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PHARMACY CONTINUING EDUCATION FROM WF PROFESSIONAL ASSOCIATES

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## “Review of Common Vaccinations”

March 2014

It is time to update & review vaccinations. This is a topic that you request most often. In this lesson, it is our goal to present the vaccines/inoculations that are most important. This lesson provides 1.25 hours (0.125 CEUs) of credit, and is intended for pharmacists in all practice settings.

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

1. Define “vaccinations.”
2. Define immunity & list the classes.
3. Describe the routes of administration of the various vaccine types.
4. Define “adjuvant” & its role in vaccines.
5. List common side effects associated with vaccines.



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## BACKGROUND

The term immunization is derived from the word *immunis* meaning safe. An immune individual is one who is protected from or not susceptible to diseases or infections caused by pathogens. Such immunity is due to either the development of antibodies in the system as a result of exposure to an antigen or to cell-mediation. Immunization is the act by which a person's system becomes resistant to an infection and prevents occurrence of a disease. The proverb "one ounce of prevention is worth a pound of cure," applies to immunizations.

Immunization and vaccination are among the most cost-effective means of fighting infectious diseases. Recent data shows that for every dollar spent, diphtheria/tetanus/pertussis (DTP) vaccine saves \$29, measles/mumps/rubella (MMR) vaccine saves \$21, trivalent oral poliovirus vaccine (OPV) saves \$6, varicella vaccine saves \$5 and *Haemophilus influenzae* type b (Hib) vaccines save \$2.

It has been estimated that more than 3 million people die worldwide annually due to lack of immunization against infectious diseases. The most prominent are measles, Hib, pertussis and neonatal tetanus. In the last few months, an outbreak of polio in the Middle East occurred among displaced populations whose children had not been vaccinated against this disease. Outbreaks of vaccine-preventable diseases may occur anywhere in the world when immunization is deficient. For various reasons, in 2008-2009 a measles outbreak occurred in Austria, Bosnia and Herzegovina, Belgium, France, Germany, Italy, Poland and Spain.

The World Health Organization (WHO) estimates that 1.5 million preventable deaths occur annually among children under 5 years of age who were not vaccinated against various diseases. This number represents 17% of total worldwide deaths of children who are under 5 years of age. The preventable diseases responsible for these deaths were: rotavirus (30%), pneumococcal disease (32%), Hib (13%), pertussis (13%), measles (8%) and tetanus (4%). In 1950 the following cases and deaths from vaccine-preventable disease were reported in the US: 5,797 cases of diphtheria caused 410 deaths, 486 cases of tetanus caused 336 deaths, 120,718 cases of pertussis caused 1,118 deaths, and 33,300 cases of polio caused 1,904 deaths. In 2014 there were no cases of diphtheria, 9 cases of tetanus, 15,215 cases of pertussis, no polio cases, 212 cases of measles, 370 cases of mumps, 4 cases of rubella and no cases of conjugated rubella syndrome (CRS) were reported. (No death data available relevant to any of these).

## IMMUNITY

Immunity, which is the resistance to infection or disease by a specific pathogen, is of two general types: active and passive.

**Active Immunity:** Active immunity is naturally acquired when a person is exposed to live pathogens and antigens. The body's immune system becomes capable of providing protection from infectious diseases by producing its own antibodies. Ancient Greeks noticed that people who survived the plague did not suffer from the disease during subsequent outbreaks.

An antigen is a live or inactivated substance such as chemicals, bacteria, viruses or pollen capable of producing an immune response. An antibody is a protein molecule (immunoglobulin) produced by the  $\beta$  lymphocytes to help eliminate an antigen. Protection provided by active immunity is permanent. Thus, if a child becomes infected with a disease such as measles, the body's immune system will produce antibodies to destroy the measles virus. If the child recovers from the infection, the next exposure to measles will cause the already present antibodies and the primed immune system to destroy the microorganism

before causing any symptoms of measles. Consequently, a second bout with measles will not occur. Active immunity can also occur as a result of antigenic stimulation by immunization with a vaccine against an infectious disease. Like having the disease, immunization can produce immunity and protection from the disease for many years, often for a lifetime. The prolonged protection produced after immunization is termed immunologic memory. Once an immune system encounters an antigen, cells known as memory  $\beta$ -cells begin to produce antibodies very rapidly and provide the needed protection.

