



A PHARMACY CONTINUING EDUCATION PROGRAM

W-F Professional Associates, Inc. 400 Lake Cook Rd., Suite 207 Deerfield, IL 60015 847-945-8050

February 2007 "Pharmacist's Perspective on Immunizations" 707-000-07-002-H01



**THIS MONTH**  
*"Immunization  
Update"*

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**The program ID # for this lesson is 707-000-07-002-H01.**

**Pharmacists completing this lesson by February 28, 2010 may receive full credit.**

**To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.**

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**The objectives of this lesson are such that upon completion the participant will be able to:**

1. Describe the 2 mechanisms by which individuals acquire an immune response.
2. Discuss both the pediatric & adult recommended immunization schedules.
3. Explain important characteristics of new vaccines approved in 2006, including the human papilloma virus, rotavirus & herpes zoster vaccines.
4. Discuss adverse effects associated with the administration of vaccines.
5. Describe the main drug interaction concerns involving vaccine administration.

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## INTRODUCTION

Immunization is an essential component of disease prevention for both children and adults. The effectiveness of immunization has been demonstrated by the global eradication of smallpox in 1977 and the elimination of poliomyelitis from the United States in 1991. In addition to the aforementioned successes, morbidity from diphtheria, pertussis, tetanus, measles, mumps, rubella, and *Haemophilus influenzae* type b has dramatically declined since the 20<sup>th</sup> century.

Immunity is defined as protection against a foreign exposure. An immune response may be acquired through 2 distinct mechanisms: **passive or active immunity**. **Passive immunity** is obtained through the transfer of a product produced by an animal or human to another human. Examples of ways to acquire passive immunity include transfusion of blood or blood products or administration of immune globulins such as hepatitis B immunoglobulin (HBIG) or varicella zoster immunoglobulin (VZIG). Passive immunity is not permanent and generally disappears with time over weeks to months. In contrast, **active immunity** refers to the protection that develops after a successful immune response within a host. Active immunity generally results in more permanent immunologic memory. Ways to acquire active immunity include the natural process of infection with a disease and immunization. Immunization results in a similar immunologic response as exposure to disease without subjecting the vaccine recipient to the disease and its complications.

Vaccines contain antigens (i.e. foreign substances) that stimulate an immune response in the host. The antigens in a vaccine may be whole or can be from an attenuated or killed microorganism as well as specific protein constituents of the organism (i.e. recombinant technology). Table 1 provides a classification of vaccines based on virus activation.

**Table 1. Classification of vaccines based on virus.**

Live vaccines (brand name)	Inactivated vaccines (brand name)
Influenza A & B (FluMist)	Tetanus-diphtheria and acellular pertusis (Infanrix, Daptacel, Tripedia)
Measles-mumps-rubella (M-M-R II) (recombinant), & inactivated poliovirus	Diphtheria & tetanus toxoids with acellular pertussis adsorbed, hepatitis B (Pediarix)
Measles (Attenuvax)	Tetanus-Diphtheria with acellular pertussis (Boostrix, Adacel)
Mumps (MumpsVax)	Tetanus-Diphtheria Toxoid (Decavac, generic)
Rubella (Meruvax II)	Tetanus Toxoid (generic)
Varicella (Varivax)	<i>Haemophilus influenzae</i> Type B conjugate (ActHib, HibTITER, PedvaxHIB)
Rotavirus vaccine (RotaTeq)	<i>Haemophilus influenzae</i> Type B conjugate & hepatitis B vaccine (Comvax)
Zoster vaccine (Zostavax)	Human papillomavirus (Gardasil)
	Hepatitis A adult (Havrix, Vaqta)
	Hepatitis A & Hepatitis B (Twinrix)
	Hepatitis B adult (Engerix-B, Recombivax HB)
	Influenza A & B (Fluvirin, Fluzone)
	Meningococcal polysaccharide (Menomune), Meningococcal conjugated (Menactra)
	Pneumococcal 7-valent (Pneumovax)
	Pneumococcal 23-valent (Pneumovax)
	Poliovirus (Ipol)

CE PRN® (ISSN 0199-5006) is owned and published by W-F Professional Associates, Inc.  
400 Lake Cook Road, Suite 207, Deerfield, Illinois 60015.

