Continuing Education

PHARMACIST & TECHNICIAN CE:

Vaccine Advancements: Transforming the Landscape of Disease Prevention

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CE FOR **PHARMACISTS & TECHNICIANS**

Learning Objectives

- Describe the role of adjuvants in vaccines
- Identify the patient populations that would benefit from mpox and respiratory syncytial virus (RSV) vaccine formulations
- Compare and contrast new and existing pneumococcal, hepatitis B, and meningococcal vaccine formulations
- Describe a communication method that can be utilized by a pharmacy professional encountering a vaccine-hesitant patient or caregiver

Vaccine advancements have shown a progression of improved safety and efficacy, preventing morbidity and mortality of serious infectious diseases. Research and technology have led to the development of novel vaccines to combat new diseases of concern. The development of new vaccine formulations for existing vaccinations offers even more benefits and safety. Despite these advancements, vaccine hesitancy is causing a decline in herd immunity, ultimately impacting global health.

Vaccine Adjuvants

A large contribution toward vaccine progression has been accomplished through vaccine adjuvants. Adjuvants are components added to vaccines that help build a stronger immune response toward an antigen. Some of the benefits of using adjuvants in vaccines include the abilities to increase efficacy while using less antigen, reduce the number of booster doses required, enhance the stability of the antigen, extend the half-life of the vaccine, and ultimately build a stronger immune response.[1]

Over the years, many different types of adjuvants have been developed, and technological innovations have enhanced their safety and efficacy. The most common adjuvants used in vaccines today include aluminum salts. Aluminum-containing adjuvants have been used for over 70 years and were initially introduced in the 1930s in the diphtheria and tetanus vaccines. Newer adjuvants have been developed to target certain components of the body's immune response to enhance long-lasting protection with fewer adverse effects. These newer adjuvants are: $AS01_B$, $AS01_E$, CpG 1018, Matrix-M™, and MF59. Table 1 outlines adjuvants used in different vaccine formulations available today.[1]

TABLE 1. Adjuvants Used in Vaccines Today[1]

Adjuvant	*Vaccines*
Aluminum	Anthrax, DT, DTaP (Daptacel® (Sanofi Pasteur Inc.)), DTaP (Infanrix® (GlaxoSmithKline)), DTaP-HepB-IPV (Pediarix® (GlaxoSmithKline)), DTaP-IPV (Kinrix® (GlaxoSmithKline)), DTaP-IPV (Quadracel® (Sanofi Pasteur Inc.)), DTaP –IPV/Hib (Pentacel® (Sanofi Pasteur Inc.)), DTaP-IPV-Hib-HepB (VAXELIS® (Sanofi Pasteur)), HepA (Havrix® (GlaxoSmithKline)), HepA (Vaqta® (Merck)), HepB (Engerix-B® (GlaxoSmithKline)), HepB (PREHEVBRIO® (VBI Vaccines)), HepB (Recombivax® (Merck)), HepA/HepB (Twinrix® (GlaxoSmithKline)), HIB (PedvaxHIB® (Merck)), HPV (Gardasil 9® (Merck)), Japanese encephalitis (Ixiaro® (Valneva)), MenB (Bexsero® (GlaxoSmithKline)), Trumenba® (Wyeth)), meningococcal (Penbraya™ (Pfizer)), Pneumococcal (Prevnar 20™ (Pfizer), VAXNEUVANCE™ (Merck)), Td (Tenivac® (Sanofi Pasteur)), Td (Mass Biologics), Td (no trade name), Tdap (Adacel® (Sanofi Pasteur)), Tdap (Boostrix® (GlaxoSmithKline)), Tick-Borne Encephalitis (TICOVAC® (Pfizer))
$AS01_B$	Zoster vaccine (Shingrix® (GlaxoSmithKline))
$AS01_E$	Arexvy® (GlaxoSmithKline)
CpG 1018	HepB (Heplisav-B® (Dynavax))
Matrix-M™	COVID-19 vaccine (Novavax COVID-19 Vaccine, Adjuvanted)
MF59	Influenza (Fluad® (Seqirus Inc.) and Fluad Quadrivalent® (Seqirus Inc.))
No adjuvant	Abrysvo® (Pfizer), Chickenpox, cholera, COVID-19 (includes mRNA Pfizer-BioNTech, mRNA Moderna and adenoviral Johnson & Johnson/Janssen), dengue, Ebola, Hib (ActHIB® (Sanofi Pasteur Inc.), HIBERIX® (GlaxoSmithKline)), measles, mumps & rubella (MMR), meningococcal (Menactra® (Sanofi Pasteur), Menveo® (GlaxoSmithKline), MenQuadfi® (Sanofi Pasteur)), polio (IPOL® (Sanofi Pasteur Inc.)), Pneumococcal (Pneumovax23® (Merck), CAPVAXIVE™ (Merck)), rabies, rotavirus, seasonal influenza (except Fluad® (Seqirus Inc.) and Fluad Quadrivalent® (Seqirus Inc.)), smallpox and monkeypox (JYNNEOS® (Bavarian Nordic)), Typhoid, yellow fever, zoster live (Zostavax® (Merck))