**Passive or Acquired Immunity:** A passively acquired immunity is a process by which the person becomes temporarily immune to an infectious disease without being affected by it. This type of immunity is achieved by transferring (usually by injection) the antibodies from animals or humans to the susceptible individual. The protection provided by passive immunity is usually temporary, lasting for a few weeks or months, after which the treated person will have no immunity to this particular disease. This relatively short lived immunity is due to the gradual degradation of the injected antibodies. Newborn infants acquire passive immunity from their mothers through the transfer of antibodies across the placenta during the last five weeks of pregnancy. The transferred antibodies play an important role in protecting the infant from a number of infectious diseases for up to one year. Another source of antibodies that can be injected, when the need arises, is antitoxin, which is a product produced in animals and contains antibodies against a specific disease. The antibodies are produced in the animal in response to injection of a specific biologic toxin. For example, when tetanus antitoxin is injected into a patient suffering from tetanus, the antitoxin tends to neutralize and counteract the toxin produced by the tetanus bacteria. Antitoxins are used to treat diseases associated with the introduction of toxins into the body such as snake and spider bites. In passive immunity, the types of preparations used to provide protection are:

1. Human immune serum globulin (gamma globulin) administered by injection,
2. Specific immune serum globulin with antibodies for a specific infection such as HBV, and
3. Animal serum and antitoxins.

## VACCINATION

Over two hundred years ago, Edward Jenner observed that milkmaids who acquired cowpox rarely contracted the deadly smallpox. That led him to inoculate a person with cowpox pus. The inoculated person became immune from smallpox. The term *vaccine* was derived from the word *vacca*, Latin for cow.

A vaccine is a suspension of infectious microorganisms, or some part thereof, administered to induce immunity by stimulating the immune system to fight or neutralize invading microorganisms, and thus protection from the infectious disease. Vaccines are administered parenterally, orally, intranasally or intradermally. Vaccines are available in two types: live attenuated vaccine and inactivated vaccine.

**Live Attenuated (Weakened) Vaccine:** Live attenuated vaccine contains living, but weakened viruses or bacteria. These microorganisms are weakened in the laboratory usually by repeated cultivating. When administered to a recipient, live attenuated vaccine must multiply within the body in order to stimulate an immune response and produce antibodies. The dose of a given virus or bacteria usually is large enough to cause an immune response, but not to result

in an infection. Destruction of the live, weakened microorganisms by environmental conditions such as heat and light or interference with their growth in the body can cause the vaccine to become ineffective (vaccination failure). While live attenuated vaccine does not cause an infection, occasionally, it may result in a mild case which would be transient. Patients who suffer from diseases like leukemia or, HIV or those taking anticancer or immunosuppressive drugs, or are under radiotherapy, may experience serious adverse effects including death because of the weakened immune system. These adverse effects may occur due to inability of the immune system to control the growth of the live attenuated microorganisms. Viral, live, attenuated vaccines are available for measles, mumps, rubella, polio, yellow fever and varicella. Bacterial, live, attenuated vaccines are available for typhoid and tuberculosis (BCG).

**Inactivated Vaccine:** Inactivated vaccine consists of infectious microorganisms killed by physical (heat) or chemical means (formalin) after growing in a culture medium. Unlike the live attenuated vaccine, inactivated vaccines neither multiply in the body nor cause infection even in immunodeficient individuals. While attenuated vaccine can stimulate the immune system following one dose, inactivated vaccine may require two or three more doses or periodic injections to boost the antibody titer, which decreases after a certain length of time. Polio, rabies, hepatitis A, pertussis, cholera, plague, and Lyme disease are examples of such inactivated vaccines.

