TOOLKIT

SECTION 6: CLINICAL CONSIDERATIONS

Last Updated August 23, 2023

Funding for this project was made possible by the Office of Disease Control, through the Illinois Department of Public Health.

CONTENTS

Expected Side Effects. 6-3

Myocarditis and Pericarditis 6-4

Preparing for Anaphylaxis 6-6

Adverse Events & Reporting. 6-8

Vaccine Administration Errors 6-10

Pediatric Vaccination 6-17

Immunocompromised Populations 6-20

People Vaccinated Outside of the U.S. 6-21

People Vaccinated as Part of a Clinical Trial 6-24

Pregnant Populations 6-25

People with Disabilities. 6-27

EXPECTED SIDE EFFECTS

It is important to discuss common side effects from COVID-19 vaccines with patients. Reassure them that these reactions are normal and will usually resolve within a few days of getting the vaccine. There are some patients who will think these reactions are a result of contracting COVID-19 from the vaccine. Side effects of the vaccine can be similar to the symptoms experienced during COVID-19 illness and can include:

- Pain, redness, and swelling on arm where vaccine was administered
- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea
- Vomiting
- Diarrhea
- Joint pain

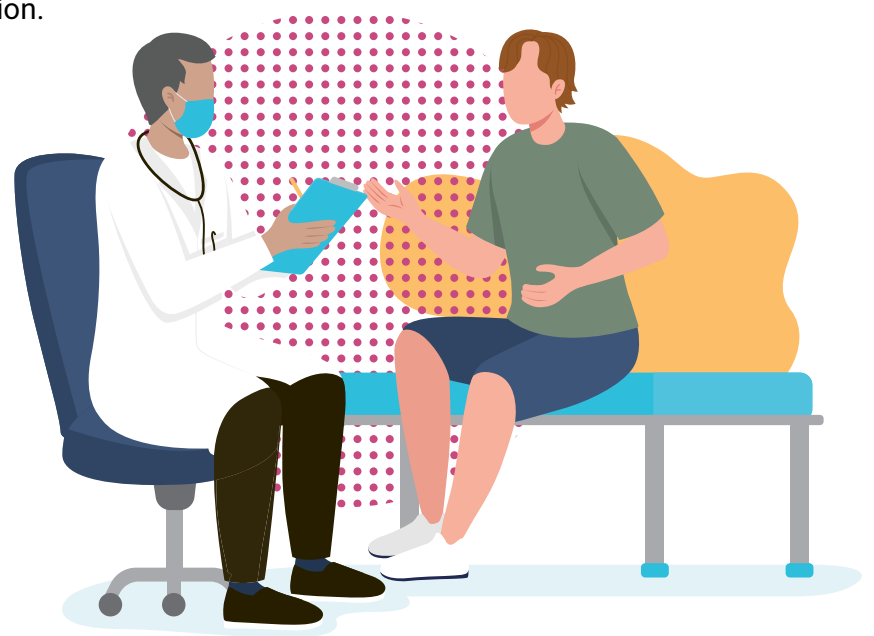
Visit the CDC website for more information on local and systematic reactions to **Pfizer**, **Moderna**, and **Novavax** products.

MYOCARDITIS AND PERICARDITIS

A rare risk for myocarditis and pericarditis has been observed following receipt of mRNA COVID-19 vaccines (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 Vaccine. **The risk is rare (fewer than 20 per 1 million vaccinations) and primarily seen in adolescent and young adult males.** It has been determined that the benefits of vaccination outweigh the risks of myocarditis or pericarditis. Additionally, the impact of these conditions after COVID-19 infection is more significant than after vaccination.

In most cases, patients who presented for medical care responded well to medications and rest and had prompt improvement of symptoms. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older. Onset was typically within several days after mRNA COVID-19 vaccination, and cases have occurred more often after the second dose than the first dose of the primary series. The CDC is investigating these reports of myocarditis and pericarditis following mRNA COVID-19 vaccination.

The CDC continues to recommend COVID-19 vaccination for everyone 6 months of age and older given the risk of COVID-19 illness and related, possibly severe, complications, such as long-term health problems, hospitalization, and even death.



MYOCARDITIS AND PERICARDITIS (CONTINUED)

Below is a table comparing the characteristics of viral myocarditis and myocarditis associated with COVID-19 vaccination.

