Pediatric COVID-19 vaccine FAQ

Introduction

The COVID-19 cases in children result in hospitalizations, deaths, MIS-C (inflammatory syndromes) and long-term complications, such as “long COVID,” in which symptoms can linger for months. The spread of the Delta variant resulted in a surge of COVID-19 cases in children throughout the summer. On October 29th, the FDA reviewed the data from Pfizer-BioNTech completed on vaccines in children 5-11 years of age and issued an EUA. The ACIP and CDC also reviewed the data and unanimously recommended vaccination in this age group, agreeing that benefits of the vaccine outweigh the known risks. Vaccination was nearly 91% effective in preventing symptomatic, mild to moderate COVID-19 infection among children aged 5-11 years, providing similar efficacy to what was seen in adult vaccine trials. There were no severe cases of COVID-19 in the pediatric trial. Vaccine side effects were like those seen in adults and with other vaccines recommended for children. All side effects were mild to moderate and self-limited. The most common side effect was pain at the injection site.[1]

FAQ

What dosing is recommended for pediatrics?

Under the EUA for the 5-11 year age group, children will receive 2 intramuscular doses of 10 mcg/0.2 mL of the Pfizer-BioNTech, BNT162b2, with a new pediatric formulation and concentration to be given 21 days apart.[1]

What are the medication safety implications of a pediatric formulation?

There is a pediatric vaccine formulation that has a different concentration, dilution instructions, stability and storage instructions.[2]

	Pediatric vaccine formulation 5 to <12 years old[3]	Adult & adolescent formulation ≥12 years old[3]
Definition	Orange cap and label with an orange border multidose vials will contain a different concentration for 5 to <12 years of age.	Purple cap and label with a purple border multidose vials contain the original concentration for 12 years of age and older.
Timing of doses	2 doses, 21 days apart	2 doses, 21 days apart
Ages eligible	5 to <12 years of age	≥ 12 years of age
Dose	10 mcg	30 mcg
Dose volume	0.2 mL	0.3 mL
Dilution volume ***0.9% Sodium Chloride Inj, USP**	1.3 mL	1.8 mL
Ultra-low temperature (ULT) Freezer[a]	6 months	9 months
Freezer	Do not store	2 weeks

Refrigerator[a]	10 Weeks	1 month
Room Temperature	12 hours prior to dilution	2 hours prior to dilution (including thaw time)
After 1st puncture[a]	Discard after 12 hours	Discard after 6 hours

[a]Expiration approved under the EUA might be different from the dates printed on the vials. Reference table: Comirnaty and Pfizer-BioNTech COVID-19 vaccine. FDA[3]

Side effects: Commonly reported side effects in the clinical trial included injection site pain (sore arm), redness and swelling, fatigue, headache, muscle and/or joint pain, chills, fever, swollen lymph nodes, nausea and decreased appetite. More children reported side effects after the second dose than after the first dose. Side effects were generally mild to moderate in severity and occurred within two days after vaccination, and most went away within one to two days.

What is the myocarditis risk in 5-11 years old patients?

In the clinical trial of 5-11 year old patients (n = 3,082), there was no observed cases of myocarditis or pericarditis through the 3-month follow-up period after the second dose. Due to the small sample size and limited follow-up time, Pfizer is required to complete long-term safety studies evaluating any potential risk of myocarditis/pericarditis associated with vaccination for 5 years.[2] There have been reports of patients aged 12 years and older presenting with myocarditis/pericarditis following the receipt of an mRNA COVID-19 vaccine. The observed risk of vaccine-related myocarditis/pericarditis appears to be highest among males under 40 years of age. In an FDA analysis of the Optum healthcare claims database, the estimated excess risk of myocarditis/pericarditis approached 200 cases per million fully vaccinated males 16 to 17 years of age and 180 cases per million fully vaccinated males 12 to 15 years of age.[2] In the majority, the onset of symptoms is within 2-7 days following the second dose. The typical symptoms for myocarditis/pericarditis are chest pain with shortness of breath and/or palpitations. Limited, short-term follow-up suggests that in most cases, symptoms resolve within 3 months. In a case series of 54 patients with a mean follow of 35 days, 87% of patients reported resolution of symptoms. Per the FDA's Vaccine Safety Datalink 3-month follow-up review, 5 of 16 (31%) and 6 of 14 (43%) 12 to 17 years old and 18 to 39 years old, respectively, reported full recovery (defined as no medication, without exercise restrictions or symptoms). It is important to rule out other potential causes of myocarditis and pericarditis as this age group is predisposed to this disease following viral, bacterial, or unknown etiology. Unlike viral infection and/or MIS-C, myocarditis/pericarditis following vaccination does not appear to impact coronary arteries.[5]

What monitoring is available for post-vaccination side-effects?

