services, including HPV vaccination, while adhering to local and national professional norms and applicable legal requirements.
- Current available evidence regarding the safety and efficacy of vaccinations should be reviewed and recognized. College Fellows should counsel their pregnant patients about vaccination in an evidence-based manner that allows patients to make an informed decision about their use. The Centers for Disease Control and Prevention (CDC) reports that no evidence exists of risk to the fetus from vaccinating pregnant women with noninfectious virus or bacterial vaccines or toxoids.
- To avoid their own personal contribution to the spread of disease, College Fellows have an ethical obligation to follow recommendations for vaccination themselves and other safety policies put into place by their local or national public health authorities such as the CDC and the College. Any perceived burdens or potential risks to clinicians themselves from vaccination do not supersede their responsibility to limit the spread of potentially harmful infectious disease.

Ethical Principles of Vaccination

The goals of vaccination are to preserve the health of individual patients as well as the health of the general

public. When the health of the individual is considered, vaccines are administered to protect the health of a single patient or, in the case of a pregnant woman, the patient and her fetus. The benefit of preventing disease in the individual also promotes public health because once immune, she will not serve as a source of contagion for others. The achievement of population immunity through the vaccination of the community slows and may prevent the spread of a communicable disease through the larger population, thereby reducing the risk to individuals from that infectious agent.

Because of these separate but related purposes, vaccinations bring to light the relationship between the ethics of individual care and the ethics of public health. It is important for College Fellows to recognize that they have responsibilities to both the individual patient and the general population. In the vast majority of cases, the goals of promoting individual and public health are aligned.

The traditional clinical ethics with which most health care professionals are familiar focuses on the health and the well-being of the individual patient (4–8). Under this model, respect for autonomy and promotion of the well-being of the individual patient are the focus of medical efforts and, in many cases, might be given precedence over the perceived interests of the population at large (4, 9). In a public health-centered ethical framework, the health of the community would be given priority over that of the individual. The public health framework reflects the ethical theory of utilitarianism, which requires actions that result in the greatest good for the greatest number (10). The need to strike a balance between these two "goods" (ie, a healthy individual who is able exercise her autonomy and a healthy community) is familiar to women's health physicians. They face this issue when considering how to allocate often-limited health care resources to patients or how to reduce risks to sexual partners of patients with sexually transmitted infections to prevent further spread.

In providing vaccines to patients, clinicians must weigh these different sets of interests. Matters can become even more complicated for health care professionals, who must consider their own interests, rights, and responsibilities when presented with the professional expectation of being vaccinated themselves in order to protect patients regardless of whether they personally have objections to or concerns about vaccination. This tension can generate ethical challenges for College Fellows.

Ethical Issues in Allocation of Vaccines

Distribution of Limited Resources

In rare circumstances, vaccine availability can be limited because of increased demand or decreased supply or both. In cases of limited availability, allocation strategies may be developed by health care or regulatory authorities to prioritize vaccine administration to specific subsets of the

population, such as children, pregnant women, or the medically vulnerable. In these circumstances, health care professionals play an important role in communicating the nature and purpose of such protocols to all patients, while simultaneously trying to fulfill their duty to address the health needs of the population as a whole.

Allocation strategies that limit access for certain groups to enhance access for other groups can generate conflict for patients and clinicians. Strategies to allocate limited resources typically involve some agreed upon basis for prioritization. At their foundation, these strategies are intended to protect more medically vulnerable members of the population, such as the elderly, pregnant women and their fetuses, and children, while also creating structures to maximize overall benefit for the community (such as the vaccination of health care workers and other key workers to minimize risk of dissemination and to protect the public infrastructure). Consistent with this approach, priorities are established that reduce the morbidity and mortality resulting from the spread of the infectious agent through the general population. In doing so, these plans should be designed not to exaggerate disparities among diverse populations that may already face barriers to health care. A recent Committee Opinion addresses ethical concerns of vaccine allocation in the context of a pandemic and examines strategies that include the priority typically given to pregnant women (3).

