Immunization Update and ACIP Highlights - October 2024

November 6, 2024

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) met on **October 23–24, 2024,** for its regular triennial vaccine meeting. For archives of minutes and slides, go to the ACIP meeting website and click on "Meeting Materials."

Key Meeting Highlights

Votes to Recommend or Approve

- **Pneumococcal Vaccines**
  - — Pneumococcal conjugate vaccines (PCV15, PCV20 or PCV21) be administered to persons ages 50 years and older
  - — Use of either PCV20 or PCV21 to complete a series (rather than PPSV23) for adults who have received a dose of PCV13 but have not completed their pneumococcal series
- **COVID-19 Vaccines**
  - — A second dose of 2024–2025 COVID-19 vaccine for adults ages 65 years and older with a six-month interval between doses
  - — A second dose of 2024–2025 COVID-19 vaccine for persons ages six months to 64 years who are moderately or severely immunocompromised with a six-month interval between doses (minimum Interval two months)
  - — May administer additional doses of 2024–2025 COVID vaccine (three or more) at least two months apart under shared clinical decision-making to persons ages six months and older who are moderately or severely immunocompromised
- **Influenza Vaccines**

  May administer either high-dose influenza vaccine (HD-IIV3) or adjuvanted influenza vaccine (aIIV3) in the VFC program for persons ages 18 years who are solid organ transplant patients on immunosuppressive medication regimens
- **Meningococcal Vaccines**

  An increased interval of six months between doses in the two-dose series of Bexsero. A three-dose series (0, 1–2, 6 months) may be used when rapid protection is needed and should be used for persons at high-risk ages 10 years and older.
- **2025 Immunization Schedules – Approve Schedule Revisions for 2025** (see page 6 for listings)
  - — Child and Adolescent Immunization Schedule
  - — Adult Immunization Schedule

No Vote — Evaluations and Discussions:

- **RSV Vaccines**
  - — RSV Vaccine Maternal/Pediatric. Vaccine Safety Datalink (VSD) study of matched vaccinated and unvaccinated pairs showed no increased risk of preterm delivery or infants small for gestational age in women receiving RSVPreF vaccine (Abrysvo) at gestational weeks 32 through 36. A potential increase in hypertensive disorder of pregnancy warrants further study. Presentation of data on candidate infant monoclonal antibody clesrovimab.
  - — RSV Vaccine Adult. Information presented on third season efficacy, vaccine safety, and use in persons younger than age 60 years..

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No Vote — Evaluations and Discussions, Continued

- **Human Papilloma Virus (HPV) Vaccine**
  - — Evaluating a potential schedule with reduced number of doses
  - — Review of schedule initiation studies for ages 9–10 years with the potential to revise the recommendation language to make initiation at those ages more standard
- **Other Vaccines**
  - — **Chikungunya vaccine.** Work Group evaluation of Bavarian Norda's virus-like particle (VLP) vaccine for use in persons ages 12 years and older
  - — **Cytomegalovirus (CMV).** Information on Moderna's CMV vaccine being in Phase 3 study in females ages 16–40 years
  - — **Mpox vaccine.** Work Group evaluation of Mpox vaccine use in persons ages 12–17 years

Meeting Details

Pneumococcal Vaccines

The ACIP voted to recommend administering a single dose of pneumococcal conjugate vaccine (PCV15, PCV20, or PCV21) to persons ages:

- 50 years and older
- 19 to 49 years with underlying conditions or risk factors who have not previously received a PCV or whose vaccine history is unknown

NOTE: If PCV15 is used, then administer PPSV23 one year or more after PCV15. A minimum interval of eight weeks is permissible if the adult is immunocompromised, has a cochlear implant or CSV leak. If PPSV23 is not available, then can administer PCV20 or PCV21 one year after PCV15.

Adults who have received a dose of PCV13 but have not completed their pneumococcal series should use PCV20 or PCV21 to complete the series rather than PPSV23.

Adults who completed their pneumococcal series by receiving a dose of PCV13 at any time and a dose of PPSV23 at or after age 65 years may have a shared clinical decision-making discussion with their licensed provider regarding a supplemental PCV20 or PCV21 dose at least five years after the last pneumococcal vaccine.

No further doses are recommended in any person who has received either a dose of PCV20 or PCV21.

These recommendations will be reevaluated as pneumococcal products in the pipeline with higher numbers of valencies are approved.

Key factors influencing the decision include:

- Relatively high burden of pneumococcal disease in adults ages 50–64 years, particularly among those with risk conditions. Currently, 33–54% of adults have a risk-based indication from ages 50–64 years.
- Potential for improved vaccine uptake through an age-based recommendation, which is easier to implement compared with current risk-based recommendation.
- Predicted health benefits from economic models despite increased net costs. The expansion of the recommendation down to age 50 has the potential to decrease disease incidence by 14–15%.
- Addressing the health equity issue that Black/African American adults have higher disease rates with earlier peak.

