Integrating Immunizations Into Practice

**ABSTRACT:** Given demonstrated vaccine efficacy, safety, and the large potential for prevention of many infectious diseases among adults, newborns, and pregnant women, obstetrician–gynecologists should embrace immunizations as an integral part of their women’s health care practice. To provide direct examples, evidence-based recommendations for three commonly administered immunizations by practicing obstetrician–gynecologists are discussed: 1) human papillomavirus vaccine, 2) influenza vaccine, and 3) tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine.

Immunization against vaccine-preventable diseases is an essential component of women’s primary and preventive health care. Obstetrician–gynecologists are an important source of information and advice on immunization for adults, adolescents, and pregnant women and can greatly improve their patient’s well-being by continued efforts to augment immunization services in their offices (1). Obstetrician–gynecologists have a tradition of providing preventive care to women. An annual visit provides an excellent opportunity to counsel patients about maintaining a healthy lifestyle and minimizing health risks. The annual health assessment should include screening, evaluation and counseling, and immunizations based on age and risk factors.

**Tips for Office Vaccination Program Success**

Many investigations have addressed successful implementation strategies that are relevant to immunizations indicated for both obstetric and gynecologic patients. Increasingly, since the 2009 H1N1 influenza pandemic and the imperative to immunize pregnant women, studies address successful strategies for immunization of pregnant women. Additionally, evidence-based strategies for increasing immunization among women who are not pregnant in office settings, such as targeted and strategic use of electronic medical records (EMRs), also are receiving attention. The following techniques have been successful in promoting immunization in office settings that are relevant to both obstetric and gynecologic patients. For recommendations on specific immunizations, see the American College of Obstetricians and Gynecologists’ (the College) immunization web site at www.immunizationforwomen.org, the College’s Annual Women’s Health Care web page at www.acog.org/wellwoman, and the Centers for Disease Control and Prevention’s (CDC) vaccines web site at www.cdc.gov/vaccines/.

**Advocate**

- Talk with the patient directly and recommend indicated immunizations. Many studies have shown that a health care provider recommendation for a vaccine is one of the strongest influences on patient acceptance (2). Physician scripts for several immunizations are available on the College’s immunization web site (see Resources).

**Identify**

- Use prompts, paper or electronic, to remind staff and health care providers which patients need to be immunized. Many EMR systems have these prompts available. Alternatively, a sticker or other type of marker can be placed on a paper chart. Electronic medical records have proved useful with reminder systems highlighting the opportunity to immunize when patients are in the office for regularly scheduled appointments.
Educate and Vaccinate

• Designate a vaccine coordinator in the office and identify a backup coordinator who is trained in the event that the designated coordinator is absent. Among other duties, the vaccine coordinator orders the vaccines, receives vaccine deliveries, and ensures the vaccines are stored properly. The vaccine coordinator and the backup coordinator should have knowledge of appropriate billing codes for vaccination services to ensure reimbursement. (For more information about the role of the vaccine coordinator and immunization coding, refer to Resources.) All state health departments have an immunization department with an immunization program manager who is able to help practices. The vaccine coordinator and the backup coordinator should know who to contact at the local or state health department for answers to immunization questions (see Resources for the web site with a complete list of state immunization program managers.)

• Educate office staff about the safety and efficacy of immunizations. Studies have shown that office personnel may express their own uncertainty or lack of knowledge to patients, which can have a detrimental effect on a patient’s willingness to receive a vaccine. In contrast, other studies have shown that a 1-hour education effort for all office staff can markedly increase office immunization rates (3, 4).

• Federal law (National Childhood Vaccine Injury Act of 1986) mandates that all vaccine providers must give patients or their parents or legal representatives the appropriate vaccine information statement (VIS) before administration of each dose of a vaccine. Use vaccine fact sheets to educate patients. Excellent fact sheets are available on the CDC and Immunization Action Coalition web sites. The College has several immunization FAQ tear pads and physician scripts available as well (see Resources). A VIS must be offered for all vaccines recommended by the CDC’s Advisory Committee on Immunization Practices (ACIP) and when using vaccines purchased from the CDC. Vaccine information statements are official documents and are not the same as vaccine fact sheets (see Resources for more information on VISs and where to find them.)

