COVID-19 Vaccine Frequently Asked Questions

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2023-2024 COVID-19 Vaccine Recommendations

What are the new COVID-19 vaccine recommendations for Fall 2023-2024? Who is eligible to receive the updated vaccine?

CDC has recommended that everyone ages 5 years and older receive one dose of an updated mRNA vaccine (2023-2024 formulation). The updated dose should be given at least two months after any previous COVID vaccine dose.

Children ages 6 months-4 years should complete a multi-dose initial series (two doses of Moderna or three doses of Pfizer-BioNTech) with at least one dose of the updated vaccine. All doses should be from the same manufacturer for this age group.

Individuals (6 months of age and older) who are moderately to severely immunocompromised may require additional doses.

If I haven't yet received my supply of updated 2023-2024 vaccine and still have doses of bivalent vaccine, can I administer it?

No. The FDA indicated that bivalent COVID vaccines are no longer authorized for use in the on September 11, 2023.

COVID Vaccine Dosing

What is the recommended interval between the doses of an mRNA COVID-19 vaccine series? How can I determine what my patient needs if they already received at least one monovalent COVID-19 dose

Please the **AAP Pediatric COVID-19 Vaccine Dosing Quick Reference Guide** for dosing intervals. This resource offers the dosing intervals for unvaccinated children and previously vaccinated children. Also included is dosing information for children with moderately or severely immunocompromising conditions.

Which Moderna or Pfizer-BioNTech vaccine dose should a child receive if they will have a birthday between doses?

A child turning from age **4 years to 5 years** between recommended doses of Pfizer or Moderna vaccine should follow dosing recommendations based on age at the start of the vaccine series.

Can you "mix and match" vaccine products for one child?

It is recommended that children who are 6 months – 4 years of age receive the same product for all COVID vaccine doses. "Mix and match" is allowable for other age groups, in that previously vaccinated individuals can receive either an updated Pfizer or Moderna COVID-19 vaccine.

A **Vaccine Adverse Event Reporting System** (VAERS) report is required following administration of a vaccine in an unauthorized manner.

In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered when FDA authorization requires that a vaccine from the same manufacturer be used. A VAERS report is not required for these exceptional situations:

- Same vaccine not available

- Previous dose unknown
- Person would otherwise not complete the vaccination series
- Person starts but unable to complete a vaccination series with the same COVID-19 vacc due to a contraindication

Additional Resources:

- AAP Pediatric COVID-19 Vaccine Dosing Quick Reference Guide
- CDC Guidance on Interchangeability of COVID-19 Vaccines

COVID Vaccine Products

Which COVID-19 vaccines have been approved and/or authorized for use in the US?

The US has two mRNA and one protein subunit COVID-19 vaccines approved for use.

Moderna mRNA Vaccine

- Spikevax Package Insert (ages 12+ years)
- FDA EUA Fact Sheet for Healthcare Professionals (ages 6 months – 11 years)

Pfizer-BioNTech mRNA Vaccine

- Comirnaty Package Insert (ages 12+ years)
- FDA EUA Fact Sheet for Healthcare Professionals (ages 6 months – 11 years)

Novavax Protein Subunit Vaccine

- FDA EUA Fact Sheet for Healthcare Professionals

What is the difference between COVID-19 mRNA, and protein subunit vaccines?

Messenger RNA (mRNA) Vaccines
These vaccines use a newer technology where mRNA is wrapped in a coating (lipid nanoparticle) so it can enter our cells. The mRNA in the vaccine teaches our cells how to make

copies of a spike protein. Once the spike protein is made, two things occur: (1) the cell breaks down the mRNA (instructions) and gets rid of them, and (2) the spike protein triggers an immune response inside of our bodies, which produces antibodies. These antibodies protect us from getting infected if the real virus enters our bodies.

