



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

Advisory Commission on Childhood Vaccines (ACCV) meeting  
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- V-safe is a vaccine safety monitoring system that lets you share with CDC how you or your dependent feel after getting a participating vaccine.
- After you register, V-safe will send you personalized and confidential health check-ins via text messages or emails to ask how you feel after vaccination.
- Which vaccines are being monitored in V-safe?
  - 2023–2024 Updated COVID-19 Vaccines
  - Respiratory Syncytial Virus (RSV) Vaccines
    - For older adults (aged 60 and older)
    - For pregnant people

For more information see: [cdc.gov/vsafe](https://cdc.gov/vsafe)

# Recent CDC vaccine safety publications

# Post-marketing safety surveillance of hexavalent vaccine in the Vaccine Adverse Event Reporting System

- Assessed the safety of hexavalent vaccine:
  - DTaP-IPV-Hib-HepB (trade name Vaxelis, MSP Vaccine Company)
- Vaccine Adverse Event Reporting System
  - June 26, 2019, through June 16, 2023
- Five hundred-one reports of adverse events (AEs) were identified
  - 21 (4.2%) were serious.
  - Most frequently reported AEs were fever (10.2%) and injection site erythema (5.4%).
- During the period of this study, a total of 2 million doses of DTaP-IPV-Hib-HepB were distributed in the US.
- AEs reported were consistent with findings from prelicensure studies.

# Epidemiology of upper limb complex regional pain syndrome in a retrospective cohort of persons aged 9-30 years, 2002-2017

- Complex regional pain syndrome (CRPS) incidence rates over a time period spanning human papillomavirus (HPV) vaccine licensure and published case reports of CRPS following HPV vaccination
- Vaccine Safety Datalink
  - Patients aged 9–30 years between January 2002 and December 2017
  - 113 cases were verified through abstraction and adjudication. Most verified cases (73%) were associated with a clear precipitating event (e.g., non–vaccine-related injury, surgical procedure). The authors identified only 1 case in which a practitioner attributed CRPS onset to HPV vaccination
- Analysis of CRPS incidence over time showed no statistically significant increases in rates following the 2006 licensure and recommendation of HPV vaccine or following the first publicized case report suggesting a link between HPV vaccination and CRPS in 2013

# Tdap vaccination during pregnancy and risk of chorioamnionitis and related infant outcomes

- An increased risk of chorioamnionitis in people receiving tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine during pregnancy has been reported
- Vaccine Safety Datalink
  - Retrospective observational cohort study of pregnant people ages 15–49 years with singleton pregnancies ending in live birth during October 2016–September 2018
  - Included 118,211 pregnant people
    - 103,258 (87%) received Tdap vaccine during pregnancy
  - The adjusted hazard ratio for chorioamnionitis in the Tdap vaccine-exposed group compared to unexposed was 0.96 (95% CI 0.90-1.03)
- Tdap vaccine exposure during pregnancy was not associated with chorioamnionitis, preterm birth, or adverse infant outcomes

# Safety of measles, mumps, and rubella vaccine in adolescents and adults in the Vaccine Safety Datalink

- Measles, mumps, and rubella vaccine (MMR) may be given to adolescents and adults
- Vaccine Safety Datalink
  - Included adolescents (aged 9–17 years) and adults (aged  $\geq 18$  years) who received  $\geq 1$  dose of MMR from January 1, 2010–December 31, 2018
  - 276,000 doses of MMR given to adolescents and adults were studied
- Clinically serious outcomes were rare
- Common non-serious outcomes included arthropathy, injection site reaction, and rash

# CDC COVID-19 vaccine safety publications

- Background rates of adverse events of special interest for COVID-19 vaccines: A multinational Global Vaccine Data Network (GVDN) analysis.
- Postmenopausal bleeding after COVID-19 vaccination.
- Simultaneous administration of mRNA COVID-19 bivalent booster and influenza vaccines.
- Safety signal identification for COVID-19 bivalent booster vaccination using tree-based scan statistics in the Vaccine Safety Datalink.
- Safety Monitoring of Novavax COVID-19 Vaccine Among Persons Aged  $\geq 12$  Years – United States, July 13, 2022 – March 13, 2023.