• Immunize office health care providers and staff as recommended. This serves to meet quality criteria for practices and ethical obligations for clinicians, to decrease vaccine-preventable illnesses for health care providers and staff, to provide leadership through example, and to develop an immunization culture in the office.

Integrate

• Institute standing orders so that any indicated vaccines can be administered to patients without an individual physician order (see Resources).

• Health care providers should document that recommended vaccines have been offered, that patients have been educated on indicated immunizations, and that the patient accepted, refused, or obtained her vaccine at an outside facility.

Other strategies that can help provide sustained and improved immunization rates in the future include immunization training in residency programs, assessing immunization knowledge on board examinations or during the annual recertification process, and increasing health care provider awareness of the safety of immunizations and familiarity with the systems in place to report adverse events such as the Vaccine Adverse Event Reporting System. Physicians should be aware that patients are protected by the National Vaccine Injury Compensation Program and if a patient believes that she has been harmed by a vaccine covered by this program she can file a claim to the U.S. Court of Federal Claims. All vaccines discussed in this document are covered by the National Vaccine Injury Compensation Program (5). (Refer to Resources for more information on the National Vaccine Injury Compensation Program.)

Immunization for Nonpregnant Women

Human Papillomavirus Vaccination

Most women’s health care providers are very familiar with human papillomavirus (HPV) vaccines and their potential for disease prevention (6). In 2006, the quadrivalent HPV vaccine was approved by the U.S. Food and Drug Administration (FDA) for use in females aged 9–26 years. Also, ACIP has recommended the initial HPV vaccination of females at ages 11 years or 12 years (7). Depending on the circumstances, the vaccine can be given to females as young as age 9 years and catch-up is recommended in females aged 13 years through 26 years. The College endorses these recommendations (8). In 2009, the bivalent HPV vaccine was approved by the FDA (9). Both vaccines protect against HPV genotypes 16 and 18 with the quadrivalent vaccine adding protection against HPV genotypes 6 and 11. Human papillomavirus genotypes 16 and 18 are associated with 70% of cervical cancer cases, and HPV genotypes 6 and 11 are associated with 90% of genital warts cases. Additionally, both vaccines protect against vulvar, vaginal, anal, and penile dysplasias and cancer that are caused by these HPV genotypes. Both vaccines require three doses over a 6-month period and are most effective in those naive to the virus, so they are targeted toward preadolescent girls. Obstetrician–gynecologists should review the vaccine history with their patients to ensure that the entire series has been completed and administer remaining doses as needed.

Should a woman with dysplasia receive the HPV vaccine? Studies demonstrate that in women who have had prior cervical dysplasia, approximately 50% of future cases...
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Considerations Surrounding Vaccinations in Pregnancy

Vaccination plays an important role for the health of the mother and the baby. There is a benefit for women to be immunized to reduce their chances of morbidity and mortality from vaccine-preventable diseases (16). Before administering a vaccine to a pregnant woman, the prenatal health care provider must know the immunogenic material in the vaccine. Live, attenuated virus vaccines, such as the MMR vaccine or the nasally delivered influenza vaccine, are not recommended in pregnancy. In contrast, vaccines that contain nonviable antigens, virus-like particles, or noninfectious yet immunogenic components of bacteria, such as the tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine and the injectable influenza vaccine, are considered safe during pregnancy. Health care providers and patients should be aware that the reassuring safety data for use of the aforementioned vaccines in pregnancy are compelling, and there is no link to vaccine administration and miscarriage. An added benefit to immunizing during pregnancy is the potential for disease prevention in newborns by way of passive antibody transfer to the fetus. Hence, offering pregnant patients influenza and Tdap vaccines is an avenue to protect newborn infants at a critically vulnerable time and before neonates can be vaccinated. Patients who decline vaccinations indicated during pregnancy should be offered and given postpartum immunization. (For a comprehensive resource on the immunizations indicated during pregnancy, see the CDC’s Guidelines for Immunizing Pregnant Women in Resources.)

A common question for obstetrician–gynecologists is whether immunizations are part of the global fee for prenatal care. Immunizations are not bundled into payments for obstetric care. Reimbursement will depend on the specific payer because not all follow Current Procedural Terminology code guidelines for the global obstetric package content. An additional factor to consider is whether the patient’s plan has coverage for the service. (Refer to Resources for more information on immunization coding for obstetrician–gynecologists.)