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CE PRN® is published eleven times per year, monthly, January through November.  
Subscription rate is \$99.00 per year. Second-Class Postage paid at Deerfield, Illinois 60015  
and at additional mailing offices.

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February 2007

This lesson provides an overview of pediatric and adult treatment recommendations for vaccines with a focus on immunizations for influenza and pneumonia; new vaccines approved in 2006 including Gardasil, RotaTeq, and Zostavax; safety concerns; and drug interactions.

### OVERVIEW OF VACCINATION SCHEDULES FOR CHILDREN AND ADULTS

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) establishes recommended immunization schedules for children, adolescents, and adults every year. These recommendations are generally published in the fall or winter; therefore, the most recent immunization schedule recommendations are from 2006. Table 2 summarizes the 2006 childhood and adolescent immunization schedule. According to the ACIP recommendations, combination vaccines may be used when appropriate.

**Table 2. Childhood and adolescent immunization schedule 2006.**

Age	Recommended Vaccines
Birth	- Hep B
1 month	- Hep B (may also be given at 2 months)
2 months	- Hep B (second dose if not given at 1 month)- DTaP- Hib- IPV- PCV
4 months	- Hep B- DTaP- Hib- IPV- PCV
6 months	- DTaP- Hib- PCV- Hep B (4 <sup>th</sup> dose may be given between 6 and 18 months) - IPV (3 <sup>rd</sup> dose may be given between 6 and 18 months)
12 to 18 months	- DTaP (usually given at 15 or 18 months)- Hep B (4 <sup>th</sup> dose if not previously given) - Hib (4 <sup>th</sup> dose at 12 or 15 months)- IPV (3 <sup>rd</sup> dose if not previously given) - MMR (12 or 15 months)- Varicella (12, 15, or 18 months)- PCV- Hep A
24 months	- MPSV4
4 to 6 years	- DTaP- IPV- MMR- Varicella (second dose if not given previously)
11 to 12 years	- Tdap- MCV4
13 to 18 years	- MCV4

Hep B=hepatitis B; DTaP=diphtheria & tetanus toxoid with acellular pertussis; Hib=*Haemophilus influenzae* Type B Conjugate; IPV=inactivated poliovirus; PCV=pneumococcal -7 valent; MMR=measles, mumps & rubella; MPSV4=meningococcal polysaccharide vaccine; MCV4=meningococcal vaccine; Tdap=tetanus toxoids & diphtheria with acellular pertussis.

In addition to the recommendations made in Table 2, the CDC provides further guidance regarding specific pediatric vaccine issues including the following:

- For newborns, the hepatitis B vaccine should be administered as soon as possible after birth. Hepatitis B immune globulin should also be given to babies born to hepatitis B surface antigen positive mothers. Infants born to mothers with unknown status should be administered the hepatitis B vaccine within 12 hours of birth.
- There are currently 3 *Haemophilus influenzae* Type B (Hib) conjugate vaccines licensed for pediatric use as individual products (ActHIB, HibTiter, and PedVaxHIB). Hib is also available in a combination vaccine with hepatitis B known as Comvax. The dose of Hib vaccine and number of shots needed varies by manufacturer.
- The fourth dose of diphtheria and tetanus toxoid with acellular pertussis (DtaP) may be given to children as early as 12 months of age if 6 months have passed since the previous dose.
- The varicella vaccine can be given at any pediatrician visit after age 12 months. If the pediatric patient is 13 years of age or older, 2 doses of varicella vaccine should be administered at an interval of at least

4 weeks.

