Immunization Update and ACIP Highlights – April 2025

May 7, 2025

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) met on **April 15 and 16** for its triennial vaccine meeting, rescheduled from February 2025. For archives of minutes and slides, go to the ACIP meeting website, Below are the key highlights:

Votes to Recommend or Approve:

- **Meningococcal Vaccines**

  Meningococcal ABCWY combination pentavalent vaccine Penmenvy® (GSK) may be used when Men ACWY and Men B are indicated at the same visit. This applies to persons ages:

  - 10 years and older at increased risk of meningococcal disease
  - 16–23 years when use of Men B vaccine has been chosen after shared clinical decision making

  Penmenvy® is FDA approved for ages 10–25 years.

- **Respiratory Syncytial Virus (RSV) Vaccines Adults**

  ACIP expanded the age when adults at increased risk of severe RSV disease should receive a single lifetime dose of RSV vaccine from 60–74 years down to 50–74 years. Abrysvo® and Arexvy® are FDA approved in theses ages with anticipated FDA approval of mResvia® for the newly recommended ages 50–59 years in **June 2025**.

- **Chikungunya Vaccines**

  Recommendations for Bavarian Norda's virus-like particle (VLP) vaccine (VIMKUNYA™) are for:

  - Laboratory workers with potential for exposure to chikungunya virus
  - Persons ages 12 years and older traveling to a location where there is a chikungunya outbreak
  - Consideration for those traveling or taking up residence for 6 months or longer in locations with elevated risk

  A precaution in persons ages 65 years and older has been added to the recommendation of Valneva's live-attenuated vaccine (IXCHIQ™) due to severe adverse events identified in post-marketing surveillance. IXCHIQ™ is approved for laboratory workers and travelers ages 18 and older.

Votes Planned for June 2025

- **Influenza vaccines:** Updates to the 2025–2026 ACIP Influenza vaccine statement
- **COVID-19 Vaccines:** Recommended use of the 2025–2026 COVID-19 vaccine formula, including the new Moderna mRNA – 1283 lower dose (10mcg/0.2mL) vaccine, for persons ages 12 and older and a potential risk-based rather than universal recommendation

- **RSV —Maternal/Pediatric:** Clesrovimab RSV monoclonal for all infants younger than 8 months
- **Meningococcal ACWY:** Expanded age for Menquadfi to infants 6 weeks to 2 years pending FDA anticipated approval in **May 2025**. When administered to this age, Menquadfi had a non-inferior immune response but more febrile/non-febrile seizures, serious adverse events, and deaths that were concerning to ACIP.
- **HPV Vaccine:** Routine recommendation for ages 9 through 12 years; recommendation of 1-dose schedule for age 9 through 14 years; still considering number of doses for those 15 and older
- **Pneumococcal vaccines:** Updated clinical guidance wording for use of pneumococcal vaccines in pregnant persons and HSCT patients
- **Mpox vaccine:** Recommendation for 2 doses (1 month apart) of JYNNEOS Mpox vaccine in adolescents ages 12–17 years at risk during an outbreak –recommendation for this age during an outbreak has more committee support than for at-risk adolescents not during an outbreak because:
    - To substantially reduce the risk of outbreaks, 50% of the at-risk population needs to be vaccinated with at least 1 dose.
    - JYNNEOS is more immunogenic in adolescents compared to adults, but is a reactogenic vaccine with similar systemic and localized reactions to adults.

No Vote — Evaluations and Discussions:

U.S. Measles Update

The 2025 measles outbreak has been concentrated in Texas with related cases in nearby states, Canada and Mexico. Cases have been identified in half of U.S. states, with 97% of cases being unvaccinated, 11% of cases were hospitalized with some measles-related deaths. CDC has provided technical assistance to states, deployed additional vaccine doses to health departments, and provided laboratory support and health alert provider outreach.

Influenza Vaccines

Strains have been chosen for the 2025–2026 influenza vaccine which include a new Influenza A/H3N1 component.

Influenza A predominated in the 2024–2025 season, with less than 3% of the specimens tested resulting Influenza B. Vaccine effectiveness (VE) results for the 2024–2025 influenza season from the US Flu VE, NVSN, and VISION networks were (range shows difference in VE between networks):

- Pediatric Outpatient: 32–60%
- Pediatric Inpatient: 63–78%
- Adult Outpatient: 36–54%
- Adult Inpatient: 41–55%

Self/caregiver-administered FluMist will be available to commercially insured persons in the 2025–2026 season. It will be adjudicated and administered through a central online pharmacy. Patients will answer screening questions for eligibility determination. Vaccine will be shipped to patient's home for arrival at a date chosen by the patient. After delivery, storage of vaccine is limited to 12 hours out of refrigerator. Patients will report administration of vaccine by text to the online pharmacy, which will report

administration to state vaccine registries. Self/caregiver FluMist will have a different NDC code than provider-administered FluMist.

COVID-19 Vaccines

VE for the 2024–2025 COVID-19 formula vaccine from COVID-NET was:

- **ED/Urgent Care**: 33% in adults, 35% in persons 65+
- **Hospital Inpatient**: 45–46% in all persons 65+, 40% in immunocompromised persons 65+

Pfizer's candidate COVID vaccine, mRNA-1283, elicits higher immune response compared to SPIKEVAX. Anticipated availability is fall of 2025.

