

# COVID-19 Vaccine Reactions and Questions

## DEFINITION

- Caller believes a child is having a reaction to a recent COVID-19 vaccine (immunization)
- Questions about the COVID-19 vaccine: efficacy, safety, eligibility, booster shots, reasons to postpone
- **Updated: July 1, 2022** (version 8)

### Vaccine Status Definitions (CDC 2022)

**Vaccines Up-to-date** ("Fully Vaccinated" is term used in the COVID-19 protocols)

- Completed the Pfizer or Moderna primary vaccine series AND also received booster shot(s) if eligible OR
- Completed the Pfizer or Moderna primary vaccine series within the last 5 months AND is not yet eligible for booster shot (mainly applies to young children) OR
- Received J&J primary vaccine AND also received booster shot(s) if eligible
- Stay up-to-date by getting all recommended boosters when eligible

**Vaccines Not Up-to-date** ("Partially" or "Unvaccinated" is term used in the COVID-19 protocols)

- Unvaccinated: Has not received any COVID-19 vaccines.
- Completed the Pfizer or Moderna primary vaccine series AND 5 or more months ago BUT has not received booster shot(s) if eligible OR
- Received only one Pfizer or Moderna vaccine OR
- Received J&J primary vaccine AND 2 or more months ago BUT has not received booster shot(s) if eligible
- **Note:** Also, if less than 14 days since a primary series shot, the person is only "partially vaccinated." *This waiting period does not apply to booster shots.*

## TRIAGE ASSESSMENT QUESTIONS

### Call EMS 911 Now

Difficulty with breathing or swallowing and starts within 2 hours after injection

*R/O: anaphylactic reaction*

Sounds like a life-threatening emergency to the triager

### See More Appropriate Protocol

Widespread hives, widespread itching or facial swelling within 2 hours after receiving COVID-19 vaccination

*Go to Protocol: Anaphylaxis (Pediatric)*

Positive COVID-19 test and recent COVID-19 vaccine

*Go to Protocol: COVID-19 - Diagnosed or Suspected (Pediatric). Reason: Vaccine does not cause a positive test.*

COVID-19 respiratory symptoms (such as runny nose, cough, sore throat, shortness of breath) and COVID-19 vaccine given recently

*Go to Protocol: COVID-19 - Diagnosed or Suspected (Pediatric). Reason: Vaccine does not cause any respiratory symptoms.*

COVID-19 exposure (close contact) with NO symptoms and recent COVID-19 vaccine

*Go to Protocol: COVID-19 - Exposure (Pediatric)*

Fever starts 2 or more days after the shot with no signs of cellulitis and possible exposure to COVID-19

*Go to Protocol: COVID-19 Diagnosed or Suspected (Pediatric). Reason: Late-onset fever not caused by vaccine.*

Reactions or questions about other vaccines

*Go to Protocol: Immunization Reactions (Pediatric)*

### **Go to ED/UCC Now (or to Office with PCP Approval)**

Recent COVID-19 vaccination with any chest pain, trouble breathing and/or change in heartbeat

*R/O: myocarditis; usually starts within 1 week of vaccination*

Sounds like a severe, unusual SYSTEMIC reaction to the triager

*R/O: mycodarditis, blood clot*

Child sounds very sick or weak to the triager (Exception: severe local reaction)

*Reason: serious complication suspected*

### **Go to Office Now**

Fever > 105 F (40.6 C)

*R/O: severe reaction*

### **Discuss With PCP and Callback by Nurse Within 1 Hour**

Fever and weak immune system (sickle cell disease, HIV, splenectomy, chemotherapy, organ transplant, chronic oral steroids, etc)

*Reason: PCP will decide if vaccine-related fever or needs to be seen*

### **See in Office Today**

Over 3 days since shot and general symptoms (such as muscle aches, headache, fussiness, chills) are getting worse

*R/O: unrelated cause*

Over 3 days since shot and redness at the injection site is very painful

*R/O: low-grade infection or COVID arm*

Fever present > 3 days

*R/O: bacterial superinfection*

### **See in Office Today or Tomorrow**

Over 3 days since shot and redness at injection site is larger than 4 inches (10 cm)