- The final dose of the pneumococcal vaccine should be given at or after 12 months of age.
- The hepatitis A vaccine should be given to all children at 1 year of age (12 to 23 months). The 2 doses of the hepatitis A vaccine sequence should be administered at least 6 months apart.
- At 24 months of age, there are no required vaccinations; however, the meningococcal vaccine is recommended at this time for children with asplenia, terminal complement deficiencies, and other high-risk conditions.
- The second dose of measles, mumps, and rubella is generally given between the ages of 4 and 6; however, it may be given at any time as long as 4 weeks have passed since the first dose and the series was initiated at or after 12 months of age.
- In addition to these scheduled vaccines, the influenza vaccine is given annually to children 6 months and above, and certain children should receive the pneumococcal 23-valent vaccine based on their concurrent health conditions.

The adult immunization schedule includes far fewer vaccinations than those recommended in the pediatric population. The recommended adult schedule is summarized in Table 3, with corresponding guidance from the CDC.

**Table 3. Adult immunization schedule as of October 2005 to September 2006.**

Age	Recommended Vaccines	Notes
19 to 49 years	- Td  - MMR  - Varicella (for patients without immunity to the virus)	1 tetanus booster dose given every 10 years; this recommendation is likely to change based on interim recommendations for use of Tdap in adults.  An MMR booster is given once during this time period for all patients without evidence of immunity; a second dose may be given for certain patients.  Influenza vaccination may be considered annually for certain patients in this age group.  2 doses of hepatitis A, 3 doses of hepatitis B, and 1 or more doses of meningococcal vaccine are indicated for certain patients age 19 and above.
50 to 64 years	- Influenza	One dose of the influenza vaccine is given every year.
≥65 years	- Influenza - Pneumococcal 23-valent	The pneumococcal vaccine may be given once or twice to high-risk patients age 19 to 64 and is given once after age 65 for all patients.  2 doses of varicella may be indicated for certain patients.  An additional MMR dose is indicated for certain patients 50 years of age or above.  2 doses of hepatitis A, 3 doses of hepatitis B, and 1 or more doses of meningococcal vaccine are indicated for certain patients age 19 and above.

## FOCUS ON VACCINATIONS FOR INFLUENZA AND PNEUMONIA

### Influenza

From 1990 through 1999, influenza has been associated with approximately 36,000 deaths annually. The influenza virus causes disease in all age groups; however, rates of serious infection and death are highest among the elderly, children less than 2 years of age, and individuals with medical conditions that place them at an increased risk for complications from the disease. The primary means of preventing influenza is vaccination, and the ACIP publishes recommendations for the prevention and control of influenza on a yearly basis. An annual influenza vaccine is recommended for the following persons at high risk for influenza-related complications and severe disease, including: children aged 6 to 59 months, pregnant women, persons aged  $\geq$  50 years, and individuals of any age with certain chronic medical conditions such as heart failure, asthma, diabetes, or seizure disorders. In addition, an annual influenza vaccination is recommended for individuals who live with or care for persons at high risk of acquiring the disease including household contacts who have frequent contact with persons at high risk and health care workers.

Currently, there are 2 types of influenza vaccine: a **live attenuated** influenza vaccine (FluMist), and an **inactivated** influenza vaccine (Fluzone; Fluvirin; FLUARIX). The **inactivated** influenza vaccine is more commonly administered to the general population. This vaccine is administered intramuscularly and contains 3 viral strains (2 influenza A and 1 influenza B) that are updated annually. The inactivated influenza vaccines are approved for use in persons aged  $\geq$  6 months (Fluzone),  $\geq$  4 years (Fluvirin), and  $\geq$  18 years (FLUARIX). Generally, the vaccine is administered once annually; however, for children 6 months to less than 9 years of age who are receiving the influenza vaccine for the first time, 2 doses are recommended to be given with a 4 week interval between injections. In contrast to the inactivated influenza vaccines, the **live attenuated** influenza vaccine is administered intranasally (1 spray in each nostril), and is approved for use in healthy persons aged 5 to 49 years. Two doses of the vaccine at an interval of 6 to 10 weeks should be administered to children between 6 months and 9 years of age who have not been previously vaccinated for influenza. Otherwise, the live influenza vaccine is administered once annually.

