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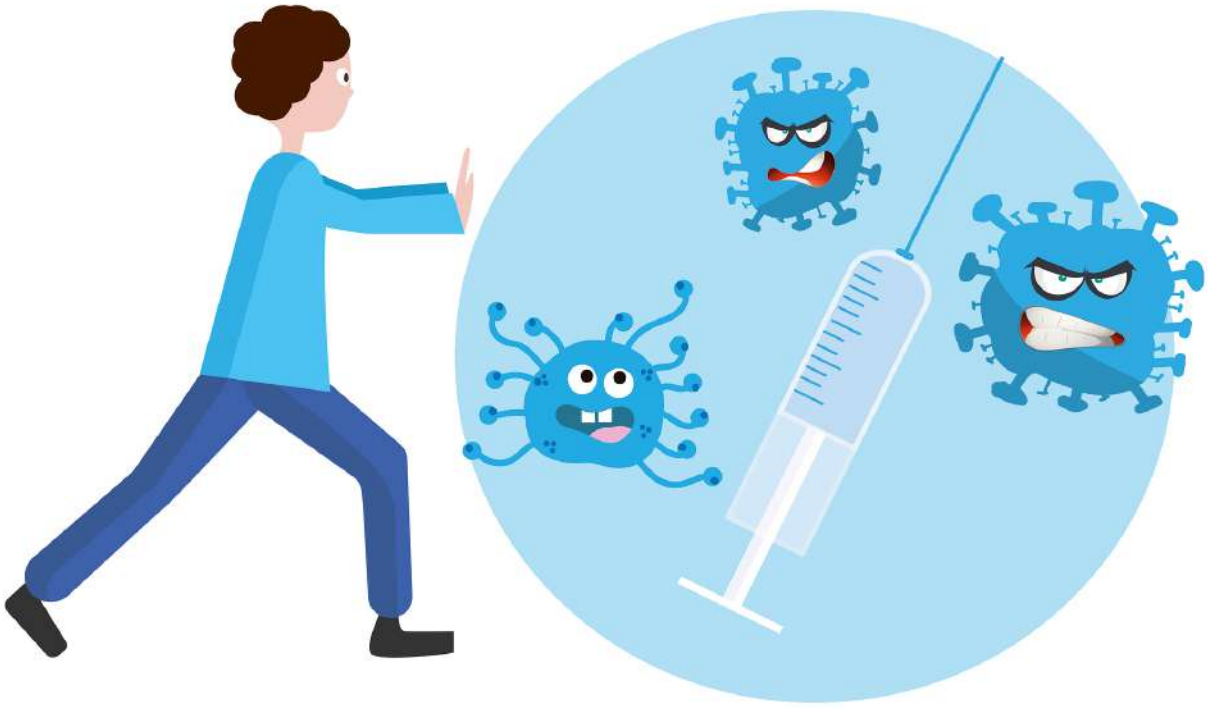
Immunization Schedules and Common Side Effects



Introduction

Vaccines can protect individuals from deadly diseases, and they can help prevent the spread of infectious agents across the planet. Due to the importance of vaccines, health care professionals should ensure patients receive relevant vaccines, while working to optimize the vaccination process. The question is, how can health care professionals ensure patients receive relevant vaccines, while working to optimize the vaccination process? This course will answer that very question, while providing insight into vaccines, vaccine preventable infections/diseases, vaccine schedules, potential vaccine adverse effects, and essential vaccine recommendations.

Section 1: Vaccines and Vaccine Preventable Infections/Diseases

Case Study 1

A 48-year-old male patient reports to a health care facility to receive an influenza vaccine. Upon questioning by a health care professional, the patient reveals that he has an egg allergy. The health care professional then asks the patient to describe what happens to him when he "eats eggs." The patient reports that when he eats eggs, he "sometimes gets a stomach ache." Upon further questioning, the patient also reports that he often avoids eating eggs, but "does eat them on occasion." The patient then asks the health care professionals if he can receive the influenza vaccine.

Case Study 2

A 28-year-old female patient presents to a health care facility for her second dose of the Pfizer-BioNTech COVID-19 vaccine. The health care professional examines the patient's records, and verifies that the patient is due for the second dose of the Pfizer-BioNTech COVID-19 vaccine. The health care professional then asks the patient if she recently experienced any of the following COVID-19 signs/symptoms: fever, chills, cough, shortness of breath, aches and pain, fatigue, headaches, nasal congestion, runny nose, sore throat, nausea, vomiting, and/or diarrhea. The health care professional also asks the patient if she experienced any adverse effects after the first dose of the Pfizer-BioNTech COVID-19 vaccine. The patient responds to both questions by saying "no." The health care professional then informs the patient that she may experience the following effects after the second dose of the Pfizer-BioNTech COVID-19 vaccine: injection-site pain, injection-site swelling, injection-site redness, fatigue, headache, muscle pain, chills,

joint pain, fever, nausea, malaise, and enlargement of lymph nodes. The patient then asks the health care professional about COVID-19 variants, and if she can receive the Moderna COVID-19 vaccine instead of the Pfizer-BioNTech COVID-19 vaccine because she read "it provides protection against all known variants."

The two case studies presented above highlight scenarios involving patient vaccination. When faced with scenarios similar to the ones highlighted in the above case studies, health care professionals should ensure patients receive relevant vaccines, while working to optimize the vaccination process. The question that remains is, how can health care professionals ensure patients receive relevant vaccines, while working to optimize the vaccination process? Health care professionals can ensure patients receive relevant vaccines, while working to optimize the vaccination process by incorporating the three essential elements of patient vaccination into their daily practice. The first of the three essential elements of patient vaccination is to possess insight into vaccines and vaccine preventable infections/diseases. With that in mind, this section of the course will review vaccine-related concepts and vaccine preventable infections/diseases. The information found within this section was derived from materials provided by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) unless, otherwise, specified (Centers for Disease Control and Prevention [CDC], 2021; World Health Organization [WHO], 2021).

What is a vaccine?

A vaccine may refer to a product that stimulates an individual's immune system to produce immunity to a specific infection/disease, protecting the person from that disease (note: immunity may refer to protection from an infectious disease; if an individual is immune to a specific disease, he or she may be exposed to the disease without becoming infected).

What is vaccination?

Vaccination may refer to the act of introducing a vaccine into the body to produce immunity to a specific disease.

Health care professionals should note the following: the terms immunization and vaccination are often used interchangeably; immunization may refer to the process by which an individual becomes protected against a specific disease through vaccination.

How does a vaccine work?

Vaccines work (i.e., provide protection against infectious agents) by introducing an infectious agent into the human body via injection, oral administration, or nasal administration (note: the term infectious agent may refer to an organism that is capable of producing an infection or infectious disease; infectious agents include: bacteria, fungi, viruses, and parasites). Once an infectious agent, such as a virus, is introduced into the human body, via a vaccine, the human body's immune system responds, and, ultimately, builds protection against the infectious agent and related infection. In other words, vaccines work by giving the human body's immune system the tools and ability necessary to prevent infection from infectious agents, such as a virus.

How does the human body's immune system respond, and, ultimately, build protection, against an infectious agent and related infection?

Once a vaccine is administered to an individual, the human body's immune system responds, and, ultimately, builds protection against the infectious agent and related infection by the following three steps:

1. The immune system recognizes the invading infectious agent.
2. The immune system produces antibodies (note: antibodies may refer to proteins produced naturally by the immune system to fight infection and disease).
3. Once antibodies are produced, the immune system develops a "strategy" and "memory" on how to prevent infection from the related infectious agent. If the infectious agent is introduced to the human body and its immune system after vaccination, the human body's immune system uses its previously developed "strategy" and "memory" to eliminate the infectious agent and prevent infection.

The human body's immune system has a form of "recall." Once the immune system "learns" a "strategy" to eliminate an infectious agent and prevent a related infection it commits the "strategy" to "memory" and "recalls" the "strategy" any time the infectious agent is introduced to the human body to provide protection against the infectious agent for years, decades, or a lifetime.

What are the main components of a vaccine?

The main components of a vaccine include: the antigen, adjuvants, antibiotics, preservatives, and stabilizers. Specific information on the aforementioned components of a vaccine may be found below.

- **Antigen** - the antigen component of a vaccine may refer to an infectious agent of foreign substance that induces an immune response, such as the production of antibodies, once in the body; the component of the vaccine that helps provide protection against infectious agents and related infections.
- **Adjuvant** - an adjuvant may refer to a substance that increases and/or modulates the body's immune response to a vaccine; a substance that boosts the immune response to a vaccine; a substance that helps increase the overall effectiveness of a vaccine. Health care professionals should note the following: aluminum and aluminum derivatives are examples of adjuvants.
- **Antibiotics** - some vaccines may contain antibiotics. Health care professionals should note the following: antibiotics may be used in some vaccines to counter the risk of dangerous bacterial infections.
- **Preservatives** - preservatives are included in vaccines to prevent potentially dangerous bacteria or fungal contamination. Health care professionals should note that thimerosal is an example of a preservative that may be found in some vaccines.
- **Stabilizers** - stabilizers are included in vaccines to protect the stability of a vaccine during transportation and storage. Health care professionals should note that gelatin is an example of a preservative that may be found in some vaccines.

What are the two main types of vaccines?

The two main types of vaccines include inactivated vaccines and live-attenuated vaccines. Specific information regarding the aforementioned types of vaccines may be found below. The information found below was derived from materials provided by the U.S. Department of Health and Human Services (U.S. Department of Health and Human Services, 2021).

- **Inactivated vaccines** - inactivated vaccines include the dead version of the infectious agent that causes a specific infection or disease. Inactivated vaccines may require several doses over time (e.g., booster shots) in order for an individual

to obtain ongoing immunity against a specific infection or disease. Health care professionals should note the following: inactivated vaccines may require yearly administration.

- **Live-attenuated vaccines** - live-attenuated vaccines use a weakened or attenuated form of an infectious agent that causes a specific infection or disease. Live-attenuated vaccines are similar to the natural infection they help prevent - therefore, they create a strong and long-lasting immune response (note: one or two doses of live-attenuated vaccines may provide an individual with a lifetime of protection against an infectious agent and the infection or disease it causes). Health care professionals should note the following: live-attenuated vaccines should be used with caution in individuals with weakened immune systems; often live-attenuated vaccines must be kept cool or cold.

Can a vaccine cause an infection?

Vaccines do not cause infections once they are administered to an individual because they, typically, only contain dead or weekend infectious agents.

How are vaccines developed and tested?

Vaccines are typically developed by drug companies and tested via a rigorous process that often involves animal testing and human clinical trials. The human clinical trial process usually involves the following three key phases: phase I, phase II, and phase III. Specific information on the three phases involved in the human clinical trial process may be found below.

- **Phase I** - phase I clinical trials often involve a small number of volunteers who receive the vaccine being tested in order to assess and determine vaccine safety and dose. Phase I clinical trials are also conducted to confirm the vaccine's ability to generate an immune response to an infectious agent.

- **Phase II** - in phase II clinical trials, the vaccine is usually administered to hundreds of volunteers, who are closely monitored for any side effects, to further assess the vaccine's ability to generate an immune response. Health care professionals should note the following: often in phase II clinical trials data is collected on disease outcomes; often participants included in a phase II clinical trial have the same characteristics (e.g., age and sex) as the individuals for whom the vaccine is intended; in phase II clinical trials some participants receive the vaccine and

others do not to allow for comparisons to be made and conclusions drawn about the vaccine being tested.

- **Phase III** - in phase III clinical trials, the vaccine is usually administered to thousands of volunteers. Health care professionals should note the following: in phase III clinical trials data is collected on disease outcomes; in phase III clinical trials some participants receive the vaccine and others do not to allow for comparisons to be made and conclusions drawn about the vaccine being tested; data from both groups is carefully compared to see if the vaccine is safe and effective against the disease it is designed to protect against.

Once the three phases involved in the human clinical trial process are complete, government agencies (e.g., the United States Food and Drug Administration [FDA]) often require additional steps to be completed before a vaccine may be introduced to the general population (note: the aforementioned additional steps may include reviews of efficacy, safety, and manufacturing for regulatory and public health policy approval).

Once a vaccine is introduced to the general population, close monitoring of the vaccine may continue to further determine its effectiveness, and to detect any unexpected adverse effects. Health care professionals should note any new or updated vaccine related information to optimize patient care.

Why should an individual get vaccinated?

Individuals should obtain vaccines to protect themselves and others from infectious agents and resulting infections/diseases.

Health care professionals should note that vaccines can protect individuals and communities from life-threatening infections/diseases.

What infections/diseases can vaccines be used to prevent?

Vaccines can be used to prevent the following infections/diseases:

- Cholera
- Coronavirus disease 2019 (COVID-19)
- Diphtheria
- Hepatitis B

- Human papillomavirus (HPV)/cervical cancer
- Influenza
- Japanese encephalitis (JE)
- Measles
- Meningitis
- Mumps
- Pertussis
- Pneumonia
- Polio
- Rabies
- Rotavirus
- Rubella
- Tetanus
- Typhoid
- Varicella
- Yellow fever

What should health care professionals know about vaccine preventable infections/diseases?

When administering care and vaccines to patients, health care professionals should possess insight into vaccine preventable infections/diseases to optimize patient care. Specific information regarding each, aforementioned, vaccine preventable infection/ disease may be found below.

Cholera

Cholera is an acute diarrhoeal infection caused by the ingestion of food or water contaminated with the bacterium *Vibrio cholerae*. The signs and symptoms of cholera include the following: profuse watery diarrhea (often referred to as “rice-water stools”),

vomiting, thirst, leg cramps, restlessness, and irritability (note: it takes between 12 hours and five days for an individual to show symptoms after ingesting contaminated food and/or water; most individuals affected by cholera do not develop any symptoms, however the bacteria may be present in feces for 1 - 10 days after infection). Risk factors for cholera include living in or traveling to at-risk cholera areas (e.g., contaminated urban areas; urban areas with poor sanitation). Health care professionals should note the following: cholera can affect children and adults; severe cases of cholera require rapid treatment with intravenous fluids and antibiotics; cholera can lead to death if left untreated.

Coronavirus disease 2019 (COVID-19)

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person. It is currently believed that the virus that causes COVID-19 is transmitted or spread through person-to-person contact (note: the term person-to-person contact may refer to the transmission of a communicable disease/illness from a host to a healthy person by way of body fluids (e.g., respiratory droplets; blood); it may be possible for an individual to obtain the COVID-19 virus by touching a surface or an object that has become contaminated with the virus; research suggests that the COVID-19 virus may live on surfaces for up to 28 days; research suggests that the incubation period for COVID-19 is 1 - 14 days). The potential symptoms of COVID-19 include the following: fever, chills, cough, shortness of breath, aches and pain, fatigue, headaches, nasal congestion, runny nose, sore throat, nausea, vomiting, and diarrhea. Risk factors for COVID-19 include: contact with an infected individual, poor hand hygiene, and improper use of a cloth mask or personal protective equipment (PPE) (note: hand hygiene may refer to the process of cleaning hands in order to prevent contamination and/or infections; PPE may refer to equipment designed to protect, shield, and minimize exposure to hazards that may cause serious injury, illness, and/or disease [e.g., facemasks, gowns, goggles, respirators, and gloves]) (CDC, 2018).

Health care professionals should note the following: COVID-19 treatment centers around supportive care; specific medications (e.g., bamlanivimab, casirivimab and imdevimab, remdesivir, and dexamethasone) may be included in COVID-19 treatment regimens to optimize patient care. Specific information regarding bamlanivimab, casirivimab and imdevimab, remdesivir, and dexamethasone may be found below. The information found below was derived from materials provided by the National Institutes of Health (NIH) and the United States Food and Drug Administration (FDA) (National Institutes of Health [NIH], 2021; United States Food and Drug Administration [FDA], 2021).

- **Bamlanivimab** - bamlanivimab is a neutralizing monoclonal antibody. Bamlanivimab targets the receptor-binding domain of the spike protein of the COVID-19 virus. The FDA issued an Emergency Use Authorization (EUA) to make bamlanivimab available for the treatment of nonhospitalized patients with mild to moderate COVID-19 who are at high risk for progressing to severe disease and/or hospitalization. Health care professionals should note the following: bamlanivimab should not be considered the standard of care for the treatment of patients with COVID-19; patients at highest risk for COVID-19 progression should be prioritized for use; bamlanivimab should not be withheld from a pregnant individual who has a condition that poses a high risk of progression to severe COVID-19, and the clinician thinks that the potential benefit of the drug outweighs potential risk. Health care professionals should also note the following: bamlanivimab must be administered by intravenous (IV) infusion; bamlanivimab may only be administered in settings in which health care professionals have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis; the dosage of bamlanivimab in adults and pediatric patients (12 years of age and older weighing at least 40 kg) is 700 mg; serious and unexpected adverse events may occur that have not been previously reported with bamlanivimab use.

