Long-Term Care Updates

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What's new in vaccines?

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Introduction

Vaccines remain an important tool for training the body to resist infection. The World Health Organization (WHO) claims that immunization currently prevents 3.5 million to 5 million deaths every year from vaccine-preventable diseases. Currently, vaccines can be used preventatively against more than 20 life-threatening diseases.[1] Innovation in the field of immunization is crucial to slowing the spread of illness and reducing mortality associated with vaccine-preventable diseases.

COVID-19

COVID-19 is an infectious viral disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and is spread via respiratory droplets. COVID-19 has a varied clinical presentation, ranging from mild cold and flu-like symptoms to more serious complications such as shortness of breath, pneumonia, heart problems, acute kidney injury, or organ failure. Individuals at risk for serious complications or hospitalizations include geriatric patients and those with underlying medical conditions (i.e., diabetes, cardiovascular disease, respiratory disease, cancer).[2] Vaccinations have been integral in reducing severity of symptoms and saving lives. According to Watson et al., an estimated 14.4 million deaths from COVID-19 were prevented in 185 countries and territories from December 8, 2020, to December 8, 2021.[3] The current vaccines authorized and available by the FDA are bivalent mRNA vaccines (Moderna, Pfizer-BioNTech) and protein subunit vaccine (Novavax, Adjuvanted).[4]

Recommendations

One important change to recommendations from the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP) from the previous year is that patients aged 65 and older as well as individuals who are moderately or severely immunocompromised are now recommended to receive a second dose of the latest vaccine (2024-2025 COVID-19 Vaccine) 6

Novel Drug Approvals (October 2024)

Brand	Generic	Indication	Mechanism of Action	Dosage Form
Hympavzi	Marstacimab-hncq	Hemophilia	TFPI antagonist	Subcutaneous injection
Itovebi	Inavolisib	Breast cancer	Kinase inhibitor	Oral tablets
Orlynvah	Sulopenem etzadroxil; probenecid	uUTI	Penem antibacterial (sulopenem); renal tubular transport inhibitor (probenecid)	Oral tablets
Vyalev	Foscarbidopa; foslevodopa	Parkinson's disease	Aromatic amino acid decarboxylation inhibitor (foscarbidopa); aromatic amino acid (foslevodopa)	Subcutaneous injection
Vyloy	Zolbetuximab-clzb	Gastric or gastroesophageal adenocarcinoma	Claudin 18.2-directed cytolytic antibody	Intravenous injection

months after their first dose. [5] The 2024–2025 COVID-19 vaccine is intended to focus on the JN.1 lineage of the Omicron variant, a more targeted approach compared to the 2023-2024 vaccine that affected a broader range of Omicron XBB sub-lineages. [6,7]

Table 1. Recommendations for COVID-19 vaccinations[6,7]