While it is easier to implement uniform recommendations across all PCV vaccines, economic models determined that PCV21 has a lower cost/QALY gained than PCV20, while use of both PCV21 and PCV20 in adults ages 50–56 years improved health outcomes.

The waning potential will be evaluated to inform a potential future recommendation for a booster dose.

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

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COVID-19 Vaccines

ACIP recommends a second dose of 2024–2025 formula COVID-19 vaccine for:

- Adults ages 65 years and older
- Persons ages six months–64 years who are moderately or severely immunocompromised with a six-month interval between doses
- Persons six months and older who are immunocompromised may receive the vaccine with an interval as short as two months after their previous dose and may receive additional doses (three or more) of vaccine spaced two months apart under shared clinical decision-making

Adults ages 65 years and older comprise two-thirds of all COVID-19-associated hospitalizations among adults. Of persons 75 years of age and older who are infected with COVID-19, one in 70 are hospitalized. Among adults ages 65 years and older who received a dose of the 2023–2024 formula COVID-19 vaccine, 20% received a second dose. Surveyed adults ages 65 years and older indicate that 34.5% would receive two doses of the 2024–2025 formula vaccine if recommended.

Influenza Vaccines

ACIP approved the recommendation to add high-dose inactivated influenza vaccine (HD-IIV3) and adjuvanted inactivated influenza vaccine (aIIV3) to the Vaccines for Children (VFC) program in persons ages 18 years who are solid organ transplant recipients on immunosuppressive medication regimens without a preference over other inactivated influenza vaccines.

End-of-season vaccine effectiveness of influenza vaccines for the 2023-2024 season was similar to interim vaccine effectiveness reported in the June 2024 ACIP meeting.

Recent human cases of Influenza A/H5N1 in the U.S. transmitted from infected cattle or poultry (27 cases in 2024) appear mild. Hemagglutinins of U.S. human influenza H5N1 viruses remain antigenically related to available candidate vaccine viruses.

Meningococcal Vaccines

The dosing interval for MenB-4C (Bexsero) has increased to six months for the two-dose schedule (0, 6 months) due to post-marketing effectiveness studies. If rapid protection is needed, then a three-dose accelerated schedule (can be used at 0, 1–2, and 6 months). If dose 2 is administered less than six months after dose 1, then a third dose is needed at least four months after dose 2. If in the three-dose series the third dose is given less than four months after dose 2, then a fourth dose is needed.

The three-dose series for Bexsero should also be administered when given to persons ages 10 years and older at increased risk for serogroup B meningococcal disease (i.e., persons with asplenia, complement component deficiencies, or complement inhibitor use; microbiologists with potential exposure and persons at increased risk during an outbreak).

Additional data was presented on the Glaxo Smith Kline (GSK) pentavalent Men ABCWY vaccine to be voted on in the February 2025 meeting and on a revised adolescent meningococcal schedule to be voted on in 2025.

RSV Immunizations – Maternal/Pediatric

The ACIP is currently evaluating the use of clesrovimab (Merck), an investigational anti-RSV monoclonal antibody to be used in infants entering their first RSV season. Its dose is 105mg/0.7mL, intramuscular single injection with no difference in dose by weight. The Work Group expressed that the trial results were promising. The efficacy was noted to be lower than nirsevimab, but the endpoints measured were different. Further analysis will be presented at the February 2025 meeting.

The Vaccine Safety Datalink (VSD) reviewed continued analysis of maternal RSV preF protein vaccine (Abrysvo) safety. The VSD study of match pairs of vaccinated and non-vaccinated patients determined no difference in preterm birth nor rates of delivery for infants small for gestation age. Some Work Group members felt that, when counseling pregnant women on maternal RSV vaccination at 32–36 weeks, messaging on potential risk of preterm

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Meeting Details, Continued

birth could be softened or discussion regarding a potential risk of preterm birth might not be needed. On the other hand, one study found an association of maternal RSV vaccine and hypertensive disorder of pregnancy that warrants further analysis by the VSD.

Respiratory Syncytial Virus (RSV) Vaccines: Adults

Arexvy is approved for an expanded age indication by the FDA for use in adults ages 50–59 at-risk for severe RSV disease. Abrysvo has recently been approved by the FDA for those at risk, ages 18–59 years. No changes were made during this meeting to the ACIP recommendations for RSV vaccines in adults. The ACIP continues to evaluate their use in adults younger than age 60 years.

Manufacturers reported durability data. Over three seasons, the Vaccine Efficacy (VE) of Arexvy against severe disease was maintained at 72.3%. For mRESVIA, VE was 56.7%. Safety and immunogenicity in immunocompromised adults and coadministration data were presented. RSV vaccines were safe and immunogenic when co-administered with influenza and/or COVID-19 vaccine. Coadministration with high-dose Fluzone did result in lower RSV titers with mRNA RSV vaccine (mRESVIA).

The FDA presented an analysis on Guillain-Barré Syndrome (GBS) post-RSV vaccination and concluded that available data support the existence of increased risk of GBS after RSV vaccination, although excess cases were rare at less than 10 cases per 1 million vaccines administered. Studies are ongoing, and the ACIP RSV Work Group concluded that the benefits of RSV vaccination outweigh the risks among currently recommended populations.