- **Casirivimab and imdevimab** - casirivimab and imdevimab are two recombinant human monoclonal antibodies. Casirivimab and imdevimab bind to nonoverlapping epitopes of the spike protein receptor-binding domain (RBD) of the COVID-19 virus. The casirivimab plus imdevimab combination blocks the binding of the RBD to the host cell and may be used in the treatment of COVID-19. The FDA issued an EUA to make the casirivimab plus imdevimab combination available for the treatment of nonhospitalized patients with mild to moderate COVID-19 who are at high risk for progressing to severe disease and/or hospitalization. Health care professionals should note the following: casirivimab plus imdevimab combination should not be considered the standard of care for the treatment of patients with COVID-19; patients at highest risk for COVID-19 progression should be prioritized for use of the drugs through the EUA; casirivimab plus imdevimab should not be withheld from a pregnant individual who has a condition that poses a high risk of progression to severe COVID-19 if the clinician thinks that the potential benefit of the drug combination outweighs potential risk. Health care professionals should also note the following: casirivimab plus imdevimab must be administered together by intravenous (IV) infusion; casirivimab and imdevimab may only be administered in settings in

which health care professionals have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis; the dosage in adults and in pediatric patients (12 years of age and older weighing at least 40 kg) is 1,200 mg of casirivimab and 1,200 mg of imdevimab administered together as a single intravenous infusion over at least 60 minutes; no dosage adjustment is recommended in pregnant or lactating women and in patients with renal impairment; serious and unexpected adverse events may occur that have not been previously reported with casirivimab and imdevimab use.

- **Remdesivir** - remdesivir is an antiviral agent. Remdesivir is currently the only drug approved by the FDA for the treatment of COVID-19. Remdesivir is indicated for treatment of adults and pediatric patients ≥ 12 years old and weighing ≥ 40 kg requiring hospitalization for COVID-19. Health care professionals should note the following: remdesivir is recommended for use in hospitalized patients who require supplemental oxygen; remdesivir is not routinely recommended for patients who require mechanical ventilation; remdesivir should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus. Health care professionals should also note the following: the recommended treatment duration for patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO) is 5 days; the treatment duration may be extended up to five additional days (10 days total) if clinical improvement is not observed; for patients requiring invasive mechanical ventilation and/or ECMO the recommended treatment duration is 10 days; the recommended dose for adults and pediatric patients (≥ 12 years old and weighing ≥ 40 kg) is 200 mg on Day 1, followed by once-daily maintenance doses of 100 mg from Day 2 administered only via intravenous infusion over 30 to 120 minutes; remdesivir is not recommended in individuals with eGFR < 30 mL/min; the potential adverse reactions associated with remdesivir include nausea.

- **Dexamethasone** - dexamethasone is a corticosteroid. Dexamethasone has been found to improve survival in hospitalized patients who require supplemental oxygen, with the greatest effect observed in patients who require mechanical ventilation. Health care professionals should note the following dexamethasone recommendation**:** administer dexamethasone 6 mg per day for up to 10 days for the treatment of COVID-19 in patients who are mechanically ventilated and in patients who require supplemental oxygen but who are not mechanically ventilated.

Diphtheria

Diphtheria is an infection caused by the bacterium *Corynebacterium diphtheriae*. The signs and symptoms of diphtheria include the following: sore throat, mild fever (e.g., 101 degrees or less), chills, and a white or grayish thick coating in the back of the nose or throat (note: the white or thick coating in the back of the nose or throat can impact swallowing and breathing). Risk factors for diphtheria include coming into close contact with an infected individual (note: diphtheria may be transmitted through person-to-person contact) and by poor hand hygiene. Health care professionals should note the following: treatment for diphtheria may include diphtheria antitoxin and antibiotics; if left untreated diphtheria may lead to abnormal heart rhythms, heart failure, paralysis, and death; according to research presented by the CDC, approximately one out of 10 people who get diphtheria dies.

Hepatitis B

Hepatitis B is a viral infection that attacks the liver. Hepatitis B is caused by the hepatitis B virus (HBV). The signs and symptoms of hepatitis B include the following: fatigue, poor appetite, stomach pain, nausea, and jaundice. Risk factors for hepatitis B include: unprotected sex, needle sharing, and syringe sharing (note: HBV may be transmitted through activities that involve percutaneous or mucosal contact with infectious blood or body fluids [e.g., semen and saliva]). Health care professionals should note the following: hepatitis B is often a short-term illness for most individuals; however hepatitis B can become a long-term, chronic infection that can lead to serious, life-threatening health issues like cirrhosis, liver cancer, and/or death.

Human papillomavirus (HPV)/cervical cancer

Human papillomavirus (HPV) is a viral infection of the reproductive tract. HPV is considered to be a sexually transmitted disease (STD) (note: a STD may refer to an infection transmitted through sexual contact). The signs and symptoms of HPV include warts on the genitals or surrounding skin. Risk factors for HPV include unprotected sex and unprotected sex with multiple partners. Health care professionals should note the following: there are more than 100 types of HPV, 14 of which may lead to cancer; HPV may lead to cervical cancer; cervical cancer is the fourth most common cancer among women globally; cervical cancer can be effectively treated if detected early.

Influenza

Influenza, otherwise known as the flu, is a respiratory infection caused by influenza viruses. The signs and symptoms of influenza include the following: fever, cough, headache, muscle and joint pain, severe malaise, sore throat, and a runny nose. Risk factors for influenza include coming into contact with an infected individual. Health care professionals should note the following: there are four types of seasonal influenza viruses, which include: influenza A virus, influenza B virus, influenza C virus, and influenza D virus; influenza A and B viruses typically circulate and cause seasonal influenza epidemics. Health care professionals should also note the following: patients at greater risk of severe disease or influenza related-complications include: pregnant women, children under 59 months, older adults, individuals with chronic medical conditions (e.g., liver or hematologic diseases), and individuals with immunosuppressive conditions (e.g., HIV/AIDS).

Japanese encephalitis (JE)

Japanese encephalitis (JE) may refer to an infection found in Asia and the west Pacific that can cause brain swelling. Japanese encephalitis is caused by the Japanese encephalitis virus. The signs and symptoms of JE include brain swelling with subsequent headaches, high fever, nausea, and disorientation (note: the JE virus is transmitted to humans through the bite of infected Culex species mosquitoes). Risk factors for JE include traveling to Asia and the west Pacific. Health care professionals should note that treatment for JE centers around supportive care.

Measles

Measles is a highly contagious disease caused by a virus. Measles is caused by a virus in the paramyxovirus family and it is normally passed through direct contact and through the air. The signs and symptoms of measles include the following: fever, a runny nose, cough, red and watery eyes, small white spots inside the cheeks, and a rash, which usually develops on the face and upper neck. Risk factors for measles include coming into close contact with an infected individual. Health care professionals should note that the first sign of measles is usually a high fever, which begins about 10 to 12 days after exposure to the related virus.

Meningitis

Meningitis is an inflammation of the protective membranes covering the brain and spinal cord. A bacterial or viral infection of the fluid surrounding the brain and spinal

cord usually causes the swelling. The signs and symptoms of meningitis include the following: a stiff neck, fever, headache, confusion, and drowsiness. Risk factors for meningitis include living in a populated community setting and a compromised immune system. Health care professionals should note that there are different types of meningitis. Health care professionals should also note the following: meningitis caused by bacteria can be deadly and requires immediate health care attention; individuals with viral meningitis, typically, do not require health care; fungal meningitis typically affects individuals with specific conditions (e.g., HIV; cancer).

Mumps

Mumps is a contagious disease that is caused by a virus. The signs and symptoms of mumps include the following: fever, headache, muscle aches, tiredness, loss of appetite, swelling of the salivary glands, and, subsequent, puffy cheeks and a tender, swollen jaw. Risk factors for mumps include prolonged, close contact with infected individuals. Health care professionals should note that mumps related complications include inflammation of the testicles, ovaries, pancreas, and brain.

Pertussis

Pertussis, otherwise known as whooping cough, is a highly contagious respiratory disease. Pertussis, or whooping cough, is caused by the bacterium *Bordetella pertussis*. The signs and symptoms of pertussis include violent coughing, which often makes it hard to breathe. Risk factors for pertussis include coming into contact with an infected individual. Health care professionals should note the following: pertussis can affect individuals of all ages - however, pertussis is very serious and deadly, for babies less than a year old; pertussis treatment may include antibiotics.

Pneumonia

Pneumonia is an infection of the lungs that can cause mild to severe illness in individuals of all ages. Viruses, bacteria, and fungi can cause pneumonia. The signs and symptoms of pneumonia include the following: cough with phlegm or pus, fever, chills, and difficulty breathing. Risk factors for pneumonia include coming into contact with an infected individual and poor hand hygiene. Health care professionals should note the following: community-acquired pneumonia occurs when an individual develops pneumonia in the community and not in a health care facility; health care-associated pneumonia occurs when an individual develops pneumonia during or following a stay in a health care facility; ventilator-associated pneumonia occurs when an individual is affected by pneumonia after being on a ventilator.

Polio

Polio, or poliomyelitis, is a disabling and life-threatening disease caused by the poliovirus. The signs and symptoms of polio include the following: sore throat, fever, tiredness, nausea, headache, stomach pain, paresthesia (note: paresthesia may refer to the feeling of pins and needles in the legs), meningitis, and paralysis. Risk factors for polio include coming into contact with an infected individual and poor hand hygiene (note: the poliovirus can be transmitted through person-to-person contact). Health care professionals should note the following: most individuals who become infected with the poliovirus will not have any visible symptoms; paralysis is the most severe symptom associated with polio, because it may lead to permanent disability and/or death; post-polio syndrome (PPS) may refer to a condition that can affect polio survivors decades after they recover from their initial poliovirus infection.

Rabies

Rabies is a fatal viral disease. Rabies is caused by the rabies virus, which can affect individuals bitten or scratched by a rabid animal. The signs and symptoms of rabies include the following: fever, headache, nausea, vomiting, agitation, anxiety, confusion, and hyperactivity. Risk factors for rabies include being bitten by a wild animal. Health care professionals should note the following: the rabies virus infects the central nervous system; if an individual does not receive the appropriate medical care after a potential rabies exposure, the virus can cause disease in the brain, ultimately resulting in death; treatment for rabies often includes wound care.

Rotavirus

Rotavirus is a disease most common in infants and young children. The signs and symptoms of rotavirus include: watery diarrhea, vomiting, loss of appetite, and dehydration. Risk factors for rotavirus include eating contaminated food and poor hand hygiene. Health care professionals should note the following: rotavirus can lead to dehydration, which, subsequently, may lead to death.

Rubella

Rubella is an acute, contagious viral infection. The signs and symptoms of rubella include: fever, rash, nausea, and mild conjunctivitis. Risk factors for rubella include coming into contact with an infected individual and poor hand hygiene (note: the rubella virus may be transmitted through person-to-person contact). Health care professionals should note the following: rubella virus infection usually causes a mild fever and rash in

children and adults; however, infections during pregnancy, especially during the first trimester, can result in miscarriage, fetal death, stillbirth, or infants with congenital malformations.

Tetanus

Tetanus, otherwise known as lockjaw, is an infection caused by a bacteria called *Clostridium tetani*. When *Clostridium tetani* invades the body, it produces a poison/toxin that causes painful muscle contractions. The signs and symptoms of tetanus include: jaw cramping, sudden, involuntary muscle tightening (i.e., muscle spasms), painful muscle stiffness all over the body, trouble swallowing, seizures, headache, fever, sweating, and changes in blood pressure and heart rate. Risk factors for tetanus include coming into contact with contaminated objects (e.g., stepping on contaminated nails or other sharp objects). Health care professionals should note the following: tetanus treatment may include tetanus immune globulin, antibiotics, and/or wound care.

Typhoid

Typhoid or typhoid fever is a life-threatening illness caused by a type of *Salmonella*. The signs and symptoms of typhoid include: weakness, stomach pain, headache, diarrhea, constipation, loss of appetite, and cough. Risk factors for typhoid include eating food or drinking a beverage that has been touched by an individual who is shedding related *Salmonella*. Health care professionals should note the following: some individuals with typhoid fever may develop a rash consisting of flat, rose-colored spots; typhoid may be treated with antibiotics.

Varicella

Varicella, otherwise known as chickenpox, is a disease caused by the varicella-zoster virus. The signs and symptoms of chickenpox include an itchy, blister-like rash that, often, first appears on the chest, back, and face. Risk factors for varicella include close contact with an individual who has chickenpox. Health care professionals should note that complications from chickenpox include: bacterial infections of the skin and soft tissues, infection of the lungs (e.g., pneumonia), infection or inflammation of the brain (e.g., encephalitis; cerebellar ataxia), hemorrhagic complications, bloodstream infections, and dehydration.

Yellow fever

Yellow fever is an acute viral haemorrhagic disease transmitted by infected mosquitoes (note: the "yellow" in the name refers to the jaundice that affects some infected

individuals). Signs and symptoms of yellow fever include: fever, headache, jaundice, muscle pain, nausea, vomiting, and fatigue. Risk factors for yellow fever include being bitten by an infected mosquito. Health care professionals should note the following: yellow fever may lead to death; treatment for yellow fever may include supportive care and antibiotics for associated infections.

Section 1: Summary

A vaccine may refer to a product that stimulates an individual's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines work (i.e., provide protection against infectious diseases) by introducing an infectious agent into the human body via injection, oral administration, or nasal administration. Once a vaccine is administered to an individual, the human body's immune system responds, and, ultimately, builds protection against the infectious agent and related infection. The main components of a vaccine include: the antigen, adjuvants, antibiotics, preservatives, and stabilizers. The two main types of vaccine include inactivated vaccines and live-attenuated vaccines. Vaccines are typically developed by drug companies and tested via a rigorous process that often involves animal testing and human clinical trials. Individuals should obtain vaccines to protect themselves and others from infectious agents and resulting infections. Vaccines can be used to prevent the following infections/diseases: cholera, COVID-19, diphtheria, hepatitis B, HPV/ cervical cancer, influenza, JE, measles, meningitis, mumps, pertussis, pneumonia, polio, rabies, rotavirus, rubella, tetanus, typhoid, varicella, and yellow fever. Health care professionals should ensure patients receive relevant vaccines.

Section 1: Key Concepts

- The first essential element of patient vaccination is to possess insight into vaccines and vaccine preventable infections/diseases.
- Vaccines work (i.e., provide protection against infectious diseases) by introducing an infectious agent into the human body via injection, oral administration, or nasal administration; vaccines work by giving the human body's immune system the tools and ability needed to prevent infection from infectious agents, such as a virus.
- Once a vaccine is administered to an individual, the human body's immune system responds, and, ultimately, builds protection against the infectious agent and related infection.

- The main components of a vaccine include: the antigen, adjuvants, antibiotics, preservatives, and stabilizers.
- The two main types of vaccine include inactivated vaccines and live-attenuated vaccines.
- Vaccines do not cause infection once they are administered to an individual.
- Vaccines are typically developed by drug companies and tested via a rigorous process that often involves animal testing and human clinical trials; the human clinical trial process usually involves the following three key phases: phase I, phase II, and phase III.
- Individuals should obtain vaccines to protect themselves and others from infectious agents and resulting infections; vaccines can protect individuals and communities from life-threatening infections/diseases.
- Vaccines can be used to prevent the following infections/diseases: cholera, COVID-19, diphtheria, hepatitis B, HPV/cervical cancer, influenza, JE, measles, meningitis, mumps, pertussis, pneumonia, polio, rabies, rotavirus, rubella, tetanus, typhoid, varicella, and yellow fever.
- Health care professionals should possess insight into the vaccine preventable infections/diseases to optimize patient care.