	Pfizer	Moderna	Novavax
Age 6 months to 4 years			
Not previously vaccinated	Three doses.	Two doses. Three doses if immunocompromised.	Not mentioned in guidelines
Previously vaccinated with 1 dose of any Moderna	Not mentioned in guidelines	One additional dose. Two additional doses if immunocompromised.	Not mentioned in guidelines
Previously vaccinated with 2 or more doses of any Moderna	Not mentioned in guidelines	One additional dose.	Not mentioned in guidelines
Previously vaccinated with 1 dose of any Pfizer	Two additional doses.	Not mentioned in guidelines	Not mentioned in guidelines
Previously vaccinated with 2 or more doses of any Pfizer	One additional dose.	Not mentioned in guidelines	Not mentioned in guidelines
Age 5 to 11 years			
Not previously vaccinated	One dose. Three doses if immunocompromised.	One dose. Three doses if immunocompromised	Not mentioned in guidelines
Previously vaccinated with 1 or more doses of Moderna or Pfizer	One additional dose. *Complete series with whichever brand was previously received before administering booster if immunocompromised.	One additional dose. *Complete series with whichever brand was previously received before administering booster if immunocompromised.	Not mentioned in guidelines
Age 12 to 18 years			
Not previously vaccinated	One dose. Three doses if immunocompromised.	One dose. Three doses if immunocompromised.	Two doses.
Previously vaccinated with any COVID-19 vaccine(s)	One additional dose. *Complete series with whichever brand was previously received before administering booster if immunocompromised.	One additional dose. *Complete series with whichever brand was previously received before administering booster if immunocompromised.	One additional dose. *Complete series with whichever brand was previously received before administering booster if immunocompromised.
Age ≥19 years			
Not previously vaccinated	One dose. Three doses if immunocompromised.	One dose. Three doses if immunocompromised.	Two doses.
Previously vaccinated with any COVID-19 vaccine(s)	One additional dose. *Complete series with whichever brand was previously received before administering booster if immunocompromised.	One additional dose. *Complete series with whichever brand was previously received before administering booster if immunocompromised.	One additional dose. *Complete series with whichever brand was previously received before administering booster if immunocompromised.
Age ≥65 years			
Previously vaccinated with any COVID-19 vaccine(s)	Additional booster.	Additional booster.	Additional booster.

NOTE: Pfizer vaccination is available as a 0.3mL IM injection. Moderna and Novavax vaccinations are available as 0.5mL IM injections. All doses should be the most current formulations on the market, which are the 2024-2025 formulations as of September 12, 2024.[6]

Pneumococcal Disease

Streptococcus pneumoniae is a gram-positive bacterium found in the respiratory tract of 5-90% of healthy individuals. There are over 100 known serotypes of this organism, but not all cause the clinical presentation associated with pneumococcal disease. Up to 5-10% of adults without children and 20-60% of school-aged children may be carriers without actually contracting the disease. Transmission, as with RSV, occurs through contact with respiratory droplets. Symptoms are often upper respiratory in nature and can include sinusitis and otitis media, but if left untreated, the disease could progress to pneumonia, bacteremia, or meningitis. Vaccination is necessary for preventing these escalations.[8]

Recommendations

On June 27, 2024, ACIP recommended the FDA approved 21-valent conjugate vaccine (PCV21) from Merck, called Capvaxive, as an option for adults aged ≥19 years who are currently recommended to receive PCV15 or PCV20. There are now currently four pneumococcal vaccines available on the market, one polysaccharide vaccine (PPSV23) and three conjugate vaccines (PCV15, PCV20, and PCV21). The addition of PCV21 to vaccine recommendations is expected to prevent additional disease caused by pneumococcal serotypes due to its coverage of an additional eight serotypes not included in other licensed vaccines.[9]

In addition to this update, the CDC implemented an updated pneumococcal vaccination recommendation, lowering the eligible age from 65 to 50 on October 23, 2024.[10] The decision to lower the age was based on the Evidence to Recommendations (EtR) framework which performed a comprehensive evaluation of various pieces of evidence to determine if the PCV21 should be recommended for U.S. adults aged 50–64 years who currently do not have a risk-based pneumococcal vaccine indication. A subgroup committee of the ACIP named the Work Group passed judgements on various evaluation points, including public health and importance, benefits and harms, values, acceptability, resource use, equity, and feasibility. The Balance of Consequences determined that "the desirable consequences probably outweigh undesirable consequences" in most of these domains. Some ACIP members were in support of lowering the vaccine age to 50 due to benefits in health equity among black adults who have higher Invasive Pneumococcal Disease (IPD) rates, immune senescence prevention, ease of implementation, and that 30–50% of adults in this age group already qualify for the vaccine's administration. Other members, however, expressed concerns about provider confusion if the recommendations for PCV21 differed from other pneumococcal vaccine recommendations. In response to this, lowering the age-based recommendation for *all* PCVs to age ≥50 years was considered for review, where it was eventually approved at the October 2024 ACIP meeting.[11]