CHARACTERISTIC	MYOCARDITIS ASSOCIATED WITH COVID-19 VACCINATION	VIRAL MYOCARDITIS
Inciting exposure	mRNA COVID-19 vaccination • Dose 2 > Dose 1	Viral illness • 30–60% with asymptomatic viral course
Demographics	Most cases in adolescents and young adults, males > females	Males > females, male incidence peaks in adolescence and gradually declines
Symptom onset	A few days after vaccination, most within a week	1–4 weeks after viral illness
Fulminant course	Rare	23%
ICU level support	~2%	~50%
Mortality/transplant	Rare	11–22%
Cardiac dysfunction	12%	60%
Recovery of cardiac function	Nearly all	~75%
Time to recovery of cardiac function (ejection fraction on cardiac echo), if initially poor	Hours to days	Days to weeks to months

Extending the interval to 8-weeks between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people as it may reduce the small risk of myocarditis and pericarditis associated with these COVID-19 vaccines.

Shorter Interval

- Immunocompromised
- High risk for severe disease
- Household members with high risk for severe disease
- High COVID-19 community levels

Longer Interval

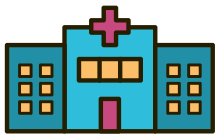
- Reduced myocarditis risk
- Adolescent and young adult males
- Optimize vaccine effectiveness

Under the current COVID-19 vaccination schedule, the extended interval applies only to children ages 6 months–5 years, depending on their vaccination history and which mRNA vaccine is administered (Table 1), and people ages 12 years and older receiving Novavax vaccine.

Sources: CDC: Update on myocarditis following mRNA COVID-19 vaccination; CDC: Recommendations for Pfizer-BioNTech and Moderna COVID-19 Vaccine Primary Series in Children 6 Months through 5 Years Old

PREPARING FOR ANAPHYLAXIS

Symptoms of anaphylaxis often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear. Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become a more severe reaction. In addition, symptoms of anaphylaxis might be more difficult to recognize in people with communication difficulties, such as long-term care facility residents with cognitive impairment, those with neurologic disease, or those taking medications that can cause sedation. Not all symptoms listed here are necessarily present during anaphylaxis, and not all patients have skin reactions. Anaphylaxis has been rarely reported following COVID-19 vaccination, but vaccine providers should still be prepared to respond.



For those sites vaccinating children:

Ensure staff are trained to recognize and respond to anaphylaxis in children aged 6 months–11 years.

SIGNS AND SYMPTOMS IN ADULTS AND CHILDREN	
Respiratory	• Sensation of throat closing or tightness • High-pitched sound while breathing • Hoarseness • Shortness of breath or wheezing • Coughing • Trouble swallowing/drooling • Nasal congestion or sneezing
Cardiovascular	• Dizziness • Fainting • Abnormally fast heart rate • Abnormally low blood pressure • Pulse difficult to find or “weak” • Cyanosis (bluish discoloration) • Pallor • Flushing
Gastrointestinal	• Nausea • Vomiting • Diarrhea • Abdominal pain • Cramps
Skin/mucosal	• Generalized hives • Widespread redness • Itching • Conjunctivitis • Swelling of eyes, lips, tongue, mouth, face, or extremities
Neurologic	• Agitation • Convulsions • Acute change in mental status • Feeling of impending doom
Other	• Sudden increase in secretions from eyes, nose, or mouth • Urinary incontinence

PREPARING FOR ANAPHYLAXIS (CONTINUED)

Should be available at all locations:

- Epinephrine (e.g., prefilled syringe, autoinjector)
- H1 antihistamine (e.g., diphenhydramine, cetirizine)
- Blood pressure monitors
- Timing device to assess pulse

If feasible, include at locations:

- Pulse oximeter
- Oxygen
- Bronchodilator (e.g. albuterol)
- H2 antihistamine (e.g., famotidine, cimetidine)
- Intravenous fluids
- Intubation kit
- Pocket mask with one-way valve (cardiopulmonary resuscitation [CPR] mask) sized for adults and children

Source: CDC: Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination

ADVERSE EVENTS & REPORTING

In all age groups, no serious adverse events (SAEs) were judged to be related to the vaccine and no deaths occurred in clinical trials.

- For persons in the 5-11 age-group trials, SAEs were uncommon in both vaccine and placebo groups (0.07% and 0.1%)

Sources: CDC Center for Preparedness and Response; CDC: Pfizer/BioNTech BNT162b2 (COVID-19 Vaccine, mRNA) Vaccine –in Individuals 5 to <12 Years of Age

Reporting in VAERS

Vaccine Adverse Event Reporting System (VAERS) is the frontline system for vaccine safety monitoring. VAERS depends on healthcare professionals to report any health problems of clinical significance that may occur after vaccination.