Influenza Vaccination

Influenza is a common respiratory infection that affects approximately 10–20% of the population annually and is responsible for significant illness, hospitalization, and death. The Centers for Disease Control and Prevention currently recommends that all persons aged 6 months and older receive the seasonal flu vaccine. Health care providers should inform pregnant women that the flu vaccine protects not only them, but also their newborns. Studies of distant and recent influenza pandemics consistently demonstrate that pregnant women disproportionately can be prevented through vaccination against HPV (10). Use of the HPV vaccine also has been shown to decrease the number of abnormal Pap test results, colposcopies, and procedures for cervical dysplasia diagnosis and treatment (10). Herd immunity has been demonstrated in areas with high coverage of the HPV vaccine. In Australia beginning in 2007, the quadrivalent HPV vaccine was made available on demand and as part of a school-based immunization program. As a result, 80–90% of females have been vaccinated against HPV. With this high coverage rate, herd immunity has already been demonstrated. The number of males presenting with new diagnoses of genital warts has decreased even though females are the population being vaccinated (11, 12). In the United States, where the vaccine is administered on demand in practitioner’s offices, approximately 50% of the female target population has received at least one dose of the vaccine (13).

Because HPV vaccines require three doses, ensuring the patient returns to complete the series can be a challenge for health care providers. Studies of the use of educational and reminder text messaging to parents of adolescents eligible for the HPV vaccination demonstrate favorable patient outcomes and increased uptake of the vaccine (14). Research using text messaging or social media tools to send patient immunization reminders is ongoing, and this health care communication strategy may prove especially appealing to the HPV vaccine target populations. If a vaccine dose is missed, the series should be resumed at the next appointment; revaccination is not necessary.

Current recommendations indicate that the HPV vaccine should not be administered in pregnancy. At present, there are little data on HPV vaccine administration in pregnancy; however, the available safety data from vaccine inadvertently administered during pregnancy are reassuring (15). Although the HPV vaccine is not recommended during pregnancy, it should be noted that it is not a live virus like the measles-mumps-rubella (MMR) vaccine. Live virus vaccines should not be given during pregnancy or immunodeficiency states. It is currently recommended that if a patient becomes pregnant while receiving the vaccine series, the doses should be stopped and not resumed until the pregnancy has ended. It is not necessary to restart the vaccine series. Results of studies confirm the safety of quadrivalent HPV vaccination during lactation.

Other Recommended Vaccinations

For additional information on other recommended vaccines such as herpes zoster (shingles) and pneumococcus, see the College’s Annual Women’s Health Care web page and the CDC’s vaccines web site (refer to Resources). It should be remembered that there are contraindications to immunizations (eg, egg allergy or Guillain-Barré syndrome) that also should be considered before vaccine administration. For additional information see the College’s immunization web site and the CDC’s vaccines web site.
experience severe sequelae, including death, when they contract influenza. Large epidemiologic studies demonstrate that low-risk, otherwise healthy pregnant women who contract nonpandemic seasonal influenza also have an increased relative risk of cardiopulmonary events in pregnancy; this risk increases with each trimester (17, 18). In 2004, coverage with the influenza vaccine in pregnant women was less than 15%, and most obstetric health care providers did not administer the vaccine in their offices (19).

In the early months of the 2009 H1N1 pandemic, the increased risk of severe complications and death in pregnant women was clearly demonstrated (20–23). That same year, the influenza vaccine coverage in pregnant women increased to a nationwide level of approximately 50%, a threefold increase from prepandemic rates of approximately 15% (24). During the 2011–2012 influenza season, these rates were sustained at approximately 47% (2).

Health care providers should inform pregnant women that the influenza vaccine protects not only them, but also their newborns. For more than two decades, it has been known that maternal influenza A antibody is transplacentally passed to the fetus and delays or diminishes the severity of influenza in the newborn (25, 26). Several more recent studies including randomized controlled trial data have demonstrated that immunizing pregnant women protects newborns against influenza and reduces hospitalizations for influenza-like illnesses for the first 6 months of the infant’s life (27, 28). This is especially important given the fact that infants younger than 6 months of age currently are not candidates for influenza immunization, thus making maternal immunization the only current mechanism of providing the antibody to the newborn.