It is critical that health care professionals understand and comply with guidelines and recommendations regarding vaccination administration and allocation promulgated by local or regional health care jurisdictions. This will be particularly important when they encounter patients who are unfamiliar with the principles underlying the recommendation or who perceive the allocation strategies as unjust or discriminatory. College Fellows should be prepared to explain to patients the importance of and the rationale for allocation mechanisms while continuing to address their patients' health care needs through alternative strategies other than vaccination. College Fellows also should be willing to provide professional expert advice to local public health jurisdictions in determining allocation and distribution guidelines.

Health Care Professionals Are Instrumental to Successful Vaccination Strategies

College Fellows can play a key role in successful vaccination strategies both through education and administration of vaccines as indicated. They are obligated to serve their patients' best interests by following authoritative guidance on vaccination for patients and clinicians, where medically appropriate and based on the best available evidence. Despite the recognized importance of vaccinations in preventing illness, barriers remain to the timely and effective vaccination of patients and health care professionals.

One barrier arises as some health care professionals continue to express concern about the safety of vaccines, particularly their use in pregnant women, and allow these concerns to alter their advice to patients. Current available evidence regarding the safety and efficacy of vaccinations should be reviewed and recognized. College Fellows should counsel their pregnant patients about vaccination in an evidence-based manner that allows patients to make an informed decision about the use of these agents in their health care. The CDC reports that no evidence exists of risk to the fetus from vaccinating pregnant women with noninfectious virus or bacterial vaccines or toxoids (11). However, a recent survey demonstrated that the concerns of a subset of obstetrician-gynecologists about vaccine safety and potential liability interfere with compliance with recommendations from the College and the CDC (12). This phenomenon was witnessed during the 2009 H1N1 influenza pandemic, during which some clinicians withheld vaccinations during the first trimester of pregnancy (despite clinical practice guidelines to the contrary) out of concerns for increased risk of teratogenic effects on the fetus (13, 14). This type of practice pattern is ethically problematic because it is counter to evidence-based patient care, a goal that is always important but particularly so among a population that is medically vulnerable during an infectious pandemic. Withholding vaccination or information about vaccinations is unacceptable because it violates the ethical obligations to respect patient autonomy and promote patient safety.

Financial and business concerns may present another barrier to vaccination practices. In a survey of obstetrician-gynecologists, almost one half found the cost and infrastructure needed to stock and administer specific vaccines to be a major challenge; insurance reimbursements were insufficient to outweigh the financial and practical challenges to offering vaccination (15). In another study, obstetrician-gynecologists expressed limited availability of time and resources to provide vaccines as a routine part of care (12). If financial or business concerns limit a physician's ability to provide vaccinations in his or her practice, the physician should provide information about alternative sources for vaccination and, when possible, refer patients to alternative community sources such as state or local health department clinics.

It is important that College Fellows educate themselves about relevant infectious agents and all possible mitigation strategies. It is a physician's ethical responsibility to be knowledgeable about current standards of practice regarding vaccines, including their indications, benefits, and risks. Their clinical practice should incorporate up-to-date evidence-based practices. Health care professionals should actively participate in efforts to develop strategies to address infectious disease control through education and patient access to vaccinations. In these ways, health care professionals can serve the best interests of their patients within the constraints of their practice environment.

Informed Consent and Patients' Decision Making Regarding the Use of Vaccinations

Informed consent is a core component of the ethical clinical relationship (10). As with all forms of medical therapy, informed consent must precede vaccination administration. In the informed consent discussion, health care professionals must discuss information central to the decision-making process for vaccination, including the indications, risks, and benefits of the vaccine and available alternatives, as well as possible consequences from nonvaccination (16). Data to inform these discussions are available to both health care professionals and the general public through Vaccine Information Statements found on the CDC's web site (<http://www.cdc.gov/vaccines/pubs/vis>). Federal law requires that a Vaccine Information Statement be given to patients (or their parents or guardians) before each dose of certain vaccines.

Because some vaccines are developed in the midst of an emergent infectious event, patients may raise questions about long-term consequences of an urgently developed vaccine. These questions should be integrated into the decision-making process, with the clinician listening to the patient's concerns and recognizing that information evolves over time while also making every reasonable effort to address fears that are not justified by scientific data. In these discussions, clinicians should emphasize the safety and benefit profiles of vaccines as outlined generally in the literature and by their respective professional organizations and national authorities such as the CDC. They should also include a discussion of the distinct benefits and risks as well as uncertainties of the vaccine's use in pregnant women, and the benefits and risks of nonvaccination. As mentioned in the previous section, the CDC reports that no evidence exists of risk to the fetus from vaccinating pregnant women with noninfectious virus or bacterial vaccines or toxoids (11). Recent reports indicate that influenza immunization of pregnant women is highly effective in reducing hospitalization related to influenza-like illness of their infants for up to 6 months of age (17, 18).