Healthcare providers who administer COVID-19 vaccines are **required by law** to report the following to VAERS:

1. Vaccine administration errors, whether or not associated with an adverse event (AE)
   - If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, VAERS reporting is required
   - If a different product from the primary series is inadvertently administered for the additional or booster (third dose), VAERS reporting is required

   VAERS reporting **is not required** for the following situations:
   - If a mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient)

ADVERSE EVENTS (CONTINUED)

2. Serious AEs regardless of whether the reporter thinks the vaccine caused the AE
    - Death
    - A life-threatening AE
    - Inpatient hospitalization or prolongation of existing hospitalization
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
    - A congenital anomaly/birth defect
    - An important medical event that, based on appropriate medical judgment, may require medical or surgical intervention to prevent one of the outcomes listed above
3. Cases of myocarditis or pericarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine
4. Cases of Multisystem Inflammatory Syndrome in adults or children
5. Cases of COVID-19 that result in hospitalization or death

Healthcare providers should report any additional clinically significant AEs to VAERS following vaccination, **even if they are not sure whether the vaccine caused the event.**

Ways to Submit an Online Report to VAERS

Option 1:

Report Online to VAERS – Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and returned to at a later time. Information will be erased if inactive for 20 minutes; you will receive a warning after 15 minutes.

Option 2:

Report using a Writable PDF Form – Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

Source: CDC: Reporting Adverse Events Following Vaccination

VACCINE ADMINISTRATION ERRORS

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. When an error occurs with a COVID-19 vaccine, follow the revaccination guidance in the table on pages 6-12, 6-13, 6-14, and 6-15 using an age-appropriate COVID-19 vaccine and formulation. Then continue with the recommended schedule of subsequent dose(s) unless otherwise noted (see footnotes).

For ALL vaccine administration errors:

- Inform the recipient and/or parent of the vaccine administration error
- Consult with the I-CARE team to determine how the dose should be entered to account for administered dose and for inventory
- Providers are required to report all COVID-19 vaccine administration errors into VAERS – even those not associated with an adverse event
- Determine how the error occurred and implement strategies for prevention. You can use this resource to help prevent vaccine administration errors!

VACCINE ADMINISTRATION ERRORS (CONTINUED)

Interim Revaccination Guidance

Revaccination is defined as repeating one or more dose(s) of vaccine. COVID-19 revaccination should be with Moderna, Novavax, or Pfizer-BioNTech regardless of vaccine administered for initial vaccination. Recipients of HCT or CAR-T-cell therapy who received 1 or more doses of COVID-19 vaccine prior to or during treatment should undergo revaccination.

Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy and should follow the currently recommended schedule for people who are unvaccinated.

Revaccination may also be considered for patients who received 1 or more doses of COVID-19 vaccine during treatment with B-cell-depleting therapies (e.g., rituximab, ocrelizumab) that were administered over a limited period (e.g., as part of a treatment regimen for certain malignancies). The suggested interval to start revaccination is about 6 months after completion of the B-cell-depleting therapy. Timing of vaccination for patients who receive B-cell-depleting therapies on a continuing basis (e.g., for treatment of certain autoimmune conditions such as rheumatoid arthritis or multiple sclerosis) is addressed in **Considerations for Timing of COVID-19 Vaccination in relation to immunosuppressive therapies**.

VACCINE ADMINISTRATION ERRORS (CONTINUED)