Other vaccines include toxoids, conjugated polysaccharides and polysaccharides. Toxoids are inactivated toxins produced by bacteria such as diphtheria, tetanus, and botulism. The inactivation process is achieved either chemically or by heat treatments. The toxicity is destroyed, but the ability to stimulate the production of antibodies to induce immunity is retained. Conjugated polysaccharides are provided by covalently joining bacterial capsular polysaccharides to a carrier protein such as the outer membrane protein of the microorganism to enhance immunogenicity. Polysaccharide vaccines consist of immunologic particles from the long chains of sugar molecules that are present in the outer coatings of encapsulated bacteria. Polysaccharide vaccines are less potent than conjugated polysaccharide vaccines.

**Adjuvants and Additives:** Adjuvants in vaccines are chemicals included in the formulation to enhance efficacy. This is achieved by stimulating the immune response to a pathogen. As such, adjuvants allow for lesser quantities of the active ingredients in a vaccine and, in some cases, fewer doses. Aluminum hydroxide, mineral oil, and aluminum phosphate are examples. Aluminum salts have been used as adjuvants in the U.S. since the 1930s. The most recently approved adjuvant is monophosphoryl lipid A. In addition, adjuvants stimulate the body to boost the immune response, stabilize the formulation of the vaccine and prevent its breakdown. Thimersol, a mercury compound, was used as a preservative to prevent microbial contamination. However, since the 2000s its use has been limited to influenza childhood vaccine. Gelatin is used in some vaccines as a stabilizer that prevents the active ingredients in the vaccine from degradation during manufacturing, transport and storage. The administration of combined, live, or killed vaccines in a single dose has no detrimental effect on their efficacies and causes no increase in adverse effects. In fact, such combination is advisable as it improves compliance for vaccination. For example, MMR vaccine gave similar results to those when each individual vaccine is administered at different sites on the same day.

Adjuvants included in vaccines are usually considered safe. The quantities of aluminum in a vaccine are very small. In the first six months of life babies receive about 4 mg of aluminum if

they receive all the recommended vaccines. However, during the same period, babies will ingest about 10 mg of aluminum if they are breast-fed, 40 mg if they are fed regular infant formula and up to 120 mg if they are fed soy-based infant formula.

Individuals who are allergic to gelatin should be observed following injection. It has been estimated that only 1 in every 2 million people are allergic to gelatin and may experience allergic reactions.

Formaldehyde is used to inactivate viruses during the manufacture of some viral vaccines (i.e., polio, hepatitis A virus) and bacterial vaccines such as diphtheria and tetanus. Even though the vaccine is purified, small quantities of formaldehyde remain. The typical amount of formaldehyde found in the blood stream of a normal individual is 10 times greater than that found in any vaccine.

There were once concerns that vaccines may have contributed to Sudden Infant Death Syndrome (SIDS). However, the Institute of Medicine (IOM) has not found any evidence to show a relationship.

Syncope (fainting) has occurred in a few cases immediately following vaccination. As a precaution, the Advisory Committee on Immunization Practices (ACIP) recommends that individuals be observed for 15 minutes after vaccination. Prominent among these vaccines are: meningococcal conjugate vaccine, tetanus toxoid, reduced diphtheria toxoid, cellular pertussis vaccine and human papillomavirus.

**Adverse Reactions:** Local reactions such as pain, swelling, and erythema at the site of injection are common and usually occur within hours following injection. They are usually mild in nature, but occasionally, the response is severe. A severe local reaction is termed *Arthus* reaction. Such reactions mostly occur following the use of inactivated vaccines, especially those that contain adjuvants.

Systemic adverse reactions consist of fever, muscle pain, headache, weakness and rash. Such reactions may occur most often following vaccination with live attenuated vaccines which contain living, but weakened microorganisms. The systemic reactions are usually mild and occur after a certain incubation period characteristic of the natural disease.

Allergic reactions such as urticaria, difficulty in breathing, wheezing, coughing and hypotension, may be caused by the antigen itself, or some component of the vaccine such as preservatives and cell culture material. Vaccine propagated in embryonic egg may cause hypersensitivity reactions such as anaphylaxis.