Human Papilloma Virus (HPV) Vaccines

In 2022, the World Health Organization (WHO) recommended a two-dose schedule for persons ages nine years or older and, as an off-label option, a single-dose schedule for those ages 9–20 years.

The HPV Work Group is reviewing data to inform policy for a two-dose schedule for persons ages 15 years and older, and one dose for persons ages nine years and older (with a subset getting two doses). Randomized control trials of 4vHPV vaccine in females ages 10–18 showed high vaccine efficacy (VE) for one dose, with similar rates to two or three doses with persistence of protection lasting out 10 years. Fifty-six countries, including England, Australia, Canada, Mexico, and most of South America, have a one-dose schedule. Merck is planning to do trials on a single dose.

While current ACIP recommendations are consistent with vaccination initiation at age nine years, the Work Group is considering modification of the wording of the current recommendation to, *"HPV vaccination is routinely recommended at age 9 to 12 years,"* to allow more flexibility. While some members seemed opposed to modifying the current "adolescent vaccine platform," data was presented from studies that indicated a higher completion rate when vaccination was started at ages 9–10 years rather than ages 11–12 years. However, due to multifaceted approaches in the studies, the contribution of lowering the initiation to 9–10 years was unclear.

Other Vaccines

- **Chikungunya**. Bavarian Nordic has developed an inactivated virus-like particle (VLP) chikungunya vaccine with appropriate immunogenicity and no safety concerns in clinical trial. Anticipated FDA approval should be in February 2025. In 2025, ACIP plans to make recommendations for persons ages 12 years and older who travel to at-risk regions, laboratory workers, residents of U.S. territories with transmission risk, and residents of U.S. states with transmission. These same populations will be considered for recommendation with the currently approved live-attenuated vaccine, currently recommended for travelers and laboratory workers ages 18 years and older.
- C**ytomegalovirus (CMV)**. A cytomegalovirus (CMV) workgroup is forming to evaluate potential CMV vaccines since Moderna's mRNA-1647 CMV vaccine (gB+pentameric Complex) is currently in phase 3 trial for females ages 16 through 40 years.
- **Mpox.** There are currently two, clade I Mpox outbreaks in the Democratic Republic of the Congo. Surveillance indicates no clade I cases in the U.S. The Orthopoxvirus Work Group is evaluating the potential use of JYNNEOS in persons ages 12–17 years.

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Meeting Details, Continued

Child/Adolescent and Adult Immunization Schedules

The 2025 ACIP Child and Adolescent Immunization Schedule and the 2025 ACIP Adult Immunization Schedule were approved with the following revisions:

- **Influenza**. New 2024–2025 formula recommended. Quadrivalent formulations were changed to trivalent. High-dose and adjuvanted influenza vaccines were recommended for solid organ transplant recipients receiving immunosuppressive medications ages 18 through 64 years with no preference over other influenza vaccines.
- **COVID-19**. New 2024–2025 formula recommended. Additional dose for persons ages 65 years and older and for immunocompromise six months after the most recent dose of 2024–2025 formula (minimum interval of two months at clinician discretion for immunocompromised additional dose and for further additional doses). COVID vaccine series by age added to "Notes."

  These interchangeability requirements were clarified regarding use of the same manufacturer:

  — For initial doses in children ages six months to four years (and for immunocompromised additional doses in those children)

  — For the initial three-dose series in immunocompromised adults (additional doses can be from any manufacturer)
- **Hib**. Vaxelis, and PedvaxHIB are preferred products for Alaska Native/American Indian populations. Guidance added for children receiving early complement component inhibitor.
- **RSV**. Administer one dose Nirsevimab in first week of life, preferably during birth hospitalization unless pregnant mother already received RSV vaccine. Pregnant mothers can only receive a dose of RSV vaccine with one pregnancy. The seasonal schedule was noted. The adult schedule was updated for ages 75 years and older and for those 60–74 with RSV risks. Those with risk can "self-attest" to qualify for vaccine.
- **Pneumococcal**. Added PCV21 to the adult schedule. Changed recommendations from ages 65 years and older to ages 50 years and older. No additional doses are needed if PCV20 or PCV21 are used. If PPSV23 is unavailable after PCV15, then providers can use PCV20 or PCV21. Pneumococcal vaccines are not to be used in pregnant women.
- **Men B**. New six-month interval for Bexsero two-dose series. Three-dose series (0, 1–2 months, 6 months) can be used when rapid protection is needed. Delay Men B until after pregnancy
- **MMRV**. Contraindicated in persons with any severity of HIV.
- **Td**. Can be used for children under age 7 years.
- **Hepatitis B**. Immunocompromised persons ages 20 years and older should receive **either**:

  — A two-dose series of Heplisav-B (which can be administered to pregnant women)

  — A three-dose series of dialysis formula Recombivax

  — A four-dose series of double-dose Engerix