Protein Subunit Vaccines

Subunit vaccines include a part (protein) of the virus that best stimulates your immune system. Once your immune system recognizes the protein subunit, it creates antibodies and defensive white blood cells. If you later become infected with the COVID-19 virus, the antibodies will fight the virus. These vaccines often include an adjuvant to increase the body's immune response.

Vaccinating Special Populations

What are the vaccine recommendations for children and adolescents who are moderately to severely immunocompromised?

Children and adolescents with certain immunocompromising medical conditions or who are receiving treatments that induce moderate to severe immune suppression should be vaccinated according to the schedule outlined in the **AAP Pediatric Vaccine Dosing Quick Reference Guide**.

Prior to and following COVID-19 vaccine administration, infection prevention measures should continue such as wearing a mask, physical distancing, and avoiding crowds and poorly ventilated indoor spaces, as immunocompromised individuals may still be at increased risk for COVID-19. Close contacts of immunocompromised individuals should receive recommended COVID-19 vaccination to provide additional protection.

Information on immunization and immunocompromised children and adolescents can be found in the:

- Red Book: **Immunization and Other Considerations in Immunocompromised Children**
- **CDC Evidence to Recommendations Framework: 2023-2024 COVID-19 Vaccine ACIP Slides (See proposed recommendations starting on page 143)**

Can I administer a COVID-19 vaccine to a patient who is currently sick with COVID-19?

COVID-19 vaccination should be deferred for patients with a current SARS-CoV-2 infection u they recover from their acute illness and the criteria to discontinue isolation has been met. Patients who are asymptomatic should receive COVID-19 vaccine following their recommended isolation period. Individuals who recently had SARS-CoV-2 infection and have concluded their isolation period may consider delaying COVID-19 vaccine by 3 months from symptom onset or positive test (if infection was asymptomatic). **Studies** have shown that increased time between infection and vaccination may result in an improved immune response to vaccination.

Side Effects/Safety

Are there any different side effects or safety concerns with the updated 2023-2024 formula mRNA vaccines?

No, the side effect and safety profile are the same as that of previous formulations.

The side effects have been similar to other routine vaccines- sore arm, redness, fatigue, fever, chills, headache, myalgia, and arthralgia. The side effects are temporary and mostly mild or moderate. Anaphylaxis has been observed following receipt of COVID-19 mRNA vaccines but this has been rare. Extremely rare cases of myocarditis or pericarditis have been reported – most often in males between 12-39 years of age. Additional information on common side effects and rare adverse reactions can be found here:

- **Possible Side Effects After Getting a COVID-19 Vaccine | CDC**
- **Selected Adverse Events Reported after COVID-19 Vaccination | CDC**

What is the safety testing that has been done on COVID-19 vaccines? How is vaccine safety monitored? How do we know it is safe long-term?

The safety follow-up for COVID-19 vaccines is essentially the same that it is for all vaccine trials. All vaccines are determined to be safe and effective before they are authorized or licensed.

Pediatric vaccine studies involve very close follow up and tracking of patient's health status and medical care post vaccination (eg. monitoring side effects, medical visits, use of new medications or changes to previous medications, and other interactions post vaccination). All reported medical events are recorded and reviewed by the study team, sponsor, an independent safety monitoring board, an ethics committee, and the FDA. Children in these studies are often followed for one to two years post vaccination and their health status is monitored for vaccine safety.

Even after authorization or licensure, safety data are collected through Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA), and pharmacovigilance. VAERS and VSD are specifically designed to monitor safety signals from simultaneous administration of multiple vaccines (ie co-administration). These programs collect information on an even larger number of persons who get vaccinated than can be collected during clinical studies.

Safety data beyond 2 years, is captured through studies performed post licensure. No licensed vaccines have been found to have an unexpected long-term safety problem, that was found only years or decades after introduction.

- **Ensuring COVID-19 Vaccine Safety in the US | CDC**

How do I report an adverse event related to administration of COVID-19 vaccine?