*R/O: low-grade infection or COVID arm*

### **See in Office Within 3 Days**

Pain and redness at the injection site lasts > 7 days

Lymph node swelling in armpit (on side of vaccine) lasts > 3 weeks

Triager thinks child needs to be seen for non-urgent acute problem

Caller wants child seen for non-urgent problem

## Home Care

COVID-19 normal vaccine reactions: LOCAL reactions at injection site (pain, swelling, redness) and normal SYSTEMIC reactions (fever, chills, feeling tired, muscle aches, headache, etc)

COVID-19 vaccine, answers to common questions

## Home Care Advice

### COVID-19 Normal Vaccine Reactions

- 1. Reassurance and Education - Normal Reactions:**
  - Vaccines protect us against serious diseases.
  - Having some temporary symptoms from the shot is normal.
  - The symptoms mean the vaccine is working. They mean your immune system is building antibodies against the vaccine. The antibodies will protect you against the real disease.
  - These brief side effects do not cause any risks to your health.
  - There is no need to see your doctor for normal reactions, such as pain, swelling, redness or fever.
- 2. COVID-19 Vaccine - Common Harmless Injection Site Reactions:**
  - In children, the side effects are similar to those seen in adults.
  - Pain and tenderness start within 8 hours (90% of patients).
  - Swelling (10%) or skin redness (5%).
  - A lymph node in the armpit on that side may become tender and swollen.
  - Local symptoms usually last 1 to 3 days.
- 3. COVID-19 Vaccine - Common Harmless Systemic (Whole Body) Reactions:**
  - Fever (15%) and chills (40%)
  - Fatigue and extreme tiredness (70%)
  - Muscle aches (50%) and headaches (60%).
  - Other brief side effects are decreased appetite, nausea, dizziness and increased sleep.
  - General symptoms start at about 12 - 24 hours.
  - They usually last 1 day, sometimes 2.
- 4. COVID-19 Vaccine Reactions:**
  - **Vaccines with 2 doses.** Symptoms are more frequent after the 2nd vaccine. The above percentages are for the 2nd dose.
  - **Vaccines with one dose.** Side effects were the same type, but a little less frequent.
  - **Booster Shots.** Side effects much the same.
  - The vaccine does not cause any respiratory symptoms such as cough, runny nose, sore throat or shortness of breath.
  - It is impossible to get COVID-19 from the vaccine. Reason: there is no live COVID-19 virus in the vaccine.
  - A serious allergic reaction is very rare. It usually occurs within 20 minutes after the shot.
- 5. Vaccine Injection Site Reactions - Treatment:**
  - Some pain, redness and swelling at the injection site is NORMAL. It means the vaccine is

working. Redness does not mean there's any infection.

- **Heat:** For redness and pain, apply a heating pad or a warm wet washcloth to the area for up to 20 minutes. Repeat as needed. Reason: will increase blood flow to the area.

- **Exception:** can use a cold pack if your PCP recommends it, but only on the day of the shot.

- **Massage:** Gently massage the injection site during the first few days. Do so several times a day.

- **NO Pain Medicine:** Try not to give any pain medicines for local reactions. Reason: pain medicines may reduce the body's normal immune response. Use local heat instead. The local pain rarely becomes bad. If pain medicine is needed, acetaminophen is preferred. (See Dosage table)

- **Hives at Injection Site:** If very itchy, can apply a 1% hydrocortisone cream OTC twice daily as needed.

#### 6. **Fever with Vaccines - Treatment:**

- Fever with vaccines is NORMAL, harmless and probably beneficial. Reason: Fever speeds up your body's immune system.

- Fever with most vaccines begins within 12 hours and lasts 1 or 2 days.

- For low grade fevers 100-102 F (37.8 to 39 C), do not give fever medicines. Reason: research has shown these meds may reduce the body's normal immune response.

- For fever above 102 F (39 C), can give medicine for discomfort if needed. Acetaminophen is preferred (See Dosage table).

- **Fluids.** Encourage cool fluids in unlimited amounts. Reason: prevent dehydration. Fluids can also lower high fevers.

- **Clothing.** Dress in normal clothing. For shivering or chills, use a blanket until it stops.

#### 7. **Systemic (Whole Body) Symptoms from the Vaccine - Treatment:**

- General symptoms usually start about 12 to 24 hours after the shot. They mean the immune system is turned on and doing its job.

- General symptoms of feeling sick usually only last for one day, sometimes 2.

- Follow the tips below to help your child feel better.

- **Tiredness:** Encourage your child to rest or even sleep. Reason: The body needs all its energy going towards building antibodies against the vaccine. If we rest, the symptoms may pass sooner.