Adjuvant Safety

Recently, concerns have been raised over the use of adjuvants in vaccines, because they have been shown to cause more local and systemic reactions compared to non-adjuvant vaccines. Vaccines containing adjuvants are tested for safety and effectiveness through clinical trials before they become licensed in the United States, similar to other drugs and vaccines. When vaccines are evaluated for safety and effectiveness, the Food and Drug Administration (FDA) considers adjuvants as a component of the vaccine; the specific adjuvant component is not approved separately. Once these vaccines are approved, they are continuously monitored by the Centers for Disease Control and Prevention (CDC) and FDA. Recently developed adjuvants have demonstrated favorable safety profiles, with short-term reactogenicity, and mild to moderate local and systemic reactions.[1,2] Despite societal concerns about vaccines containing adjuvants, the benefits of vaccinations with recent adjuvant innovations far outweigh the risks of immune-related adverse effects.

Coadministration with Other Vaccines

Limited safety data on the coadministration of two or more vaccines containing non-aluminum adjuvants has been an area of concern, due to the potential increase of local and systemic reactogenicity. The July and August 2023 Morbidity and Mortality Weekly Reports (MMWR) acknowledge that the coadministration of respiratory syncytial virus (RSV) vaccines with other vaccines is acceptable but disclose limited immunogenicity data on coadministration of RSV vaccines with other vaccines.[3] Evidence from coadministration of the GlaxoSmithKline (GSK) RSV vaccine with the adjuvanted quadrivalent inactivated influenza vaccine demonstrated lower antibody titers, but the clinical significance of this finding is unknown.[4] Due to limited safety data on coadministration of two or more vaccines containing non-aluminum adjuvants, the Advisory Committee on Immunization Practices (ACIP) recommends that if a non-aluminum adjuvant vaccine needs to be administered with another vaccine, then a non-adjuvanted vaccine should be considered. When providers are trying to determine whether adjuvant vaccines should be co-administered with other vaccines, they should consider:

1. If the patient is up to date with currently recommended vaccines
2. The patient's ability to return for additional vaccine doses
3. The patient's risk for acquiring vaccine-preventable diseases
4. Vaccine reactogenicity profiles
5. The patient's preference

More efficacy and safety data on coadministration of adjuvant vaccines with other vaccines needs to be obtained to provide more guidance on this topic.[3]

In summary, the addition of adjuvants in vaccines helps to strengthen vaccine immunity. Technological innovations and breakthroughs of new adjuvants have helped to reduce reactogenicity associated with them while providing vaccine efficacy and stability. Providers should consider patient-specific factors when determining if adjuvant vaccines should be co-administered with other vaccines due to the limited efficacy and safety data available today.

New Vaccine Entities

Vaccine research and technological innovations have led to the breakthroughs of novel vaccines to overcome new diseases of concern such as mpox and RSV.

Mpox

Mpox is a viral illness caused by the monkeypox virus, which was originally discovered in research monkeys in Denmark in 1958. In May 2022, a sudden outbreak of mpox spread throughout Europe, North and South America, and all six World Health Organization (WHO) regions. This outbreak resulted in nearly 87,000 cases and 112 deaths worldwide. It is commonly spread to humans from animals, such as squirrels, rats, monkeys, and prairie dogs, though human-to-human transmission is possible and drives rapid spread of outbreaks. Data suggests sexual transmission is a major cause of human transmission, as viral loads are high in bodily fluids.[5]

Mpox is characterized by a painful rash or mucosal lesions, which often initially present in the oropharynx and then appear on the skin. The clinical course typically involves fever, fatigue, and enlarged lymph nodes prior to the development of skin lesions, which then evolve through several phases and eventually crust over. Symptoms typically resolve within 3 to 4 weeks after onset.[5]

In August 2022, the FDA issued an emergency use authorization (EUA) for the Jynneos® (Bavarian Nordic) mpox vaccine. This vaccine is an attenuated, live, non-replicating smallpox and monkeypox vaccine that stimulates an immune response to the orthopox viruses. The vaccine is intended to be used for prevention of mpox disease in adults who are deemed to be at high risk for infection. Patients eligible for vaccination include those with known or suspected exposure to someone with mpox, those who engage in high-risk sexual behaviors, such as men who have sex with men or who have multiple sexual partners, and those who may have workplace exposure. According to the CDC, vaccination within four days of exposure may prevent the onset of mpox, while vaccination within two weeks of exposure may reduce disease severity.[6] Jynneos® (Bavarian Nordic) is a two-dose series administered four weeks apart. This vaccine may be administered intradermally or subcutaneously. Intradermal administration produces a robust immune response at smaller doses, although both forms of administration have been found to be equally efficacious. Both routes of administration are considered interchangeable within the series. While a single dose of the vaccine provides some protection, it is recommended that a patient receives both doses to optimize immune response against infection. Mpox vaccination is typically well tolerated but may result in redness, pain, swelling, and induration at the site of administration. The risk of local reactions may be greater with intradermal administration compared to subcutaneous. Potential systemic adverse effects include fatigue, headache, nausea, fever, and chills.[6]