Patients receiving the inactivated influenza vaccine should be counseled regarding the fact that the inactivated vaccine contains noninfectious killed viruses and cannot cause influenza. The most frequently occurring adverse effect of inactivated influenza vaccine administration is a local reaction including soreness at the injection site. In addition, the inactivated vaccine should not be administered to persons known to have an anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine without initially consulting a physician. The live attenuated influenza vaccine has a much longer list of individuals who should not receive the vaccine including persons  $<$  5 years or  $\geq$  50 years of age, persons with chronic medical conditions, children or adolescents receiving aspirin or other salicylates (due to the association between Reye syndrome and wild-type influenza), persons with a history of Guillain-Barre syndrome, pregnant women, and individuals with a history of hypersensitivity to any of the components of the live vaccine or to eggs.

### Pneumonia

Between 2 and 4 million individuals in the United States develop community-acquired pneumonia, and 600,000 people are hospitalized due to this condition annually. The pneumococcal bacterium (i.e. *Streptococcus pneumoniae*) is responsible for many upper and respiratory tract infections. Currently, there are 2 types of pneumococcal vaccines available that aid in preventing invasive pneumococcal disease – a **pneumococcal polysaccharide vaccine** for adults (Pneumovax) and a **pneumococcal conjugate vaccine** for children (Prennar). Pneumovax is recommended to be administered to all individuals over 65 years of age, individuals with immune deficiencies or those undergoing treatments to suppress the immune system, patients with kidney disease or kidney transplants, patients with problems in the spleen, and alcoholics. In addition, adults with any condition that increases the risk for pneumonia should be vaccinated. Generally, protection lasts for over 6 years in most people, although the protective value of the vaccine may be lost at a faster rate among the elderly. A redose of Pneumovax may be given to high-risk patients (see Table 3). Prennar is recommended to be administered to all children up to age 2. Children up to age 5 who are at risk for pneumonia or complications of influenza, such as children with sickle cell disease, those with immune deficiencies, or those with chronic medical conditions are also candidates for the vaccine. Other children ages 2 to 5 who are

at higher risk for serious pneumococcal infections, children in day care, socially or economically disadvantaged children, and those who have had frequent or complicated acute middle ear infections within the past year should be considered for vaccination with Prevnar as well. Prevnar is given intramuscularly generally in a 4 dose schedule. For previously unvaccinated infants, the first 3 doses of Prevnar are given at approximately 2 month intervals with the initial dose in the series given at 2 months of age, although it may be given to infants as young as 6 weeks of age. The final dose in the 4 dose series should be administered at approximately 12 to 15 months of age, and at least 2 months after the third dose. Older infants and children who are previously unvaccinated and are beyond the age of the routine infant schedule may receive Prevnar; however, the vaccine schedule for these children varies by age at first dose. For children who receive a first dose of Prevnar at 7 to 11 months of age, a total of 3 doses are given. The first 2 doses must be given at least 4 weeks apart with a third dose after the one-year birthday, separated from the second dose by at least 2 months. Between 12 to 23 months of age at first dose, a total of 2 doses are given separated by at least 2 months. Previously unvaccinated children e" 24 months through 9 years of age may be given only 1 dose of Prevnar.

### **NEW VACCINES IN 2006**

Three new vaccines were approved in 2006 including: the **human papillomavirus vaccine** (Gardasil; Merck), **rotavirus vaccine** (RotaTeq; Merck), and **zoster vaccine** (Zostavax; Merck).

#### **Human papillomavirus vaccine (Gardasil)**

Infection due to human papillomavirus (HPV), which causes genital warts and cervical cancer, is a common sexually transmitted disease. Approximately 20 million Americans are believed to be infected with HPV. The CDC believes that 100 types of HPV exist; however, the main causes of cervical cancer in the United States are HPV-16 and HPV-18. These types account for up to 70% of cervical cancer cases.

