



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

Advisory Commission on Childhood Vaccines (ACCV) meeting
June 2, 2022

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COVID-19 vaccines

COVID-19 Vaccine Recommendations

- CDC's Advisory Committee on Immunization Practices (ACIP) currently has recommendations for the use of three different COVID-19 vaccines
 - Pfizer-BioNTech COVID-19 Vaccine
 - Moderna COVID-19 Vaccine
 - J&J/Janssen COVID-19 Vaccine
- CDC recommends everyone ages 5 years and older get vaccinated against COVID-19.
- Everyone ages 12 years and older should also get a COVID-19 booster shot: 5 months after the second dose for Pfizer-BioNTech and Moderna vaccines, or two months after the J&J/Janssen vaccine.
- Recommendations available at:
<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>

Considerations for a second booster dose

- The following people are eligible to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after their first booster dose:
 - People ages 50 years and older
 - People ages 12 years and older who are moderately or severely immunocompromised
 - People ages 18 years and older who received Janssen COVID-19 vaccine as both a primary and a booster dose

COVID-19 Vaccinations in the United States

- As of May 12, 2022
- People who received at least one dose: 257.7 million
- People fully vaccinated: 220.5 million
- People with a first booster dose: 102 million
- People with a second booster dose: 10.9 million

Source: CDC COVID Data Tracker: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

ACIP held additional meetings to discuss topics related to COVID-19 vaccines

- December 16, 2021
- January 5, 2022
- February 4, 2022
- April 20, 2022

Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices — United States, December 2021

- Cases of thrombosis with thrombocytopenia syndrome and Guillain-Barré syndrome have been reported after receipt of Janssen COVID-19 vaccine.
- On December 16, 2021, after reviewing updated vaccine effectiveness and safety data, the Advisory Committee on Immunization Practices made a preferential recommendation for the use of mRNA COVID-19 vaccines over the Janssen adenoviral-vectored COVID-19 vaccine in all persons aged ≥ 18 years in the United States.
- Pfizer-BioNTech or Moderna mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination. The Janssen COVID-19 vaccine may be considered in some situations, including for persons with a contraindication to receipt of mRNA COVID-19 vaccines.

Source: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a4.htm>

Considerations for Extended Intervals for Administration of Primary Series Doses of mRNA COVID-19 Vaccines

- People ages 12 through 64 years, and especially males ages 12 through 39 years, may consider getting the second dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) 8 weeks after the first dose.
- A longer time between the first and second doses may increase how much protection the vaccines offer, and further minimize the already rare risk of heart problems, including myocarditis and pericarditis.

ACIP COVID-19 Vaccine Safety Technical (VaST) Work Group

Safety assessment of booster doses on April 20, 2022

VaST assessment

COVID-19 vaccine first booster dose safety data to inform second dose booster vaccination

- VaST has provided assessments on booster dose safety at 4 ACIP meetings
- Today's assessment included data from VSD as well as v-safe, VAERS, VA
- Reactogenicity is similar to or lower than that seen after the primary series
- Myocarditis risk appears lower than after a primary series dose 2
- Further work and analyses are needed to understand pericarditis risk
- While data do not suggest safety concerns beyond those previously identified, VaST will carefully monitor data on myocarditis and pericarditis after booster doses

CDC COVID-19 vaccine safety publications, part 1

- Safety monitoring of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to Vaccine Adverse Events Reporting System and v-safe
- COVID-19 Vaccine Safety in Children Ages 5-11 years — United States, November 3-December 19, 2021
- Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults — United States, September 22, 2021-February 6, 2022
- Monitoring the safety of COVID-19 vaccines in pregnancy in the US
- Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020-July 22, 2021