RSV

RSV also causes a substantial health burden. Globally, RSV is estimated to infect over 64 million people and cause 160,000 deaths annually.[7] In the U.S., RSV infection is estimated to lead to more than 2.1 million outpatient visits and 58,000 hospitalizations among children under age 5 annually. Additionally, RSV is estimated to cause about 14,000 annual deaths in U.S. adults over age 65.[7,8]

RSV is a common respiratory virus that infects the lungs and airways. It is the most common cause of bronchiolitis in children under age 1, and nearly all children within the U.S. have been infected by age 2.[7,8] Symptoms of RSV include runny nose, decreased appetite, coughing, sneezing, and wheezing, which typically appear in stages. In young infants with RSV, the only identifiable symptoms may be irritability, decreased activity, and respiratory complications.[9]

Infection with RSV varies in severity, ranging from mild, cold-like symptoms in most patients to serious illness and even death in vulnerable individuals, including premature and young infants, children with chronic lung disease or congenital heart disease, and those over age 65. Most people recover from RSV infection within one to two weeks; however, some individuals may develop severe infection requiring hospitalization.[7] RSV can also lead to the exacerbation of serious conditions such as asthma, chronic obstructive pulmonary disease (COPD), and congestive heart failure.[10]

RSV can be transmitted via bodily fluids, direct contact with an infected individual, or surface transfer. The virus may be contagious for 3 to 8 days and up to two weeks before the patient starts showing signs of illness. Some infants and those with weakened immune systems can be contagious for up to four weeks.[11]

Traditionally, RSV has had a season, similar to "influenza season," where the virus is typically more prevalent. In most regions of the U.S. and other areas with similar climates, RSV season typically starts during the fall and peaks in the winter.[12]

Within the past few years, four RSV vaccine formulations have become available to prevent RSV infection in the most vulnerable patients.

AREXVY® (GlaxoSmithKline)

The first RSV vaccine was approved in May 2023 by the FDA. It is a recombinant, adjuvanted vaccine that works by promoting active immunization against RSV prefusion F3 (RSVPre3) glycoprotein to protect against RSV-A and/or B-associated lower respiratory tract disease. The adjuvanted formulation has been shown to increase RSV-specific CD4+ T-cell frequencies.[13,14]

AREXVY® is a single-dose intramuscular injection. The CDC recommends an RSV vaccine for adults ages 75 years and older and for adults ages 60 to 74 who are at an increased risk for severe RSV. Risk factors include frailty, advanced age, residence in a nursing home or long-term care facility, or other factors deemed by a health care provider as likely to increase the risk for severe respiratory disease.[15] In May 2024, AREXVY® became FDA approved for patients between the ages of 50 to 59 who are at increased risk for lower respiratory tract infections, including patients with chronic pulmonary, cardiovascular, kidney, and liver disease, and diabetes mellitus. However, at the time of article submission, the ACIP had not yet altered its recommendations for AREXVY®.[16]

AREXVY® has been found to be both safe and effective in clinical trials, demonstrating high efficacy against symptomatic RSV infection during the first RSV season after vaccination. However, vaccine efficacy declined going into the second RSV season, and re-vaccination at 12 months did not appear to provide any additional benefit. Adverse effects of the recombinant, adjuvanted RSV vaccine include headache, myalgia, and fatigue.[3]

ABRYSVO®(Pfizer)

The second RSV vaccine, ABRYSVO®(Pfizer), was approved by the FDA in May 2023. This is also a recombinant, bivalent vaccine, given as a single intramuscular dose, similar to AREXVY®. ABRYSVO® works by promoting active immunization against RSV prefusion F glycoprotein to protect against RSV-A and/or B-associated lower respiratory tract disease. When administered to pregnant patients, antibodies to RSV antigens are transferred to the fetus to protect infants up to 6 months of age from RSV-associated lower respiratory tract disease.[17,18]

This RSV vaccine is indicated for active immunization for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years and older, with the same CDC recommendations for those who should receive it as AREXVY®.[15] It is also indicated for use in patients under 60 years of age for seasonal administration, between the months of September and January, during pregnancy from 32 weeks and 0 days through 36 weeks and 6 days of gestational age. For pregnant patients falling outside of these specifications, vaccination is not recommended. This RSV vaccine can be administered regardless of previous RSV infection. There are currently no ACIP recommendations or data for RSV vaccination in subsequent pregnancies.[15] Adverse effects include pain at the injection site, headache, nausea, and myalgia.[19]

mResvia® (Moderna)

Approved by the FDA in May of 2024, mResvia® is a messenger ribonucleic acid (mRNA) vaccine that promotes active immunization against RSV prefusion F glycoprotein to protect against lower respiratory tract disease associated with RSV-A and/or RSV-B.[20] The mResvia® RSV vaccine is given as a single intramuscular dose.