Interim Revaccination Guidance

TYPE	ADMINISTRATION ERROR/DEVIATION	INTERIM RECOMMENDATION
Site/route	Incorrect site (i.e., site other than the deltoid muscle or vastus lateralis muscle)	Do not repeat dose.
	Incorrect route (e.g., subcutaneous)	• Do not repeat dose. • Inform the recipient of the potential for local and systemic adverse events.
Age	Unauthorized age group (recipients younger than age 6 months)	Do not give another dose at this time.*
	Recipients transitioning from age 4 years to 5 years during the primary series who start a 3-dose Pfizer-BioNTech primary series with the product for ages 6 months–4 years (**maroon cap and label border**) and incorrectly receive the product for ages 5–11 years (**orange cap and label**) for either dose 2 or 3	• Do not repeat primary series dose 2 or 3 • If the error occurred with dose 2, administer the bivalent Pfizer-BioNTech product for ages 6 months–4 years (**maroon cap and label border**) for the third primary series dose at least 8 weeks after the second primary series dose
Product and dosage	Higher-than-authorized dose administered (e.g., incorrect dose volume, incorrect product resulting in higher-than-authorized dose)	Do not repeat dose.†‡
	Lower-than-authorized dose administered (e.g., leaked out of the syringe, equipment failure, recipient pulled away, incorrect product resulting in lower-than-authorized dose)	• Repeat dose immediately (no minimum interval).†§ • However, if a half-volume dose of vaccine is administered to a patient recommended for the full volume, another half-volume dose can be administered on the same clinic day, and the 2 doses can count as 1 full dose.
	Monovalent mRNA vaccine dose administered for a bivalent mRNA dose (if bivalent booster indicated)	• Repeat the dose using an age-appropriate bivalent mRNA vaccine • If dose given in error was the first dose, space repeat dose by at least 4 weeks; for other doses, space repeat dose after the dose given in error by at least the minimum interval
Storage and handling	Dose administered after improper storage and handling (i.e., temperature excursion)	Contact the manufacturer for information on the stability of the vaccine.¶ If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).§
	Dose administered past the expiration/beyond-use date	Contact the manufacturer for information on the stability of the vaccine.¶ If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).§

special notations on 6-16

VACCINE ADMINISTRATION ERRORS (CONTINUED)

Interim Revaccination Guidance

TYPE	ADMINISTRATION ERROR/DEVIATION	INTERIM RECOMMENDATION
Intervals	Any COVID-19 dose administered prior to the minimum interval[#]	Repeat dose. Space repeat dose after the dose given in error by at least the minimum interval (Table 2 and Table 3).[§]
	Any COVID-19 vaccine dose administered at any interval after the recommended interval[#]	• Do not repeat dose. There is no maximum interval. • This deviation from CDC guidance does not require VAERS reporting.
Diluent (Pfizer-BioNTech COVID-19 Vaccine formulation only [orange cap and maroon cap])	ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	Administer the authorized dose immediately (no minimum interval).
	No diluent, resulting in higher than authorized dose	Do not repeat dose.[†] Inform the recipient of the potential for local and systemic adverse events.
	Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% sodium chloride)	Contact the manufacturer for information on the stability of the vaccine.[¶] If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).[§]
	Vaccine is mixed with too little diluent	Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.[†]
	Vaccine is mixed with too much diluent	Repeat dose immediately (no minimum interval).[§]
	Single-use vial of diluent is used to mix multiple vials of vaccine	Do not repeat dose. Inform patient of the potential for bacterial infection.
Diluent (Pfizer-BioNTech COVID-19 formulation that should not be mixed with diluent, i.e., gray cap)	Vaccine is mixed with any diluent (i.e., any type or volume of diluent)	Contact the manufacturer for information on the stability of the vaccine.[¶] If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).[§]

special notations on 6-16

VACCINE ADMINISTRATION ERRORS (CONTINUED)

Interim Revaccination Guidance

TYPE	ADMINISTRATION ERROR/DEVIATION	INTERIM RECOMMENDATION

Interchangeability	Bivalent mRNA vaccines from different manufacturers administered for initial vaccination to recipients ages 6 months–5 years	• Recipients ages 6 months–4 years who received 1 Moderna and 1 Pfizer-BioNTech vaccine dose for the first 2 doses of a 3-dose series should receive a third dose of either Moderna or Pfizer-BioNTech vaccine at least 8 weeks after the second dose.
		  • If Moderna is used, administer 0.25 mL/25 ug (**dark blue cap** and **gray label border**).
		  • If Pfizer-BioNTech is used, administer 0.2 mL/3 ug (**maroon cap and label border**).
		• Recipients age 5 years who received Moderna as a second dose following a first dose of Pfizer-BioNTech:
		  • If not moderately or severely immunocompromised, do not administer any more vaccine doses; considered a single-dose Pfizer-BioNTech vaccination series.
		  • If moderately or severely immunocompromised, administer a third dose of either Moderna (0.25mL/25 ug; **dark blue cap** and **gray label border**) or Pfizer-BioNTech (0.2mL/10 ug; **orange cap and label border**) at least 4 weeks after the second dose.