Section 1: Key Terms

Vaccine - a product that stimulates an individual's immune system to produce immunity to a specific infection/disease

Immunity - protection from an infectious disease

Vaccination - the act of introducing a vaccine into the body to produce immunity to a specific disease

Immunization - the process by which an individual becomes protected against a specific disease through vaccination

Infectious agent - an organism that is capable of producing an infection or infectious disease

Antibodies - proteins produced naturally by the immune system to fight infection and disease

Antigen - an infectious agent of foreign substance that induces an immune response, such as the production of antibodies, once in the body

Adjuvant - a substance that increases and/or modulates the body's immune response to a vaccine; a substance that boosts the immune response to a vaccine; a substance that helps increase the overall effectiveness of a vaccine

Cholera - an acute diarrhoeal infection caused by the ingestion of food or water contaminated with the bacterium *Vibrio cholerae*

Coronavirus disease 2019 (COVID-19) - a respiratory illness that can spread from person to person

Person-to-person contact - the transmission of a communicable disease/illness from a host to a healthy person by way of body fluids

Hand hygiene - the process of cleaning hands in order to prevent contamination and/or infections (CDC, 2018)

Personal protective equipment (PPE) - equipment designed to protect, shield, and minimize exposure to hazards that may cause serious injury, illness, and/or disease (CDC, 2018)

Diphtheria - an infection caused by the bacterium *Corynebacterium diphtheriae*

Hepatitis B - a viral infection that attacks the liver

Human papillomavirus (HPV) - a viral infection of the reproductive tract

Sexually transmitted disease (STD) - an infection transmitted through sexual contact

Influenza (otherwise known as the flue) - a respiratory infection caused by influenza viruses

Japanese encephalitis (JE) - an infection found in Asia and the west Pacific that can cause brain swelling

Measles - a highly contagious disease caused by a virus

Meningitis - an inflammation of the protective membranes covering the brain and spinal cord

Mumps - a contagious disease that is caused by a virus

Pertussis (otherwise known as whooping cough) - is a highly contagious respiratory disease

Pneumonia - an infection of the lungs that can cause mild to severe illness in individuals of all ages

Polio (otherwise known as poliomyelitis) - a disabling and life-threatening disease caused by the poliovirus

Paresthesia - the feeling of pins and needles in the legs

Post-polio syndrome (PPS) - a condition that can affect polio survivors decades after they recover from their initial poliovirus infection

Rabies - a fatal viral disease

Rotavirus - a disease most common in infants and young children

Rubella - an acute, contagious viral infection

Tetanus (otherwise known as lockjaw) - an infection caused by a bacteria called *Clostridium tetani*

Typhoid - a life-threatening illness caused by a type of *Salmonella*

Varicella (otherwise known as chickenpox) - a disease caused by the varicella-zoster virus

Yellow fever - an acute viral haemorrhagic disease transmitted by infected mosquitoes

Section 1: Personal Reflection Question

How can insight into vaccines and vaccine preventable infections/diseases help to optimize the vaccination process?

Section 2: Vaccine-Related Information

The second essential element of patient vaccination is to maintain a working knowledge of specific vaccines. Essentially, health care professionals should be familiar with vaccine-related information such as: indication, dose, route of administration, vaccine schedules, storage, contraindications, warnings and precautious, considerations for special patient populations, and other related concepts (note: the term vaccine schedule may refer to a series of vaccinations, including the timing of all vaccine doses; a timeline

for optimal vaccine administration; when an individual should receive a specific vaccine; vaccine schedules may be based on age and/or need). This section of the course will review and highlight vaccine-related information for specific vaccines. The information found below was derived from materials provided by the FDA (FDA, 2021).

Vaxchora

Vaccine notes - Vaxchora is a live oral cholera vaccine indicated for active immunization against disease caused by *Vibrio cholerae* serogroup O1. Vaxchora is approved for use in persons 2 through 64 years of age traveling to cholera-affected areas. Health care professionals should administer Vaxchora a minimum of 10 days before potential exposure to cholera. Health care professionals should instruct recipients to avoid eating or drinking for 60 minutes before and after oral ingestion of vaxchora. Health care professionals should store Vaxchora buffer component and active component packets refrigerated at 36°Fto 46°F(2°Cto 8°C). Vaxchora packets should not be out of refrigerated storage for more than 12 hours prior to reconstitution; when out of refrigerated storage, packets should not be exposed to temperatures above 80°F. The most common adverse reactions associated with vaxchora include: tiredness, headache, abdominal pain, nausea, vomiting, lack of appetite, and diarrhea.

Safety notes - contraindications associated with Vaxchora include the following: severe allergic reaction (e.g., anaphylaxis)to any ingredient of Vaxchora or to a previous dose of any cholera vaccine. Warnings and precautious associated with Vaxchora include the following: the safety and effectiveness of Vaxchora have not been established in immunocompromised individuals; Vaxchora may be shed in the stool of recipients for at least seven days.

Considerations for special patient populations - there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to vaxchora during pregnancy.

Pfizer-BioNTech COVID-19 Vaccine

Vaccine notes - the Pfizer-BioNTech COVID-19 vaccine is indicated for individuals 16 years of age and older. The Pfizer-BioNTech COVID-19 vaccine is provided in a multidose vial, which may include up to six doses per vial. The vaccine must be mixed with diluent before administration (note: after dilution, vials must be stored between 2°C and 25°C and used within six hours of dilution). The recommended dose for the Pfizer-BioNTech COVID-19 vaccine is 0.3 mL. The vaccine should be administered via intramuscular (IM) injection in the deltoid muscle. The vaccine should be administered in a 2-dose series

separated by 21 days (note: individuals should not be scheduled to receive the second dose earlier than recommended; second doses administered within a grace period of four days earlier than the recommended date for the second dose are considered valid; both doses are required). The Pfizer-BioNTech COVID-19 vaccine may be stored in one of the following three options: ultra-cold freezer between -80°C and -60°C (-112°F and -76°F) up to the expiration date; thermal shipping container using a controlant temperature monitoring device (TMD) (note: a temperature monitoring device (TMD) may refer to a measurement instrument that is capable of recording temperature over a defined period of time); refrigerator between 2°C and 8°C (36°F and 46°F) for up to 5 days (120 hours). Health care professionals should open the Pfizer-BioNTech COVID-19 vaccine thermal shipping container no more than twice per day for up to three minutes at a time**.** Vaccination should be offered to individuals regardless of whether they have a history of prior symptomatic or asymptomatic COVID-19 virus infection; vaccination of an individual with a known current COVID-virus infection should be deferred until the individual has recovered from acute illness. The most common adverse reactions associated with the Pfizer-BioNTech COVID-19 vaccine include: injection-site pain, injection-site swelling, injection-site redness, fatigue, headache, muscle pain, chills, joint pain, fever, nausea, malaise, and lymphadenopathy.

Safety notes - contraindications associated with the Pfizer-BioNTech COVID-19 vaccine include: severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components; immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components; immediate allergic reaction of any severity to polysorbate. Warnings and precautious associated with the Pfizer-BioNTech COVID-19 vaccine include the following: moderate or severe acute illness may occur; history of an immediate allergic reaction to any other vaccine or injectable therapy; individuals that receive the Pfizer-BioNTech COVID-19 vaccine should be monitored for the occurrence of immediate adverse reactions; individuals with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and individuals with a history of anaphylaxis due to any cause should be monitored for 30 minutes after vaccination; all other individuals should be monitored for approximately 15 minutes after vaccination.

Considerations for special patient populations - the Pfizer-BioNTech COVID-19 vaccine does not include use in individuals younger than 16 years of age.

Moderna COVID-19 Vaccine

Vaccine notes - the Moderna COVID-19 vaccine is indicated for individuals 18 years of age and older. The Moderna COVID-19 vaccine is provided in a multidose vial, which may include up to 10 doses per vial. The Moderna COVID-19 vaccine should not be mixed with a diluent (note: after the first dose has been withdrawn, Moderna COVID-19 vaccine vials must be stored between 2°C and 25°C (46°F and 77°F) and used within six hours; health care professionals should discard the Moderna COVID-19 vaccine vial when there is not enough vaccine to obtain a complete dose; health care professionals should not combine residual vaccine from multiple vials to obtain a dose). The recommended dose for the Moderna COVID-19 vaccine is 0.5 mL. The Moderna COVID-19 vaccine should be administered via intramuscular (IM) injection in the deltoid muscle. The vaccine should be administered in a 2-dose series separated by 28 days (note: a series started with the Moderna COVID-19 vaccine should be completed with the Moderna COVID-19 vaccine; individuals should not be scheduled to receive the second dose earlier than recommended; second doses administered within a grace period of four days earlier than the recommended date for the second dose are considered valid; both doses are required). The Moderna COVID-19 vaccine may be stored in one of the following two options: in a freezer between -25°C and -15°C (-13°F and 5°F) up to the expiration or beyond use date (BUD); in a refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days prior to its first use. Vaccination should be offered to individuals regardless of whether they have a history of prior symptomatic or asymptomatic COVID-19 virus infection; vaccination of an individual with a known current COVID-virus infection should be deferred until the individual has recovered from acute illness. The most common adverse reactions associated with the Moderna COVID-19 vaccine include: injection-site pain, fatigue, headache, muscle pain, chills, nausea, vomiting, and fever.

Safety notes - contraindications associated with the Moderna COVID-19 vaccine include: severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components; immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components; immediate allergic reaction of any severity to polysorbate. Warnings and precautious associated with the Moderna COVID-19 vaccine include the following: moderate or severe acute illness may occur; history of an immediate allergic reaction to any other vaccine or injectable therapy; individuals that receive the Moderna COVID-19 vaccine should be monitored for the occurrence of immediate adverse reactions; individuals with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and

individuals with a history of anaphylaxis due to any cause should be monitored for 30 minutes after vaccination; all other individuals should be monitored for approximately 15 minutes after vaccination.

Considerations for special patient populations - there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to the Moderna COVID-19 vaccine during pregnancy. The safety and effectiveness of the Moderna COVID-19 vaccine have not been assessed in individuals less than 18 years of age.

The Janssen COVID-19 Vaccine

Vaccine notes - the Janssen COVID-19 vaccine is indicated for individuals 18 years of age and older. The Janssen COVID-19 vaccine is a suspension for intramuscular injection administered as a single dose (0.5mL). Each vial contains five doses. Health care professionals should store unpunctured multi-dose vials of the Janssen COVID-19 vaccine at 2°C to 8°C (36°F to 46°F) (note: protect from light). Health care professionals should not store the Janssen COVID-19 vaccine frozen. The most common adverse reactions associated with the Janssen COVID-19 vaccine include: injection-site pain, injection-site erythema, injection-site swelling, headache, fatigue, myalgia, nausea, and fever.

Safety notes - contraindications associated with the Janssen COVID-19 vaccine include: do not administer the Janssen COVID-19 vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 vaccine. Warnings and precautious associated with the Janssen COVID-19 vaccine include the following: appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 vaccine; individuals that receive the Janssen COVID-19 vaccine should be monitored for the occurrence of immediate adverse reactions.

Considerations for special patient populations - the Janssen COVID-19 vaccine does not include use in individuals younger than 18 years of age.

Diphtheria and Tetanus Toxoid Adsorbed

Vaccine notes - Diphtheria and Tetanus Toxoid Adsorbed is a vaccine indicated for active immunization against diphtheria and tetanus. Diphtheria and Tetanus Toxoids Adsorbed is approved for use in children from six weeks through six years of age. The five dose immunization series consists of an injection administered at 2, 4, 6, 15 - 18 months and

between four and six years of age. Diphtheria and Tetanus Toxoid Adsorbed is supplied in single dose (0.5 mL) vials. Diphtheria and Tetanus Toxoids Adsorbed should be stored at 2° to 8°C (35° to 46° F) (note: do not freeze). The most common adverse reactions associated with Diphtheria and Tetanus Toxoid Adsorbed include: crying, fever, and loss of appetite.

Safety notes - contraindications associated with Diphtheria and Tetanus Toxoid Adsorbed include: severe allergic reaction (e.g., anaphylaxis) after a previous dose of Diphtheria and Tetanus Toxoids Adsorbed or any other diphtheria toxoid or tetanus toxoid-containing vaccine, or any other component of the vaccine. Warnings and precautious associated with Diphtheria and Tetanus Toxoid Adsorbed include the following: if Guillain-Barré syndrome occurred within six weeks of receipt of prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following Diphtheria and Tetanus Toxoids Adsorbed vaccine; apnea following intramuscular vaccination has been observed; syncope has been reported following vaccination.

Considerations for special patient populations - Diphtheria and Tetanus Toxoids Adsorbed is not approved for use in individuals seven years of age and older.

Daptacel

Vaccine notes - Daptacel is a vaccine indicated for active immunization against diphtheria, tetanus, and pertussis as a five dose series in infants and children six weeks through six years of age. The five dose immunization series consists of a 0.5 mL intramuscular injection administered at 2, 4, 6 and 15 - 20 months of age, and at 4 - 6 years of age. Daptacel is supplied in single dose (0.5 mL) vials. Daptacel should be stored at 2° to 8°C (35° to 46°F) (note: do not freeze). The most common adverse reactions associated with Daptacel include: fussiness, irritability, inconsolable crying, and decreased activity/lethargy.

Safety notes - contraindications associated with Daptacel include the following: severe allergic reaction (e.g. anaphylaxis) after a previous dose of any diphtheria toxoid, tetanus toxoid, or pertussis-containing vaccine, or any component of Daptacel; encephalopathy within seven days of a previous pertussis-containing vaccine with no other identifiable cause; progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized. Warnings and precautious associated with Daptacel include the following: if Guillain-Barré syndrome occurred within six weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be

increased following Daptacel; apnea following intramuscular vaccination has been observed; syncope has been reported following vaccination.

Considerations for special patient populations - Daptacel is not approved for use in individuals seven years of age and older.

Engerix-B

Vaccine notes - Engerix-B is a vaccine indicated for immunization against infection caused by all known subtypes of hepatitis B virus. Individuals from birth through 19 years of age should receive a series of three doses (0.5 mL each) on a 0-, 1-, 6-month schedule. Individuals 20 years of age and older should receive a series of three doses (1 mL each) on a 0-, 1-, 6-month schedule. Engerix-B is a sterile suspension available in the following presentations: 0.5-mL (10 mcg) prefilled syringes; 1-mL (20 mcg) single-dose vials and prefilled syringes. Health care professionals should store Engerix-B refrigerated between 2° and 8°C (36° and 46°F) (note: do not freeze). The most common adverse reactions associated with Engerix-B include injection-site soreness and fatigue.

Safety notes - contraindications associated with Engerix-B include the following: severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B-containing vaccine, or to any component of Engerix-B, including yeast. Warnings and precautious associated with Engerix-B include the following: the tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions; temporarily defer vaccination of infants with a birth weight less than 2,000 g born to hepatitis B surface antigen (HBsAg)-negative mothers; apnea following intramuscular vaccination has been observed; syncope has been reported following vaccination.

Considerations for special patient populations - the timing of the first dose in infants weighing less than 2,000 g, at birth, depends on the HBsAg status of the mother.

Gardasil 9

Vaccine notes - Gardasil 9 is a vaccine indicated in girls and women nine through 45 years of age for the prevention of the following diseases: cervical, vulvar, vaginal, anal, oropharyngeal, and other head and neck cancers caused by HPV types 16,18, 31, 33, 45, 52, and 58; genital warts (condyloma acuminata) caused by HPV types 6 and 11. Gardasil 9 is also indicated in boys and men nine through 45 years of age for the prevention of the following diseases: anal, oropharyngeal, and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58; genital warts (condyloma acuminata) caused by HPV types 6 and 11. The recommended dose of Gardasil 9 is 0.5 mL. Gardasil 9 is

provided as a 0.5-mL suspension for injection as a single-dose vial and prefilled syringe. Individuals ages nine through 14 years should receive the 3-dose regimen of Gardasil 9 at 0, 2, 6 months. Individuals ages 15 through 45 years should receive the 3-dose regimen of Gardasil 9 at 0, 2, 6 months. Health care professionals should store Gardasil 9 refrigerated at 2 to 8°C (36 to 46°F) (note: do not freeze). The most common adverse reactions associated with Gardasil 9 include: injection-site pain, injection-site swelling, injection-site erythema, and headache.

Safety notes - contraindications associated with Gardasil 9 include the following: hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or after a previous dose of Gardasil 9. Warnings associated with Gardasil 9 include the following: vaccines may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended; syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination; when syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.