Tetanus, Diphtheria, and Pertussis Vaccination

Pertussis (also called whooping cough) is a highly infectious bacterial disease. Adults can develop severe symptoms and sequelae from pertussis, but infants (particularly those younger than 4 months), have increased attack rates (19-fold) as well as heightened risks for serious morbidity that requires hospitalization and mortality (nearly 1% of affected newborns) from the disease. Most of these infants (75%) appear to have been exposed to the disease by family members (29).

In 2006, Tdap was approved by the FDA for use in adolescents and adults. Because infants do not start their vaccination series against these pathogens (by way of the diphtheria and tetanus toxoids and pertussis vaccine) until age 2 months, in 2006, the CDC recommended this vaccine be given to women immediately postpartum and to others who will have close contact with the infant such as family members and caregivers (30). This approach of striving to immunize all who will have close contact with the newborn is referred to as “cocooning.” The College supports this recommendation (31). Recent pertussis epidemics have produced reassuring safety data on the use of Tdap in pregnancy. The safety data, along with the difficulty of implementing the cocooning strategy effectively, the proven paradigm of maternal vaccination for newborn benefit (the demonstration of high transplacental antibody transfer from mother to newborn), and cost-effectiveness evaluations generated the recommendation that Tdap be administered during pregnancy. The ACIP recommends that providers of prenatal care implement a Tdap immunization program for pregnant women (32). Health care personnel should administer a dose of Tdap to pregnant women. For women not previously vaccinated with Tdap, and if Tdap is not administered during pregnancy, Tdap should be administered immediately postpartum to the woman in order to reduce the risk of transmission to the newborn (33). (Refer to Resources for specific recommendations on the ACIP web site.)

There is evolving information on Tdap for women who are not pregnant and the need for revaccination. See the College’s Annual Women’s Health Care web page, the College’s immunization web site, and the CDC’s vaccines web site.

Recommendations

The College has developed numerous resources including a dedicated immunization web site to help equip obstetrician–gynecologists to become routine vaccinators. Increasing provider awareness combined with the many suggestions in this document will work to enhance vaccine uptake. Given demonstrated vaccine efficacy, safety, and the large potential for prevention of many infectious diseases among adults, newborns, and pregnant women, obstetrician–gynecologists should embrace immunizations as an integral part of their women’s health care practice. The College offers the following recommendations:

- Talk with the patient directly and recommend indicated immunizations. Many studies have shown that a health care provider recommendation for a vaccine is one of the strongest influences on patient acceptance.
- Designate a vaccine coordinator in the office and identify a backup coordinator who is trained in the event that the designated coordinator is absent. Among other duties, the vaccine coordinator orders the vaccines, receives vaccine deliveries, and ensures the vaccines are stored properly.
- Federal law (National Childhood Vaccine Injury Act of 1986) mandates that all vaccine providers must give patients or their parents or legal representatives the appropriate vaccine information statement (VIS) before administration of each dose of a vaccine.
- Use prompts, paper or electronic, to remind staff and health care providers which patients need to be immunized. Many EMR systems have these prompts available.
• The ACIP has recommended the initial HPV vaccination of females at ages 11 years or 12 years. Depending on the circumstances, the vaccine can be given to females as young as age 9 years and catch-up is recommended in females aged 13 years through 26 years. The College endorses these recommendations.
• Health care providers should document that recommended vaccines have been offered, that patients have been educated on indicated immunizations, and that the patient accepted, refused, or obtained her vaccine at an outside facility.
• The Centers for Disease Control and Prevention currently recommend that all persons aged 6 months and older receive the seasonal flu vaccine. Health care providers should inform pregnant women that the flu vaccine protects not only them, but also their newborns.
• The ACIP recommends that providers of prenatal care implement a Tdap immunization program for pregnant women. Health care personnel should administer a dose of Tdap to pregnant women.

References
9. FDA licensure of bivalent human papillomavirus vaccine (HPV2, Cervarix) for use in females and updated HPV vaccination recommendations from the Advisory Committee on Immunization Practices (ACIP). Centers for
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(Tdap) in pregnant women and persons who have or anticipate having close contact with an infant aged <12 months—Advisory Committee on Immunization Practices (ACIP), 2011. Centers for Disease Control and Prevention (CDC). MMWR Morb Mortal Wkly Rep 2011;60:1424–6. [PubMed] [Full Text]