Available at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

CDC COVID-19 vaccine safety publications, part 2

- Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021
- Guillain-Barré Syndrome after COVID-19 Vaccination in the Vaccine Safety Datalink
- Case Series of Thrombosis with Thrombocytopenia Syndrome after COVID-19 vaccination—United States, December 2020 to August 2021
- Reported Cases of Multisystem Inflammatory Syndrome in Children in Children (MIS-C) Aged 12-20 Years in the United States Who Received COVID-19 Vaccine, December 2020 through August 2021
- Multisystem Inflammatory Syndrome in Adults after SARS-CoV-2 infection and COVID-19 vaccination

Available at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

CDC COVID-19 vaccine safety publications, part 3

- Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices – United States, December 2021
- Successes of the CDC monitoring systems in evaluating post-authorization safety of COVID-19 vaccines
- Expected Rates of Select Adverse Events After Immunization for Coronavirus Disease 2019 Vaccine Safety Monitoring

Available at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

CDC vaccine safety publications about topics other than COVID- 19

A Decade Of Data: Adolescent Vaccination In The Vaccine Safety Datalink, 2007 through 2016

- Between May 2005 and March 2007, three vaccines were recommended by the Advisory Committee on Immunization Practices for routine use in adolescents in the United States: quadrivalent meningococcal conjugate vaccine (MenACWY), tetanus, diphtheria and acellular pertussis vaccine (Tdap), and human papillomavirus vaccine (HPV).
- Conclusion: the high vaccine uptake and multitude of vaccine combinations administered concurrently in the adolescent population of the Vaccine Safety Datalink provide historical patterns with which to compare future adolescent vaccination campaigns.

Full citation at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

Association of the COVID-19 Pandemic with Routine Childhood Vaccination Rates and Proportion Up to Date with Vaccinations Across 8 US Health Systems in the Vaccine Safety Datalink

- The COVID-19 pandemic has affected routine vaccine delivery in the US and globally.
- This study compared trends in pediatric vaccination before and during the pandemic and to evaluate the proportion of children up to date with vaccinations by age, race, and ethnicity.
- Conclusion: as of September 2020, childhood vaccination rates and the proportion who were up to date remained lower than 2019 levels.

Full citation at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

The Childhood Vaccination Schedule and the Lack of Association with Type 1 Diabetes

- This was a retrospective cohort study of children born between 2004 and 2014 in 8 US health care organizations that participate in the Vaccine Safety Datalink.
- Conclusion: the recommended schedule is not positively associated with the incidence of T1DM in children.

Full citation at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

Risk of Guillain-Barré Syndrome Following Recombinant Zoster Vaccine in Medicare Beneficiaries

- This study assessed the risk of Guillain-Barré syndrome after administration of recombinant zoster vaccine (RZV or Shingrix), which is administered in 2 doses 2 to 6 months apart using Medicare claims data.
- Conclusions: this study identified a slightly increased risk of Guillain-Barré syndrome during the 42 days following RZV vaccination in the Medicare population, with approximately 3 excess Guillain-Barré syndrome cases per million vaccinations.

Full citation at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

Safety of Influenza Vaccination During Orthopaedic Surgery Hospitalizations

- This study evaluated whether influenza vaccination during hospitalization for orthopaedic surgery increases evaluations for infection post-discharge, because patients and clinicians often cite fear of this potential outcome.
- Conclusions:
 - There was no evidence of a substantial increased risk of infection-related outcomes associated with influenza vaccination during hospitalization for orthopaedic surgery.
 - This supports the recommendation of vaccinating orthopaedic surgery patients against influenza perioperatively.

Full citation at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

Safety surveillance of meningococcal group B vaccine (Bexsero®), Vaccine Adverse Event Reporting System, 2015-2018

- This study assessed the post-licensure safety profile of Bexsero®, a four-component *Neisseria meningitidis* serogroup B vaccine (MenB-4C) by examining reports received in the Vaccine Adverse Event Reporting System (VAERS).
- Conclusion: analysis of passive surveillance data from over 5.6 million doses of MenB-4C distributed in the United States did not reveal new safety concerns.