Considerations for special patient populations - there is a pregnancy exposure registry to monitor pregnancy outcomes in women exposed to Gardasil 9 during pregnancy.

Afluria Quadrivalent Influenza Vaccine

Vaccine notes - Afluria Quadrivalent is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Afluria Quadrivalent is approved for use in individuals six months of age and older. The recommended dose for Afluria Quadrivalent is 0.5 mL. Individuals nine years and older should receive one dose. Afluria Quadrivalent is a suspension for injection supplied in the following three presentations: 0.25 mL pre-filled syringe (single dose); 0.5 mL pre-filled syringe (single dose): 5 mL multi-dose vial (0.25 mL or 0.5 mL). Health care professionals should store Afluria Quadrivalent refrigerated at 2 - 8°C (36 - 46°F) (note: do not freeze). The most common adverse reactions associated with Afluria Quadrivalent include: injection-site pain, myalgia, and headache.

Safety notes - contraindications associated with Afluria Quadrivalent include the following: severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine. Warnings and precautious associated with Afluria Quadrivalent include the following: appropriate

medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Considerations for special patient populations - there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Afluria Quadrivalent during pregnancy. The safety and effectiveness of Afluria Quadrivalent in individuals less than six months of age have not been established.

Fluad (Influenza Vaccine, Adjuvanted)

Vaccine notes - Fluad is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. Fluad is approved for use in persons 65 years of age and older. Fluad should be administered as a single 0.5 mL dose via intramuscular injection. Fluad is an injectable emulsion supplied in 0.5 mL single-dose, pre-filled syringes. Fluad should be refrigerated at 2°C to 8°C (36°F to 46°F) (note: protect from light; do not freeze). The most common adverse reactions associated with Fluad include: injection-site pain, fatigue, myalgia, and headache.

Safety notes - contraindications associated with Fluad include the following: severe allergic reaction to any component of the vaccine, including egg protein, or after a previous dose of any influenza vaccine. Warnings and precautious associated with Fluad include the following: if Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give Fluad should be based on careful consideration of the potential benefits and risks.

Considerations for special patient populations - Fluad is not approved for use in persons < 65 years of age.

FluMist Quadrivalent (Influenza Vaccine Live, Intranasal)

Vaccine notes - FluMist is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FluMist Quadrivalent is approved for use in persons 2 through 49 years of age. FluMist is for intranasal administration. The recommended dose of FluMist is 0.2 mL. Individuals 2 years through 8 years of age may receive one or two doses separated by one month. Individuals 9 years through 49 years of age should receive one dose. Each FluMist 0.2mL dose is a suspension supplied in a single-dose pre-filled intranasal sprayer. Health care professionals should store FluMist refrigerated at 2 - 8°C (36 - 46°F) (note: do

not freeze). The most common adverse reactions associated with FluMist include runny nose and nasal congestion.

Safety notes - contraindications associated with FluMist include the following: severe allergic reaction (e.g., anaphylaxis) to any component of FluMist Quadrivalent, including egg protein, or after a previous dose of any influenza vaccine; concomitant aspirin therapy in children and adolescents. Warnings and precautious associated with FluMist include the following: children younger than five years of age with recurrent wheezing and persons of any age with asthma may be at increased risk of wheezing following the administration of FluMist Quadrivalent; if Guillain-Barré syndrome has occurred within six weeks of any prior influenza vaccination, the decision to give FluMist Quadrivalent should be based on careful consideration of the potential benefits and risks.

Considerations for special patient populations - FluMist Quadrivalent is not approved for use in persons 65 years of age and older.

Ixiaro

Vaccine notes - Ixiaro is a vaccine indicated for active immunization for the prevention of disease caused by Japanese encephalitis virus (JEV). Ixiaro is approved for use in individuals 2 months of age and older. The recommended dose for children 2 months to <3 years of age is 0.25 mL. The recommended dose for individuals over the age of 3 years is 0.5 mL. Most individuals should receive 2 doses of Ixiaro, 28 days apart from each other. Health care professionals should store Ixiaro in a refrigerator at 2° to 8° C (35° to 46° F) (note: do not freeze). The most common adverse reactions associated with Ixiaro include: injection-site reaction redness, fever, and diarrhea.

Safety notes - contraindications associated with Ixiaro include the following: severe allergic reaction, (e.g., anaphylaxis,) after a previous dose of Ixiaro, any other Japanese Encephalitis Virus vaccine, or any component of Ixiaro, including protamine sulfate. Warnings and precautious associated with Ixiaro include the following: Ixiaro contains protamine sulfate, a compound known to cause hypersensitivity reactions in some individuals.

Considerations for special patient populations - the safety and effectiveness of Ixiaro have not been established in infants younger than two months of age.

Measles, Mumps, and Rubella Virus Vaccine Live (M-M-R II)

Vaccine notes - M-M-R II is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older. The recommended dose of M-M-R II is 0.5 mL. M-M-R II should be administered subcutaneously. The first dose of M-M-R II should be administered at 12 to 15 months of age. The second dose of M-M-R II should be administered at 4 to 6 years of age. M-M-R II is a suspension for injection (0.5-mL dose) supplied as a lyophilized vaccine to be reconstituted using accompanying sterile diluent. Before reconstitution, health care professionals should refrigerate the lyophilized vaccine at 36°F to 46°F (2°C to 8°C). Health care professionals should store accompanying diluent in the refrigerator (36°F to 46°F; 2°C to 8°C) or at room temperature (68°F to 77°F, 20°C to 25°C) (note: do not freeze the diluent). The most common adverse reactions associated with M-M-R II include: fever, syncope, headache, dizziness, malaise, irritability, diarrhea, nausea, and vomiting.

Safety notes - contraindications associated with M-M-R II include the following: hypersensitivity to any component of the vaccine; immunosuppression; moderate or severe febrile illness; active untreated tuberculosis; pregnancy. Warnings and precautious associated with M-M-R II include the following: use caution when administering M-M-R II to individuals with a history of febrile seizures; use caution when administering M-M-R II to individuals with anaphylaxis or immediate hypersensitivity following egg ingestion; use caution when administering M-M-R II to individuals with a history of thrombocytopenia; evaluate individuals for immune competence prior to administration of M-M-R II if there is a family history of congenital or hereditary immunodeficiency; immune globulins (IG) and other blood products should not be given concurrently with M-M-R II.

Considerations for special patient populations - the M-M-R II vaccine is contraindicated for use in pregnant women.

Measles, Mumps, Rubella and Varicella Virus Vaccine Live (Proquad)

Vaccine notes - Proquad is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age. Health care professionals should administer a 0.5-mL dose of ProQuad subcutaneously. The first dose should be administered at 12 to 15 months of age. The second dose should be administered at four to six years of age. Proquad is available as a suspension for injection (0.5-mL dose) supplied as a lyophilized vaccine to be reconstituted using

accompanying sterile diluent. ProQuad may be stored at refrigerator temperature (36° to 46°F, 2° to 8°C) for up to 72 hours prior to reconstitution. Health care professionals should discard any ProQuad vaccine stored at 36° to 46°F which is not used within 72 hours of removal from 5°F (-15°C) storage. The most common adverse reactions associated with Proquad include: injection-site pain, fever, and irritability.

Safety notes - contraindications associated with Proquad include the following: hypersensitivity to any component of the vaccine; immunosuppression; moderate or severe febrile illness; active untreated tuberculosis; pregnancy. Warnings and precautious associated with Proquad include the following: administration of ProQuad (dose 1) to children 12 to 23 months old who have not been previously vaccinated against measles, mumps, rubella, or varicella, nor had a history of the wild-type infections, is associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with M-M-R II; exercise caution when administering ProQuad to persons with an individual or family history of febrile seizures; use caution when administering ProQuad to children with anaphylaxis or immediate hypersensitivity following egg ingestion; use caution when administering ProQuad to children with thrombocytopenia; evaluate individuals for immune competence prior to administration of ProQuad if there is a family history of congenital or hereditary immunodeficiency; avoid close contact with high-risk individuals susceptible to varicella because of possible transmission of varicella vaccine virus; IGs and other blood products should not be given concurrently with ProQuad; avoid using salicylates for six weeks after vaccination with ProQuad.

Considerations for special patient populations - ProQuad is contraindicated for use in pregnant women.

Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria (Menactra)

Vaccine notes - Menactra is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra is approved for use in individuals 9 months through 55 years of age (note: Menactra does not prevent *N meningitidis* serogroup B disease). The recommended Menactra dose is 0.5 mL for intramuscular injection. Children 9 through 23 months of age should receive two doses, three months apart. Individuals 2 through 55 years of age should receive a single dose. A single booster dose may be given to individuals 15 through 55 years of age at continued risk for meningococcal disease, if at least 4 years have elapsed since the prior dose. Store at 2° to 8°C (35° to 46°F) (note: do not freeze;

frozen/previously frozen products should not be used). The most common adverse reactions associated with Menactra include: injection-site tenderness, irritability, drowsiness, appetite loss, vomiting, and fever.

Safety notes - contraindications associated with Menactra include the following: severe allergic reaction (e.g., anaphylaxis) after a previous dose of a meningococcal capsular polysaccharide-, diphtheria toxoid- or CRM197-containing vaccine, or to any component of Menactra. Warnings and precautious associated with Menactra include the following: individuals previously diagnosed with Guillain-Barré syndrome (GBS) may be at increased risk of GBS following receipt of Menactra; the decision to give Menactra should take into account the potential benefits and risks.

Considerations for special patient populations - there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Menactra during pregnancy. Menactra is not approved for use in infants under 9 months of age.

Meningococcal Group B Vaccine (Bexsero)

Vaccine notes - Bexsero is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. Bexsero is approved for use in individuals aged 10 through 25 years. Bexsero is for intramuscular use only. Health care professionals should administer two doses (0.5-mL each) of Bexsero at least one month apart. Bexsero suspension for intramuscular injection is available in 0.5-mL single-dose prefilled syringes. Health care professionals should store Bexsero refrigerated, at 36°F to 46°F (2°C to 8°C) (note: do not freeze; protect from light). The most common adverse reactions associated with Bexsero include: injection-site pain, myalgia, erythema, fatigue, headache, nausea, and arthralgia.

Safety notes - contraindications associated with Bexsero include the following: hypersensitivity, including severe allergic reaction, to any component of the vaccine, or after a previous dose of Bexsero. Warnings and precautious associated with Bexsero include the following: the tip caps of the prefilled syringes contain natural rubber latex, which may cause allergic reactions.

Considerations for special patient populations - safety and effectiveness of Bexsero have not been established in children younger than 10 years; safety and effectiveness of Bexsero have not been established in adults older than 65 years.

Pneumococcal 13-valent Conjugate Vaccine (Prevnar 13)

Vaccine notes - Prevnar 13 is a vaccine indicated for the following: active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in children six weeks through five years of age (prior to the 6th birthday); active immunization for the prevention of otitis media caused by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F; active immunization for the prevention of invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in children six years through 17 years of age (prior to the 18th birthday); active immunization for the prevention of pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults 18 years of age and older. Children six weeks through five years should receive a four-dose immunization series consisting of a 0.5 mL intramuscular injection administered at 2, 4, 6, and 12 - 15 months of age. Children six through 17 years of age and adults should receive a single dose. Prevnar 13 is a 0.5 mL suspension for intramuscular injection, supplied in a single-dose prefilled syringe. Health care professionals should store Prevnar 13 refrigerated at 2°C to 8°C (36°F to 46°F) (note: do note freeze; Prevnar 13 is stable at temperatures up to 25°C (77°F) for four days). The most common adverse reactions associated with Prevnar 13 include: injection-site pain, fever, irritability, decreased appetite, fatigue, and sleep problems.

Safety notes - contraindications associated with Prevnar 13 include the following: severe allergic reaction (e.g., anaphylaxis) to any component of Prevnar 13 or any diphtheria toxoid-containing vaccine. Warnings and precautious associated with Prevnar 13 include the following: apnea following intramuscular vaccination has been observed in some infants born prematurely; decisions about when to administer an intramuscular vaccine, including Prevnar 13, to infants born prematurely should be based on consideration of the individual infant's medical status, and the potential benefits and possible risks of vaccination.

Considerations for special patient populations - safety and effectiveness of Prevnar 13 in children below the age of six weeks have not been established.

Pneumococcal Vaccine, Polyvalent (Pneumovax 23)

Vaccine notes - Pneumovax 23 is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F) in persons 50 years of age or older and persons aged ≥ 2 years who are at

increased risk for pneumococcal disease. Pneumovax 23 should be administered in a single dose, either by intramuscular injection or subcutaneous injection. Pneumovax 23 is a clear, sterile solution supplied in a (0.5-mL dose) single-dose prefilled syringe. health care professionals should store Pneumovax 23 at 2 - 8°C (36 - 46°F). The most common adverse reactions associated with Pneumovax 23 include: injection-site pain/soreness/ tenderness, injection-site swelling, headache, and fatigue.

Safety notes - contraindications associated with Pneumovax 23 include the following: severe allergic reaction (e.g., anaphylaxis) to any component of Pneumovax 23. Warnings and precautious associated with Pneumovax 23 include the following: use caution and appropriate care for individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

Considerations for special patient populations - Pneumovax 23 is not approved for use in children younger than two years of age. Response to vaccination may be diminished in immunocompromised individuals.

Poliovirus Vaccine Inactivated (Ipol)

Vaccine notes - Ipol is a vaccine indicated for active immunization of infants (as young as six weeks of age), children, and adults for the prevention of poliomyelitis caused by poliovirus Types 1, 2, and 3. It is recommended that all infants (as young as six weeks of age), unimmunized children, and adolescents not previously immunized be vaccinated routinely against paralytic poliomyelitis. All children should receive four doses of Ipol at ages 2, 4, 6 to 18 months, and 4 to 6 years. Health care professionals should store Ipol at 2°C to 8°C (35°F to 46°F). The most common adverse reactions associated with Ipol include: injection-site pain, tiredness, irritability, and fever.

Safety notes - contraindications associated with Ipol include the following: a history of hypersensitivity to any component of the vaccine, including 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, and polymyxin B; no further doses should be given if anaphylaxis or anaphylactic shock occurs within 24 hours of administration of one dose of vaccine. Warnings and precautious associated with Ipol include the following: Neomycin, streptomycin, polymyxin B, 2-phenoxyethanol, and formaldehyde are used in the production of this vaccine - although purification procedures eliminate measurable amounts of the aforementioned substances, traces may be present, and allergic reactions may occur in persons sensitive to the aforementioned substances.

Considerations for special patient populations - children and adolescents with a previously incomplete series of polio vaccine should receive sufficient additional doses

of Ipol vaccine to complete the series; interruption of the recommended schedule with a delay between doses does not interfere with the final immunity; there is no need to start the series over again, regardless of the time elapsed between doses.

Rabies Vaccine (Imovax)

Vaccine notes - Imovax is indicated for pre-exposure and post-exposure prophylaxis against rabies. Imovax Rabies vaccine is approved for use in all age groups. Previously unvaccinated individuals should receive five intramuscular doses (1 mL each) of Imovax Rabies vaccine, one dose immediately after exposure (Day 0) and one dose 3,7, 14, and 28 days later. Imovax Rabies vaccine is supplied in a tamper evident unit dose box. The freeze-dried vaccine is stable if stored in the refrigerator between 2°C and 8°C (35°F to 46°F) (note: do not freeze). The most common adverse reactions associated with Imovax include: headache, nausea, abdominal pain, muscle aches, and dizziness.

Safety notes - contraindications associated with Imovax include the following: known hypersensitivity reaction to any component of the vaccine. Warnings and precautious associated with Imovax include the following: do not inject the vaccine into the gluteal area as administration in this area may result in lower neutralizing antibody titers; the product is provided in a single dose vial; the single dose vial contains no preservative, it is not to be used as a multi dose vial for intradermal injection; in both pre-exposure and post-exposure immunization, the full 1.0 mL dose should be given intramuscularly; serum sickness type reactions have been reported in persons receiving booster doses of rabies vaccine for pre-exposure prophylaxis; contains albumin, a derivative of human blood.

Considerations for special patient populations - it is not known whether Imovax Rabies vaccine is excreted in human milk.