This RSV vaccine is indicated to prevent RSV-associated lower respiratory tract disease in patients 60 or older.[21] The ACIP recommends vaccination for all patients 75 or older and for patients aged 60 to 74 who are at increased risk of RSV. Adverse effects include pain at the injection site, fatigue, headache, and myalgia.[21]

Nirsevimab (Beyfortus® (Sanofi))

Nirsevimab is not technically a vaccine, but it confers long-lasting protection from RSV and is currently being utilized in a manner similar to routine childhood vaccination.[22] Nirsevimab is a monoclonal antibody that works as an RSV F protein-directed fusion inhibitor and is a human immunoglobulin G1 (IgG1) kappa monoclonal antibody with anti-RSV activity that promotes passive immunization. It was FDA approved in July 2023 and is administered via intramuscular injection during an infant's first RSV season utilizing weight-based dosing.[15,22]

Nirsevimab is indicated for the prevention of RSV lower respiratory tract infections in neonates and infants less than 8 months of age born during or entering their first RSV season.[22] It is also indicated for pediatric patients up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.[15] General recommendations for administration of nirsevimab require consideration of the infant's age and maternal vaccination status.[23]

To summarize ACIP's current RSV immunization recommendations at the time of article submission:

- Adults ages 75 years and older should receive a single dose of an RSV vaccine.[21]
- Adults ages 60 to 74 years at an increased risk for severe RSV should receive a single dose of an RSV vaccine.[21]
- Either maternal RSV vaccination with ABRYSVO® (Pfizer), during 32 weeks 0 days through 36 weeks 6 days gestation in the months of September through January, or immunization of the infant with RSV monoclonal antibody to prevent severe RSV disease is recommended.[15,22]

New Formulations for Existing Vaccines

Beyond the development of new vaccines to prevent mpox and RSV, there are also new formulations available for existing vaccines, such as pneumococcal, hepatitis B, and meningococcal, that pharmacists may be providing to patients.

Pneumococcal

Each year, pneumococcal disease accounts for over 150,000 hospitalizations and over 3,000 deaths in the U.S. Pneumococcal disease refers specifically to an acute bacterial infection caused by *Streptococcus pneumoniae,* which is transmitted via direct contact with respiratory secretions from an infected person. An infection with *S. pneumoniae* may present as disseminated or invasive (i.e., bacteremia, meningitis, arthritis, peritonitis), lower respiratory (i.e., pneumonia), or upper respiratory (i.e., sinusitis, otitis media) infection. Those infected most commonly experience fever, shortness of breath, joint pains, chills, and confusion, though symptoms depend on the type of infection.[24,25]

Immunization against *S. pneumoniae* can help protect those who are more susceptible to pneumococcal disease. Older adults, young children, and those with certain health or lifestyle factors are more likely to be affected by pneumococcal disease. Health and lifestyle factors that increase risk for pneumococcal infection include alcoholism;

cigarette smoking; chronic heart, liver, or lung disease; chronic renal failure; cochlear implant; asplenia; cerebrospinal fluid leak; diabetes mellitus; HIV infection; generalized malignancy; and other immunocompromising conditions.[24]

Pneumococcal vaccines create antibodies (immunoglobulin G) against the polysaccharide capsule of *S. pneumoniae*, causing destruction of *S. pneumoniae* serotypes. The number included in the vaccine name indicates how many serotypes the vaccine creates antibodies against (i.e., Prevnar 20™ (Pfizer) creates antibodies against 20 serotypes). There are currently four approved pneumococcal vaccine formulations available in the U.S.: Pneumococcal Polysaccharide Vaccine 23, also known as PPSV23 or Pneumovax 23® (Merck), was approved in 1983; adjuvanted Pneumococcal Conjugate Vaccine 15, also known as PCV15 or Vaxneuvance™ (Merck), was approved in July 2021, and adjuvanted Pneumococcal Conjugate Vaccine 20, also known as PCV20 or Prevnar 20™ (Pfizer), was approved for adults in June 2021 and children in April 2023. Most recently, Pneumococcal 21-valent Conjugate Vaccine, also known as PCV21 or CAPVAXIVE™ (Merck), was approved for use in June 2024.[24] Recommendations for pneumococcal immunizations are rapidly changing as new formulations are approved. Current ACIP recommendations are mainly based on age and risk factors. Children should receive four doses of either PCV15 or PCV20 at ages 2 months, 4 months, 6 months, and between 12-15 months. For children who missed receiving immunization against pneumococcal disease during these timeframes, the CDC's catch-up schedule on the CDC website should be followed.[26]