The COVID-19 work group favors a risk-based recommendation for certain ages for the next formula of COVID vaccine. ACIP committee members were less enthusiastic about a risk-based recommendation and sited continued disease severity concerns in all ages, higher risk of long COVID and MIS-C in those unvaccinated, potentially lower vaccination uptake with increased complexity of recommendations, and desire not to undermine vaccine confidence.

Current concerns about a risk-based recommendation include:

- 1 in 5 children and adolescents hospitalized for COVID-19 are admitted to the ICU with 41% of these having no underlying medical condition.
- 1 in 5 adults hospitalized for COVID-19 were admitted to the ICU. Adults ages 65+ comprise 68% of adults hospitalized with COVID-19.
- A 2023 survey estimated that 9.2 million adults have had long COVID.
- 74% of adults have at least 1 condition that puts them at higher risk for severe disease; which caused committee members to question why a risk-based recommendation would be necessary in a high incidence population.

RSV Vaccines and Immunizations Maternal/Pediatric

A second long-acting monoclonal antibody to protect infants against RSV was discussed. Clesrovimab (Merck) is not yet approved by the FDA. It has a target action date of **June 10, 2025**. For this vaccine:

- **Recommendation** is only for infants <8 months of age and would not be indicated for second year administration to higher-risk infants. NOTE: Clesrovimab and nirsevimab recommendations would be the same with no preference expressed for infants ages <8 months.
- **Dosage** is 105mg/0.7mL, intramuscular single injection with no difference in dose by infant weight.
- **Storage requirements** are at refrigerator temperature with a maximum of 48 hours at room temperature.
- **Efficacy** against RSV appears to be sustained although the half-life for Clesrovimab is shorter than for nirsevimab (42 vs. 71 days).

Human Papilloma Virus (HPV) Vaccine

There are 37,800 HPV-attributable cancers in the U.S each year. In the 19 years since HPV vaccine licensure, we have seen high vaccine efficacy, high population impact, and strong herd immunity effect from the vaccine program. Quadrivalent HPV vaccine-type prevalence has declined 85% among 14- to 24-year-old, sexually experienced females from the pre-vaccine era to 2018.

ACIP reviewed studies examining a 1-dose vaccine schedule. Review results included the following:

- **Sixty-seven (67)** countries have adopted a 1-dose schedule for some ages.
- The KEN SHE randomized control trial of young women ages 15–20 given 1 dose of HPV vaccine showed **98% VE** for HPV types 16/18 with 36-month duration of protection.
- In the IARC-India trial of girls 10-18 who had received 1 dose, **VE was 92%** against HPV 16/18 with a median follow-up time of 12 years.
- A Costa Rica study showed **99.4% seropositivity** 16 years after vaccination of women ages 18–24 years with 1 dose of HPV vaccine. Small decreases in antibody GMC were seen, but modeling of pooled studies estimates lifelong protection at best case and 25-year protection at worst case.

Models switching to 1-dose HPV vaccination project similar reductions in HPV and cervical cancer incidence when compared to continuing with 2 doses in the U.S. Outstanding questions informing a 1-dose schedule include protection against cancer of sites other than cervix as well as efficacy and immunogenicity in males, those who are immunocompromised, and older age groups.

The ACIP does not plan to change the recommendation that immunocompromised persons receive a 3-dose series. Also, it will not change recommendation for shared clinical decision making for persons ages 27 through 45 years, although the recommended number of doses may change.

Currently in the U.S., 5.7% of HPV vaccines are initiated at ages 9–10. Stakeholders have asked ACIP to modify its recommendation wording. Changing the wording of vaccine initiation age to a routine recommendation for ages 9–12 would allow information systems to more readily program clinician prompts to start the series at age 9 rather than age 11, which may increase series completion by age 13 years. A change in wording would align the ACIP's recommendations more closely to those of the AAP and American Cancer Society. Some adolescent stakeholders are concerned that starting the HPV vaccine earlier could weaken the adolescent visit platform, but since the meningococcal vaccine series initiation age may also change, that may not be an important factor.

Votes for both recommendation changes are anticipated for the June 2025 meeting.

Cytomegalovirus (CMV) Vaccine

Congenital Cytomegalovirus (cCMV) infection occurs in 4.5 per 1,000 live births in the U.S (16,000 births per year) resulting in 3,000 with cCMV disease. It is the most common cause of birth defects in the U.S. and causes 80 neonatal deaths per year. Most newborns with cCMV infection have no clinical signs at birth and are not diagnosed. Vertical maternal transmission occurs most commonly at birth with little sequelae to the infant. Maternal transmission is less common in the first trimester but causes the highest level of symptoms and abnormalities in those infants infected.

Results from a phase 3 study of Moderna's mRNA-1647 CMV candidate vaccine (gB+pentameric Complex) in females ages 16–40 years are anticipated next year. Low CMV awareness and potential need for serologic screening may pose implementation challenges.