Gardasil is a recently approved quadrivalent HPV vaccine that targets HPV-16 and HPV-18, as well as 2 additional HPV types, HPV-6 and HPV-11, that are responsible for 80% of cases of genital warts. Clinical data reveal that the HPV vaccine reduces the rate of high-grade cervical lesions or carcinoma, in situ, significantly with efficacy rates at or near 100%. The ACIP has recommended that HPV vaccine should be routine for girls age 11 to 12 years. Additional recommendations allow for vaccination of girls beginning at age 9 and for women age 13 to 26 years. It is preferred that vaccination be initiated prior to a woman becoming sexually active and exposed to HPV; however, sexually active women should still be vaccinated. The HPV vaccine should be administered intramuscularly as 3 separate 0.5 mL doses with the second dose following the initial dose by 2 months and then the last dose administered 6 months after the first dose. Patients should be counseled that the HPV vaccine may not result in protection in all vaccine recipients, that the vaccine is not intended to be used for treatment of active genital warts or cervical cancer, that the HPV vaccine does not protect against disease caused by all HPV types, and that pregnant women are not recommended to receive the HPV vaccine.

#### **Rotavirus**

Rotavirus is a common cause of gastroenteritis in young children and is the leading cause of hospitalization and death due to acute gastroenteritis in infants and young children worldwide. Although increased hand washing and other sanitary measures may help control the spread of the disease, vaccination is the best way to protect against the disease. The first rotavirus vaccine (RotaShield) was withdrawn from the market in 1999 due to its association with intussusception, a rare form of bowel obstruction. The incidence of this complication was estimated to be about 1 in 10,000 patients vaccinated.

Recently, a new rotavirus vaccine has become available in the United States (RotaTeq). This vaccine is an oral, live vaccine consisting of 5 human-bovine reassortant viruses. In a large randomized controlled trial assessing the safety of the new rotavirus vaccine in over 68,000 infants ranging in age from 6 to 12 weeks, 27 confirmed cases of intussusception were found in the year following initial vaccine or placebo administration, and there was no significant difference observed between treatment groups. Overall, the efficacy of the rotavirus vaccine was evaluated in 4,512 infants, and it was determined that the vaccine had 74% efficacy in preventing gastroenteritis of any severity and 98% efficacy in preventing severe gastroenteritis. The new rotavirus vaccine is administered orally in 3 ready-to-use liquid doses. The initial dose of the rotavirus vaccine should be admin-

istered at 6 to 12 weeks of age, with the subsequent doses given at 4 to 10 week intervals. After 32 weeks of age, the third dose should not be administered.

### Zoster Vaccine

Herpes zoster, commonly referred to as shingles, occurs when dormant varicella-zoster virus (in the sensory ganglia) is reactivated. The incidence of herpes zoster is significantly increased with advancing age, as is the severity of the outbreak. The zoster infection itself is characterized by a minor rash; however, after the rash heals, many patients experience severe neuropathic pain known as postherpetic neuralgia. The neuralgia may persist for years and is difficult to manage.

The new zoster vaccine (Zostavax) has been evaluated in over 38,000 adults over age 60 in 1 clinical trial. In this study, vaccination with zoster vaccine was associated with fewer cases of confirmed herpes zoster as compared to placebo (315 vs. 642). In addition, vaccination was associated with significantly fewer reports of postherpetic neuralgia, and the median duration of pain and discomfort of the neuralgia, if it developed, was significantly less for zoster vaccine recipients as compared to placebo (21 vs. 24 days). The zoster vaccine was well tolerated. Adverse reactions that occurred at a significantly higher frequency among the treatment group were reactions at the injection site such as varicella-like rash, erythema, pain/tenderness, swelling, pruritus, and warmth. There was no difference between the groups in terms of death.