Adults 19 to 64 years of age with any risk factors or underlying medical conditions listed above and adults 65 years and older should receive either PCV20 or PCV15. If PCV15 is used, the adult should receive one dose of PPSV23 at least one year later. If PCV20 is used, no further doses of pneumococcal vaccines are currently recommended.[26]

The newest pneumococcal vaccine formulation is CAPVAXIVE™ (Merck), which is Pneumococcal 21-valent Conjugate Vaccine. CAPVAXIVE™ provides coverage against eight serotypes of *S. pneumoniae* most commonly responsible for invasive pneumococcal disease, which are not covered by other pneumococcal vaccine formulations. CAPVAXIVE™ helps the body to develop an immune response via the same mechanism as other pneumococcal vaccines. The CDC and ACIP recently recommended PCV21 (CAPVAXIVE™) as another option for adults 19 years or older requiring a dose of PCV.[27,28]

All pneumococcal vaccine formulations are intramuscular injections. Common adverse effects identified with the pneumococcal vaccine formulations include pain at the injection site, fatigue, myalgias, and fever. These adverse effects are typically mild and resolve within one to three days.[24]

The CDC has developed a resource to aid in the determination of patient eligibility for pneumococcal vaccination. PneumoRecs VaxAdvisor is a tool available online or through a mobile app. Inclusion of the patient's age, pertinent health conditions, and any previously received pneumococcal immunizations will help determine patient pneumococcal vaccine eligibility.[29]

Hepatitis B

Hepatitis B Virus (HBV) is a vaccine-preventable, communicable disease impacting the liver that is transmitted via percutaneous or mucosal exposure of infectious bloody or bodily fluids. There are approximately 900,000 reported chronic HBV infections in the U.S., with an estimated 1.9 million infections when accounting for underrepresentation in at-risk patient populations. Common risk factors associated with HBV include injection drug use, multiple sex partners, surgery, and other sexual and bloodborne risk behaviors.[30]

Since the inception of the hepatitis B vaccine in the early 1980s, the number of reported HBV cases significantly declined, although recent reduction has stalled. This stagnant progression aligns with low hepatitis B vaccination rates among adults 19 years and older, and adults with known risk factors.[30]

HBV can range from asymptomatic to symptomatic hepatitis. Signs of acute hepatitis B appear an average of 90 days after exposure. Most common symptoms include abdominal pain, nausea/vomiting, dark urine or clay-colored stools, fatigue, fever, jaundice, joint pain, and loss of appetite.[31]

Currently, there are four hepatitis B vaccine formulations available. The three single-antigen recombinant adjuvant vaccines include Recombivax HB® (Merck), which was FDA approved in 1986, followed by Engerix-B® (GlaxoSmithKline) in 1989, and Heplisav-B® (Dynavax) in 2017. PreHevbrio® (VBI Vaccines) is the only three-antigen recombinant adjuvant vaccine and was FDA approved in 2021. These vaccines provide prevention of HBV infection caused by all known subtypes of the HBV by inducing antibodies to hepatitis B surface antigen (HBsAg). The Heplisav-B® (Dynavax) and PreHevbrio® (VBI Vaccines) formulations are FDA approved for adults 18 years or older, in comparison to Engerix-B® (GlaxoSmithKline) and Recombivax HB® (Merck), which are approved for all eligible ages. Hepatitis B vaccinations have historically been administered intramuscularly as a three-dose series, at 0, 1, and 6 months in adults, and 0, 1-2, and 6-18 months in children.[32-34]

The development of Heplisav-B® (Dynavax) introduced the first two-dose hepatitis B vaccine formulation administered intramuscularly 4 weeks apart. Engerix-B® (GlaxoSmithKline) and Recombivax HB® (Merck), are interchangeable to complete the vaccination series, while Heplisav-B® cannot be combined with any other hepatitis B vaccine formulation to complete the series. Two doses of Heplisav-B® are required to complete the series. Patients on hemodialysis should follow a separate dosing schedule of 3-4 doses. Of the hepatitis B vaccine formulations, Heplisav-B® and PreHevbrio® (VBI Vaccines) are not recommended in pregnancy. Engerix-B® (GlaxoSmithKline) and Recombivax HB® (Merck), are the preferred formulations in pregnant patients. Common adverse effects associated with hepatitis B vaccination include injection site pain, headache, fatigue and myalgia.[32-34]

