



IMA Public Health Committee – December 2023

Noteworthy Recent Developments in Adult Vaccines

There have been some recent developments in vaccine recommendations for adults. An RSV vaccine for older adults is now available for adults 60 years of age and older, and eligible individuals should discuss with their healthcare providers whether to receive the vaccine. An RSV vaccine is recommended for pregnant individuals during 32 through 36 weeks gestation, using seasonal administration, to protect their infants from RSV. Adults should ensure they are fully vaccinated against polio, particularly given recent community transmission within the United States. The mpox vaccine, JYNNEOS, is recommended for persons 18 years and older at risk for mpox. A pentavalent formulation of meningococcal vaccine is now available for use when MenACWY and MenB are indicated at the same visit.

Respiratory Syncytial Virus (RSV) vaccine for older adults

1. RSV is estimated to contribute to 60,000-160,000 hospitalizations and 6,000-10,000 deaths per year among adults 65 years and older in the United States.
2. In May 2023, the U.S. Food and Drug Administration (FDA) approved two RSV vaccines for use in individuals 60 years of age and older to prevent lower respiratory tract disease caused by RSV.
3. In June 2023, CDC recommended that adults 60 years of age and older may receive a single dose of RSV vaccine, using shared clinical decision-making.
4. In clinical trials, RSV vaccines showed good vaccine efficacy (approximately 80-94%) in preventing symptoms of lower respiratory tract disease, such as cough, sputum production, shortness of breath, and wheezing, with greater efficacy against more severe disease. The vaccine has good durability over at least 2 years.
5. The trials were not powered to show whether vaccination reduced the risk of hospitalization or death from RSV.
6. Among approximately 38,000 participants in the clinical trials who received the vaccine, there were 6 reports of neuroinflammatory events, such as Guillain-Barré syndrome and acute disseminated encephalomyelitis (ADEM), and 20 reports of atrial fibrillation. These issues will continue to be studied in post-marketing surveillance studies.
7. Individuals most likely to benefit from the RSV vaccine include those for whom an RSV infection may have serious consequences, such as those who:
 - a. have chronic medical conditions, such as lung disease, chronic heart disease, diabetes, neurologic conditions, etc.
 - b. are residents of long-term care facilities
 - c. are immunocompromised
 - d. are frail or very elderly
8. Shared clinical decision-making means that an individual should discuss with their healthcare provider whether a particular vaccine is right for them; there is no blanket recommendation for individuals in a particular age group or with specific risk factors.

RSV vaccine for pregnant individuals

1. RSV is the leading cause of hospitalization in infants in the United States, and each year an estimated 58,000-80,000 children younger than 5 years are hospitalized due to RSV infection, with the highest rates of hospitalization among infants 0-5 months.
2. Although premature infants and those with medical conditions such as lung disease or congenital heart disease are at highest risk of RSV, about 80% of children hospitalized with RSV were previously healthy.
3. On August 21, 2023, the FDA approved Pfizer's Abrysvo, an RSV vaccine for use in pregnant individuals who are between 32 and 36 weeks gestational age of pregnancy, to prevent lower respiratory tract disease (LRTD) and severe LRTD caused by RSV in their infants from birth through 6 months of age.
4. When a pregnant individual receives the RSV vaccine, they produce antibodies that are passed through the placenta and protect the infant against RSV after birth.
5. When given in clinical trials to pregnant individuals between 24 and 36 weeks gestational age, the vaccine reduced the risk of severe LRTD in the infant by 81.8% within 90 days after birth, and 69.4% within 180 days after birth.
6. In a subgroup of study participants who were 32 through 36 weeks gestational age, of whom approximately 1,500 received the vaccine and 1,500 received placebo, the vaccine reduced the risk of LRTD by 34.7%, and reduced the risk of severe LRTD by 91.1% within 90 days after birth when compared to placebo. Within 180 days after birth, the vaccine reduced the risk of LRTD by 57.3% and by 76.5% for severe LRTD, when compared to placebo.
7. Given concern about a "numerical imbalance" in preterm births in RSV vaccine recipients (5.7%) compared to those who received placebo (4.7%), the vaccine was approved for pregnant individuals between 32 and 36 weeks gestation only. The data available at this time are insufficient to conclude whether the vaccine caused or did not cause preterm birth.
8. On September 22, 2023, the CDC recommended seasonal administration of one dose of the RSV vaccine for pregnant people during weeks 32 and 36 weeks of pregnancy, to prevent RSV lower respiratory tract infection in infants.
9. Nirsevimab, a monoclonal antibody that can be administered to infants aged <8 months born during or entering their first RSV season, remains an option to prevent RSV infections in infants. In most cases, infants born \geq 14 days after maternal RSV vaccination will not also need nirsevimab.
10. Healthcare providers should discuss both options with pregnant people to help them decide how to best protect their infant from RSV. Note that during the 2023-2024 respiratory virus season, limited supply of nirsevimab may impact this discussion. CDC has issued a [Health Advisory](#) to assist healthcare providers with the decision-making process.

Vaccination against polio

1. In June 2022, a case of paralytic poliomyelitis was confirmed in an unvaccinated immunocompetent adult resident of New York who lived in a county with historically low vaccination rates against polio. The individual had not traveled outside the United States during the potential exposure period, indicating community transmission of poliovirus.
2. Although most adults in the United States likely received polio vaccination as part of routine childhood vaccinations, individuals who are unvaccinated or incompletely vaccinated are susceptible to paralytic polio if exposed to poliovirus.