	Two or more doses of monovalent mRNA vaccine from different manufacturers previously administered to recipients ages 6 months–4 years	• Administer 1 dose of either Moderna or Pfizer-BioNTech vaccine at least 8 weeks after last monovalent dose:
		  • If Moderna is used, administer 0.25 mL/25 ug (**dark blue cap** and **gray label border**).
		  • If Pfizer-BioNTech is used, administer 0.2 mL/3 ug (**maroon cap and label border**).

special notations on 6-16

VACCINE ADMINISTRATION ERRORS (CONTINUED)

Interim Revaccination Guidance

TYPE	ADMINISTRATION ERROR/DEVIATION	INTERIM RECOMMENDATION
Interchangeability	Bivalent mRNA vaccine dose from one manufacturer administered to recipients ages 6 months–4 years who previously received 1 or more doses of a monovalent mRNA vaccine from a different manufacturer	• If previously received 1 monovalent mRNA vaccine dose, do not repeat the dose and administer 1 dose of either Moderna or Pfizer-BioNTech vaccine at least 8 weeks after the first bivalent dose. • If previously received 2 or 3 monovalent mRNA vaccine doses, do not repeat the dose; any combination of the recommended number of doses is considered valid.
	Bivalent Moderna dose(s) administered to recipients age 5 years who previously received monovalent dose(s) of Pfizer-BioNTech	• Do not repeat dose(s).
	Bivalent mRNA vaccines from different manufacturers administered for the first 2 doses of a 3-dose initial vaccination series to recipients ages 6 years and older who are moderately or severely immunocompromised	• Administer a third age-appropriate dose of either Moderna or Pfizer-BioNTech at least 4 weeks after the second dose.

special notations on 6-16

VACCINE ADMINISTRATION ERRORS (CONTINUED)

Interim Revaccination Guidance Special Notations

* Do not administer the second dose until the person becomes eligible to receive vaccination (either by reaching the authorized age or if the authorization is extended to include additional age groups), even if this results in the second dose being administered after the recommended interval between doses. In addition to the minimum age, some experts suggest delaying the second dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis from mRNA COVID-19 vaccine.

† If the administration error resulted in a higher-than-authorized vaccine dose, in general a subsequent dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the subsequent dose, this dose may be delayed, but this decision should be assessed on a case-by-case basis.

‡ FDA authorization allows for dosing options for certain situations where a child transitions from a younger to older age group. If the dosing is in accordance with the FDA EUA, it is not considered an error and VAERS reporting is not indicated.

§ An 8-week interval between the first and second doses of mRNA and Novavax COVID-19 vaccines may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it may reduce the small risk of myocarditis and pericarditis associated with these vaccines. The authorized interval (4 weeks for Moderna and 3 weeks for Novavax and Pfizer-BioNTech) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about an individual's higher risk of severe disease.

¶ As of the date of this update, current manufacturer contact information is:

- Pfizer: 1-877-VAX-CO19 (1-877-829-2619)
- Moderna: 1-866-MODERNA (1-866-663-3762); **medinfo@modernatx.com**
- Novavax: 1-844-NOVAVAX (1-844-668-2829)

Please see the package inserts and EUA provider factsheets for the most up-to-date manufacturer information.

Vaccine doses administered up to 4 days before the minimum interval may be counted and do not need to be repeated.

Source: CDC: COVID-19 Vaccine Administration Errors and Deviations

PEDIATRIC VACCINATION

Side Effects

Children may experience fewer side effects than adolescents or young adults. Children with evidence of prior infection may have fewer side effects than those without evidence of prior infection. Routine antipyretic or analgesic medications can be taken if appropriate. In general, aspirin is not recommended for use in children and adolescents <18 years due to risk of Reye's Syndrome. The most common systemic reactions include fatigue, headache, chills, and muscle pain. The most common local reaction in clinical trials for children 2-11 was mild pain at the injection site.

MIS-C

Giving a COVID-19 vaccination after an MIS-like illness is beneficial. The COVID-19 vaccination benefits outweigh the theoretical risk of a MIS-like illness for people who meet all the following criteria:

1. Clinical recovery has been achieved, including return to normal cardiac function;
2. It has been ≥90 days since their diagnosis of MIS-C

***Note:** A study found that 2 doses of the Pfizer-BioNTech vaccine were highly effective in preventing MIS-C in persons ages 12–18. The estimated effectiveness was 91% in fully vaccinated children. All critically ill MIS-C patients were unvaccinated.

- Younger children were not included because they were not eligible for the vaccine during the study period.