Table 2. CDC Guidelines for pneumococcal vaccination[12,13,14]

Vaccination	PCV15 or PCV20	PPSV23	PCV21 (Capvaxive)
Patient Population	• Children ≤ 5 years • Age 5-49 years with risk conditions* and no previous PCV • Age ≥ 50 years and no previous PCV • PCV20 only: patients who previously received PCV13 and have not yet received all recommended PPSV23 doses	• Ages 2-18 years with risk conditions* who received PCV15 • Age ≥ 19 who received PCV15 • Previously received PCV13 • Patients who previously received PCV13 and have not yet received all recommended PPSV23 doses	• Ages 19-49 years with risk conditions* and no previous PCV • Age ≥ 50 years and no previous PCV • Age ≥ 19 years who previously received PCV13 and have not yet received all recommended PPSV23 doses

*Risk factors include: alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, cerebrospinal fluid leak, diabetes mellitus, generalized malignancy, human immunodeficiency virus (HIV), Hodgkin disease, immunodeficiency/immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, sickle cell disease, and other hemoglobinopathies.

Capvaxive is administered as a single 0.5mL intramuscular injection via prefilled syringe. As such, there are no requirements for preparation or reconstitution aside from the need to attach a needle to the Luer Lock syringe tip. It should be stored in the refrigerator between 2 and 8°C (36 to 46°F) until use and protected from light. Do not freeze Capvaxive.[15]

Respiratory Syncytial Virus

Respiratory syncytial virus (RSV) is a virus that typically causes mild, self-limiting upper respiratory symptoms; however, some patient populations are at risk for more severe presentation. Older adults and children under the age of 1 year can develop pneumonia or other respiratory complications that could potentially lead to hospitalization. The virus spreads through droplet contact, often due to sneezing, coughing, or touching contaminated surfaces. Precautions to avoid such

contact are especially important during the peak season for viral transmission, occurring between during the fall and winter in the United States.[16] Table 3 below provides a comparison of the products currently on the market for RSV vaccination.

Table 3. Comparison of RSV Vaccines[17,18,19]

	Arexvy	**Abrysvo**	**mResvia**
Product	Respiratory Syncytial Virus Vaccine, Adjuvated Suspension for IM Injection	Respiratory Syncytial Virus Vaccine, Solution for IM Injection	Respiratory Syncytial Virus Vaccine, Suspension for IM Injection
Manufacturer	GlaxoSmithKline	Pfizer, Inc.	ModernaTX, Inc.
Pharmacologic category	Inactivated (Viral); Vaccine, Recombinant		mRNA Vaccine
Indication	Prevention of LRTD caused by RSV in people 60 years of age and older. Immunizations in individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.	Prevention of LRTD caused by RSV in people 60 years of age and older. Immunization of pregnant individuals at 32 through 36 weeks gestational age for prevention of LRTD in infants from birth to 6 months of age. Immunization of individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV	Prevention of LRTD caused by RSV in people 60 years of age and older.
Dosage	Administer 0.5 mL IM as a single dose		
Preparation for administration	Prior to use, powder (lyophilized antigen vial) must be reconstituted with the liquid (adjuvant vial).	Reconstitute with provided syringe of sterile water diluent component.	Thaw pre-filled syringes to room temperature [15 to 25°C (59 to 77°C)] before administering.
Storage requirements after preparation	Administer immediately or store in the refrigerator between 2°C (35.6°F) and 8°C (46.4°F) or at room temperature [up to 25°C (77°F)] for up to 4 hours. Protect vials from light. Do not freeze.	Administer immediately or store at room temperature [15 to 30°C (59 to 86°F)] and use within 4 hours. Do not store in refrigerated conditions. Do not freeze.	Administer immediately or store at 8 to 25°C (46 to 77°F) for up to 24 hours after removal from refrigerated conditions. Do not refreeze or return to refrigerator. Do not shake.
Adverse reactions	Most commonly reported (≥ 10%) were injection site pain, fatigue, myalgia, headache, and arthralgia	Most commonly reported (≥ 10%) were fatigue, headache, injection site pain, muscle pain, fatigue (patients ≥ 60 years), and nausea (pregnant individuals)	Most commonly reported (≥ 10%) were injection site pain, fatigue, headache, myalgia, arthralgia, axillary swelling or tenderness, and chills
Availability	FDA approved May 2023; available now	FDA approved May 2023; available now	FDA approved May 2024; available now