Caution must be maintained regarding vaccinations given to expectant mothers. Live attenuated vaccines usually should be avoided. The exception is polio and yellow fever if the risk of exposure to the disease is high. Vaccination with rubella, measles, mumps and varicella are contraindicated in immunosuppressed persons. Administration of inactivated or live vaccine to breast feeding mothers is normally safe.

**Effectiveness of Vaccines:** The effectiveness of vaccines may diminish or fail to produce the desired effect if: 1) the patient's immune system does not have an adequate level of  $\beta$ -cells to produce antibodies to the vaccine; 2) intake of anti-inflammatory drugs; and, 3) the presence of diseases such as HIV.

## VACCINE-PREVENTABLE INFECTIOUS DISEASES

**Diphtheria** is caused by *Corynebacterium diphtheriae* and affects the respiratory tract. It is very contagious and can be transmitted by contact with saliva, coughing or sneezing. The toxin produced by the microorganism causes fever, swollen glands in the neck, nausea, vomiting and formation of sticky material on the tonsils, pharynx and nasal cavity.

**German Measles (Rubella)** is caused by an RNA virus. Its name is derived from the Latin word *rubellus* meaning reddish, a characteristic of the disease. It was first recognized in Germany in 1814. It is less contagious and severe than measles. It produces a rash similar to measles, but less extensive. Rubella may cause complications during pregnancy in that it may cause fetal defects.

**Haemophilus Influenza type b (Hib)** is a bacterium that affects children under the age of 5 years. It is transmitted through inhalation of contaminated airborne droplets produced as a result of coughing or sneezing.

**Hepatitis A** is infection of the liver caused by Hepatitis A Virus (HAV), which is an enterovirus-like, RNA agent.

**Hepatitis B** (HBV) is responsible for causing acute and chronic hepatitis, cirrhosis and hepatocellular carcinoma. It is caused by a virus that contains antigenic components. It resides in the blood, serous body fluids, saliva and semen. Transmission of the infection occurs following sexual contact or use of contaminated needles.

**Human Papillomavirus** (HPV) is a viral infection which is considered a sexually transmitted disease. It is considered a cause of cervical cancer in women and can cause genital warts in men.

**Influenza** is a highly contagious disease of the respiratory tract which is transmitted primarily through inhalation of contaminated droplets from an infected person as a result of sneezing or coughing. Symptoms include fever, chills, dry cough, headache and sore throat. The infection is seasonal. Trivalent Inactivated Influenza Vaccine (TIV) is given every year, either in the fall or winter.

**Polio (Poliomyelitis)** is an acute contagious viral infection that affects the gray matter of the spinal cord, and may result in paralysis. It is transmitted primarily via the fecal-oral route. Once the virus enters the central nervous system, it may cause destruction of the neurons, leading to muscle weakness and paralysis. Symptoms may include fever, sore throat, fatigue and pain.

**Measles (Rubeola)** is a communicable systemic infection caused by a paramyxovirus. It is encountered primarily in school-age children with outbreaks in winter and spring. It is transmitted via inhalation of infected airborne respiratory droplets. The main symptom is the emergence of a skin rash (Koplik's spots). Other symptoms may include fever, rhinitis, watery eyes, loss of appetite, cough and spots which may appear on the buccal mucosa. Complications of measles include pneumonia, encephalitis, otitis media and diarrhea.

**Meningococcal Disease** is caused by *Neisseria meningitidis* which can spread rapidly leading to illness and death. Children up to 5 years of age and adults between the ages of 15 to 25 are most vulnerable. The microorganisms may cause infection of the fluid and membranes covering the brain and spinal cord. Furthermore, infection in the blood stream (septicemia) may occur.

**Mumps** is an acute, contagious infection caused by a paramyxovirus and characterized by painful inflammation and swelling of the salivary glands, especially the parotids. Other symptoms include fever, muscular aches, chills, headache, anorexia and pain below the ear. It is transmitted through inhalation of infected airborne droplets.