Eligible patients for routine hepatitis B vaccination include newborns receiving their first dose within 24 hours of birth, along with unvaccinated children younger than 19 years of age. ACIP also recommends the hepatitis B vaccine series to adults between the ages of 19 to 59, adults 60 years and older with risk factors for HBV (e.g., chronic liver disease; HIV infection; sexual exposure risk; current or recent recreational injection drug use; percutaneous or mucosal risk for exposure to blood [ESRD, diabetes], incarceration, travel to countries with high or intermediate endemic for HBV), and adults 60 years and older who do not meet risk criteria.[32] Adults 60 years and older without risk factors for hepatitis B may receive the hepatitis B vaccine series. Previous recommendations encouraged administration to all patients who requested it, but new ACIP language for adults 60 years and older without known risk factors encourages providers to offer hepatitis B vaccination, instead of waiting for the patient to request it. ACIP highlights that those who have completed a hepatitis B vaccination series or with history of HBV infection should not receive additional hepatitis B vaccination. They acknowledge there are situations when revaccination is recommended, including non-responder infants born to a mother testing positive for hepatitis B surface antigen (HBsAg), health care providers, and patients on hemodialysis. ACIP recommendations also acknowledge that limited access to serologic testing should not hinder vaccination. Serologic testing is not required for vaccination, and it is recommended to vaccinate when testing is not available.[30]

Meningococcal

Meningococcal disease encompasses a spectrum of infections caused by *Neisseria meningitidis* and is classified into 12 serogroups according to the composition of the polysaccharide capsule. Only six serogroups (A, B, C, W, X, and Y) cause most cases of meningococcal disease.[35] *N. meningitidis* is transmitted via contact with respiratory secretions from an infected individual, and humans are the only host. Those infected with *N. meningitidis* may experience fever, headache, and stiffness of the neck.[36]

Cases of meningococcal disease in the U.S. have been on the rise, with 422 confirmed and probable cases documented in 2023, which is the largest number of cases since 2014.[37] The CDC estimates that between 10 and 15 of every 100 people diagnosed with meningococcal disease will die.[38] Of those who survive infection, approximately 1 in 5 will experience long-term effects, such as neurological complications, deafness, damage to the brain, or limb loss.[35]

Those who are most likely to become infected with meningococcal disease include children under the age of one year, teens, those between the ages of 16 and 23 years, and adults 65 years and older. Additionally, people with weakened immune systems due to disease or medication therapies are at higher risk for infection, specifically those with disorders of the complement system, functional or anatomic asplenia, or HIV infection. Patients receiving complement inhibitors such as eculizumab and ravulizumab are also at higher risk for infection from meningococcal disease. Certain lifestyle factors may also predispose patients to higher risk of infection. Those living in close quarters with others, such as college students in dormitories and members of the military living in barracks, are at higher risk for infection.[34] Lastly, those who travel to the "meningitis belt" in sub-Saharan Africa may be at higher risk for infection with meningococcal disease.[39]

Currently, there are a variety of meningococcal vaccines available in the United States. There are three quadrivalent non-adjuvant meningococcal conjugate (MenACWY) vaccines, two serogroup B adjuvant meningococcal (MenB) vaccines, and one pentavalent adjuvant vaccine covering serogroups ABCWY available. Trade names for the MenACWY vaccines include Menveo® (GlaxoSmithKline), which was approved in February 2010, and MenQuadfi® (Sanofi Pasteur), which was approved in April 2020. Many people are familiar with Menactra® (Sanofi Pasteur), which was a previously approved

TABLE 2. Vaccine Formulations[41]

Vaccine	*Abbreviation*	*Trade Names*
Mpox	Mpox	Jynneos® (Bavarian Nordic) (2-dose series)
Respiratory syncytial virus	RSV	Arexvy® (GlaxoSmithKline) (1 dose) Abrysvo™ (Pfizer) (1 dose) mRESVIA (Moderna) (1 dose)
Pneumococcal conjugate	PCV15 PCV20 PCV21	Vaxneuvance™ (Merck) (1 dose) Prevnar20™ (Pfizer) (1 dose) CAPVAXIVE™ (Merck) (1 dose)
Pneumococcal polysaccharide	PPSV23	Pneumovax 23® (Merck) (1 dose)
Hepatitis B	HepB	Engerix-B® (GlaxoSmithKline) (3-dose series) Heplisav-B® (Dynavax) (2-dose series) PreHevbrio® (VBI Vaccines) (3-dose series) Recombivax HB® (Merck) (3-dose series)
Meningococcal serogroups A, C, W, Y	MenACWY-CRM MenACWY-TT	Menveo® (GlaxoSmithKline) (1- 2 dose series) MenQuadfi® (Sanofi Pasteur) (1-2 dose series)
Meningococcal serogroup B	MenB-4C MenB-FHbp	Bexsero® (GlaxoSmithKline) (2-dose series) Trumenba® (Wyeth) (2-3 dose series)
Meningococcal serogroup A, B, C, W, Y	MenACWY-TT MenB-FHbp	Penbraya™ (Pfizer) (2-dose series)

quadrivalent meningococcal vaccine but is no longer in production. Trumenba® (Wyeth), approved in October 2014, and Bexsero® (GlaxoSmithKline), approved in January 2015, are the trade names for the MenB immunization formulations.[40] The most recently approved meningococcal immunization, Penbraya™ (Pfizer), was approved in November 2023 and includes a combination of the serogroups of the other vaccine formulations. These vaccines work by introducing antigens to the immune system to induce the production of serogroup-specific bactericidal antibodies.[35,41]

