



# Centers for Disease Control and Prevention (CDC) Immunization Safety Office (ISO) Update

Advisory Commission on Childhood Vaccines (ACCV) meeting  
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# Advisory Committee on Immunization Practices (ACIP)

September and October 2022 meeting highlights

ACIP meeting materials available at: <https://www.cdc.gov/vaccines/acip/meetings/index.html>

# Pneumococcal Vaccines

- ACIP considered whether PCV20 should be recommended for certain adults who previously received PCV13
- ACIP approved the following recommendations by majority vote:
  - Adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak who have received both PCV13 and PPSV23 with incomplete vaccination status are recommended to complete their pneumococcal vaccine series by receiving either a dose of PCV20 at least 5 years after the last pneumococcal vaccine dose or PPSV23 as previously recommended.
  - Shared clinical decision-making is recommended regarding administration of PCV20 for adults aged  $\geq 65$  years who completed their vaccine series with both PCV13 and PPSV23. If a decision to administer PCV20 is made, a dose of PCV20 is recommended at least 5 years after the last pneumococcal vaccine dose.
  - Adults who have received PCV13 only are recommended to receive a dose of PCV20 at least 1 year after the PCV13 dose or PPSV23 as previously recommended to complete their pneumococcal vaccine series.

# Chikungunya vaccines

- Chikungunya is a mosquito-borne viral disease characterized by acute onset of fever and often severe joint pain
- No chikungunya vaccine ever licensed in United States or globally
- Multiple chikungunya vaccines in development
- One manufacturer initiated rolling submission of BLA to FDA in August 2022 and licensure possible during 2023
- The ACIP work group purpose is to develop policy options for ACIP's consideration for U.S. persons at risk of chikungunya, including
  - Travelers
  - Residents of U.S. territories and states with, or at risk of, transmission

# Polio Vaccines

- A case of paralytic polio occurred in New York State in June 2022 in an unimmunized, immunocompetent young adult
  - A single paralytic case implies hundreds or thousands of infections
- Current ACIP Polio Immunization Recommendations: Adults
  - Adults who are unvaccinated or have incomplete vaccination for poliovirus should talk to their doctor about getting vaccinated
  - Adults at increased risk of exposure to poliovirus may receive one lifetime booster dose
- The ACIP work group will consider whether additional recommendations should be made

# Respiratory Syncytial Virus Vaccines - Older Adults

- Two vaccine manufacturers presented clinical trial safety and efficacy findings for RSV candidate vaccines in development
- The work group will consider whether either vaccine should be recommended for all older adults

# Respiratory Syncytial Virus Vaccines - Maternal/Pediatric

- RSV is the leading cause of hospitalization in U.S. infants
- Nirsevimab is an investigational antibody in development
- The ACIP work group will consider
  - Should nirsevimab be recommended for all infants <8 months of age entering their first RSV season and all infants born during the RSV season?
  - Should nirsevimab be recommended for children <24 months of age entering their second RSV season who remain at increased risk of severe disease?

# Meningococcal Vaccines

- The ACIP work group will be considering three issues over the next year:
  - Incorporate Menveo One-Vial into current Menveo recommendations
  - Develop recommendations for new pentavalent vaccines (MenABCWY)
  - Consider whether to recommend MenACWY vaccination for people experiencing homelessness

# Influenza Vaccines

- Presentations were given on three different topics:
  - Clinical trial to compare safety of Flublok Quadrivalent (RIV4) versus IIV4 in pregnancy
    - RIV4 was non-inferior to IIV4 for adverse birth outcomes
  - Influenza activity update
    - Influenza activity remains low in the US overall, but is increasing
  - Influenza vaccine effectiveness update
    - 2021–2022 influenza vaccination provided low to non-significant protection against predominant influenza A/H3N2 illness of varying severity

# Dengue Vaccines

- Most dengue cases in US states are associated with travel to endemic areas
- Dengue is considered endemic in six US territories and freely associated states
- Dengvaxia is indicated for the prevention of dengue in individuals 9-16 years of age with laboratory confirmation of previous dengue virus infection and living in endemic areas
  - The first Dengvaxia dose in Puerto Rico was administered on September 7, 2022
- A new dengue vaccine is in development: Takeda TAK-003 dengue vaccine

# Monkeypox Vaccines

- During May 2022, a global monkeypox outbreak began, predominantly affecting men who have sex with men
- Some cases in women, children, and men who do not report recent male-to-male sexual contact
- Case counts decreasing after peak in August
- JYNNEOS vaccine doses administered and reported to CDC as of October 11, 2022: 906,325
- The ACIP work group will review available data to inform monkeypox vaccine policy, including recommendations for use of these vaccines in U.S. population during ongoing outbreak