Full citation at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

Postmarketing safety surveillance of high-dose quadrivalent influenza vaccine: Reports to the Vaccine Adverse Event Reporting System

- On November 4, 2019, the Food and Drug Administration approved high-dose quadrivalent influenza vaccine (Fluzone High-Dose Quadrivalent; QIV-HD) for active immunization for the prevention of influenza disease in individuals 65 years of age and older.
- From July 30, 2020 through June 30, 2021, VAERS received 2,122 reports after QIV-HD. The vast majority (2,018; 95.1%) were non-serious and included events that had been observed in the prelicensure clinical trial, such as injection site reactions, fever, headache, and nausea.

Full citation at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

Advisory Committee on Immunization Practices (ACIP)

January and February 2022 meetings topics other than COVID-19

Cholera Vaccine

- In February 2022, ACIP voted for the following new recommendation:
 - Lyophilized CVD 103-HgR is recommended for children and adolescents aged 2-17 years traveling to an area with active cholera transmission.

Tick-borne Encephalitis (TBE) Vaccine

- In February 2022, ACIP voted for the following new recommendations:
 - TBE vaccination is recommended for laboratory workers with a potential for exposure to TBE virus.
 - TBE vaccination is recommended for persons who are moving or traveling to a TBE endemic area and will have extensive exposure to ticks based on their planned outdoor activities and itinerary.
 - TBE vaccine may be considered for persons traveling or moving to a TBE-endemic area who might engage in outdoor activities in areas ticks are likely to be found. The decision to vaccinate should be based on an assessment of their planned activities and itinerary, risk factors for a poorer medical outcome, and personal perceptions and tolerance of risk.

Influenza Vaccines

- Evidence was reviewed to address the following question:
 - Do the relative benefits and harms of HD-IIV, aIIV, and RIV (referred to collectively as enhanced influenza vaccines, or EIVs) as compared with one another and with standard-dose unadjuvanted influenza vaccines (SD-IIVs) favor the use of any one or more of these vaccines over other age-appropriate influenza vaccines for persons ≥ 65 years of age.
- Conclusions:
 - Overall, there is evidence of benefit favoring each EIV over SD-IIVs.
 - No strong evidence favoring one EIV over others among studies providing direct comparisons.

Hepatitis B Vaccines

- There was a presentation on the Safety & Immunogenicity of a 3-Antigen Hepatitis B Vaccine, PreHevbrio™ [Hepatitis B Vaccine (Recombinant)].
- An ACIP vote is not needed, as PreHevbrio will be another non-inferior vaccine option to be used within the existing HepB recommendations.

Respiratory Syncytial Virus (RSV)

- ACIP has formed an RSV work group which will consider recommendations for use of RSV vaccines and monoclonal antibodies targeting protection of children aged <18 years.
 - The first vote by ACIP is not expected until 2023
- Respiratory syncytial virus (RSV) is a major cause of lower respiratory illness, particularly among infants and children and among older adults and adults with chronic medical conditions.
- RSV vaccine and monoclonal antibody development has progressed in the past decade with over 40 candidate vaccines and monoclonal antibodies currently in development.
- Target populations for whom these products are intended include infants and young children, pregnant women, and older adults.

MMR Vaccine

- Currently there is only one licensed measles, mumps, rubella (MMR) vaccine in the U.S. (M-M-R II, Merck).
- ACIP MMR work group established to evaluate safety and immunogenicity of new candidate MMR vaccine (Priorix, GSK), compared to M-M-R II.
- Policy topic under consideration: Equivalency and usage of a new MMR vaccine (Priorix, GSK) compared to the currently licensed MMR (M-M-R II, Merck).
- Priorix is not currently licensed by FDA.

Pneumococcal Vaccines

- Policy questions being considered by the work group
 - Should PCV15 be routinely recommended for U.S. children <2 years of age as an option for pneumococcal conjugate vaccination according to currently recommended dosing and schedules?
 - Should PCV15 be recommended for U.S. children with underlying medical conditions 2–18 years of age as an option for pneumococcal conjugate vaccination according to currently recommended dosing and schedules?

Thank You

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 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.