An updated CSTE/CDC MIS-C surveillance case definition is effective as of January 1, 2023

- Continues to require illness in persons <21 requiring hospitalization or resulting in death characterized by evidence of systemic inflammation
- Narrows what types of signs and symptoms count toward clinical criteria
- Changes some of the lab criteria, as well as timeframes during which lab and epi linkage criteria must be met
- Prioritizes features of MIS-C that distinguish it from similar pediatric inflammatory conditions
- May not capture all cases and is not intended to replace clinical judgement

Sources: CDC: Science Brief; CDC: Morbidity and Mortality Weekly Report, January 14, 2022

PEDIATRIC VACCINATION (CONTINUED)

Pfizer-BioNTech Pediatric Vaccine Clinical Trials

Pfizer's pediatric vaccine trials were conducted to evaluate the safety, tolerability, and immunogenicity of the Pfizer-BioNTech vaccine on a 3-dose schedule (first 2 doses given approximately 21 days apart, with the third dose given 8 weeks after the second) in children ages 6 months to under 2 years (3 µg). The third 3-µg dose was well tolerated among 1,678 children under 5 years of age with a safety profile comparable to the placebo. Vaccine efficacy of 80.3% was observed in descriptive analysis of three doses during a time when Omicron was the predominant variant. No safety concerns were identified.

The safety of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for administration as the third dose of a three-dose primary series following two doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age is based on safety data from the following:

- A clinical study which evaluated a booster dose of Pfizer-BioNTech's investigational bivalent COVID-19 vaccine (original and omicron BA.1) in individuals greater than 55 years of age,
- Safety data from clinical trials which evaluated primary vaccination in individuals 6 months of age and older with the monovalent Pfizer-BioNTech COVID-19 vaccine,
- Safety data from clinical trials which evaluated booster vaccination in individuals 5 years of age and older with the monovalent Pfizer-BioNTech COVID-19 vaccine, and
- Postmarketing safety data with the monovalent Pfizer-BioNTech COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

PEDIATRIC VACCINATION (CONTINUED)

Moderna's Pediatric Vaccine Trials

The KidCOVE trial enrolled 11,700 participants between the ages of 6 months and 11 years old and 6,700 participants between the ages of 6 to 17 in the US and Canada. Dosage was dependent on age:

- Children 6 months through <6 years received two 25 µg doses
- Children 6 to <12 years received two 50 µg doses
- Children 12 to <18 years received two 100 µg doses

Side effects were similar to other pediatric vaccines. Rates of fever greater than 38°C were:

- 17.0% in ages 6 months – under 2 years
- 14.6% in 2 years – under 6 years
- 23.9% in 6 years – under 12 years
- Fever greater than 40°C was seen in only a few children (0.2% in each age group)

No deaths, myocarditis, pericarditis, or MIS-C were reported.

The safety of a single booster dose of the Moderna COVID-19 Vaccine, Bivalent for children 6 months through 5 years of age is supported by safety data from a clinical study which evaluated a booster dose of Moderna's investigational bivalent COVID-19 vaccine (original and omicron BA.1), safety data from clinical trials which evaluated primary and booster vaccination with the monovalent Moderna COVID-19 Vaccine, and postmarketing safety data with the monovalent Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent.

Novavax Clinical Trials

The most common local reaction of the Novavax vaccine was pain/tenderness at the injection site, redness and swelling were reported less frequently. The most common systemic reactions were fatigue/malaise, headache, and muscle pain. Most symptoms were mild to moderate in severity and resolved within 1-3 days. Symptoms were most frequent in people ages 12-64, compared to those 65 years and older, and after dose 2 compared to dose 1. Cases of myocarditis and pericarditis were identified in clinical trials of Novavax COVID-19 vaccine and have also been reported during post-authorization use outside the United States. These findings suggest that an increased risk for these conditions may be present after receiving Novavax COVID-19 vaccine.

Sources: Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccines, Novavax COVID-19 Vaccine, Adjuvanted

IMMUNOCOMPROMISED POPULATIONS

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19. Everyone, including immunocompromised people, should receive a COVID-19 vaccine if they are 6 months and older as soon as possible. Some moderately or severely immunocompromised people should get an additional primary vaccine. An additional dose* is considered part of the primary dose series in immunocompromised individuals. Currently, the recommendation for an additional dose is listed below and is summarized in the chart as indicated in **section five - Vaccine Administration.**

Recommendations vary based on age and immune status at the time of eligibility for that dose.