# Coronavirus Disease 2019 (COVID-19) Vaccines

- At the September 1, 2022 meeting, ACIP voted to recommend use of updated (bivalent) COVID-19 boosters
  - Pfizer-BioNTech for people ages 12 years and older
  - Moderna for people ages 18 years and older
- On October 12, 2022, CDC recommended use of updated (bivalent) COVID-19 boosters in people ages 5 years and older
- Monovalent mRNA vaccines are no longer authorized as booster doses

# Coronavirus Disease 2019 (COVID-19) Vaccines

- COVID-19 in pregnant people and infants ages 0-5 months

## Summary

- COVID-19 can cause severe disease in pregnant people and infants.
- COVID-19 vaccination of pregnant people is safe for pregnant people and infants.
- Maternal monovalent mRNA COVID-19 vaccination protects pregnant people and infants ages 0-5 months from COVID-19, including from severe disease and hospitalization.
- Monovalent vaccine effectiveness was lower during Omicron predominance, when there was mismatch between the vaccine and predominant circulating variant.
- **Everyone, including people who are pregnant, trying to become pregnant, may become pregnant, and who are breastfeeding, should stay up to date with COVID-19 vaccines and get the recommended updated (bivalent) booster, when eligible.**

# Coronavirus Disease 2019 (COVID-19) Vaccines

## Pediatric COVID-19 vaccines

- COVID-19 vaccination is the single **best way** to protect people from serious COVID-19 illness
  - COVID-19 vaccines continue to be effective in reducing the risk of severe disease, hospitalization and death, including against the currently circulating Omicron variants
  - Many children haven't yet initiated COVID-19 vaccine primary series
- The **benefits** of COVID-19 vaccination **outweigh** the known and potential risks, including the very small risk of myocarditis or pericarditis

# Coronavirus Disease 2019 (COVID-19) Vaccines

- ACIP voted to approve a resolution to add vaccines for the prevention of COVID-19 to the Vaccines For Children (VFC) program
- The Vaccines For Children (VFC) program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay
- Eligible Groups: All children aged 6 months through 18 years
- Once COVID-19 vaccines are commercialized and no longer available under the U.S. Government's National COVID-19 Response, VFC providers will be able to order the vaccines through the VFC program
- The timeline for commercialization of COVID-19 vaccines in the US has not yet been finalized

# Recent CDC vaccine safety publications

# Active Post-Licensure Safety Surveillance for Recombinant Zoster Vaccine Using Electronic Health Record Data

- Recombinant zoster vaccine was licensed in 2017 to prevent herpes zoster and its complications in older adults.
- This Vaccine Safety Datalink (VSD) study of adults aged 50 years and older monitored 10 pre-specified priority outcomes, including stroke, anaphylaxis, and Guillain-Barré Syndrome (GBS) from January 2018 through December 2019.
- No sustained increased risk of any monitored outcome for RZV recipients was found.
- The study confirmed pre-licensure trial findings of increased risks of systemic and local reactions.
- Despite a large sample, uncertainty remained regarding potential association with GBS due to the limited number of confirmed GBS cases that were observed.

Full citation at: <https://pubmed.ncbi.nlm.nih.gov/36193854/>

# Association Between Aluminum Exposure from Vaccines Before Age 24 Months and Persistent Asthma at Age 24-59 Months

- This observational study suggests a possible association between exposure to aluminum in some childhood vaccines and development of persistent asthma in children.
- The study consisted of 326,991 children and found that cumulative exposure to aluminum from vaccines during the first two years of life was associated with a small increased risk of persistent asthma in children ages 2-5 years.
- There is overwhelming evidence of the benefits of vaccines. CDC is not changing the current routine childhood vaccination recommendations based on this single study. Small amounts of aluminum are included in many routine childhood vaccines to help the body build a stronger immunity from diseases.
- Further investigation is needed to explore the potential risk of aluminum exposure from routine childhood vaccines on the development of persistent asthma in children; efforts are underway.

Full citation at: <https://pubmed.ncbi.nlm.nih.gov/36180331/>

# CDC COVID-19 vaccine safety publications, part 1

- Association between history of SARS-CoV-2 infection and severe systemic adverse events after mRNA COVID-19 vaccination among U.S. adults.
- Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States.
- Safety of Booster Doses of Coronavirus Disease 2019 (COVID-19) Vaccine in Pregnancy in the Vaccine Adverse Event Reporting System.
- COVID-19 mRNA Vaccine Safety Among Children Aged 6 Months–5 Years — United States, June 18, 2022–August 21, 2022.

## CDC COVID-19 vaccine safety publications, part 2

- Safety Monitoring of Pfizer-BioNTech COVID-19 Vaccine Booster Doses Among Children Aged 5–11 Years — United States, May 17–July 31, 2022.
- Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination.
- Health Care Utilization in the 6 Months Following SARS-CoV-2 Infection.
- Menstrual irregularities and vaginal bleeding after COVID-19 vaccination reported to v-safe active surveillance, USA in December 2020 - January 2022: an observational cohort study.

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