**Pertussis (Whooping Cough)** is caused by the bacterium *Bordetella pertussis* which is transmitted by direct contact with infected respiratory, airborne droplets. Early symptoms resemble those of the common cold. Later on the disease develops into a violent and choking cough with a "whoop" sound. Babies may develop pneumonia, seizures and brain damage.

**Rotavirus** is commonly known as stomach flu, and is a genus of a double-stranded RNA virus. It causes severe gastroenteritis, especially in children. It is estimated that 500,000 children die each year from this virus that was discovered in 1973. Adults are rarely affected. The virus is transmitted by the fecal-oral route.

**Tetanus (lockjaw)** is caused by a bacterium (*Clostridium tetani*) found in the soil. It usually enters the body via a wound. Once in the circulation, the bacteria produce toxins that cause serious and painful spasms and stiffness of all muscles including those of the jaw. Three out of ten people who acquire the disease die from it. Over 250,000 persons worldwide die annually from tetanus.

**Varicella (Chickenpox)** is an acute, highly contagious infection caused by varicella zoster virus (VZV). It is a member of the herpes virus group that also causes herpes zoster (Shingles). The main symptom is itchy, macular eruptions (vesicles) which are preceded by moderate fever, malaise, and headache. The vesicles on the skin eventually burst within a few days and begin to crust. These crusted lesions disappear within 20 days.

## SUMMARY

Immunization is the process which results in enhancing the ability of the body to fight and prevent infectious diseases by fortifying the immune system. This can be acquired naturally following recovery from an infection, through vaccination. Immunization has resulted in a dramatic decrease in the cases of infectious diseases worldwide. In fact, some of the most dreaded diseases are things of the past. To be effective, vaccinations must follow a strict schedule from infancy to adulthood.

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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?  
 Define "vaccinations." YES NO  
 Define immunity & list the classes. YES NO  
 Describe vaccine routes of administration YES NO  
 Define "adjuvant" & its role in vaccines YES NO  
 List common side effects associated with vaccines YES NO

2. Was the program independent & non-commercial YES NO  
 Low Relevance Very Relevant  
 3. Relevance of topic 1 2 3 4 5 6 7  
 4. What did you like most about this lesson? \_\_\_\_\_  
 5. What did you like least about this lesson? \_\_\_\_\_

**Please Mark the Correct Answer(s)**

1. **Which statement is correct about immunization?**  
 A. Process of administering a vaccine  
 B. Can cause an infectious disease  
 C. Occurs due to development of antibodies following exposure to infections  
 D. A & B
2. **Rotavirus:**  
 A. Invades the CNS  
 B. Affects adults more than children  
 C. Causes severe gastroenteritis  
 D. Is transmitted by inhalation of contaminated droplets
3. **Protection provided by passive immunity:**  
 A. Is permanent  
 B. Lasts only 5 years  
 C. Lasts from childhood thru adolescence  
 D. Is temporary, lasting for a few weeks or months
4. **An activated vaccine must be given in at least 5 doses administered periodically**  
 A. True B. False
5. **Which of these is an adjuvant used in vaccine formulation?**  
 A. Formalin B. Aluminum hydroxide  
 C. Fatty acids D. Thimersol
6. **Vaccines propagated in embryonic egg may cause anaphylaxis**  
 A. True B. False
7. **Rubella:**  
 A. Is chicken pox vaccine  
 B. Is another name for German measles  
 C. Symptoms more severe than Rubeola  
 D. Affects only children over 12 y/o
8. **Hepatitis A:**  
 A. Is transmitted via sexual contact  
 B. Is transmitted via food or drinks contaminated with the virus  
 C. Is transmitted by using contaminated needles  
 D. Leads to cancer & active chronic hepatitis
9. **An antibody is:**  
 A. A protein molecule produced by β-lymphocytes  
 B. A killed virus that is injected to prevent allergy  
 C. A component of bacterial cells  
 D. Administered by inhalation for acquiring immunity
10. **Varicella is a member of the herpes virus group.**  
 A. True B. False

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**CE Provider Tracking # with CEBroker.com is 50-3170.**



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