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Immunization Guidelines for Pregnant Women

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Abstract
There are many misconceptions among the general public regarding the administration of vaccinations during pregnancy. It is imperative for pharmacists to be current regarding guidelines and updates about recommended vaccines. Data from the Centers for Disease Control and Prevention (CDC) indicate that while some vaccines are highly recommended during pregnancy, others have limited safety data or are contraindicated. As new data emerges on the safety and efficacy of immunizations during pregnancy, pharmacists should continue to review the literature to stay up-to-date on vaccination recommendations. The CDC also has information available for pharmacists and other health care professionals regarding the use of other vaccines during pregnancy, including vaccines for travel, not covered in this article.

Background
Administering adult immunizations has become an important role of the pharmacist. The availability of the pharmacist to the public, including weekends and extended hours, places the pharmacist in a unique position in patient care to have a major impact on reducing vaccine-preventable illnesses and deaths. Healthy People 2020 indicates the significance of this topic, as one of its objectives is to "increase immunization rates and reduce preventable infectious diseases." However, despite progress in this endeavor, it is estimated that approximately 42,000 adults and 300 children in the United States will die each year from vaccine-preventable diseases. Some speculate that one of the reasons the United States has fallen short of the national goal is due to misconceptions the public may have about the safety and efficacy of current vaccines. These misconceptions may be magnified during pregnancy, when special concern is taken for the mother and unborn child. As pharmacists have the opportunity to educate patients about the importance of vaccines, and also may be able to administer certain vaccines per state laws, it is imperative for pharmacists to be up-to-date on the current guidelines about recommended vaccines for pregnant women.

There are a few general principles regarding pregnancy and vaccine safety. First, administering live, attenuated viral or live bacterial vaccines is contraindicated in pregnant women due to the theoretical risk of transmitting to the developing fetus. Second, considerations of risks and benefits to individual patients in the context of general guidelines must be considered (Table 1). If the patient is at a high risk of disease exposure, if an infection could cause harm to the mother or fetus or if the vaccine is unlikely to cause harm the benefits of vaccinating could outweigh the potential risks. Finally, the mother's current and past medical history, including allergy to any component of the vaccine product, must be taken into consideration when determining whether she should receive a specific vaccine.

Recommended Vaccines
Influenza (Inactivated)
It is recommended by the American College of Obstetricians and Gynecologists (ACOG), the U.S. Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) that women who are pregnant during influenza season should receive an inactivated influenza vaccine during any trimester of pregnancy. It is recommended that pregnant women be given the inactivated injectable influenza vaccine instead of the live attenuated influenza vaccine (LAIV) administered as a nasal spray, which is contraindicated during pregnancy.

Tetanus, Diphtheria, and Pertussis (Tdap)
Pertussis is a contagious, respiratory illness, also known as whooping cough, which is caused by the bacteria Bordetella pertussis. According to the CDC, there has been an increase in the number of outbreaks of pertussis in 2012 throughout the United States, with nearly 34,000 cases reported. Of these cases, 16 deaths have occurred, with the majority of these occurring in infants less than three months old. Tetanus is caused by the bacteria Clostridium tetani transmitted through contaminated, punctured, or deep tissue wounds. In the past few years, an average of 29 cases were reported in the United States, with about half of the patients being 50 years of age or older. Most of the cases are due to not receiving the primary vaccine series or not following up with the booster vaccine. The bacteria Corynebacterium diphtheria can be acquired through the nasopharynx or cutaneously. Diphtheria occurrence in the United States has greatly decreased in the past few years and is rare in the United States; however, it continues to be endemic in other parts of the world.
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Currently, the CDC recommends that pregnant women who have not been previously vaccinated with Tdap receive one dose of Tdap preferably later in pregnancy (after 20 weeks gestation) to confer the greatest protection to the newborn. If a Td booster is indicated for a pregnant woman for wound management, and she has not previously received a Tdap vaccine, Tdap should be administered. Recently, the ACIP endorsed a provisional recommendation that all pregnant women, regardless of vaccination history, receive a Tdap dose during the third trimester or post-partum; this recommendation has not yet been fully endorsed by the CDC.12 If a woman does not receive this vaccine during her pregnancy, it is recommended to be given immediately after delivery while still in the health care facility.4 Likewise, it is recommended that close contacts of the newborn (immediate and extended family members and caregivers) receive vaccine at least two weeks before interacting with the infant. Due to the re-emergence of pertussis in the United States, this strategy, known as “cocooning,” is being advocated to reduce transmission to newborns who are too young to receive the vaccine themselves.13

Vaccines That May Be Used In Some Circumstances

Hepatitis A
There are two hepatitis A inactivated vaccines licensed for use in the United States. The safety of these vaccinations during pregnancy has not been completely determined, but the risk could be assumed to be low since it is not a live vaccine.14 Since there is no definitive evidence on the safety of the vaccine, the risk associated with receiving the vaccination should be compared against the risk for hepatitis A in a pregnant woman who may or may not be at a high risk for exposure to the virus.15