Zostavax is a live attenuated vaccine that is administered subcutaneously as a single dose. Recently, the ACIP voted to unanimously recommend that adults 60 years of age and older be vaccinated with the zoster vaccine in order to prevent the occurrence of shingles. The zoster vaccine is contraindicated in patients with immunodeficiency disorders, those with active untreated tuberculosis, patients receiving immunosuppressant therapy, and women who are or may be pregnant.

### ADVERSE EVENTS

Overall, vaccination is regarded as a safe and effective process for prevention of infectious diseases. Fever and injection site reactions (pain, erythema, and edema) are the most commonly reported side effects with vaccination. These reactions are short-lived and generally alleviated by use of acetaminophen. Malaise is also commonly experienced. More serious adverse reactions such as seizures are very rare, and the CDC states that it is difficult to calculate an incidence due to the lack of events. Adverse reactions associated with particular vaccines are summarized in Table 4; effects listed as rare are those with association to the vaccine.

**Table 4. Adverse events associated with specific vaccines.**

Vaccine	Adverse events	Rare adverse effects
DTaP	<ul style="list-style-type: none"> <li>• Fever</li> <li>• Injection site reaction</li> <li>• Diarrhea</li> <li>• Vomiting</li> </ul>	<ul style="list-style-type: none"> <li>• Rash</li> </ul>
Hib	<ul style="list-style-type: none"> <li>• Fever</li> <li>• Injection site reactions</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Hepatitis A	<ul style="list-style-type: none"> <li>• Injection site reactions</li> <li>• Headache</li> <li>• Fever</li> </ul>	<ul style="list-style-type: none"> <li>• Allergic reactions</li> </ul>
Hepatitis B	<ul style="list-style-type: none"> <li>• Injection site reactions</li> <li>• Fever</li> </ul>	<ul style="list-style-type: none"> <li>• Stevens-Johnson syndrome</li> <li>• Neurologic effects</li> </ul>
Influenza vaccine	<ul style="list-style-type: none"> <li>• Fever</li> <li>• Tenderness at the site</li> <li>• Flu-like syndrome</li> </ul>	<ul style="list-style-type: none"> <li>• Anaphylaxis</li> </ul>

Vaccine	Adverse events	Rare adverse effects
Influenza (intranasal)	<ul style="list-style-type: none"> <li>• Runny nose</li> <li>• Congestion</li> <li>• Cough</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
MMR	<ul style="list-style-type: none"> <li>• Fever</li> <li>• Rash</li> <li>• Swollen lymph nodes</li> </ul>	<ul style="list-style-type: none"> <li>• Anaphylaxis</li> <li>• Seizures</li> <li>• Encephalitis</li> </ul>
Meningococcal	<ul style="list-style-type: none"> <li>• Localized erythema</li> <li>• Fever</li> <li>• Injection site reactions</li> <li>• Headache</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Pneumococcal 7-valent	<ul style="list-style-type: none"> <li>• Injection site reactions</li> <li>• Fever</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Pneumococcal 23-valent thrombocytopenic	<ul style="list-style-type: none"> <li>• Injection site reactions</li> <li>• Fever</li> </ul>	<ul style="list-style-type: none"> <li>• Relapse of previously stable immune purpura</li> </ul>
Poliovirus	<ul style="list-style-type: none"> <li>• Injection site reactions</li> <li>• Fever</li> <li>• Irritability</li> <li>• Sleepiness</li> <li>• Fussiness/crying</li> </ul>	<ul style="list-style-type: none"> <li>• No cases of paralysis since movement to the inactivated poliovirus</li> </ul>
HPV	<ul style="list-style-type: none"> <li>• Injection site reactions</li> <li>• Fever</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Rotavirus	<ul style="list-style-type: none"> <li>• Fever</li> <li>• Gastroenteritis</li> </ul>	<ul style="list-style-type: none"> <li>• Intussusception (occurred at a similar rate in the placebo group)</li> </ul>
Tdap	<ul style="list-style-type: none"> <li>• Injection site reactions</li> <li>• Headache</li> <li>• Fatigue</li> <li>• Fever</li> </ul>	<ul style="list-style-type: none"> <li>• Anaphylaxis</li> <li>• Guillain Barre syndrome (causal relationship)</li> </ul>
Varicella	<ul style="list-style-type: none"> <li>• Injection site reactions</li> <li>• Fever</li> </ul>	<ul style="list-style-type: none"> <li>• Rash (Chickenpox-like)</li> </ul>
Zoster vaccine	<ul style="list-style-type: none"> <li>• Injection site reactions</li> <li>• Headache</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

