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

Advisory Commission on Childhood Vaccines (ACCV) meeting

June 18, 2021

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COVID-19 vaccines

COVID-19 ACIP Vaccine Recommendations

- The 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
  - Janssen COVID-19 Vaccine
- Recommendations available at:

  https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

COVID-19 Vaccinations in the United States

- As of June 7, 2021
- Vaccine doses administered: 302,851,917
- People vaccinated with at least one dose: 171,310,738
- Percent of population ≥ 18 years of age with at least one dose: 63.7%

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

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

- April 14, 2021
- April 23, 2021
- May 12, 2021

Thrombosis with Thrombocytopenia Syndrome (TTS) following Janssen COVID-19 vaccine

- Thrombosis occurs when blood clots block blood vessels
- Platelets (thrombocytes) are blood cells that help blood to clot; Thrombocytopenia is a condition in which the blood platelet count is low
- As of April 12, 2021, VAERS had received 6 reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia following 6.86 million Janssen vaccine doses administered
  - This was greater than the number expected based on background rates
- Symptom onset appears to occur from several days to up to 2 weeks after vaccination
- The Janssen vaccine is an adenoviral vector vaccine
  - TTS does not appear to be associated with mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech or Moderna)

Use of the Janssen COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome

- On April 13, 2021, CDC and the Food and Drug Administration (FDA) recommended pausing use of the Janssen COVID-19 vaccine after reports of thrombosis with thrombocytopenia syndrome (TTS) among vaccine recipients.
- On April 23, the Advisory Committee on Immunization Practices concluded that the benefits of resuming Janssen COVID-19 vaccination among persons aged ≥18 years outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization, which includes a new warning for rare clotting events among women aged 18–49 years.
- Resuming use of the Janssen COVID-19 vaccine will ensure flexibility, choice, and improved access. Education about TTS risk with Janssen COVID-19 vaccine is critical.

Source: https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm

Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years

- On May 10, 2021, the Food and Drug Administration expanded Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine to include adolescents aged 12–15 years.
- On May 12, 2021, after a systematic review of all available data, the Advisory Committee on Immunization Practices made an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in adolescents aged 12–15 years for the prevention of COVID-19.
- The Pfizer-BioNTech COVID-19 vaccine is the first COVID-19 vaccine approved for use in adolescents and has high efficacy against symptomatic COVID-19. Vaccination will be important to protect adolescents against symptomatic COVID-19 disease and to reduce community transmission of SARS-CoV-2.

Source: https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm

Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination

- Since April 2021, there have been increased reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna).
- These reports are rare, given the number of vaccine doses administered, and have been reported particularly in adolescents and young adults.
- CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination.
- Most patients who received care responded well to medicine and rest and quickly felt better.
- CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older, given the greater risk of COVID-19 illness and related, possibly severe complications.

Source: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

COVID-19 vaccine safety publications

- Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines. JAMA Insights 2021 April 5.
- Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. N Engl J Med 2021 April 21.
- US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021. JAMA 2021 April 30.
- Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine — United States, March-April 2021. MMWR Morb Mortal Wkly Rep. 2021 April 30.
- Anxiety-Related Adverse Event Cluster After Janssen COVID-19 Vaccination — Five U.S. Mass Vaccination Sites, April 2021 MMWR Morb Mortal Wkly Rep. 2021 April 20.

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

Advisory Committee on Immunization Practices (ACIP)

May 5, 2021 meeting topics

Rabies Vaccine

- Discussion about updating the rabies vaccine pre-exposure prophylaxis (PrEP) recommendations for children
- Pre-exposure prophylaxis (PrEP) is recommended for select populations for specific reasons, e.g., international travelers

Dengue Vaccine

- Dengue virus is transmitted by *Aedes* mosquitoes
- There are four types of Dengue virus and an individual can be infected multiple times
  - Dengue infection can range from asymptomatic or mild to severe
  - The second dengue infection has the highest risk for a poor outcome
  - People without a previous dengue infection are at an increased risk of severe dengue and hospitalization following vaccination, therefore laboratory-confirmation of past dengue infection is needed prior to vaccination
- ACIP continued to discuss development of recommendations for the CYD-TDV dengue vaccine (Dengvaxia)
- Policy Question: Should 3-doses of Dengvaxia be administered routinely to persons 9-16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas?

Recent Publications

Myopericarditis after vaccination, Vaccine Adverse Event Reporting System (VAERS), 1990-2018

- Su JR, et al. *Vaccine*. 2021 Jan 29; 39(5):839-845.
- **Summary:** Myopericarditis, an inflammation of the heart muscle and tissue around the heart, has many causes including viral infections. While not confirmed as a cause, myopericarditis after vaccination has been periodically reported. Researchers identified reports of myopericarditis following vaccination submitted to the Vaccine Adverse Event Reporting System (VAERS) from 1990–2018. During 1990–2018, VAERS received a total 620,195 reports: 708 (0.1%) met the case definition or were physician-diagnosed as myopericarditis. Most (79%) reports described males, 69% were serious, and 72% had symptom onset within 2 weeks of vaccination. Overall, smallpox (59%) and anthrax (23%) vaccines were most commonly reported, with higher reporting rates only after smallpox vaccine. Myopericarditis remains rarely reported after vaccines licensed for use in the United States. In this analysis, myopericarditis was most commonly reported after smallpox vaccine, and less commonly after other vaccines.

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

Postmarketing safety surveillance of quadrivalent recombinant influenza vaccine: Reports to the vaccine adverse event reporting system

- Woo EK and Moro PL. *Vaccine.* 2021 Mar 4;S0264-410X(21)00232-2.
- **Summary:** In 2016, the Food and Drug Administration approved recombinant hemagglutinin quadrivalent influenza vaccine (RIV4) for individuals 18 years of age and older. Through June 30, 2020, VAERS received 849 reports after RIV4 vaccination. The vast majority (810; 95%) were non-serious. Postmarketing safety surveillance will continue to be vital for understanding the benefits and risks of quadrivalent recombinant influenza vaccine.

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

Thank You

For more information, contact CDC
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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.