Hepatitis B
Hepatitis B virus (HBV) is prevalent worldwide and is responsible for one million deaths per year. There is a higher prevalence in developing countries with limited medical facilities, and it is most common in young adults. The virus can be transmitted perinatally from mother to infant at birth.16 The impact of perinatal transmission is indicated by the fact that approximately 40 percent of infants born to infected mothers in the United States develop chronic HBV. In order to decrease the risk of transmission during birth, preventive measures, such as screening pregnant women for the presence of the hepatitis B surface antigen (HBsAg), can be instituted.17 The presence of HBsAg in serum signifies an infection, and the carrier rates for this antigen are 10 to 15 percent.16 Additional preventive measures include individual case management of women and infants with HBV, immunoprophylaxis given to infants born of infected women, and a continued series of HBV vaccines for the infant.17 Due to perinatal transmission, it is recommended that pregnant women at high risk of contracting HBV receive the hepatitis B vaccine. Women at high risk include those being evaluated or treated for a sexually transmitted infection (STI), those who have had more than one sex partner in the past six months, those using injection drugs and those who have had intercourse with a HBsAg positive partner.4 The vaccine is a recombinant DNA or plasma-derived vaccine, containing noninfectious HBsAg, which is given in three doses via the intramuscular route.16 Limited data infer that fetuses of women who receive the vaccine are at low risk for adverse effects.4

Since the vaccine contains a noninfectious antigen for hepatitis B, the vaccine is not contraindicated for pregnant women. If the mother is immunized, the antibodies may passively transfer to the fetus. A study was conducted to test the efficacy of two different dosing regimens during pregnancy, where the first group received two doses of the vaccine and the second group received three doses. Pregnant women who received the three-dose regimen had statistically significantly higher levels of maternal antibodies. The antibody

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**Table 1. Summary of Immunization Guidelines for Pregnant Women.**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Form</th>
<th>Route</th>
<th>General Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis A</td>
<td>Inactivated</td>
<td>IM</td>
<td>May be used if benefit outweighs risk</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Inactivated</td>
<td>IM</td>
<td>Recommended in some circumstances</td>
</tr>
<tr>
<td>Herpes zoster (shingles)</td>
<td>Live</td>
<td>SC</td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Human papillomavirus (HPV)</td>
<td>Inactivated</td>
<td>IM</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Influenza, trivalent inactivated</td>
<td>Inactivated</td>
<td>IM, ID</td>
<td>Recommended</td>
</tr>
<tr>
<td>Influenza, live attenuated (LAIV)</td>
<td>Live</td>
<td>Nasal spray</td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Measles, mumps, rubella (MMR)</td>
<td>Live</td>
<td>SC</td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Meningococcal conjugate (MCV4)</td>
<td>Inactivated</td>
<td>IM</td>
<td>Inadequate data for recommendation</td>
</tr>
<tr>
<td>Tetanus, diphtheria, pertussis (Tdap)</td>
<td>Inactivated</td>
<td>IM</td>
<td>Recommended</td>
</tr>
<tr>
<td>Varicella</td>
<td>Live</td>
<td>SC</td>
<td>Contraindicated</td>
</tr>
</tbody>
</table>

*IM = intramuscular; ID = intradermal; SC = subcutaneous*
levels in the infants were higher in the three-dose regimen group at the time of birth; the levels declined in the months following delivery. The vaccine did not cause any significant side effects during the study and the immune response was excellent. This study concluded that the hepatitis B vaccine is safe in pregnancy and has high immunogenic results.\(^6\)

**Vaccines That Are Contraindicated/Not Recommended Measles, Mumps and Rubella (MMR)**

Measles, Mumps and Rubella (MMR) is a live, trivalent, attenuated measles, mumps and rubella vaccine. Measles, mumps and rubella are commonly known as childhood diseases that may have some serious and even fatal complications.\(^1\) Measles is a contagious viral infection that most often presents with fever, cough, acute rhinitis, and an erythematous, maculopapular rash.\(^3,19\) Severe side effects often include pneumonia and encephalitis.\(^3\) Mumps is a contagious virus often spread via air droplets, saliva or fomites. It presents with fever, malaise, parotiditis and myalgia.\(^19\) Mumps can lead to further complications including meningoencephalitis and other neurologic complications such as deafness.\(^3\) Rubella, also known as the German measles, can affect children and adults. It often has a mild presentation, but infection during the first trimester can cause serious birth defects, such as congenital rubella syndrome (CRS), which can be cardiac, ophthalmologic, auditory and/or neurologic in nature.\(^19\)

As the MMR vaccine is a live, attenuated vaccine, it is contraindicated during pregnancy.\(^3,4\) Women should be informed to avoid pregnancy for at least 28 days after receiving the MMR vaccination. However, routine pregnancy testing before administering the MMR vaccine is not recommended.\(^4\) A woman who conceives within four weeks of administration of the MMR vaccine should be counseled on the theoretical risk of CRS; receipt of the vaccine should not be the basis to terminate a pregnancy.\(^3,4\) Rubella-susceptible women who are not vaccinated because they may be pregnant should be counseled about the risk of CRS and educated to avoid exposure to rubella; they should be vaccinated as soon as they are no longer pregnant.\(^4\) Pharmacists can educate all women of childbearing potential on the importance of MMR vaccination before pregnancy.