IM: intramuscular, LRTD: lower respiratory tract disease, FDA: Food and Drug Administration

Recommendations

The most notable change from the previous year is an added indication to both the Arexvy and Abrysvo vaccines. Arexvy's labeled indications now include immunizations for individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.[17] Additionally, the Abrysvo indications now include immunizations for individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.[18] Table 4 below lists factors that place a patient at increased risk for severe RSV disease for the purpose of determining vaccine eligibility.

Risk Factor
• Chronic lung disease (chronic obstructive pulmonary disease, asthma, etc.)
• Cardiovascular disease [congestive heart failure, coronary artery disease, etc. (excluding isolated hypertension)]
• Moderate or severe immune compromise
• Diabetes mellitus with end organ damage
• Severe obesity (body mass index ≥ 40 kg/m^2)
• Neurologic or neuromuscular conditions
• Advanced chronic kidney disease
• Liver disorders
• Hematologic disorders
• Residence at a long-term care facility
• Frailty

Note: List is not all-inclusive. Shared-decision making should be used to determine if a patient has any additional factors that may put them at risk for severe respiratory infection.

Clinical Data Review

In a randomized controlled trial done with the Arexvy vaccine, immunobridging studies were carried out to determine if individuals aged 50–59 with chronic medical conditions had antibody responses to RSV that compared to the antibody responses of individuals 60 years of age and older, as initially indicated. Participants aged 50 through 59 were randomized to receive Arexvy (n = 386) or saline placebo (n = 191) while the older comparator group (n = 381) received Arexvy. Criteria for immunobridging had to be met to consider use of the vaccine. Results of the upper limit (UL) of the 95% confidence interval (CI) for the geometric mean titer (GMT) ratio (comparing individuals of $\geq$ 60 years to those 50–59 with chronic conditions) was ≤1.50 (0.8, 0.8), and the UL of the 95% CI for the difference in seroresponse rates (SRR) between the two age groups was ≤10% (6.5%, 7.2%) for both RSV-A and RSV-B subtypes, demonstrating an antibody response that met immunobridging criteria. [17]

Abrysvo expanded their indications to include patients aged 18 through 59 years at increased risk of LRTD caused by RSV due to a multicenter, randomized, double-blind, placebo-controlled study. In this study, individuals 18 through 59 years of age (n=437) at increased risk of LRTD caused by RSV were compared to patients greater than 60 years of age (n=410) in a separate study, 44% of which had chronic medical conditions. Both groups were compared based on the assessment of the effectiveness of the RSV neutralizing geometric mean titers (GMTs) and seroresponse rates. For RSV A and RSV B, lower bounds of the 2-sided 95% CIs were greater than 0.667 for the ratio of neutralizing GMTs, and the 2-sided 95% CIs were greater than 10% for the percentage difference in neutralizing titer seroresponse rates, ultimately demonstrating non-inferiority and an appropriateness to treat.[18]

Conclusion

Due to evolving diseases and medical advancements, vaccine schedules and recommendations are updated frequently to reflect the most recent and current information. This allows for effective and safe care to reach communities and individuals for protection and prevention from severe disease, hospitalization, or death. [21] It is recommended to routinely check ACIP for updated guidelines because changes can occur throughout the year. Healthcare providers are a valuable resource to patients regarding vaccine information and administration; leaving a lasting impact on the communities served.

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