Lyme Disease Vaccine

A work group has been formed to evaluate 2 new vaccines currently in clinical trials.

Details Supporting April 2025 Meeting Votes

Questions regarding immunization?
Please contact Tamara Sheffield, MD, MPA, MPH, Medical Director, Immunization Programs, Intermountain Healthcare, at **801-442-3946**.

Meningococcal Vaccines

Pentavalent Meningococcal ACWY + Meningococcal B vaccine (Men ABCWY:Penmenvy®) was licensed in February 2025.

Men ABCWY is non-inferior to Men ACWY except for serogroup A when comparing 1-dose of either vaccine. It was non-inferior to Men ACWY in all serogroups after 2 doses.

There were slightly more unsolicited adverse events with Men ABCWY than with Men B. Men ABCWY had lower hSBA titers than Men B given at 0 and 6 months and was non-inferior to Men B (0, 6) in only 2 of the 4 vaccine indicator reference strains.

Using the pentavalent Men ABCWY when both Men ACWY and Men B are indicated is a cost-saving strategy, but using Men ABCWY when only Men ACWY or only Men B are indicated is massively cost prohibitive.

A vote for a revised adolescent meningococcal schedule is still anticipated in 2025.

Respiratory Syncytial Virus (RSV) Vaccines – Adults

The FDA expanded is approval of Arexvy® RSV vaccine to include ages 50–59 years for at-risk persons. It expanded its approval of Abrysvo® RSV vaccine to include ages 18–59 years for at-risk persons. FDA approval of mResvia® RSV vaccine is anticipated in **June 2025** to include ages 18–59 years for at-risk persons.

The ACIP voted to approve the use of 1 lifetime dose of Abrysvo® and Arexvy® RSV vaccine in persons at risk for lower respiratory disease caused by RSV ages 50 through 59 years. The work group continues to evaluate the evidence around administering the vaccine to younger adults.

There are an estimated 15,000–20,000 annual hospitalizations of adults ages 50–59 years. Adults ages 50–59 years who are hospitalized with RSV have similar underlying conditions as those in hospitalized adults ≥60 years but more often have asthma, immune compromise, and severe obesity. One million doses of protein subunit RSV vaccine in persons ages 50–59 are estimated to avert 2,000 hospitalizations, 430 ICU stays, and 130 deaths and to cause 0–18 vaccine-attributable cases of GBS.

Vaccination of persons 50–59 years with RSV vaccine appears to be cost-effective. Vaccination with subunit vaccines is more cost effective than vaccination with mRNA vaccine.

Revaccination elicits a “boost” in neutralizing antibody immune response but does not appear to reach post-dose 1 antibody levels, even after waiting 3 years to revaccinate after the initial dose of Arexvy®. For mRESVIA®, neutralizing antibody response at 12 and 24 months met non-inferiority criteria when compared with post-dose 1 titers but were lower with the 24-month interval. People with lower titers appear to respond better to revaccination. Cellular immune response data from GSK shows revaccination boosts T-cell response to post-dose 1 level or higher. The relative importance of the cellular response for protection is unknown.

Chikungunya Vaccines

Travelers to areas of Chikungunya outbreak for 1 week incur a risk of 667 cases of clinical disease per 100,000 travelers, hospitalization of 27 cases per 100,000, and clinical arthralgia at 12 months of 2.5 cases per 100,000. Travelers to non-outbreak areas have 1/100th that risk.

Bavarian Nordic's inactivated virus-like particle (VLP) chikungunya vaccine (VIMKUNYA™) was approved by the FDA in **February 2025**. Seroresponse rate was 98% 21 days post vaccination and 85% 6 months post vaccination. There were no safety concerns in clinical trial.

ACIP recommends VLP chikungunya vaccine for:

- Persons ages ≥12 years traveling to a country or territory where there is a chikungunya outbreak.
- Consideration for persons aged ≥12 years traveling or taking up residence in a country or territory without an outbreak but with elevated risk for U.S. travelers (e.g., planning travel for 6 months or more.
- Laboratory workers with a potential for exposure to chikungunya. There were 4 cases in lab workers in the U.S. in the past 10 years.

Valneva's live-attenuated vaccine (IXCHIQ™) is approved for lab workers and travelers ages 18 years and older. It has caused severe or prolonged chikungunya-like adverse reactions identified in post-marketing surveillance, specifically in persons ages 65 years and older, and a precaution for those ages 65 and older has been added to the vaccine recommendation.

Pregnancy is also a precaution for any chikungunya vaccine. Clinical guidance includes:

- Avoiding risk of chikungunya virus exposure, if possible.
- In general, deferring vaccination until after delivery; however, if risk of exposure is high, where possible, avoiding 1st trimester and ideally administering >2 weeks prior to birth.
- Considering vaccination if exposure risk is high given the risk for severe adverse outcomes of infection, particularly if intrapartum transmission occurs
- Preferring non-live VLP vaccine if both VLP and live-attenuated vaccines are available.
- Assuring breastfeeding mothers that non-live vaccines poses no risk as breastfeeding is neither a contraindication nor a precaution for chikungunya VLP vaccine (VIMKUNYA™).