According to the CDC, people with any of the characteristics listed below should be considered moderately or severely immunocompromised, including:

- Receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppressive therapy)
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, or Wiskott-Aldrich syndrome)
- Advanced HIV infection (people with HIV and CD4 cell counts less than 200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., 20 mg or more of prednisone or equivalent per day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

Individuals should talk to their healthcare provider about their medical condition and whether getting an additional primary vaccine is appropriate for them. Individuals can self-attest to their moderately or severely immunocompromised status and receive COVID-19 vaccine doses wherever vaccines are offered. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.

Source: **CDC: COVID-19 Vaccines for Moderately or Severely Immunocompromised People**

PEOPLE VACCINATED OUTSIDE OF THE U.S.

For people that have been vaccinated outside of the United States, there are guidelines based on:

- The vaccine(s) received for the primary series
- Whether the primary series was completed
- Whether a booster dose was received

The charts below are directly from the CDC's guidance on vaccinations given outside of the U.S. and can be viewed online here.

Received a COVID-19 vaccine that is FDA-approved or FDA-authorized

VACCINATION HISTORY	RECOMMENDED ACTIONS
Received 1 or more monovalent mRNA vaccine dose(s)	• Administer 1 bivalent mRNA vaccine dose if age 6 years and older.† • See Table 1 if age 6 months–5 years.
Received 1 or 2 Novavax vaccine dose(s)	• Administer 1 bivalent mRNA dose.†‡
Received 1 bivalent mRNA vaccine dose after completion of primary series	• Do not repeat if age 5 years and older.† • See Table 1 if age 6 months–4 years. • See Special situation (after table footnotes).

Source: CDC: Use of COVID-19 Vaccines in the United States

PEOPLE VACCINATED OUTSIDE OF THE U.S. (CONTINUED)

Received a COVID-19 vaccine listed for emergency use by the WHO but not approved or authorized by the FDA[‡§]

VACCINATION HISTORY	RECOMMENDED ACTIONS
Received all recommended primary doses for that vaccine	• Administer a bivalent mRNA dose
Received partial primary series for that vaccine	• Administer an age-appropriate mRNA dose if eligible *[†] • See Table 1 if age 6 months–5 years.
Received a monovalent booster dose after completion of primary series	• Administer a bivalent mRNA dose
Received a bivalent mRNA booster dose after completion of primary series	• Do not repeat • See Special Situation (after table footnotes)

Source: CDC: Use of COVID-19 Vaccines in the United States

PEOPLE VACCINATED OUTSIDE OF THE U.S. (CONTINUED)

Received all or some of the recommended doses of COVID-19 vaccines that are NOT FDA-authorized, FDA-approved, or among those listed for emergency use by the WHO

VACCINATION HISTORY	RECOMMENDED ACTIONS
Received any number and combination of vaccine doses	• Doses received do not count toward vaccination in the U.S. • Start vaccination at least 28 days after the last dose of vaccine • Vaccinate according to the US schedule

* People ages 6 months and older should receive 1 bivalent mRNA dose at least 2 months after their last monovalent vaccine dose. People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first bivalent mRNA vaccine dose.

† A monovalent Novavax booster dose (instead of a bivalent mRNA dose) may be used in limited situations in people ages 18 years and older who have not received any previous booster dose(s). The Novavax booster dose is administered at least 6 months after the last primary series dose.

‡ COVID-19 vaccines that are listed for emergency use by WHO, but are not approved or authorized by FDA, have not been evaluated for efficacy or safety by the CDC or ACIP.

§ This scenario also includes people who received a heterologous primary series or booster dose composed of doses of COVID-19 vaccines listed for emergency use by WHO, at least one of which is not FDA-approved or FDA-authorized.

Special situation: Do not administer a second bivalent mRNA vaccine dose if the person previously received a bivalent Moderna or Pfizer-BioNTech mRNA vaccine dose containing the original SARS-CoV-2 strain and Omicron BA.1 variant unless the person is age 65 years or older: These people have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first bivalent mRNA vaccine dose.

Source: CDC: Use of COVID-19 Vaccines in the United States

PEOPLE VACCINATED AS PART OF A CLINICAL TRIAL

Participants in clinical trials within or outside the United States who received all the recommended primary series doses of a vaccine listed for emergency use by WHO (i.e., not placebo) that is not FDA-approved or FDA-authorized are considered to be up to date with their COVID-19 vaccines when they have received 1 bivalent mRNA vaccine dose. At this time, only the Medicago COVID-19 Vaccine in people ages 18 years and older and Sanofi-GSK COVID-19 Vaccine in people ages 18–59 years meet these criteria.