All children between 11 and 12 years of age should receive a dose of a MenACWY formulation. They should also receive a booster dose of the MenACWY formulation at 16 years of age. Those who miss the 11-to-12 year immunization window should receive a dose of MenACWY between 13 and 15 years of age. These adolescents may receive their booster at any time between age 16 and 18 as long as they wait a minimum of 8 weeks between doses. Those who do not receive an initial dose within the 11-to-12 year or 13-to-15 year windows should receive just one dose of MenACWY. This vaccine formulation is not recommended for routine use in adults 19 years and older.[41]

There are different recommendations for vaccinating patients with the previously mentioned disease states that increase the risk for meningococcal disease. These recommendations vary based on patient age, condition, and vaccine formulation. MenB is a two-dose series recommended only for those who have immunocompromising conditions, are traveling to a high-risk area, or are affected by an outbreak of meningococcal disease. Patients between 16 to 23 years of age are eligible for immunization with a MenB formulation, but the same formulation must be used for both doses in the series. In patients receiving Bexsero® (GlaxoSmithKline), the second dose may be administered as soon as 1 month later, and in those receiving Trumenba® (Wyeth), the second dose may be given 6 months later. Patients eligible for both MenACWY and MenB immunizations should receive Penbraya™ (Pfizer).[40] If a patient is due for a second immunization against MenACWY after receiving Penbraya™ (Pfizer), any of the MenACWY formulations may be used. However, if a patient is due for a second immunization against MenB after receiving Penbraya™ (Pfizer), Trumenba® (Wyeth) must be used at least 6 months later.[42]

All meningococcal immunizations are intramuscular injections. Menveo® (GlaxoSmithKline) is available as both a single-dose vial and a vial that must be reconstituted. The single-dose vial is only approved for patients between the ages of 10 and 55 years old; all patients not within this age group should receive the reconstituted formulation.[35] Those who receive immunization against meningococcal disease may experience swelling or tenderness at the injection site, headache, fatigue, and fever. These adverse effects resolve within one to three days.[40]

Table 2 outlines the vaccine formulations, abbreviations, and brand names presented within this publication.[43]

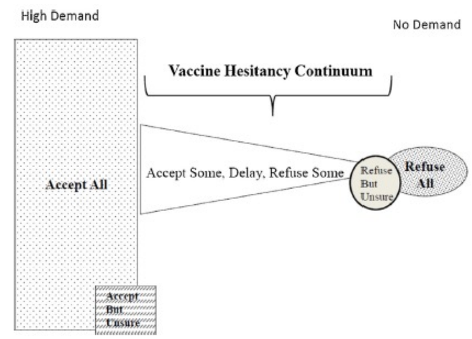
Role of the Pharmacy Team

Even with all the advancements in preventing disease that vaccines provide, less than 100% uptake means patients remain unprotected and at risk for serious infections or even death. Pharmacists and the entire pharmacy team can play an important role in increasing vaccination rates.

Each time a team member interacts with a patient is an opportunity to recommend vaccines. For instance, patients who have certain medical conditions or are a certain age may not realize they are due for a pneumococcal or hepatitis B vaccine. The strong relationships the pharmacy team builds with their patients can be leveraged to recommend appropriate vaccines. Pharmacy dispensing software, Wisconsin Immunization Registry (WIR), or electronic health record (EHR) prompts or flowsheets can be utilized to identify patients in need of vaccination. Even if the pharmacy or site does not provide certain vaccines, a recommendation from a pharmacy professional can still make a positive impact and may increase the likelihood that a patient will receive a vaccine.[44,45]

Many patients may recognize the need for a yearly influenza vaccine, which presents a great time to recommend additional vaccines. In most circumstances, patients can receive more than one vaccine on the same day. It can be difficult for patients to return to a pharmacy or clinic for vaccines, so maximizing each visit is critical.

FIGURE 1. The Continuum of Vaccine Hesitancy Between Full Acceptance and Outright Refusal of All Vaccines



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It is also important for the pharmacy team to advocate for patients to receive recommended vaccines and to have discussions about vaccines with their patients. This may be an opportunity to address vaccine hesitancy. Vaccine hesitancy, according to the WHO's Strategic Advisory Group of Experts on Immunization (SAGE), is defined as "delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence."[46] Figure 1 illustrates the continuum of vaccine hesitancy, from outright refusal to full acceptance of vaccines.[46]