Rotavirus Vaccine, Live, Oral (Rotarix)

Vaccine notes - Rotarix is a vaccine indicated for the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types. Rotarix is approved for use in infants six weeks and up to 24 weeks of age. The recommended Rotarix dose is 1 mL administered orally. The first dose of Rotarix should be administered to infants beginning at six weeks of age. The second dose of Rotarix should be administered after an interval of at least four weeks and up to 24 weeks of age. Rotarix should be administered within 24 hours of reconstitution. After reconstitution, health care professionals should store Rotarix refrigerated at 2° to 8°C (36° to 46°F) or at a controlled room temperature up to 25°C

(77°F) (note: do not freeze; discard the reconstituted vaccine in biological waste container if not used within 24 hours). The most common adverse reactions associated with Rotarix include: fussiness, irritability, cough, runny nose, fever, loss of appetite, and vomiting.

Safety notes - contraindications associated with Rotarix include the following: a demonstrated history of hypersensitivity to the vaccine or any component of the vaccine. Warnings and precautious associated with Rotarix include the following: the tip caps of the prefilled oral applicators of diluent contain natural rubber latex which may cause allergic reactions; administration of Rotarix in infants suffering from acute diarrhea or vomiting should be delayed.

Considerations for special patient populations - safety and effectiveness of Rotarix in infants younger than six weeks or older than 24 weeks of age have not been evaluated.

Rotavirus Vaccine, Live, Oral, Pentavalent (RotaTeq)

Vaccine notes - RotaTeq is a vaccine indicated for the prevention of rotavirus gastroenteritis caused by types G1, G2, G3, G4, and G9. RotaTeq is approved for use in infants 6 weeks to 32 weeks of age. The vaccination series consists of three ready-to-use liquid doses of RotaTeq administered orally starting at 6 to 12 weeks of age, with the subsequent doses administered at 4- to 10-week intervals. The third dose should not be given after 32 weeks of age. RotaTeq, 2 mL, is a solution for oral use, it is a pale yellow clear liquid that may have a pink tint. Health care professionals should store RotaTeq refrigerated at 2 - 8°C (36 - 46°F). The most common adverse reactions associated with RotaTeq include: diarrhea, vomiting, irritability, otitis media, nasopharyngitis, and bronchospas.

Safety notes - contraindications associated with RotaTeq include the following: a demonstrated history of hypersensitivity to the vaccine or any component of the vaccine; history of Severe Combined Immunodeficiency Disease (SCID); history of intussusception. Warnings and precautious associated with RotaTeq include the following: vaccine virus transmission from vaccine recipient to non-vaccinated contacts has been reported; caution is advised when considering whether to administer RotaTeq to individuals with immunodeficient contacts.

Considerations for special patient populations - RotaTeq is not approved for individuals 32 weeks of age and older.

Typhoid Vi Polysaccharide Vaccine (Typhim Vi)

Vaccine notes - Typhim Vi is indicated for active immunization of individuals two years of age or older for the prevention of typhoid fever caused by *Salmonella typhi*. One dose of the vaccine should be given at least two weeks prior to expected exposure. Typhim Vi is supplied ad a single-dose syringe, without needle (0.5 mL). The syringe or vial and the packaging should be inspected prior to use for evidence of leakage, premature activation of the plunger, or a faulty tip seal. Health care professionals should store Typhim Vi at 2° to 8°C (35° to 46°F) (note: do not freeze; discard if the vaccine has been frozen). The most common adverse reactions associated with Typhim Vi include: malaise, fever, diarrhea, and nausea.

Safety notes - contraindications associated with Typhim Vi include the following: history of hypersensitivity to any component of the vaccine. Warnings and precautious associated with Typhim Vi include the following: allergic reactions have been reported; care is to be taken by the health care professional for the safe and effective use of Typhim Vi vaccine; epinephrine injection (1:1000) must be immediately available following immunization should an anaphylactic or other allergic reaction occur due to any component of the vaccine; syncope has been reported following vaccination.

Considerations for special patient populations - the safety and immunogenicity of Typhim Vi vaccine in children under two years of age has not been established.

Typhoid Vaccine Live Oral Ty21a (Vivotif)

Vaccine notes - Vivotif is indicated for the immunization of adults and children greater than six years of age against disease caused by *Salmonella typhi*. Patients should receive four doses of Vivotif. The vaccine capsule should be swallowed approximately one hour before a meal with a cold or lukewarm drink. Vivotif should be stored between 2 °C and 8 °C (35.6 °F - 46.4 °F). Vivotif is supplied in a single foil blister containing four doses of vaccine in a single package. The most common adverse reactions associated with Vivotif include: abdominal pain, nausea, headache, fever, diarrhea, vomiting, and skin rash.

Safety notes - contraindications associated with Vivotif include the following: hypersensitivity to any component of the vaccine or the enteric-coated capsule; the vaccine should not be administered to individuals during an acute febrile illness. Warnings and precautious associated with Vivotif include the following: Vivotif (Typhoid Vaccine Live Oral Ty21a) is not to be taken during an acute gastrointestinal illness; the vaccine should not be administered to individuals receiving sulfonamides and antibiotics

since these agents may be active against the vaccine strain and prevent a sufficient degree of multiplication to occur in order to induce a protective immune response; postpone taking the vaccine if persistent diarrhea or vomiting is occurring; unless a complete immunization schedule is followed, an optimum immune response may not be achieved; not all recipients of Vivotif will be fully protected against typhoid fever; vaccinated individuals should continue to take personal precautions against exposure to typhoid organisms (i.e., travelers should take all necessary precautions to avoid contact or ingestion of potentially contaminated food or water).

Considerations for special patient populations - the safety and efficacy of Vivotif has not been established in children under six years of age; Vivotif is not indicated for use in children under six years of age.

Varicella Virus Vaccine Live (Varivax)

Vaccine notes - Varivax is indicated for active immunization for the prevention of varicella in individuals 12 months of age and older. The recommended dose of Varivax is 0.5-mL. Health care professionals should administer Varivax subcutaneously. In children (12 months to 12 years of age) the first dose should be administered at 12 to 15 months of age, and the second dose should be administered at 4 to 6 years of age (note: there should be a minimum interval of 3 months between doses). In adolescents (≥ 13 years of age) and adults two doses should be administered at a minimum interval of four weeks. Varivax suspension for injection (0.5-mL dose) is supplied as a lyophilized vaccine to be reconstituted using the accompanying sterile diluent. Varivax may be stored at refrigerator temperature (36°F to 46°F, 2°C to 8°C) for up to 72 continuous hours prior to reconstitution. Vaccine stored at 2°C to 8°C which is not used within 72 hours of removal from +5°F (−15°C) storage should be discarded. The most common adverse reactions associated with Varivax include injection-site pain and fever.

Safety notes - contraindications associated with Varivax include the following: a history of severe allergic reaction to any component of the vaccine (including neomycin and gelatin) or to a previous dose of varicella vaccine; immunosuppression; moderate or severe febrile illness; active untreated tuberculosis; pregnancy. Warnings and precautious associated with Varivax include the following: evaluate individuals for immune competence prior to administration of Varivax if there is a family history of congenital or hereditary immunodeficiency; avoid close contact with high-risk individuals susceptible to varicella because of possible transmission of varicella vaccine virus; IG and other blood products should not be given concomitantly with Varivax; avoid

use of salicylates for six weeks following administration of Varivax to children and adolescents.

Considerations for special patient populations - do not administer Varivax to females who are pregnant; pregnancy should be avoided for three months following vaccination with Varivax.

Yellow Fever Vaccine (YF-Vax)

Vaccine notes - YF-Vax is indicated for active immunization of individuals nine months of age and older who met one or more of the following criteria: living in or traveling to endemic areas; travelling internationally to countries that require evidence of vaccination from entering travelers or; laboratory personnel who might be expose to virulent yellow fever virus or to concentrated preparations of the yellow fever vaccine strain by direct or indirect contact or by aerosols should by vaccinated. Health care professionals should administer a single subcutaneous injection of 0.5 mL to patients. A single dose of yellow fever vaccine provides long-lasting protection to most healthy individuals. However, an additional dose of yellow fever vaccine may be given to individuals who might not have had an adequate or sustained immune response to prior yellow fever vaccination and who continue to be at risk for exposure to yellow fever virus. Health care professionals should store YF-Vax at 2° to 8°C (35° to 46°F) (note: do not freeze). The most common adverse reactions associated with YF-Vax include: mild headaches, myalgia, and low-grade fever.

Safety notes - contraindications associated with YF-Vax include the following: a history of acute hypersensitivity reaction to any component of the vaccine; do not administer YF-Vax to anyone with a history of acute hypersensitivity to eggs or egg products due to a risk of anaphylaxis. Warnings and precautious associated with YF-Vax include the following: severe allergic reactions (e.g., anaphylaxis) may occur following the use of YF-Vax, even in individuals with no prior history of hypersensitivity to the vaccine components; appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Considerations for special patient populations - there is an increased risk of severe systemic adverse reactions to YF-Vax in individuals 60 years of age and older; monitor older adult individuals for signs and symptoms of yellow fever vaccine-associated viscerotropic disease, which typically occurs within 10 days post-vaccination.

Section 2: Summary

The second essential element of patient vaccination is to maintain a working knowledge of specific vaccines. Health care professionals should be familiar with vaccine-related information such as: indication, dose, route of administration, vaccine schedules, storage, contraindications, warnings and precautious, considerations for special patient populations, and other related concepts. Health care professionals should consider vaccine-related information before administering vaccines to patients.

Section 2: Key Concepts

- The second essential element of patient vaccination is to maintain a working knowledge of specific vaccines.
- Health care professionals should be familiar with vaccine-related information such as: indication, dose, route of administration, vaccine schedules, storage, contraindications, warnings and precautious, considerations for special patient populations, and other related concepts.

Section 2: Key Terms

Vaccine schedule - a series of vaccinations, including the timing of all vaccine doses; a timeline for optimal vaccine administration; when an individual should receive a specific vaccine

Temperature monitoring device (TMD) - a measurement instrument that is capable of recording temperature over a defined period of time

Section 2: Personal Reflection Question

Why is it important for health care professionals to maintain a working knowledge of specific vaccines?

Section 3: Vaccine Recommendations

The third and final essential element of patient vaccination is to follow related recommendations. This section of the course will review vaccine recommendations. The information found within this section of the course was derived from materials provided by the CDC unless, otherwise, specified (CDC, 2021).

Vaccine Recommendations

- **Effectively store vaccines** - ineffective vaccine storage can reduce or destroy vaccine potency, and the vaccine's ability to provide protection against infections and/or diseases. Therefore, health care professionals should effectively store vaccines. Effective vaccine storage occurs when vaccines are adequately stored and maintained in a manner which maintains their potency and ability to provide protection against infections and/or diseases. It is the responsibility of all health care professionals, who handle vaccines or administer vaccines, to ensure effective vaccine storage. Health care professionals should note the following: vaccines should continue to be stored at recommended temperatures immediately upon receipt and until use; vaccines licensed for refrigerator storage should be stored at 2°C - 8°C (36°F - 46°F). Health care professionals should also note the following: damage to a vaccine exposed to temperatures outside of the recommended range might not be apparent visually; vaccines that have been stored at inappropriate temperatures should not be administered unless public health authorities or the manufacturer determines it is safe and effective; vaccines exposed to inappropriate temperatures that are inadvertently administered to patients should generally be repeated; inactivated vaccines should generally be repeated as soon as possible; live vaccines should be repeated after a 28-day interval from the invalid dose to reduce the risk for interference from interferon on the subsequent dose.
- **Evaluate vaccine expiration dates** - all vaccines have an expiration date determined by the manufacturer that must be observed. Health care professionals should record vaccine expiration dates and lot numbers on a stock or inventory record for each vaccine vial when a vaccine shipment is received. When vaccines are removed from storage, health care professionals should note whether an expiration window exists for vaccines stored at room temperature or at an intermediate temperature (e.g., a single-component varicella vaccine that is stored frozen must be discarded after 72 hours of storage at refrigerator temperature). An expiration window may also apply to vaccines that have been reconstituted (e.g., after reconstitution, a MMR vaccine should be kept at refrigerator temperature and must be administered within 8 hours). Health care professionals should note the following: doses of expired vaccines that are administered inadvertently to patients, generally, should not be counted as valid and should be repeated; inactivated vaccines should generally be repeated as soon as possible; live vaccines should be repeated after a 28-day interval from the

invalid dose to reduce the risk for interference from interferon on the subsequent doses.

- **Work to maintain vaccine schedules** - a vaccine schedule may refer to a series of vaccinations, including the timing of all vaccine doses; a timeline for optimal vaccine administration; when an individual should receive a specific vaccine (note: vaccine schedules may be based on age and/or need). Vaccine schedules are essential to optimizing the vaccination process. Therefore, health care professionals should work to maintain vaccine schedules when administering care to patients. Health care professionals should note the following: health care professionals may maintain vaccine schedules by ensuring patients receive routine vaccines. Health care professionals should also note that vaccine schedules are especially relevant when administering care to patients 18 years of age and younger. Specific information regarding vaccine schedules for patients 18 years of age and younger may be found below.

    - **Diphtheria, tetanus, and pertussis (DTaP) vaccination** - DTaP vaccination should occur in a 5-dose series at 2, 4, 6, 15 - 18 months, 4 - 6 years of age. Health care professionals should note the following: DTaP vaccine dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3; a 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

    - ***Haemophilus influenzae* type b vaccination** - *Haemophilus influenzae* type b vaccination with ActHIB, Hiberix, or Pentacel should occur in a 4-dose series at 2, 4, 6, 12 - 15 months. *Haemophilus influenzae* type b vaccination with PedvaxHIB should occur in a 3-dose series at 2, 4, 12 - 15 months. Health care professionals should note the following: unvaccinated patients at age 15 - 59 months should be administered 1 dose.

    - **Hepatitis A vaccination** - Hepatitis A vaccination should occur in a 2-dose series (note: the minimum interval between doses is 6 months) beginning at age 12 months. Health care professionals should note the following: unvaccinated individuals through age 18 years should complete a 2-dose series (note: the minimum interval between doses is 6 months).

    - **Hepatitis B vaccination** - Hepatitis B vaccination (with monovalent HepB vaccine only) should occur within hours after birth. If the child's mother is

HBsAg-negative, the child is medically stable, and the child's weight is ≥ 2,000 grams, the child should receive 1 dose within 24 hours of birth. If the child's mother is HBsAg-negative and the child's weight is < 2,000 grams, the child should receive 1 dose at chronological age 1 month or hospital discharge. If the child's mother is HBsAg-positive, health care professionals should administer HepB vaccine and hepatitis B immune globulin (HBIG) (in separate limbs) within 12 hours of birth, regardless of birth weight (note: for infants < 2,000 grams, health care professionals should administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month). Health care professionals should note the following: if the child's mother's HBsAg status is unknown, health care professionals should administer HepB vaccine within 12 hours of birth, regardless of birth weight.

- **Human papillomavirus (HPV) vaccination** - HPV vaccination is routinely recommended at age 11 - 12 years. Patients aged 9 - 14 years should receive, at initial vaccination, a 2-dose series at 0, 6 - 12 months (note: the minimum interval between doses is 5 months; health care professionals should repeat dose if administered too soon). Patients age 15 years or older, at initial vaccination, should receive a 3-dose series at 0, 1 - 2 months, 6 months (note: the minimum intervals between dose 1 to dose 2 is 4 weeks; the minimum intervals between dose 2 to dose 3 is 12 weeks; the minimum intervals between dose 1 to dose 3 is 5 months; health care professionals should repeat dose if administered too soon). Health care professionals should note the following: if the vaccination schedule is interrupted, the series does not need to be restarted; the minimum age for vaccination is 9 years.

- **Influenza vaccination** - health care professionals may use any influenza vaccine appropriate for age and health status annually. Health care professionals should note the following: if a patient has an egg allergy, with symptoms limited to hives only, health care professionals may use any influenza vaccine appropriate for age and health status annually; if a patient has an egg allergy, with symptoms other than hives (e.g., angioedema; respiratory distress), health care professionals should administer vaccine in a medical setting under supervision of health care professionals who can recognize and manage severe allergic reactions.

- **Measles, mumps, and rubella vaccination** - measles, mumps, and rubella vaccination should be administered in a 2-dose series at 12 - 15 months, 4 - 6 years of age. Health care professionals should note the following: dose 2 may be administered as early as 4 weeks after dose.