# CDC COVID-19 vaccine safety publications, continued

- Safety of simultaneous vaccination with COVID-19 vaccines in the Vaccine Safety Datalink.
- Medically Attended Acute Adverse Events in Pregnant People After Coronavirus Disease 2019 (COVID-19) Booster Vaccination.
- Reporting rates for VAERS death reports following COVID-19 vaccination, December 14, 2020-November 17, 2021.
- Safety of COVID-19 mRNA Vaccination Among Young Children in the Vaccine Safety Datalink.
- CDC COVID-19 Vaccine Pregnancy Registry: Design, data collection, response rates, and cohort description.

Advisory Committee on Immunization Practices (ACIP)  
meeting highlights

# COVID-19 Vaccines

- Since September 2022, bivalent mRNA COVID-19 vaccines have been recommended in the United States, but the variants these vaccines were designed to protect against are no longer circulating widely.
- In September and October 2023, the Food and Drug Administration approved and authorized updated 2023–2024 Formula monovalent XBB.1.5 component–containing COVID-19 vaccines, formulated to target current variants more closely, specifically Omicron variant XBB.1.5, for persons aged  $\geq 6$  months.
- On September 12, 2023, the Advisory Committee on Immunization Practices recommended vaccination with updated COVID-19 vaccines for all persons aged  $\geq 6$  months.

# Meningococcal Vaccines

- ACIP approved the following recommendations by majority vote at its October 25-26, 2023 meeting and they have been adopted by the CDC Director.
- Pfizer's MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit.\*

\*1) Healthy individuals aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccination, 2) 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.

# Mpox Vaccines

- ACIP approved the following recommendations by majority vote at its October 25-26, 2023 meeting and they have been adopted by the CDC Director.
- ACIP recommends vaccination\* with the 2-dose§ JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox¶

\*This is an interim recommendation that ACIP will revisit in 2-3 years

§Dose 2 administered 28 days after dose 1

¶Persons at risk:

- 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  $\geq 1$  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
- Sexual partners of persons with the risks described in above
- Persons who anticipate experiencing any of the above

# Respiratory Syncytial Virus (RSV) Vaccines – Maternal

- In August 2023, the Food and Drug Administration approved Pfizer RSV vaccine for pregnant persons at 32–36 weeks' gestation to prevent RSV-associated lower respiratory tract infection (LRTI) in infants aged <6 months.
- On September 22, 2023, CDC's Advisory Committee on Immunization Practices recommended RSV vaccine for pregnant persons at 32–36 weeks' gestation using seasonal administration (meaning September–January in most of the United States) to prevent RSV-associated LRTI in infants aged <6 months.

# Influenza Vaccines

- Influenza Vaccines in Pregnancy presentations:
  - Safety of Quadrivalent Recombinant Influenza Vaccine in Pregnant Women and their Infants
  - Pregnancy Outcomes with cclIV4 (Flucelvax): Post Marketing Study
  - Effectiveness of Maternal Influenza Vaccination during Pregnancy Against Influenza-associated Hospitalizations & ED Visits in Infants <6 Months of Age

# Influenza Vaccines

- Co-administration of Vaccines in Adults presentations:
  - Safety of Simultaneous versus Sequential Administration of mRNA COVID-19 and Quadrivalent Inactivated Influenza (IIV4) Vaccines
  - Safety of Simultaneous Vaccination with Zoster Vaccine Recombinant (RZV) and Quadrivalent Adjuvanted Inactivated Influenza Vaccine (aIIV4)
  - Update on COVID-19 and Influenza Vaccine Safety