There are two platforms for vaccine-associated potential side effects: V-safe and Vaccine Adverse Event Reporting System (VAERS). V-safe is a health checking application available on all smartphone platforms. Under V-safe, the vaccinated individual (or parent/legal guardian) can register. This platform is free of charge and helps the CDC look at any possible trend of vaccine side effects. VAERS reporting is a passive reporting system. All healthcare providers are required to report any adverse event listed by the vaccine manufacturer. Healthcare providers can also list other potential adverse events that could be associated with the vaccine administration.[6]

Does the COVID-19 vaccine effect puberty?

During the clinical trials, researchers found no evidence of the COVID-19 vaccine affecting puberty, the reproductive system, or a child's hormone development.[2] Additionally, based on what we know about how the mRNA technology used in the Pfizer-BioNTech vaccine works, there is no medically plausible reason to suspect that the vaccine will have any impact on the body's natural development.

How long does immunity last after a primary series?

At this time, the only data we have in this age group is 2 months following the second dose.[2] The duration of this protection will continue to be monitored in healthy and immunocompromised vaccinated children. If it is observed that immunity is decreasing, that information will be shared with the FDA and CDC for further guidance.[2]

How should I approach vaccinating a patient that is almost 12 years old or turns 12 years old between dose 1 and 2?

The recommendation from ACIP is the patient should receive the vaccine associated with the patients age at the time of administration. For those patients that are close to turning 12 years old, anecdotal information provided during the ACIP meeting discussion was to look at the timing of the age change, the exposure of the patient, and the current community transmission. In the clinical trials, there were 7 children turning 12 between the first and second doses. All of those children remained on the 10 mcg (5-11 years old) dose.[2] Under the EUA, a child turning 12 years old during their vaccine dosing can receive either 10 mcg (5-11 years old) dose or the 30 mcg (≥12 years old) dose and be considered fully vaccinated. This change in dose will not be considered a dosing error under the EUA.[1]

Has there been any discussion around vaccination of pediatric patients who have already been infected?

Published immunologic and a growing body of epidemiologic evidence indicates that vaccination after infection significantly enhances protection and further reduces risk of reinfection.[7] The Pfizer serological information published in the clinical trial for 5-11 years old showed that patients with a baseline serologic GMTs had enhanced GMTs following 1 month of the 2nd dose. Current literature evaluated during the booster shot discussion supported evidence of waning immunity and positive cases in patients with a previous history of positive infection.[8]

What if my area isn't experiencing a surge?

It is recommended to get vaccinated to have adequate coverage at the time of the next surge. Full vaccination and 90% protection was demonstrated 7 days after the second dose.[2] Currently, in most areas of the country, we are on the downward trend from the delta surge. Based on typical virus epidemiology, another surge will come with additional mutations of the virus. It is unclear when another surge will arrive. Due to this uncertainty in timing, it is advisable to get vaccinated when age-appropriate vaccines are approved.

Can other vaccines be co-administered with COVID-19 vaccines?

COVID-19 vaccine may be administered without regard to timing of other vaccines. Due to muscle size in the 5-11 years old patients, if multiple vaccines are administered at a single visit, administer each vaccine in a different injection site or spaced 1 inch or more apart. For the younger patients aged 5 to 10 years, if more than 2 vaccines are injected into a single limb, the anterolateral thigh (vastus lateralis) muscle is the preferred site.[6]

What is the status of Moderna's submission in 12-17 years old and 5-11 years old?

Moderna submitted the 12-17 years old data in June 2021. The FDA did a full review of the data and sent questions back to Moderna requiring further evaluation for myocarditis. At this time Moderna has concluded they will wait to submit the 5-11 years old data that is currently pending completion until they have the additional investigation completed with the 12-17 years old age group.[9]

What information do we have about supply kits?

There are supply kits provided by the US Government and distributed by McKesson. The inventory contained in the ancillary kits are listed below.

- Diluent vials (10 mL)
- Needles (25G x 1”)
- Mixing needle (21-25G x 1.5”)
- Syringes for administration (1 mL); syringes for mixing (3 mL or 5 mL)
- Alcohol pads
- Vaccination record cards
- Needle gauge and length chart for children
- Face Shields
- Surgical masks

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