DTaP=diphtheria & tetanus toxoid with acellular pertussis; Hib=*Haemophilus influenzae* Type B Conjugate; IPV=inactivated poliovirus; PCV=pneumococcal -7 valent; MMR=measles, mumps & rubella; Tdap=tetanus toxoids & diphtheria with acellular pertussis.

The CDC recognizes a public fear of immunization in terms of vaccine relationship to development of autism. One major concern has been the potential link of the MMR vaccine to autism. This concern was recognized in 1998 with the publication of an article describing chronic enterocolitis in 12 children with autism. The authors of the publication suggested that the children's developmental disorders were temporally associated with use of the MMR vaccine; however, they later stated that they did not establish a causal link between

the vaccine and autism and retracted the "interpretation on the findings".

Subsequent to that initial paper, several articles involving substantially more subjects (approximately 548,000) have failed to find a causal relationship. The CDC and other expert groups now conclude that current scientific evidence does not support a link between MMR and autism.

Another common concern with vaccines is the preservative thimerosal, an ethylmercury preservative. Thimerosal has been used as a preservative in vaccines since the 1930s; however, in 1997 the Food and Drug Administration (FDA) began to review the risk of all mercury containing food and drugs as part of the FDA Modernization Act of 1997. Although no evidence of serious harm was found due to vaccination with thimerosal-containing vaccines, FDA concluded that the content in vaccines may result in an intake of mercury that exceeds recommended levels during a child's first 6 months of life. Notably, the amount would have exceeded Environmental Protection Agency limits, but not FDA or World Health Organization guidelines. The guidelines pertain to methylmercury (an environmental contaminant).

Based on the FDA findings, the Public Health Service agencies (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers agreed to reduce or eliminate thimerosal levels in vaccines. This was done as a precautionary measure in 1999, and thimerosal has been eliminated from routine childhood vaccinations with the exception of some influenza vaccines. Worldwide thimerosal-containing vaccines are still used especially in developing countries. Experts agree that protection from vaccine-preventable disease far outweighs any potential risks from thimerosal exposure.

### DRUG INTERACTIONS

The main drug interaction concern with vaccines involves immunosuppressive therapy. Immune response to vaccination may be insufficient in patients receiving immunosuppressant drugs such as high-dose corticosteroids (for example 20 mg/day or 2 mg/kg/day of prednisone) or radiation therapy. It is advisable to separate the administration of live vaccines and immune globulins or blood products in order to avoid inactivation of the vaccine. In general, live vaccines may be given 14 to 30 days before, or 6 to 8 weeks after administration of such products.

The majority of commercially available vaccines can be given simultaneously at separate injection sites. This includes measles-mumps-rubella, inactivated polio, hepatitis B, diphtheria-tetanus-pertussis, *Haemophilus influenzae* Type B, varicella, and influenza. Data reveal that the immunogenicity of the vaccines is not harmed by concurrent administration.

Less data are available for the newly approved vaccines. The HPV vaccine may be given at the same time as hepatitis B, but data on concurrent administration with other vaccines are not available. Rotavirus vaccine may be given with hepatitis B, pneumococcal conjugate, *Haemophilus influenzae* Type B, and inactivated polio vaccines. Rotavirus vaccine has also been given concurrently with diphtheria and tetanus toxoids combined with acellular pertussis, and does not affect the immunogenicity of tetanus and diphtheria antigens; however, validation of the pertussis assays is still under review. No data are available regarding the simultaneous use of zoster vaccine with other vaccines.