Pharmacy team members can employ motivational interviewing (MI) skills to engage patients or caregivers in discussions about vaccine hesitancy. MI is a patient-centered approach that seeks to increase a person's own internal motivation to change, often addressing hesitancy or ambivalence. The five core communication skills of MI include: (1) asking open-ended questions; (2) affirming the patient's statements; (3) reflective listening; (4) summarizing; and (5) informing and advising only if the patient gives permission.[47] When a pharmacy team member is talking to a patient who is concerned about the safety of vaccines, MI may include establishing honest dialogue, acknowledging that vaccines may be associated with adverse events, balancing the risk of adverse events against disease risk, addressing specific patient or caregiver concerns, providing other resources, and ensuring ongoing communication.[48]

One communication method encouraged by the CDC is SHARE.[49] SHARE is the acronym for:

- **SHARE** the reasons why the vaccine is right for the patient given his or her age, health status, lifestyle, occupation, or other risk factors.
- **HIGHLIGHT** positive experiences with vaccines (personal or in your practice), as appropriate, to reinforce the benefits and strengthen confidence in vaccination.
- **ADDRESS** patient questions and any concerns about the vaccine, including adverse effects, safety, and vaccine effectiveness in plain and understandable language.
- **REMIND** patients that vaccines protect them and their loved ones from many common and serious diseases.
- **EXPLAIN** the potential costs of getting a vaccine-preventable illness, including serious health effects, time lost (such as missing work or family obligations), and financial costs.[49]

The CDC and other organizations, such as the American Academy of Allergy, Asthma, and Immunology, provide helpful information for the pharmacy team and healthcare providers to address common patient safety concerns.[50,51] Taking the first step of opening dialogue with a patient to recommend certain vaccines and listen to their questions or concerns is important. A patient may need to have several conversations with more than one healthcare provider before they decide to receive a vaccine.

Conclusion

Vaccination provides one of the greatest contributions to global health. Development and innovations in vaccine formulations offer improved safety and efficacy of the vaccines available today. Vaccine hesitancy is causing a decline in herd immunity, resulting in lower vaccinations rates, which is ultimately impacting public health. Strategies to overcome vaccine hesitancy through communication and MI will address the need to understand and overcome apprehension about vaccination.

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Assessment Questions

1. What is the main reason adjuvants are used as a component of certain vaccines?
   a. Decreasing the half-life of the antigen
   b. Decreasing the stability of the antigen in the vaccine
   c. Increasing the number of booster doses needed
   d. Increasing vaccine efficacy using less antigen

2. Which of the following vaccines contain a non-aluminum adjuvant?
   a. Abrysvo® (Pfizer) - RSV
   b. Adacel® (Sanofi Pasteur) - Tdap
   c. Arexvy® (GlaxoSmithKline) - RSV
   d. Gardasil 9® (Merck) - HPV

3. **True or False:** JT is a 38 y/o male who comes to your pharmacy to ask about mpox vaccine. He describes having sex with other men, and often has multiple partners. These are considered risky sexual behaviors that warrant receiving the Mpox vaccine.
   a. True
   b. False

4. Which of the following patients would be most appropriate for receiving Arexvy® (GlaxoSmithKline), RSV vaccine?
   a. A 33 y/o female who is expecting her first child in December 2024
   b. A 45 y/o health care worker
   c. A 6 month-old child
   d. A 68 y/o male

5. Which of the following pneumococcal vaccines is most appropriate as the primary series for children?
   a. PCV15 (Vaxneuvance™ (Merck))
   b. PCV20 (Prevnar 20™ (Pfizer)
   c. PPSV23 (Pneumovax 23® (Merck))
   d. Either A or B
   e. All of the above

6. TO is a 48 y/o female patient with Diabetes Mellitus Type 2. Which of the following is the most appropriate pneumococcal vaccine regimen for TO?
   a. PCV15 (Vaxneuvance®)
   b. PCV20 (Prevnar 20™ (Pfizer))
   c. PPSV23 (Pneumovax 23® (Merck))
   d. Either A or B
   e. None of the above

7. MJ is a 35 y/o male presenting to the pharmacy to finish his hepatitis B vaccine series. He received one dose of Heplisav-B® (Dynavax) 2 months ago. What hepatitis B formulation would be most appropriate to complete the hepatitis B vaccine series?
   a. Heplisav-B® (Dynavax)
   b. Engerix-B® (GlaxoSmithKline)
   c. Recombivax HB® (Merck)
   d. Any of the above formulations will complete the series

8. **True or False:** Penbraya™ (Pfizer) can be substituted for existing meningococcal vaccines for all adolescents.
   a. True
   b. False

9. LP, a 60 y/o male patient who is due for several vaccines, comes to your pharmacy. He states he is hesitant to receive any vaccines, especially those that contain adjuvants. What communication method may be most helpful when discussing vaccines with LP?
   a. Providing LP with educational booklets from CDC
   b. Reiterating to LP all the benefits of vaccines
   c. Shaming LP into receiving the vaccines
   d. Utilizing motivational interviewing skills to discuss vaccines with LP

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