In addition, health care professionals should respect patients' informed refusal of vaccinations. For some patients, receiving vaccines conflicts with personal or cultural beliefs (19). For others, the perceived uncertainty of scientific research on vaccine safety hinders their acceptance of clinical recommendations for vaccination, despite the safety profile of vaccines and demonstrated benefit to pregnant patients (13). This issue commonly arises in the context of pregnancy, where research on pregnant women has been more limited than research involving other segments of the population (20). In such cases, health care professionals should counsel patients thoroughly about the risks of nonvaccination for themselves, household members who could be affected, and

the population at large. In cases where vaccination is declined, although termination of the physician-patient relationship is a possible option, it is often counterproductive and disruptive. Instead, College Fellows have the opportunity to put alternative strategies into place to protect the health of the patient and that of the general community. Such strategies include patient education to monitor and manage symptoms at home and behavioral approaches to reduce risk associated with infection and transmission. Although these strategies help to mitigate harms, they continue to be inferior in reducing risk compared to vaccination, and patients who refuse vaccination should be aware of the potential consequences of depending on alternative approaches to infection control.

Another component of patients' decisions regarding infection control and prevention is the possibility of participation in clinical trials for newly developed vaccines. Clinical vaccine research is an important step in the translation of knowledge from the laboratory to patient care. Participation in clinical trials is a choice generally available to many patients as they consider all their health care options, including interventions as part of standard care or clinical research. Although exceptions do exist, pregnant women are typically excluded from initial and some postmarketing stages of drug trials principally out of concern for the possible effects of the drug on the fetus. The ethical and practical consequence of this exclusion is a limitation of information about vaccine safety and efficacy for pregnant women and the fetus (20). The lack of long-term data, in turn, has a direct influence on the quality of care delivered to pregnant women and the ability of patients to make informed decisions about vaccination during pregnancy. Only by developing well-designed trials that safely include pregnant women will the necessary outcomes and safety data become available. Efforts should be made to open research trials to pregnant women, when possible.

Adolescents also seek reproductive and sexual health care, and this brings challenges that must be addressed (21). The vaccination of adolescents poses unique ethical challenges for obstetrician-gynecologists relative to privacy, confidentiality, and informed consent. Because gynecologic practice often includes care for adolescents, College Fellows face a particular set of ethical challenges associated with vaccination intended to promote their sexual health. The recent availability of vaccination for HPV exemplifies the ethical issues associated with providing care to minors; HPV vaccination guidelines recommend that girls and women aged 9–26 years of age be immunized (22, 23). College Fellows should respect the importance of protecting adolescents' access to reproductive health care services, including HPV vaccination, while adhering to local and national professional norms and applicable legal requirements for parental consent or notification.

Traditionally, minors may provide informed assent rather than consent for medical therapies. In contrast

to informed consent, informed assent entails involving young patients in discussions and decisions about their care as appropriate for their developmental stage. This approach respects the developing independence and autonomy of minors by allowing them to be involved in their medical decision making, while acknowledging the need to obtain authorization to treat from their parents or guardians (24). Informed assent from the minor patient before treatment should always be the goal of the health care provider. The adolescent deserves a careful age-appropriate discussion of the benefits and potential risks of any treatment, including vaccination. Careful assessment of the need for treatment and the functional role of the parent in guidance and support for the minor patient facing a health care decision are also required.

With some exceptions, this practice holds true for adolescents seeking vaccinations. In all states, statutes addressing the treatment of minors allow adolescents younger than 18 years access to testing and treatment for sexually transmitted infections (25). Policies regarding adolescents' ability to independently access the HPV vaccine are currently under debate (26, 27). The College remains a strong advocate for respecting adolescents' confidentiality as a way to minimize any barriers in their sexual and reproductive health care (21). It is important that College Fellows familiarize themselves with the laws, regulations, and policies in their jurisdictions, particularly as these guidelines evolve with public and professional discussions.