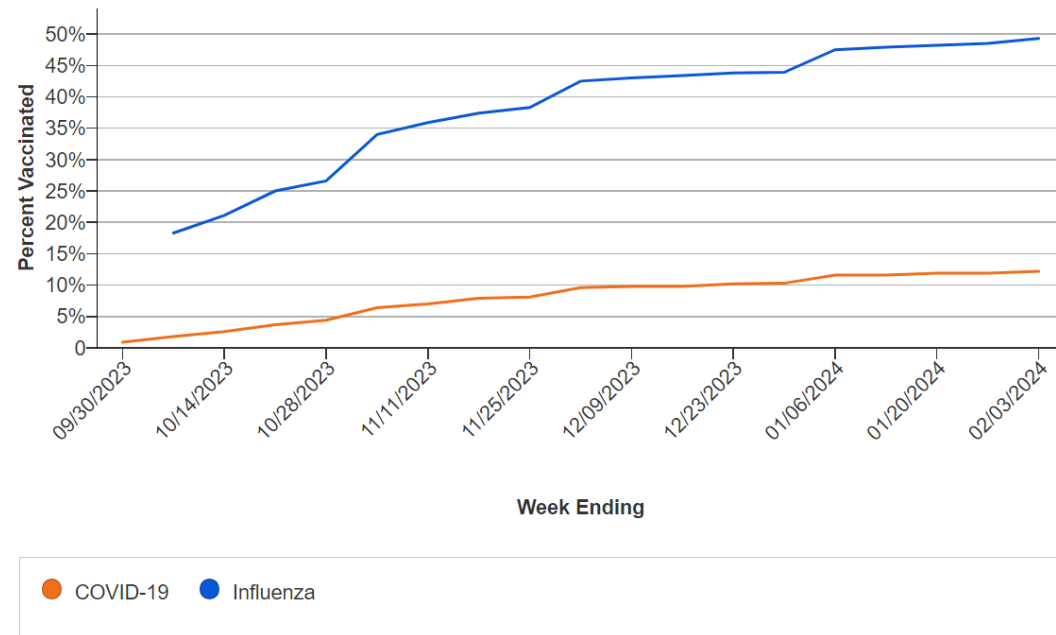
# Vaccination coverage

# Respiratory Illness Vaccination Trends 2023-2024, based on weekly updated National Immunization Survey (NIS) findings, data as of 02/08/2024

## Children aged 6 months – 17 years

### Weekly Cumulative Percent Vaccinated in the United States

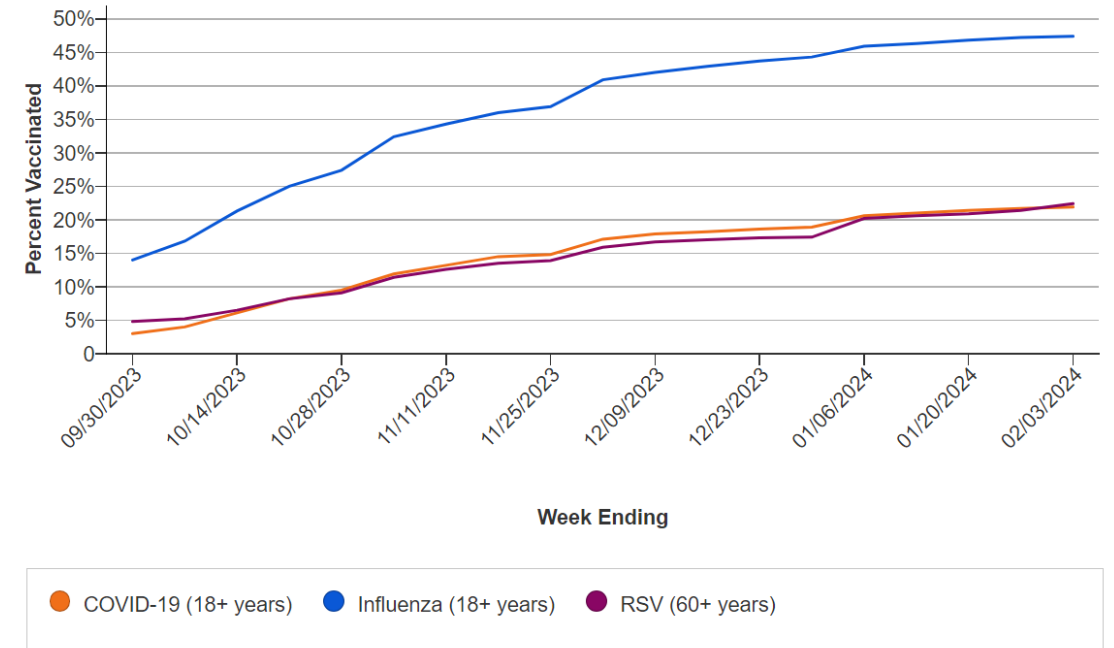
Cumulative percent of children 6 months-17 years vaccinated with COVID-19 or influenza vaccine.



## Adults aged 18+ years

### Weekly Cumulative Percent Vaccinated in the United States

Cumulative percent of adults vaccinated with COVID-19 (18+ years), influenza (18+ years), or RSV (60+ years) vaccine.



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.