- **Meningococcal serogroup A, C, W, Y vaccination** - meningococcal serogroup A, C, W, Y vaccination should occur in a 2-dose series at 11 - 12 years, 16 years of age. Health care professionals should note the following: the Menactra vaccine should be administered either before or at the same time as DTaP.

- **Meningococcal serogroup B vaccination** - the vaccine Bexsero should be administered in a 2-dose series at least 1 month apart. The vaccine Trumenba should be administered in a 2-dose series at least 6 months apart (note: if dose 2 is administered earlier than 6 months, health care professionals should administer a third dose at least 4 months after dose 2). Health care professionals should note the following: Bexsero and Trumenba are not interchangeable; the same product should be used for all doses in a series.

- **Pneumococcal vaccination** - pneumococcal vaccination, with PCV_{13} should occur in a 4-dose series at 2, 4, 6, 12–15 months. Health care professionals should note the following: the minimum age for vaccination, with PCV_{13}, is 6 weeks.

- **Poliovirus vaccination** - poliovirus vaccination should occur in a 4-dose series at ages 2, 4, 6 - 18 months, 4 - 6 years. Health care professionals should administer the final dose on or after age 4 years and at least 6 months after the previous dose. Health care professionals should note the following: in the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak; the minimum age for poliovirus vaccination is 6 weeks.

- **Rotavirus vaccination** - rotavirus vaccination with Rotarix should occur in a 2-dose series at 2 and 4 months. Rotavirus vaccination with RotaTeq should occur with a 3-dose series at 2, 4, and 6 months. Health care professionals should note the following: if any dose in the series is either RotaTeq or unknown, default to a 3-dose series.

    - **Tetanus, diphtheria, and pertussis (Tdap) vaccination** - 1 dose of a Tdap should be administered during each pregnancy, preferably during the early part of gestational weeks 27 - 36. Adolescents age 11 - 12 years should receive 1 dose of Tdap. Health care professionals should note the following: Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.
    - **Varicella vaccination** - Varicella vaccination should occur in a 2-dose series at 12 - 15 months, 4 - 6 years. Health care professionals should note the following: dose 2 may be administered as early as 3 months after dose 1; a dose administered after a 4-week interval may be counted; ensure individuals age 7 - 18 years, without evidence of immunity, have a 2-dose series.

- **Assess patients' vaccination histories** - before vaccines are administered to patients, health care professionals should assess patients' vaccination histories to determine required vaccines. Health care professionals should note the following: vaccination histories can, typically, be found in medical records, on personal vaccination cards, and in immunization systems or registries.
- **Assess patients' allergies** - before vaccines are administered to patients, health care professionals should assess patients' allergies to determine if a specific vaccine is safe for a specific patient. Health care professionals should note that the most relevant allergies to the administration of vaccines include the following: an allergy to the specific vaccine in question, or any component of the vaccine in question; a latex allergy because some vaccines include latex caps or other latex parts; and an egg allergy. Health care professionals should also note the following: when assessing patient allergies health care professionals should ask patients questions regarding the type of allergic reactions associated with their particular allergy to determine if the patient's allergy is in fact a true allergy (e.g., if a patient reports injection-site pain or any other known side effect of a vaccine as an allergic reaction, then the patient's allergy may not be a true allergy). Additionally, health care professionals should note that anaphylaxis reactions indicate a true allergy to a vaccine.
- **Note considerations for individuals with a known and confirmed egg allergy** - some individuals with a known and confirmed egg allergy may have an allergic reaction or an allergic-type reaction from specific vaccines. Therefore, health care professionals should note considerations for individuals with a known and

confirmed egg allergy when administering specific vaccines. Information regarding egg allergies and relevant vaccines may be found below.

- **Influenza vaccines** - all but the recombinant inactivated influenza vaccine may have come into contact with egg protein. Individuals with a history of an egg allergy should receive recombinant inactivated vaccine (if 18 years or older), or IIV. All vaccines should be administered in settings in which health care professionals and equipment for rapid recognition and treatment of anaphylaxis are available.
- **Measles, Mumps, and Rubella Virus Vaccine Live (M-M-R II)** - use caution when administering M-M-R II to individuals with anaphylaxis or immediate hypersensitivity following egg ingestion.
- **Measles, Mumps, Rubella and Varicella Virus Vaccine Live** - use caution when administering vaccines to children with anaphylaxis or immediate hypersensitivity following egg ingestion.
- **Yellow fever vaccine** - the yellow fever vaccine contains egg protein. Individuals who are able to eat eggs or egg products may receive the vaccine. However, potential hypersensitivity reactions might occur in persons with a history of minor reactions to eggs. For egg-sensitive persons, a scratch test or intradermal test can be performed before administering the vaccine to check for reactivity. If a person has a severe egg-sensitivity or has a positive skin test to the vaccine, but the vaccination is recommended because of their travel destination-specific risk, desensitization can be performed under direct supervision of a physician experienced in the management of anaphylaxis.

- **Screen patients for vaccine contraindications** - before a vaccine is administered, health care professionals should screen patients for specific vaccine contraindications. Contraindications to vaccination, or vaccine contraindications, are conditions under which vaccines should not be administered (i.e., if a patient has a contraindication for a vaccine, he or she should not receive the vaccine). Health care professionals should note the following: severely immunocompromised individuals, generally, should not receive live vaccines; because of the theoretical risk to the fetus, women known to be pregnant generally should not receive live, attenuated virus vaccines; individuals who experienced encephalopathy within seven days after administration of a previous

dose of pertussis-containing vaccine not attributable to another identifiable cause should not receive additional doses of a vaccine that contains pertussis; Severe Combined Immunodeficiency (SCID) disease and a history of intussusception are both contraindications to the receipt of rotavirus vaccines. Health care professionals should also note the following: often vaccine contraindications are temporary (e.g., pregnancy); vaccinations may be administered at a later time when the condition leading to a vaccine contraindication no longer exists.

- **Screen patients for vaccine precautions** - in addition to vaccine contraindications, health care professionals should screen patients for vaccine precautions before a vaccine is administered to a patient. A vaccine precaution is a condition that may increase the risk for a serious adverse reaction, and/or compromise the ability of the vaccine to produce immunity, while potentially leading to diagnostic confusion. Health care professionals should note the following: the presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines; the decision to administer or delay vaccination because of a current or recent acute illness depends on the severity of symptoms and etiology of the condition; vaccination should be deferred for individuals with a moderate or severe acute illness; the aforementioned precaution may avoid diagnostic confusion between manifestations of the underlying illness and possible adverse effects of vaccination or superimposing adverse effects of the vaccine on the underlying illness. Health care professionals should also note the following: an individual with a moderate or severe acute illness may be vaccinated as soon as the acute illness has improved.

- **Determine the recommended route of administration** - before a vaccine is administered to a patient, health care professionals should determine the recommended route of administration. Health care professionals should note that vaccines may be administered by the following routes: oral route, intranasal route, intradermal route, intramuscular route, and by the subcutaneous route. Health care professionals should also note the following: when administering a vaccine by injection, health care professionals should choose the correct needle size based on the route, age, patient size, and injection technique.

- **Work to prevent vaccine related adverse reactions** - as previously highlighted, vaccines may lead to vaccine related adverse reactions (e.g., injection-site pain; fever). A vaccine related adverse reaction may refer to an undesirable side effect that occurs after a vaccination. Vaccine related adverse reactions are, typically,

classified into one of the following three categories: local, systemic, or allergic reactions. Local reactions (e.g., redness) are usually the least severe and most frequent. Systemic reactions (e.g., fever) occur less frequently observed when compared to local reactions. Severe allergic reactions (e.g., anaphylaxis) are the least frequent reactions (i.e., severe allergic reactions are rare). Health care professionals should note that one of the best methods to prevent vaccine related adverse reactions is to screen patients for relevant allergies, contraindications, and precautions.

- **Monitor patients for vaccine related adverse reactions** - after a vaccine is administered to a patient, health care professionals should monitor the patient for vaccine related adverse reactions. When monitoring a patient for vaccine related adverse reactions, health care professionals should pay particular attention to the signs and symptoms of an allergic reaction (e.g., local or generalized hives or angioedema; hypotension; and shock). Health care professionals should also pay particular attention to the more specific signs and symptoms of anaphylaxis, which include the following: sensation of throat closing or tightness; stridor (i.e., high-pitched sound while breathing); hoarseness; respiratory distress (e.g., shortness of breath or wheezing); coughing; trouble swallowing/drooling; nasal congestion; rhinorrhea; sneezing; nausea; vomiting; diarrhea; abdominal pain; cramps; dizziness; fainting; tachycardia (i.e., abnormally fast heart rate); hypotension (i.e., abnormally low blood pressure); weak pulse, cyanosis (i.e., bluish discoloration); pallor; flushing; generalized hives; widespread redness; itching; conjunctivitis; swelling of the eyes, lips, tongue, mouth, face, or extremities; agitation; convulsions; acute change in mental status; sense of impending doom (i.e., a feeling that something bad is about to happen); sudden increase in secretions (from eyes, nose, or mouth); urinary incontinence. Health care professionals should note the following: anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than one body system is involved) or are serious or life-threatening in nature, even if they involve a single body system [e.g., hypotension respiratory distress, or significant swelling of the tongue or lips]). Health care professionals should also note the following: symptoms of anaphylaxis often occur within 15 - 30 minutes of vaccination; however, it may take several hours for symptoms to appear; early signs of anaphylaxis can resemble a mild allergic reaction; symptoms of anaphylaxis might be more difficult to recognize in people with communication difficulties, such as long-term care facility residents with cognitive impairment, those with neurologic disease, or those taking medications that can

cause sedation. Additionally, health care professionals should note the following: when monitoring patients for vaccine related adverse reactions (e.g., an allergic reaction), health care professionals should keep the following emergency equipment and medications in close proximity: epinephrine (e.g., prefilled syringe, autoinjector), H1 antihistamine (e.g., diphenhydramine, cetirizine), blood pressure monitor, timing device to assess pulse, Ppulse oximeter, oxygen, bronchodilator (e.g., albuterol), H2 antihistamine (e.g., famotidine, cimetidine), intravenous fluids, intubation kit, and adult-sized pocket mask with one-way valve (i.e., cardiopulmonary resuscitation [CPR] mask). Furthermore, health care professionals should note that this particular recommendation may be relevant and essential when administering COVID-19 vaccines; individuals that receive COVID-19 vaccines should be monitored for the occurrence of immediate adverse reactions; individuals with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and individuals with a history of anaphylaxis due to any cause should be monitored for 30 minutes after vaccination; all other individuals should be monitored for approximately 15 minutes after vaccination; COVID-19 vaccination locations should have at least three doses of epinephrine available at all times, and the ability to quickly obtain additional doses to replace supplies after epinephrine is administered to a patient.

- **Note considerations for anaphylaxis management in special populations** - to build on the previous recommendation, health care professionals should note considerations for anaphylaxis management in special populations when monitoring patients for vaccine related adverse reactions. Specific considerations for anaphylaxis management in special populations may be found below.

    - **Older adults, including long-term care facility residents** - there are no contraindications to the administration of epinephrine for the treatment of anaphylaxis. Epinephrine is the first-line treatment for anaphylaxis. Health care facilities providing vaccination to older adults, including long-term care facility residents, should have health care professionals available to monitor older adult patients for the signs and symptoms of anaphylaxis, and to administer epinephrine and/or other anaphylaxis treatment options, when applicable.

    - **Pregnant individuals** - pregnant individuals with anaphylaxis should be managed the same as non-pregnant individuals. As with all patients with

anaphylaxis, pregnant individuals should be transported to a health care facility for treatment and/or monitoring.

- **Individuals with a precaution to vaccination or those with a history of anaphylaxis due to any cause** - individuals with a precaution to vaccination or those with a history of anaphylaxis due to any cause should receive vaccines in a health care facility or environment where health care is immediately available.

- **Treat and manage acute allergic reactions** - if a patient has an acute allergic reaction to a vaccine (e.g., anaphylaxis), health care professionals should immediately work to treat and manage such a reaction. Immediate-immunoglobulin E (IgE)-mediated (type 1) immune reactions (e.g., anaphylaxis) usually occur within minutes of vaccine administration. Immediate acute allergic reaction recognition and initiation of treatment are required to prevent possible progression to respiratory failure or cardiovascular collapse. Health care professionals should note the following: for respiratory or cardiovascular symptoms, or other signs or symptoms of anaphylaxis, immediate intramuscular epinephrine is the treatment of choice; antihistamines (e.g., diphenhydramine; cetirizine) may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis; caution should be used if oral medications are administered to people with impending airway obstruction; if hypotension is present, the patient should be placed in a recumbent position with the legs elevated; maintenance of the airway, oxygen administration, and intravenous normal saline might be necessary; after the patient is stabilized, health care professionals should make arrangements for immediate transfer to an emergency health care facility for additional evaluation and treatment, when applicable; anaphylaxis may recur after patients begin to recover, monitoring in a health care facility for several hours is advised, even after complete resolution of signs and symptoms.

- **Document and report and adverse reactions/events** - health care professionals should document and report specific adverse reactions and/or events, including anaphylaxis, that occur following vaccination or due to a specific vaccine. Health care professionals should document and report specific adverse reactions and/or events internally, within their health care organization, and to the Vaccine Adverse Event Reporting System (VAERS). Health care professionals should note that they may be required by law to document and report specific adverse

reactions and/or events, including anaphylaxis, that occur following vaccination or due to a specific vaccine.

- **Conduct medication reconciliations** - health care professionals should conduct a medication reconciliation before administering vaccines to patients. A medication reconciliation may refer to a process of comparing the medications an individual is taking (or should be taking) with newly ordered medications (Joint Commission, 2021). Health care professionals should note the following information regarding medication reconciliations: medication reconciliations are intended to identify and resolve medication discrepancies; medication reconciliations should address medication duplications, omissions, and interactions, and the need to continue current medications; the type of information health care professionals should use to reconcile medications include (among others) medication name, dose, frequency, route, and purpose; health care professionals should identify the information that needs to be collected in order to reconcile current and newly ordered medications and to safely prescribe medications in the future (Joint Commission, 2021). Health care professionals should also note the following: when conducting medication reconciliations, health care professionals should identify any medications that may interact with vaccines.

- **Use at least two patient identifiers when providing care, treatment, and services** - to help prevent medical errors from occurring, health care professionals should use at least two patient identifiers when providing care, treatment, and services (note: the term medical error may refer to a preventable adverse effect of care that may or may not be evident or causes harm to a patient) (Joint Commission, 2021). Health care professionals should note the following: medical errors can occur in virtually all stages of diagnosis and treatment; to help prevent medical errors from occurring, health care professionals should reliably identify a patient as the individual for whom the health care service or treatment is intended; health care professionals should match the health care service or treatment to the intended patient; acceptable patient identifiers may be the individual's name, an assigned identification number, telephone number, or other person-specific identifier (Joint Commission, 2021). Health care professionals should also note the following: health care professionals should use at least two patient identifiers when administering medications or vaccines, blood, or blood components; when collecting blood samples and other specimens for clinical testing; and when providing treatments or procedures; the patient's room

number or physical location should not be used as a patient identifier (Joint Commission, 2021).

- **Improve the safety of using medications** - to build on the previous recommendation, health care professionals can also help prevent medical errors from occurring by working to improve the safety of using medications and vaccines. Health care professionals should note the following: health care professionals can work to improve the safety of using medications and vaccines by verifying all medication and vaccine labels both verbally and visually; labeling each medication or vaccine as soon as it is prepared; and by immediately discarding any medication or vaccines found unlabeled (Joint Commission, 2021).

- **Practice effective hand hygiene** - when administering vaccines, health care professionals should practice effective hand hygiene. Hand hygiene may refer to the process of cleaning hands in order to prevent contamination and/or infections (CDC, 2018). Hand hygiene is most effective when dirt, soil, microorganisms, and other contaminants are removed from the hands. Health care professionals should complete effective hand hygiene when evaluating, assessing, and administering vaccines to all patients. Specific information regarding effective hand hygiene may be found below. The information found below was derived from materials provided by the CDC (CDC, 2018).

    - Health care professionals may use a variety of different products to carry out effective hand hygiene. The following products are typically available to health care professionals and may be used to carry out effective hand hygiene: detergents, plain soap, antimicrobial (medicated) soap, antiseptic agents, and alcohol-based handrubs.