Source: **CDC: Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Pfizer-BioNTech COVID-19 Vaccine for Primary, Additional, and/or Booster Doses**

PREGNANT POPULATIONS

Should pregnant, recently pregnant, or lactating people get vaccinated?

Yes! People who are pregnant or were recently pregnant are more likely to get severely ill with COVID-19 compared with people who are not pregnant. Pregnancy can increase risk of severe complications due to COVID-19; this includes hospitalization, mechanical ventilation, and even death. Vaccination helps prevent severe illness from COVID-19. Additionally, pregnancies affected by COVID-19 are at increased risk for preterm birth and stillbirths, and other severe complications. If an individual is vaccinated and breastfeeding, the antibodies made by their body can be passed through breast milk and will help protect their newborn from the virus.

Evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy is growing. This data suggests that the benefits of receiving a COVID-19 vaccine outweigh any known or potential risks of vaccination during pregnancy. There is no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems in women or men.

Source: CDC: COVID-19 Vaccines While Pregnant or Breastfeeding

What are the recommendations?

The American College of Obstetricians and Gynecologists (ACOG) strongly recommends all pregnant and 6-week post-partum individuals get vaccinated.

When should the vaccines be given during pregnancy?

If someone is pregnant, they should be vaccinated as soon as possible. COVID-19 vaccines can be given during any trimester, although evidence suggests that vaccines given later in pregnancy (after 21 weeks) are 80% effective at preventing COVID-19 related hospitalization in infants younger than 6 months. Additionally, COVID-19 vaccines can be administered at the same time as other vaccines.

PREGNANT POPULATIONS (CONTINUED)

What are the side effects of vaccination for pregnant populations?

Pregnant people experience the same side effects as a non-pregnant person from vaccines. Additionally, COVID-19 vaccines can be administered at the same time as other vaccines.

There is no evidence that suggests these vaccines cause miscarriage, fertility problems, or preterm birth.

What does the data say?

- A study published in January 2022, found that serious adverse outcomes from COVID-19 infection, including urgent care admissions and perinatal death, were more likely in unvaccinated compared to vaccinated pregnant people.
- A 2022 MMWR study found that maternal vaccination during pregnancy helped prevent COVID-19-related hospitalization of infants aged <6 months by 61%.
- A 2021 MMWR study found that pregnancies affected by COVID-19 are at increased risk for preterm birth and stillbirths and might be at increased risk for other complications.

For more information, visit the CDC website, OR ACOG guidelines.

Protect mothers, protect infants.

START VACCINATING TODAY!

PEOPLE WITH DISABILITIES

According to the CDC, most people with disabilities are not more likely to become infected with or have severe illness from COVID-19. However, some people with disabilities might be more likely to get infected or have severe illness because of underlying medical conditions, congregate living settings, or systemic health and social inequities. **Adults with disabilities are three times more likely than adults without disabilities to have heart disease, diabetes, cancer, or a stroke.**

Ensure the following conditions are met when vaccinating people with disabilities:

- Clear and effective communication, including availability of interpreter services, that is accessible and meets the requirements of the Americans with Disabilities Act, and other accessibility laws, and ensures that support persons, family members, and/or guardians are present or available in-person or virtually to support individuals with informed decision making
- Vaccination education and outreach provided while recognizing the right to self-determination
- Providing reasonable accommodations to address potential access barriers to COVID-19 vaccination, such as lack of accessible equipment, inability to read public information or signage, and inability to access vaccination locations
- Conduct individualized assessments and avoid discriminatory judgements about "quality of life" relating to a person's underlying disability

PEOPLE WITH DISABILITIES (CONTINUED)

Follow the AAP's considerations for vaccinating children and youth with developmental disabilities:

- Where is the best place for the patient to receive the vaccine?
- Prepare the patient and family with a story or other resources
- Have a plan for potential side effects
- Include familiar staff
- Minimize wait times
- Identify low stimulation waiting and administration spaces
- Have distraction or pain management techniques available
- Encourage patient to bring comfort items

Sources: Illinois.gov Guidance Affirming Non-Discrimination in Medical Treatment; CDC: People with Disabilities; AAP: COVID-19 Vaccination for Children and Youth with Developmental Disabilities

Check out the CDC's website and AAP's page on supporting, caring for, and vaccinating people with disabilities during COVID-19