Vaccination of Health Care Professionals

College Fellows should recognize the personal role that they play in preventing transmission of infectious agents. Because clinicians come into contact with numerous potentially vulnerable patients throughout the day, they may become infected and be sources for transmission of highly contagious diseases. To avoid their own personal contribution to the spread of disease, College Fellows have an ethical obligation to follow recommendations for vaccination themselves and other safety policies put into place by their local or national public health authorities such as the CDC and the College. Any perceived burdens or potential risks to clinicians themselves from vaccination do not supersede their responsibility to limit the spread of potentially harmful infectious disease.

Several perspectives support this ethical imperative that health care professionals be vaccinated when clinically appropriate. First, data demonstrate that vaccination among health care professionals can reduce the spread of infectious disease throughout inpatient and outpatient populations (28). Second, vaccination prevents infectious illness among medical staff, thus minimizing the use of health care resources that could be used for patients and the general population. Third, with the prevention of illness, fewer physicians will be absent because of illness, potentially increasing the number of health care person-

nel available during times of an infectious outbreak (28). Finally, in being compliant with medically appropriate vaccination strategies, health care professionals send an important message to their patients about the benefits of vaccination, which may, in turn, increase their patients' willingness to be vaccinated.

Despite the evidence pointing to the benefit of vaccination, compliance with voluntary vaccination programs for health care professionals has been disappointing. Some of the leading reasons cited for noncompliance were perception of low risk of contracting the infectious agent, diminished perception of the potential severity of an infectious outbreak, fear of adverse events from vaccination, and lack of time and opportunity for vaccination (29, 30). Thus, consideration of mandatory vaccination has emerged in response to poor compliance rates among physicians. Mandatory vaccination of health care professionals may be an ethically justified strategy in cases in which the harm to patients and the general population is believed to outweigh the autonomy of individual physicians (31–35). Mandates should be put in place only if supported by valid data about the efficacy and safety of the vaccine. In addition, public health plans that include mandatory vaccination will be most beneficial if they are developed in cooperation with key stakeholders and consider the needs of individual practitioners, institutions, and communities.

Any such vaccine mandates should include recognized exceptions for medical contraindications as well as an active opt-out mechanism for those physicians who profess conscientious objections to vaccination; however, practitioners should be reminded that there is a high standard applied to the qualification of conscientious objections of those who decline. Trivial justifications may not be recognized.

Those who elect to opt out of vaccination also must recognize the potential harm they are bringing to patients and their local health care environment because of their choice to refuse vaccination. In the case of a live vaccine where the recipient may serve as a possible source of transmission of the agent to pregnant patients or patients with compromised immune systems, the risk of harm to patients might outweigh the benefit based on the patient population being served. In such cases, other strategies should be in place to protect the health of patients should clinicians themselves become ill. Preemptive plans, such as the mandatory use of respiratory masks and other mechanisms including contact precautions to facilitate infection control, will be vital for these individuals and should be developed in conjunction with local infectious disease experts and institutional administrators.

Although clinician vaccination is the best protective strategy for his or her patients, voluntary absenteeism by the clinician in the case of illness is another strategy, albeit less than sufficient to protect patient health. Such a strategy is flawed because it does not protect the patient in the period of asymptomatic infec-

tion. Furthermore, clinicians must also clearly recognize that absenteeism is not an effective alternative to vaccination because it ultimately compromises the care of patients and populations in the setting of a pandemic by removing their services from the environment.

Physicians should recognize that there also may be potential professional consequences for themselves from declining vaccination. For example, loss of employment may result if their employer makes vaccination a condition of employment.

Conclusion

Vaccines continue to play an essential role in the care delivered by College Fellows. Because of their growing importance in the prevention of infectious disease in the individual patient and the larger community, it is vital that College Fellows be prepared to navigate the practical and ethical challenges that come with vaccination. Included in these considerations is the decision for College Fellows to become vaccinated and, if the decision is made to opt out of vaccination, to be cognizant of the potential consequences to themselves and their patients. Health care professionals have an ethical obligation to keep their patients' best interests in mind by following evidence-based guidelines to encourage patients to be vaccinated and to be vaccinated themselves.

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