### SUMMARY

The CDC and ACIP recommend immunization schedules for children, adolescents, and adults on an annual basis. Pharmacists should remain current on changes made to the yearly immunization schedules. In addition, pharmacists need to remain informed about new vaccine approvals such as Zostavax, Gardasil, and RotaTeq in order to counsel patients effectively regarding their appropriate use. The safety of routine vaccination is undeniable, and pharmacists need to allay unfounded fears among the general population in order to maximize the benefits of immunization.

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Fill in the information below, answer questions and return **Quiz Only** for certification of participation to:  
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CHECK IF NEW ADDRESS  **ARE YOU LICENSED IN FLORIDA? IF YES FL LIC** \_\_\_\_\_

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**LESSON EVALUATION**

Please fill-out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

- |  |     |    |
|--|-----|----|
| Describe the 2 mechanisms by which individuals acquire an immune response    | Yes | No |
| Discuss both pediatric & adult recommended immunization schedules            | Yes | No |
| Explain important characteristics of new vaccines approved in 2006           | Yes | No |
| Discuss adverse effects associated with administration of vaccines           | Yes | No |
| Describe the main drug interaction concerns involving vaccine administration | Yes | No |

2. Was the program independent & non-commercial?

- |  |      |   |   |         |   |     |                |
|--|------|---|---|---------|---|-----|----------------|
|  | Poor |   |   | Average |   | Yes | No             |
|  | 1    | 2 | 3 | 4       | 5 | 6   | Excellent<br>7 |

3. Relevance of topic to your practice

4. What did you like most about this lesson? \_\_\_\_\_

5. What did you like least about this lesson? \_\_\_\_\_

(WATCH OUR WEBSITE FOR RESULTS OF PARTICIPANT EVALUATIONS)

**Quiz—Please Select the Most Correct Answer**

- |  |  |
|--|--|
| <p>1. Transfusion of blood or blood products is an example of a way to acquire immunity.<br/>                 A. True<br/>                 B. False</p> <p>2. Which group is recommended to receive an annual influenza vaccination?<br/>                 A. Pregnant women<br/>                 B. Persons aged <math>\geq 50</math> years<br/>                 C. Children aged 6 to 59 months<br/>                 D. All of these</p> <p>3. To prevent invasive pneumococcal infections, all children up to age 2 should receive:<br/>                 A. Prevnar<br/>                 B. Pneumovax<br/>                 C. MMR<br/>                 D. Fluvirin</p> <p>4. The human papillomavirus vaccine is a treatment for existing cervical cancer.<br/>                 A. True<br/>                 B. False</p> <p>5. Which syndrome has been falsely suspected to be caused by administration of the MMR vaccine?<br/>                 A. Attention deficit hyperactivity disorder<br/>                 B. Mercury poisoning<br/>                 C. Seizure disorders<br/>                 D. Autism</p> | <p>6. Fever &amp; injection site reactions are the most commonly reported side effects with vaccination.<br/>                 A. True<br/>                 B. False</p> <p>7. The main safety concern with administration of Rota Teq is:<br/>                 A. Gastroenteritis<br/>                 B. Intussusception<br/>                 C. Diarrhea<br/>                 D. Irritable bowel syndrome</p> <p>8. The immune response to vaccination may be insufficient in patients receiving immunosuppressive therapy.<br/>                 A. True      B. False</p> <p>9. The Public Health Service agencies, the American Academy of Pediatrics, &amp; vaccine manufacturers have all agreed to reduce or eliminate thimerosal levels in vaccines.<br/>                 A. True      B. False</p> <p>10. The child &amp; adolescent immunization schedule recommends that at 24 months of age there are no required vaccinations; however, the meningococcal vaccine may be administered at this time for certain children.<br/>                 A. True<br/>                 B. False</p> |
|--|--|

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