    - The major indications for hand hygiene can be broken down into the following five key moments:

        1. Before patient contact
        2. Before an aseptic procedure or task
        3. After a body fluid exposure risk occurs
        4. After touching a patient
        5. After contact with a patient's surroundings

- Health care professionals should engage in hand hygiene if exposure to potential spore-forming pathogens is strongly suspected or proved (note: handwashing with soap and water is the preferred means).
- Health care professionals should engage in hand hygiene before handling an invasive device for patient care.
- Health care professionals should engage in hand hygiene after contact with body fluids or secretions, mucous membranes, non-intact skin, or wound dressings.
- Health care professionals should engage in hand hygiene if moving from a contaminated body site to another body site during the care of the same patient.
- Health care professionals should engage in hand hygiene after contact with inanimate surfaces and objects (e.g., medical equipment) in the immediate vicinity of a patient.
- Health care professionals should engage in hand hygiene after removing sterile or non-sterile gloves.
- Health care professionals should engage in hand hygiene before handling medications or vaccines (note: hand hygiene in the previous case may include the use of an alcohol-based handrub or handwashing with either plain or antimicrobial soap and water).
- Health care professionals should wash their hands with soap and water when they are visibly dirty or visibly soiled with blood or other body fluids or after using the toilet.
- Health care professionals should follow the steps in the following procedure when washing their hands with soap and water to optimize hand hygiene results. The duration of the entire handwashing procedure should last between 40 - 60 seconds.

  <u>Hand Hygiene Procedure with Soap and Water</u>

  1. The health care professional should wet his or her hands with water.
  2. The health care professional should apply enough soap to cover all hand surfaces.

3. The health care professional should rub his or her hands palm to palm.
4. The health care professional should rub the right palm over the left dorsum with interlaced fingers and vice versa.
5. The health care professional should rub his or her hands palm to palm with fingers interlaced.
6. The health care professional should rub the backs of fingers to opposing palms with fingers interlocked.
7. The health care professional should engage in rotational rubbing of the left thumb clasped in the right palm and vice versa.
8. The health care professional should engage in rotational rubbing, backwards and forwards with clasped fingers of the right hand in the left palm and vice versa.
9. The health care professional should then rinse his or her hands with water.
10. The health care professional should then dry his or her hands thoroughly with a single use towel.
11. Finally, the health care professional should use a towel to turn off the faucet.

- Health care professionals should use an alcohol-based handrub when their hands are not visibly soiled to reduce bacterial counts.
- Health care professionals should follow the steps in the following procedure when using an alcohol-based formulation to optimize hand hygiene results. The duration of the entire procedure should last between 20 - 30 seconds. When using an alcohol-based formulation, health care professionals should note the following: alcohol-based handrubs with optimal antimicrobial efficacy usually contain 75% to 85% ethanol, isopropanol, or n-propanol, or a combination of the aforementioned products.

  <u>Hand Hygiene Procedure with an Alcohol-Based Formulation</u>

1. The health care professional should first apply a palmful of alcohol-based product in a cupped hand, making sure to cover all surfaces.
2. The health care professional should then rub his or her hands palm to palm.
3. The health care professional should rub the right palm over the left dorsum with interlaced fingers and vice versa.
4. The health care professional should rub his or her hands palm to palm with fingers interlaced.
5. The health care professional should rub the backs of his or her fingers to opposing palms with fingers interlocked.
6. The health care professional should engage in the rotational rubbing of the left thumb clasped in the right palm and vice versa.
7. The health care professional should engage in rotational rubbing, backwards and forwards with clasped fingers of the right hand in the left palm and vice versa.
8. Finally, health care professionals should note that their hands are "safe" once they are dry.

- **Don personal protective equipment (PPE), when appropriate** - when administering vaccines to patients, health care professionals should don PPE, when appropriate. PPE may refer to equipment designed to protect, shield, and minimize exposure to hazards that may cause serious injury, illness, and/or disease (CDC, 2018). Essentially, donning PPE can prevent the spread of infectious materials and agents to patients and other health care professionals. Health care professionals should note that PPE can include a variety of different types of equipment such as: facemasks, respirators, gowns, and gloves. Health care professionals should also note the following: health care professionals should not touch a contaminated piece of PPE; health care professionals should place used PPE in the appropriate waste container; health care professionals should wash their hands or use an alcohol-based hand sanitizer after removing all PPE (CDC, 2018). Additionally, health care professionals should note the following: cloth masks are not considered to be PPE and should not be worn for the care of patients with suspected or confirmed COVID-19 or other situations where the use of a respirator or a facemask is recommended; health care professionals should

wear eye protection in addition to their facemasks to ensure the eyes, nose, and mouth are protected from exposure to respiratory secretions during patient care encounters, when applicable; health care professionals should wear an N95 or equivalent or higher-level respirator, instead of a facemask, for aerosol generating procedures and/or surgical procedures that might pose higher risk for transmission if the patient has COVID-19 (note: a N95 respirator may refer to a particulate-filtering, face piece respirator that filters at least 95% of airborne particles; a N95 respirator should fit firmly against the face in a manner that does not leave any open gaps between the skin and the N95 respirator seal).

- **Ensure safe injection practices are followed** - safe injection practices may refer to the proper use and handling of supplies for administering injections and infusions (e.g., syringes, needles, fingerstick devices, intravenous tubing, medication vials, and parenteral solutions) (CDC, 2018). Safe injection practices are intended to prevent the transmission of infectious diseases between one patient and another, and/or between a patient and a health care professional during preparation and administration of parenteral medications or vaccines. Specific information regarding safe injection practices may be found below. The information found below was derived from materials provided by the CDC (CDC, 2018).

    - Whenever possible, health care professionals should use commercially manufactured or pharmacy-prepared prefilled syringes (e.g., saline).
    - Health care professionals should avoid unwrapping syringes prior to the time of use.
    - Health care professionals should never administer medications or vaccines from the same syringe to multiple patients.
    - Health care professionals should not administer medications or vaccines from single-dose or single-use vials, ampoules, or bags or bottles of intravenous solution to more than one patient.
    - Clean the access diaphragms of medication vials with 70% alcohol and allow the alcohol to dry before inserting a device into the vial.
    - Health care professionals should dispose of used syringes and needles at the point of use in a sharps container that is closable, puncture-resistant, and leak-proof.

- Health care professionals should use single-use, disposable fingerstick devices (e.g., lancets) to obtain samples for checking a patient's blood glucose, PT/INR, etc.
- Health care professionals should dispose of single-use, disposable fingerstick devices after each use.
- Health care professionals should be sure to adhere to federal and state requirements for protection of health care professionals from exposure to bloodborne pathogens.

- **Apply fall precautions** - due to the potential adverse effects associated with vaccines (e.g., syncope), patients receiving vaccines may be susceptible to falls. Thus, health care professionals should apply fall precautions to patients receiving vaccines. Health care professionals should note that fall precautions constitute the basics of patient safety and should be applied in all health care facilities to all patients. Specific fall precautions may be found below.

  Fall Precautions

  - Familiarize the patient with his or her environment
  - Have the patient demonstrate call light use
  - Maintain the call light within patient reach
  - Keep a patient's personal possessions within safe reach of the patient
  - Have sturdy handrails in patient bathrooms, rooms, and hallways
  - Place the patient's bed in a low position when a patient is resting in bed; raise the patient's bed to a comfortable height when the patient is transferring out of bed
  - Keep patient bed brakes locked
  - Keep wheelchair wheel locks in the locked position when stationary
  - Keep non slip, comfortable, well-fitting footwear on the patient
  - Use night lights or supplemental lighting
  - Keep floor surfaces clean and dry

    - Clean up all spills promptly
    - Keep patient care areas uncluttered
    - Follow safe patient handling practices
- **Maintain adequate vaccine records** - according to information provided by the CDC, health care providers who administer vaccines covered by the National Vaccine Injury Compensation Program (VICP) are required under the National Childhood Vaccine Injury Act to ensure that the permanent medical record of the recipient (or a permanent office log or file) indicates the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine (CDC, 2017). This Act applies to any vaccine for which there is a routine recommendation for childhood vaccination, even if many or most doses of the vaccine are administered to adults (e.g., influenza vaccine). In addition, the provider is required to record the edition date of the VIS distributed and the date those materials were provided. The Act considers a health-care provider to be any licensed health care professional, organization, or institution, whether private or public (including federal, state, and local departments and agencies), under whose authority a specified vaccine is administered. This information should be kept for all vaccines, not just for those required by the Act. Providers and staff members also should systematically update patients' permanent medical records to reflect any documented episodes of adverse events after vaccination and any serologic test results related to vaccine-preventable diseases (CDC, 2017).
- **Utilize Immunization Information Systems (IISs)** - IISs (formerly referred to as immunization registries) are confidential, population-based, computerized information systems that collect and consolidate vaccination data from multiple health care providers within a geographic area (CDC, 2017). Health care professionals should note the following: IISs are a critical tool that can increase and sustain vaccination coverage by consolidating vaccination records from multiple providers, generating reminder and recall vaccination notices for each person, and providing official vaccination forms and vaccination coverage assessments; health care professionals should be aware of state and/or regional IISs and requirements for reporting (CDC, 2017).
- **Follow relevant health care organizations' policies and procedures** - health care organizations may have specific policies and procedures regarding vaccines and

vaccine administration. Health care professionals should be aware of and follow any health care organization policies and procedures related to vaccines and vaccine administration. Health care professionals should note the following: if a health care organization does not have specific policies and procedures regarding vaccines and/or vaccine administration, health care professionals should consider developing such policies and procedures.

- **Pursue opportunities to further health care education and remain up to date on relevant vaccine information** - finally, health care information is always being updated. Thus, health care professionals should pursue opportunities to further their education. Remaining up to date on relevant vaccine information can help health care professionals in their daily practice and can further their understanding of how to optimize the vaccination process. Health care professionals should note the following: due to the evolving nature of the COVID-19 pandemic, health care professionals should focus special attention on any relevant and developing information regarding COVID-19 vaccines (e.g., emerging information on currently available vaccines; information on any new vaccines).

Section 3: Summary

The third and final essential element of patient vaccination is to follow related recommendations. Vaccine recommendations include the following: effectively store vaccines; evaluate vaccine expiration dates; work to maintain vaccine schedules; assess patients' vaccination histories; assess patients' allergies; note considerations for individuals with a known and confirmed egg allergy; screen patients for vaccine contraindications; screen patients for vaccine precautions; determine the recommended route of administration; work to prevent vaccine related adverse reactions; monitor patients for vaccine related adverse reactions; note considerations for anaphylaxis management in special populations; treat and manage acute allergic reactions; document and report and adverse reactions/events; conduct medication reconciliations; use at least two patient identifiers when providing care, treatment, and services; improve the safety of using medications; practice effective hand hygiene; don personal protective equipment (PPE), when appropriate; ensure safe injection practices are followed; apply fall precautions; maintain adequate vaccine records; utilize Immunization Information Systems (IISs); follow relevant health care organizations' policies and procedures; pursue opportunities to further health care education and remain up to date on relevant vaccine information.

Section 3: Key Concepts

- The third essential element of patient vaccination is to follow vaccine recommendations.

Section 3: Key Terms

Vaccine contraindication - conditions under which vaccines should not be administered

Vaccine precaution - a condition that may increase the risk for a serious adverse reaction, and/or compromise the ability of the vaccine to produce immunity, while potentially leading to diagnostic confusion

Vaccine related adverse reaction - an undesirable side effect that occurs after a vaccination

Medication reconciliation - a process of comparing the medications an individual is taking (or should be taking) with newly ordered medications (Joint Commission, 2021)

Medical error - a preventable adverse effect of care that may or may not be evident or causes harm to a patient (Joint Commission, 2021)

N95 respirator - a particulate-filtering, face piece respirator that filters at least 95% of airborne particles

Safe injection practices - the proper use and handling of supplies for administering injections and infusions

Immunization Information Systems (IISs) - confidential, population-based, computerized information systems that collect and consolidate vaccination data from multiple health care providers within a geographic area (CDC, 2017)

Section 3: Personal Reflection Question

How can health care professionals use the above recommendations to optimize the vaccination process?

Section 4: Case Studies Revisited

The two case studies presented at the beginning of this course will be revisited in this section to further explore the concepts found within this course. Each case study will be represented below, followed by a case study review. The case study review includes the

types of questions health care professionals should ask themselves when considering and administering vaccines. Additionally, reflection questions will be posed, within the case study review, to encourage further internal debate and consideration regarding the presented case study and vaccines. The information found within this section of the course was derived from materials provided by the CDC unless, otherwise, specified (CDC, 2021).

Case Study 1

A 48-year-old male patient reports to a health care facility to receive an influenza vaccine. Upon questioning by a health care professional, the patient reveals that he has an egg allergy. The health care professional then asks the patient to describe what happens to him when he "eats eggs." The patient reports that when he eats eggs, he "sometimes gets a stomach ache." Upon further questioning, the patient also reports that he often avoids eating eggs, but "does eat them on occasion." The patient then asks the health care professionals if he can receive the influenza vaccine.

Case Study 1 Review

What patient details may be relevant to vaccination?

The following patient details may be relevant to vaccination: a 48-year-old male patient reports to a health care facility to receive an influenza vaccine; upon questioning, by a health care professional, the patient reveals that he has an egg allergy; the health care professional then asks the patient to describe what happens to him when he "eats eggs;" the patient reports that when he eats eggs, he "sometimes gets a stomach ache;" the patient also reports that he often avoids eating eggs, but "does eat them on occasion."

Are there any other patient details that may be relevant to vaccination; if so, what are they?

How are each of the aforementioned patient details relevant to vaccination?

Each of the previously highlighted patient details may be relevant to vaccination. The potential relevance of each patient detail may be found below.

A 48-year-old male patient reports to a health care facility to receive an influenza vaccine - the previous patient detail is relevant because it provides context for vaccination.

Upon questioning, by a health care professional, the patient reveals that he has an egg allergy - the previous patient detail is relevant because an egg allergy may impact influenza vaccination. When administering vaccines to patients, health care professionals should screen patients for allergies, vaccine contraindications, and vaccine precautions. Asking patients questions about potential allergies, vaccine contraindications, and vaccine precautions may be an effective means to screen patients. If patient questioning reveals a potential allergy, vaccine contraindication, and/or vaccine precaution, health care professionals should ask follow up questions to obtain further information. Health care professionals should note the following: any relevant information regarding potential allergies, vaccine contraindications, and vaccine precautions should be documented.

The health care professional then asks the patient to describe what happens to him when he "eats eggs" - the previous patient detail is relevant because health care professionals should ask patients follow up questions regarding any reported patient allergies to determine if the reported allergy is a true allergy. Health care professionals should note the following: when assessing patient allergies, health care professionals should ask patients questions regarding the type of allergic reactions associated with their particular allergy to determine if the patient's allergy is in fact a true allergy (e.g., if a patient reports injection-site pain or any other known side effect of a vaccine as an allergic reaction, then the patient's allergy may not be a true allergy). Health care professionals should also note that anaphylaxis reactions indicate a true allergy to a vaccine.

The patient reports that when he eats eggs, he "sometimes gets a stomach ache" - the previous patient detail is relevant because it may indicate the patient's egg allergy is not a true allergy. Health care professionals should note that individuals with a true egg allergy may experience the following: hives, angioedema, respiratory distress, lightheadedness, and/or recurrent emesis.

Upon further questioning, the patient also reports that he often avoids eating eggs, but "does eat them on occasion" - the previous patient detail is relevant because it may further indicate the patient's egg allergy is not a true allergy. Health care professionals should note the following: individuals who are able to eat lightly cooked eggs (e.g., scrambled eggs) without a reaction are unlikely to be allergic to eggs.

What other ways, if any, are the previous patient details relevant to vaccination?

Should the patient receive the influenza vaccine?