Healthcare providers are required by law to report to **Vaccine Adverse Event Reporting System** (VAERS):

- Any adverse event listed in the **VAERS Table of Reportable Events Following Vaccination** that occurs within the specified time period after vaccination
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Healthcare providers are strongly encouraged to report:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors

Co-Administration

Can COVID-19 vaccine be co-administered with other childhood or adolescent immunizations?

Yes, the AAP supports co-administration (or vaccination in the days before and after) of routine childhood and adolescent immunizations and seasonal immunization (such as nirsevimab and flu vaccine), with COVID-19 vaccines for children and adolescents who are behind on or due for immunizations (based on the CDC/AAP Recommended Child and Adolescent Immunization Schedule).

When co-administering with other vaccines, it is recommended that a different injection site (at least 1 inch apart) be used. If co-administered with a more reactogenic vaccine (eg, adjuvanted or high dose influenza vaccine and COVID-19 vaccine), consider using a different limb.

Is co-administration acceptable for all populations of children and adolescents, including those who are immunocompromised?

Since the mRNA COVID-19 vaccines are not live vaccines, it is expected that the safety and efficacy will be similar to other vaccines that are co-administered. Immunocompromising conditions are not contraindications to receipt of the mRNA COVID-19 vaccines. In general, simultaneously administered vaccines are recommended to ensure optimal age-specific protection and fewer medical visits. As with all vaccines, patients should be informed about the likely timing of potential side effects and adverse events related to each vaccine.

Are there any differences or concerns with co-administration of COVID-19 vaccine with live attenuated vaccines?

No. The mRNA COVID-19 vaccines are not live vaccines and no additional safety or efficacy issues are expected with co-administration with live attenuated vaccines. Co-administration is particularly important for children and adolescents who are behind on routinely recommended vaccines because it promotes timely receipt of vaccination and reduces the number of medical visits for the patient.

Vaccine Coding and Payment

Which CPT codes should I use? Will I get paid for vaccine administration?

A full listing of COVID-19 vaccine codes can be found on the **Getting Paid** page.

With new vaccine products or new vaccine recommendations, there may be a delay in CPT codes being valued and loaded into payer systems. As a result, practices might consider confirming that payers have updated their payment systems prior to submitting claims.

Talking to Families

How can pediatricians build trust with families who may express vaccine hesitancy

Parents and caregivers trust pediatricians. Pediatricians should listen to families' questions, take the information, and provide clear, consistent information. They should state what is currently known and unknown. They should not overemphasize "potentials" – neither potential risks nor potential benefits. More information on how to communicate effectively can be found at **Communicating with Families and Promoting Vaccine Confidence**.

Pediatricians can also utilize resources in the **AAP COVID-19 Vaccine Communications Toolkit** to promote vaccine confidence. Consider ways that patients and families in your practice like to receive information and use these mechanisms to debunk common myths and answer frequently asked questions.

- **Strategies For Building Covid-19 Vaccine Confidence | The National Academies Press (nap.edu)**

Do children and adolescents need special consent or assent to receive COVID-19 vaccines?

State and/or local laws determine who is able to consent or assent for COVID-19 vaccines; the same as other vaccines. In most places and instances, a parent's consent is required for a child or adolescent to receive a vaccine. While this may not always require a signature, you may consider obtaining one for COVID-19 vaccines as vaccines for children < 12 years of age are still authorized under an EUA. Health care providers administering the vaccine should inform vaccine recipients of the following: (1) FDA has authorized emergency use of the vaccine in children under 12 years of age (2) known and potential risks and benefits related to emergency

use (3) that they have the option to accept or refuse the product and (4) be informed of any available alternatives to the product and their known risks and benefits. Each recipient should receive a fact sheet that includes essential information about the vaccine.

- FDA EUA Fact Sheet for Recipients and Caregivers – Moderna Vaccine
- FDA EUA Fact Sheet for Recipients and Caregivers – Pfizer-BioNTech Vaccine
- FDA EUA Fact Sheet for Recipients and Caregivers – Novavax Vaccine

Don't see what you're looking for? Submit your question for consideration.

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