3. In June 2023, CDC updated recommendations for polio vaccine in adults. Specifically, the recommendations were clarified to state:
 - a. Adults who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with inactivated polio vaccine (IPV).
 - b. Adults who have received a primary series of trivalent oral polio vaccine (tOPV) or IPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV. Situations that put adults at increased risk of exposure to poliovirus include:
 - Travelers who are going to countries where polio is epidemic or endemic
 - Laboratory and healthcare workers who handle specimens that might contain polioviruses
 - Healthcare workers or other caregivers who have close contact with a person who could be infected with poliovirus
 Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.

Vaccination against mpox

1. In May 2022, an unprecedented global outbreak of mpox (formerly known as monkeypox) was detected. Cases in the United States increased rapidly and peaked in August 2022. In Idaho, 15 cases were reported between June and October 2022.
2. This global outbreak of mpox is still ongoing. In Idaho, after a year of no reported mpox cases, cases were again reported in October 2023 and continue to be reported as of November 2023.
3. JYNNEOS vaccine is licensed in the U.S. for subcutaneous administration in individuals 18 years of age and older for prevention of smallpox and mpox. The U.S. Food and Drug Administration (FDA) issued an [Emergency Use Authorization \(EUA\)](#) in August 2022 to also allow for use of JYNNEOS vaccine:
 - a. By subcutaneous injection for prevention of mpox disease in individuals younger than 18 years of age
 - b. By intradermal injection for prevention of mpox disease in individuals 18 years of age and older
 JYNNEOS is administered via 2 vaccine doses, 28 days apart, regardless of route (SQ vs ID).
4. CDC recommends vaccination* with the 2-dose JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox. Persons at risk include:
 - a. Gay, bisexual, and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had one of the following:
 - A new diagnosis of ≥ 1 sexually transmitted disease
 - More than one sex partner
 - Sex at a commercial sex venue
 - Sex in association with a large public event in a geographic area where mpox transmission is occurring
 - b. Sexual partners of persons with the risks described above
 - c. Persons who anticipate experiencing any of the above
 *This is an interim recommendation that ACIP will revisit in 2-3 years.
5. JYNNEOS may also be given as post-exposure prophylaxis (PEP), ideally within 4 days after exposure, but up to 14 days after may still provide some protection.

6. Providers can find a list of sites that report carrying the mpox vaccine on this webpage: <https://www.cdc.gov/poxvirus/mpox/vaccines/vaccine-recommendations.html>. In addition, local public health districts may be able to assist in locating or providing mpox vaccine.

Meningococcal vaccine

1. In October 2023, the FDA approved Pfizer's Penbraya as the first and only pentavalent immunization that confers protection against the 5 most common meningococcal serogroups - A, B, C, W-135, and Y - in individuals 10 through 25 years of age.
2. CDC has recommended that Pfizer's MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit. Indications include:
 - a. Healthy individuals aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccination
 - b. Individuals aged 10 years and older at increased risk of meningococcal disease (e.g., due to persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia) due for both vaccines

References

ACIP June 2023 Live Meeting Archive
<https://www.youtube.com/watch?v=LISLEQ-aLA0>

ACIP Presentation Slides: September 22, 2023
<https://www.cdc.gov/vaccines/acip/meetings/slides-2023-09-22.html>

ACIP Recommendations
<https://www.cdc.gov/vaccines/acip/recommendations.html>
ACIP Shared Clinical Decision-Making Recommendations
<https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html>

CDC, Health Alert Network, Limited Availability of Nirsevimab in the United States – Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023-2024 Respiratory Virus Season
<https://emergency.cdc.gov/han/2023/han00499.asp>

CDC, Mpox Vaccine Recommendations
<https://www.cdc.gov/poxvirus/mpox/vaccines/vaccine-recommendations.html>

CDC, RSV Surveillance & Research
<https://www.cdc.gov/rsv/research/index.html>

CDC, RSV For Healthcare Providers
<https://www.cdc.gov/rsv/clinical/index.html>

FDA News Release, August 21, 2023
<https://www.fda.gov/news-events/press-announcements/fda-approves-first-vaccine-pregnant-individuals-prevent-rsv-infants>

FDA, October 20, 2023 Approval Letter - PENBRAYA

<https://www.fda.gov/media/173225/download?attachment>

Hall CB, Weinberg GA, Blumkin AK, et al. Respiratory syncytial virus-associated hospitalizations among children less than 24 months of age. *Pediatrics*. 2013;132(2):e341-e348.

<https://doi.org/10.1542/peds.2013-0303>

Link-Gelles R, Lutterloh E, Schnabel Ruppert P, et al. Public Health Response to a Case of Paralytic Poliomyelitis in an Unvaccinated Person and Detection of Poliovirus in Wastewater — New York, June–August 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:1065-1068. DOI:

<http://dx.doi.org/10.15585/mmwr.mm7133e2>

Mina Suh and others, Respiratory Syncytial Virus Is the Leading Cause of United States Infant Hospitalizations, 2009–2019: A Study of the National (Nationwide) Inpatient Sample, *The Journal of Infectious Diseases*, Volume 226, Issue Supplement_2, 15 August 2022, Pages S154–S163, <https://doi.org/10.1093/infdis/jiac120>

VRBPAC meeting materials, Fleming-Dutra K, CDC, RSV Epidemiology and Disease Burden in Infants from Birth through 6 Months of Age

<https://www.fda.gov/media/168259/download>