Based on the information presented in the case study, the patient should receive the influenza vaccine. Health care professionals should note the following information regarding an egg allergy and influenza vaccines:

- Individuals with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccines; any licensed and recommended influenza vaccine (i.e., any form of IIV or RIV) that is otherwise appropriate for the recipient's age and health status may be used;
- Individuals who report experiencing reactions to egg involving symptoms other than hives, such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may similarly receive any licensed and recommended influenza vaccine (i.e., any form of IIV or RIV) that is otherwise appropriate for the recipient's age and health status; the selected vaccine should be administered in an inpatient or outpatient medical setting (e.g., hospitals, clinics, health departments, and physician offices); vaccine administration should be supervised by a health care professional who is able to recognize and manage severe allergic conditions;
- A previous severe allergic reaction to an influenza vaccine, regardless of the component suspected of being responsible for the reaction, is a contraindication to future receipt of the vaccine;
- According to information provided by the CDC, individuals with egg allergies no longer need to be observed for an allergic reaction for 30 minutes after receiving an influenza vaccine; individuals with a history of egg allergy of any severity should receive any licensed, recommended, and age-appropriate influenza vaccine;
- Most influenza shots and the nasal spray influenza vaccines are manufactured using egg-based technology; they may contain a small amount of egg proteins, such as ovalbumin; however, studies that have examined the use of both the nasal spray vaccine and influenza shots in egg-allergic and non-egg-allergic patients indicate that severe allergic reactions in individuals with egg allergies are unlikely (CDC, 2020).

How can health care professionals provide patients with information regarding an egg allergy and influenza vaccines?

What should the health care professional consider before administering the vaccine to the patient?

The health care professional should consider the following vaccine recommendations before administering the vaccine to the patient:

- **Evaluate vaccine expiration dates** - all vaccines have an expiration date determined by the manufacturer that must be observed.
- **Determine the recommended route of administration** - before a vaccine is administered to a patient, health care professionals should determine the recommended route of administration (e.g., oral route; intranasal route; intradermal route; intramuscular route; subcutaneous route).
- **Treat and manage acute allergic reactions** - if a patient has an acute allergic reaction to a vaccine (e.g., anaphylaxis), health care professionals should immediately work to treat and manage such a reaction.
- **Document and report any adverse reactions/events** - health care professionals should document and report specific adverse reactions and/or events, including anaphylaxis, that occur following vaccination or due to a specific vaccine.
- **Use at least two patient identifiers when providing care, treatment, and services** - to help prevent medical errors from occurring, health care professionals should use at least two patient identifiers when providing care, treatment, and services (note: the term medical error may refer to a preventable adverse effect of care that may or may not be evident or causes harm to a patient) (Joint Commission, 2021).
- **Practice effective hand hygiene** - when administering vaccines health care professionals should practice effective hand hygiene.
- **Don personal protective equipment (PPE), when appropriate** - when administering vaccines to patients, health care professionals should don PPE when appropriate.
- **Ensure safe injection practices are followed** - safe injection practices may refer to the proper use and handling of supplies for administering injections and infusions (e.g., syringes, needles, fingerstick devices, intravenous tubing, medication vials, and parenteral solutions) (CDC, 2018). Safe injection practices are intended to prevent the transmission of infectious diseases between one patient and another,

and/or between a patient and a health care professional during preparation and administration of parenteral medications or vaccines.

Are there any other vaccine recommendations that may be relevant to patient vaccination; if so, what are they?

Case Study 2

A 28-year-old female patient presents to a health care facility for her second dose of the Pfizer-BioNTech COVID-19 vaccine. The health care professional examines the patient's records, and verifies that the patient is due for the second dose of the Pfizer-BioNTech COVID-19 vaccine. The health care professional then asks the patient if she recently experienced any of the following COVID-19 signs/symptoms: fever, chills, cough, shortness of breath, aches and pain, fatigue, headaches, nasal congestion, runny nose, sore throat, nausea, vomiting, and/or diarrhea. The health care professional also asks the patient if she experienced any adverse effects after the first dose of the Pfizer-BioNTech COVID-19 vaccine. The patient responds to both questions by saying "no." The health care professional then informs the patient that she may experience the following effects after the second dose of the Pfizer-BioNTech COVID-19 vaccine: injection-site pain, injection-site swelling, injection-site redness, fatigue, headache, muscle pain, chills, joint pain, fever, nausea, malaise, and enlargement of lymph nodes. The patient then asks the health care professional about COVID-19 variants, and if she can receive the Moderna COVID-19 vaccine instead of the Pfizer-BioNTech COVID-19 vaccine because she read "it provides protection against all known variants."

Case Study 2 Review

<u>What patient details may be relevant to vaccination?</u>

The following patient details may be relevant to vaccination: a 28-year-old female patient presents to a health care facility for her second dose of the Pfizer-BioNTech COVID-19 vaccine; a health care professional examines the patient's records, and verifies that the patient is due for the second dose of the Pfizer-BioNTech COVID-19 vaccine; the health care professional then asks the patient if she recently experienced any of the following COVID-19 signs/symptoms: fever, chills, cough, shortness of breath, aches and pain, fatigue, headaches, nasal congestion, runny nose, sore throat, nausea, vomiting, and diarrhea. The health care professional also asks the patient if she experienced any adverse effects after the first dose of the Pfizer-BioNTech COVID-19 vaccine; the patient responds to both questions by saying "no;" the health care professional then informs the patient that she may experience the following effects after the second dose of the Pfizer-

BioNTech COVID-19 vaccine: injection-site pain, injection-site swelling, injection site redness, fatigue, headache, muscle pain, chills, joint pain, fever, nausea, malaise, and enlargement of lymph nodes; the patient then asks the health care professional about COVID-19 variants; the patient also asks the health care professional if she can receive the Moderna COVID-19 vaccine instead of the Pfizer-BioNTech COVID-19 vaccine because she read "it provides protection against all known variants."

Are there any other patient details that may be relevant to vaccination; if so, what are they?

How are each of the aforementioned patient details relevant to vaccination?

Each of the previously highlighted patient details may be relevant to vaccination. The potential relevance of each patient detail may be found below.

A 28-year-old female patient presents to a health care facility for her second dose of the Pfizer-BioNTech COVID-19 vaccine - the previous patient detail is relevant because it provides context for vaccination.

A health care professional examines the patient's records, and verifies that the patient is due for the second dose of the Pfizer-BioNTech COVID-19 vaccine - the previous patient detail is relevant because health care professionals should examine patient records to verify vaccination schedules, especially when they relate to COVID-19 vaccines. Health care professionals should note the following: the Pfizer-BioNTech COVID-19 vaccine should be administered in a 2-dose series separated by 21 days (note: individuals should not be scheduled to receive the second dose earlier than recommended; second doses administered within a grace period of four days earlier than the recommended date for the second dose are considered valid; both doses are required); the Moderna COVID-19 vaccine should be administered in a 2-dose series separated by 28 days (note: individuals should not be scheduled to receive the second dose earlier than recommended; second doses administered within a grace period of four days earlier than the recommended date for the second dose are considered valid; both doses are required).

The health care professional then asks the patient if she recently experienced any of the following COVID-19 signs/symptoms: fever, chills, cough, shortness of breath, aches and pain, fatigue, headaches, nasal congestion, runny nose, sore throat, nausea, vomiting, and diarrhea - the previous patient detail is relevant because health care professionals should ask patients about COVID-19 signs/symptoms before they receive the vaccine. Health care professionals should note the following: COVID-19 vaccination of an

individual with a known, current COVID-19-virus infection should be deferred until the individual has recovered from acute illness.

The health care professional also asks the patient if she experienced any adverse effects after the first dose of the Pfizer-BioNTech COVID-19 vaccine - the previous patient detail is relevant because health care professionals should ask patients if they experienced any adverse effects after a COVID-19 vaccine. Health care professionals should note the following: the most common adverse reactions associated with the Pfizer-BioNTech COVID-19 vaccine include: injection-site pain, injection-site swelling, injection-site redness, fatigue, headache, muscle pain, chills, joint pain, fever, nausea, malaise, and lymphadenopathy; the most common adverse reactions associated with the Moderna COVID-19 vaccine include: injection-site pain, fatigue, headache, muscle pain, chills, nausea, vomiting, and fever. Health care professionals should also note the following: contraindications associated with the Pfizer-BioNTech COVID-19 vaccine/the Moderna COVID-19 vaccine include: severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components; immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components; immediate allergic reaction of any severity to polysorbate; individuals with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and individuals with a history of anaphylaxis due to any cause should be monitored for 30 minutes after COVID-19 vaccination; all other individuals should be monitored for approximately 15 minutes after COVID-19 vaccination.

The patient responds to both questions by saying "no" - the previous patient detail is relevant because health care professionals should note and effectively document patient responses to COVID-19 vaccination-related questions. Health care professionals should note the following: health care documentation may refer to a digital or an analog record detailing the administration of health care to patients; if completed effectively, health care documentation can be used in daily practice by health care professionals to communicate vital patient information to other health care professionals in order to facilitate positive health care outcomes and to decrease the potential for negative health care outcomes, such as adverse events and patient mortalities; regarding COVID-19, effective health care documentation may be used as a method to review patient cases and to ensure all aspects of an individual patient's health care are noted and evaluated to maximize therapeutic outcomes; in order for health care documentation to be considered effective, it must function as a viable form of communication, as well as a means to establish a detailed record of health care administration.

The health care professional then informs the patient that she may experience the following effects after the second dose of the Pfizer-BioNTech COVID-19 vaccine: injection-site pain, injection-site swelling, injection-site redness, fatigue, headache, muscle pain, chills, joint pain, fever, nausea, malaise, and enlargement of lymph nodes - the previous patient detail is relevant because health care professionals should provide patients with information regarding vaccine adverse effects.

The patient then asks the health care professional about COVID-19 variants - the previous patient detail is relevant because health care professionals should make an effort to answer patient questions about COVID-19 or any COVID-19 variants. Health care professionals should note the following: viruses constantly change through mutation; virus mutations lead to variants; multiple variants of the virus that causes COVID-19 have been documented in the United States and throughout the world during the COVID-19 pandemic. Health care professionals should also note the following information regarding COVID-19 variants:

- **Variant B.1.1.7** - variant B.1.1.7 was identified in the United Kingdom (UK) in the Fall of 2020. Variant B.1.1.7 spreads easily and quickly when compared to other COVID-19 variants. Research indicates that variant B.1.1.7 may be associated with an increased risk of death compared to other COVID-19 variants. Health care professionals should note that variant B.1.1.7 was first detected in the United States at the end of December 2020.
- **Variant B.1.351** - variant B.1.351 emerged independently in South Africa. Variant B.1.351 also spreads easily and quickly when compared to other COVID-19 variants. Variant B.1.351 may also be more deadly. Health care professionals should note that variant B.1.351 was detected in the United States at the end of January 2021.
- **Variant P.1** - variant P.1 emerged in Brazil, and was first identified in travelers from Brazil, who were tested during routine screening. Variant P.1 contains a set of additional mutations that may affect its ability to be recognized by antibodies. Health care professionals should note that variant P.1 was first detected in the United States at the end of January 2021.

The patient also asks the health care professional if she can receive the Moderna COVID-19 vaccine instead of the Pfizer-BioNTech COVID-19 vaccine because she read "it provides protection against all known variants" - the previous patient detail is relevant because patients may make requests for specific COVID-19 vaccines. That being said, a 2-

dose series started with the Pfizer-BioNTech COVID-19 vaccine should be completed with the Pfizer-BioNTech COVID-19 vaccine, and a 2-dose series started with the Moderna COVID-19 vaccine should be completed with the Moderna COVID-19 vaccine. Health care professionals should note the following: studies suggest that antibodies generated through vaccination with currently authorized vaccines recognize known variants.

What other ways, if any, are the previous patient details relevant to vaccination?

Should the patient receive the Pfizer-BioNTech COVID-19 vaccine?

Based on the information presented in the case study, the patient should receive the second dose of the Pfizer-BioNTech COVID-19 vaccine. Health care professionals should note the following information regarding the Pfizer-BioNTech COVID-19 vaccine: the Pfizer-BioNTech COVID-19 vaccine is indicated for individuals 16 years of age and older; the Pfizer-BioNTech COVID-19 vaccine is provided in a multidose vial, which may include up to six doses per vial; the Pfizer-BioNTech COVID-19 vaccine must be mixed with diluent before administration; after dilution, vials must be stored between 2°C and 25°C and used within six hours of dilution; the recommended dose is 0.3 mL; the vaccine should be administered via intramuscular (IM) injection.

How can health care professionals provide patients with information regarding the Pfizer-BioNTech COVID-19 vaccine?

What should the health care professional consider before administering the vaccine to the patient?

The health care professional should consider the following vaccine recommendations before administering the vaccine to the patient:

- **Effectively store vaccines** - ineffective vaccine storage can reduce or destroy vaccine potency, and the vaccine's ability to provide protection against infections and/or diseases. Therefore, health care professionals should effectively store vaccines. Effective vaccine storage occurs when vaccines are adequately stored and maintained in a manner which maintains their potency and ability to provide protection against infections and/or diseases.
- **Evaluate vaccine expiration dates** - all vaccines have an expiration date determined by the manufacturer that must be observed.
- **Work to maintain vaccine schedules** - a vaccine schedule may refer to a series of vaccinations, including the timing of all vaccine doses; a timeline for optimal

vaccine administration; when an individual should receive a specific vaccine (note: vaccine schedules may be based on age and/or need). Vaccine schedules are essential to optimizing the vaccination process.

- **Determine the recommended route of administration** - before a vaccine is administered to a patient, health care professionals should determine the recommended route of administration (e.g., oral route; intranasal route; intradermal route; intramuscular route; subcutaneous route).
- **Treat and manage acute allergic reactions** - if a patient has an acute allergic reaction to a vaccine (e.g., anaphylaxis), health care professionals should immediately work to treat and manage such a reaction.
- **Document and report any adverse reactions/events** - health care professionals should document and report specific adverse reactions and/or events, including anaphylaxis, that occur following vaccination or due to a specific vaccine.
- **Use at least two patient identifiers when providing care, treatment, and services** - to help prevent medical errors from occurring, health care professionals should use at least two patient identifiers when providing care, treatment, and services (note: the term medical error may refer to a preventable adverse effect of care that may or may not be evident or causes harm to a patient) (Joint Commission, 2021).
- **Practice effective hand hygiene** - when administering vaccines, health care professionals should practice effective hand hygiene.
- **Don personal protective equipment (PPE), when appropriate** - when administering vaccines to patients, health care professionals should don PPE when appropriate.
- **Ensure safe injection practices are followed** - safe injection practices may refer to the proper use and handling of supplies for administering injections and infusions (e.g., syringes, needles, fingerstick devices, intravenous tubing, medication vials, and parenteral solutions) (CDC, 2018). Safe injection practices are intended to prevent the transmission of infectious diseases between one patient and another, and/or between a patient and a health care professional during preparation and administration of parenteral medications or vaccines.

Are there any other vaccine recommendations that may be relevant to patient vaccination; if so, what are they?

Section 4: Summary

When administering vaccines, health care professionals should screen patients for allergies, vaccine contraindications, and vaccine precautions. Health care professionals should also work to complete effective health care documentation, answer patient questions, and provide patients with relevant information. Additionally, health care professionals should ask patients questions to identify any areas of concern that may not be obviously apparent. Health care professionals should note that, often, one of the main goals of patient vaccination is to facilitate the safe and effective administration of vaccines to, ultimately, protect individuals from, potentially, life-threatening infections/ diseases.

Section 4: Key Concepts

- When administering vaccines, health care professionals should screen patients for allergies, vaccine contraindications, and vaccine precautions.
- When administering vaccines, health care professionals should work to complete effective health care documentation, answer patient questions, and provide patients with relevant information.
- When administering vaccines, health care professionals should ask patients questions to identify any areas of concern that may not be obviously apparent.
- One of the main goals of patient vaccination is to facilitate the safe and effective administration of vaccines.

Section 4: Key Terms

Health care documentation - a digital or an analog record detailing the administration of health care to patients

Section 4: Personal Reflection Question

Why is it important for health care professionals to complete effective health care documentation when administering vaccines to patients?

Conclusion

Vaccines are an essential element of health care. They can protect individuals from deadly diseases, and they can help prevent the spread of infectious agents across the

planet. Therefore, health care professionals should ensure patients receive relevant vaccines, while working to optimize the vaccination process. Health care professionals can ensure patients receive relevant vaccines, while working to optimize the vaccination process by incorporating the three essential elements of patient vaccination into daily practice. The three essential elements of patient vaccination include the following: obtain insight into vaccines and vaccine preventable infections/diseases; maintain a working knowledge of specific vaccines; and follow vaccine recommendations.

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