**Herpes Zoster (Zoster)**

The live attenuated vaccine used to prevent shingles is contraindicated for use in pregnant women. Although most women in the age group recommended to receive the zoster vaccine are not likely to bear children due to decreased fertility, it can be beneficial to educate high risk patients. If a woman capable of becoming pregnant receives the vaccine, she should wait 28 days following administration of the zoster vaccine to conceive. If a pregnant woman has inadvertently received the live attenuated vaccine within one month of conception, in most cases, the decision to terminate a pregnancy should not be completely based on the administration of the zoster vaccine during pregnancy.\(^4\)

**Varicella**

The varicella virus causes the highly contagious childhood disease commonly known as chicken-pox. It rarely causes serious complications, but in some cases it can cause encephalitis and pneumonia. Typically, the risk of serious events increases with age.\(^3\)

Since the varicella vaccine contains the live, attenuated varicella zoster virus, it is contraindicated in pregnancy.\(^3,4\) Currently, the effect of the varicella vaccine on the fetus is unknown. Non-pregnant women receiving the vaccination should avoid becoming pregnant for one month after the injection. Women who conceive within four weeks of receipt of the vaccine should be counseled on theoretical risks to the fetus; pregnancy termination based on exposure to the vaccine is not warranted.\(^4\)

If a susceptible pregnant woman is exposed to the varicella virus, administration of the varicella zoster immune globulin (VZIG) should be strongly considered due to a higher risk of severe varicella and complications.\(^4\) According to the CDC guidelines, "Administration of VZIG to these women has not been found to prevent viremia, fetal infection, congenital varicella syndrome or neonatal varicella. Thus, the primary indication for VZIG in pregnant women is to prevent complications of varicella in the mother rather than to protect the fetus."\(^4\)

**Human papillomavirus (HPV)**

About twenty million Americans are currently infected by the human papillomavirus (HPV), and each year 6 million more are infected. The vaccine may help prevent the occurrence of cervical cancer, which affects about 12,000 women in the United States each year. There are two versions of the vaccine available in the United States. The vaccine is given in a three-dose series and is recommended for individuals aged nine to 26 years.\(^20\) The CDC states that the HPV vaccine is not recommended for pregnant women. If a woman discovers she is pregnant between doses of the vaccine, it is preferred that she wait until the end of her pregnancy to receive the next dose; however, no medical interventions are needed.\(^4,21\) A pregnancy test is not required before administration of the HPV vaccine.\(^4\)

**Inadequate data**

**Meningococcal Conjugate (MCV4)**

Meningococcal disease, caused by the pathogen *Neisseria meningitidis*, is one of the leading causes of bacterial meningitis in the United States.\(^22\) *N. meningitidis* is a gram negative diplococcus bacterium that commonly colonizes in the respiratory tract. It is transmitted by air droplets or contact with respiratory tract secretions.\(^23\) Approximately 2400 to 3000 cases occur each year, and it is estimated that 10 to 14 percent of cases are fatal, despite the timely administration of antibiotic therapy.\(^22\) Other serious sequelae include hearing loss, neurologic disorders and the potential for the loss of a limb.\(^23\)

Meningococcal conjugate is a tetravalent meningococcal vaccine containing polysaccharide serogroups A, C, Y, and W-135 conjugated to diphtheria toxoid. It has been approved by the U.S. Food and Drug Administration for active immunization of adolescents and adults 11 to 55 years of age.\(^23\) Routine vaccination is recommended for high-risk individuals.
including, but not limited to, military recruits, patients with anatomic or functional asplenia, patients with terminal complement component deficiencies and college students living in dormitories. However, currently there is no data available on the safety of MCV4 during pregnancy.

### Conclusion

While general guidelines have been presented here, the risks and benefits of administering specific vaccines during pregnancy must be determined for each patient. Table 1 summarizes the general recommendations presented in this article.

Pharmacists can educate patients about the vaccines recommended for use during pregnancy as well as the importance of vaccinating other family members. Pharmacists can also administer specific vaccines per state laws and protocols. Finally, pharmacists can help protect the public’s health by reporting any exposures to vaccines during pregnancy, or any known outcomes to mother or child, to the respective vaccine manufacturers to be recorded in their pregnancy registries. Through education, reporting and provision of services, pharmacists can promote public health and primary prevention.

### References