- **Poor appetite or even nausea:** Drink extra fluids. Stay well hydrated. Reason: Good hydration keeps the body working at peak performance.

- **Chills:** Wrap your child in a blanket. Reason: Warmth speeds up blood flow.

- **Muscle aches:** Take a warm bath or shower.

- **Fussiness:** Younger children may be more fussy than normal. They need extra holding and comforting.

#### 8. **COVID Arm - Rare Normal Reaction:**

- A few people get a large red blotchy rash at the injection site. It's called "COVID arm" and is harmless. Incidence: less than 1 per 100 people.

- **Size:** The red rash can be 2 to 4 inches (5 to 10 cm) wide. This is larger than normally seen with most vaccines.

- **Location:** Around the upper arm injection site. Sometimes the rash is largest below the injection site.

- **Onset:** Starts 3 to 14 days (average 8 days) after the vaccine.

- **Symptoms:** rash often feels itchy. Any tenderness (pain to touch) is usually mild.

- **Duration:** usually goes away in about a week. Sometimes it looks pink for another week.

- **Outcome:** No complications or long-term problems.

- **Cause:** harmless local immune reaction to the vaccine. Happens mainly with Moderna vaccine, rarely with Pfizer vaccine.

- **Future vaccines:** Safe to receive future vaccines and boosters. With second shot, symptoms start sooner. They can be the same or milder.

#### 9. **Call Back If:**

- Fever lasts over 3 days

- Redness becomes larger than 4 inches (10 cm) after 3 days

- Redness after 3 days becomes very painful to touch
- Your child becomes worse

## COVID-19 Vaccine Answers to Common Questions

### 1. COVID-19 Vaccines - Efficacy Questions:

- **Vaccine Efficacy:** All the vaccines approved by the FDA for use in the US are highly effective at preventing COVID-19 complications. The protection against getting the new variants has gone down some, but most people have mild symptoms or none if they get infected. The vaccines continue to prevent serious symptoms, complications and the need for hospital or ICU admission, even for the variants. They are much more effective than flu vaccines.
- **Other Major Benefits:** Vaccines also prevent the rare serious delayed onset complications from COVID-19 infections that can occur in some unlucky people. One example is multisystem inflammatory syndrome in children (also called MIS-C). Another is "long hauler" symptoms (such as brain fog or chronic breathing problems). Key: Vaccines prevent death from COVID-19 infections.
- **Vaccines and Normal Life:** Having almost everyone vaccinated is the only way we can get back to normal. Normal means no masks, open schools, safe to travel, safe to visit grandparents, less mental health crisis and no deaths from COVID-19.
- **Best Vaccine:** Any vaccine approved by the FDA is highly effective and safe. Get the first one that becomes available to you. They will help protect you and your family.

### 2. COVID-19 Vaccines - Protection and Booster Shot Questions:

- **Start of Vaccine Protection:** Full protection is reached about 2 weeks after you complete the primary vaccine series or immediately after getting a booster.
- **Duration of Vaccine Protection:** Research data has confirmed that protection for serious complications is still high at 6 months after completing the vaccine series. Experts predict this protection may last for 12 months or longer from boosters, but we need to wait for more data.
- **COVID-19 Primary Vaccine Series:** CDC recommends the COVID-19 vaccine primary series for all children age 6 months and older.
- **Booster Shot(s):** Booster vaccines are recommended for those 5 years and older after completing their primary vaccine series. Get your booster(s) when eligible. See the CDC website if you aren't sure when you need a booster.
- **COVID-19 Variants and Vaccine Protection:** For now, the current vaccines protect against serious complications from the current variants in the US. The vaccinated person usually does not get seriously ill. If they do, they develop either a mild illness or an asymptomatic infection. They are protected against serious symptoms and any complications. By contrast, natural immunity does not protect against some of the variants.
- **Breakthrough cases** are COVID-19 infections that happen despite vaccine protection. They are more common with new variants. Many do not cause significant symptoms. Some get mild symptoms. The vaccine prevents almost all hospital admissions and deaths.
- **Quarantine after Exposure:** If you are up-to-date on your COVID-19 vaccines and booster(s), you do not have to quarantine after close contact with a COVID-19 infected person. However, fully vaccinated people should get tested 5 days after an exposure to COVID-19. You should also wear a mask for 10 days when you are around other people.

### 3. COVID-19 Vaccine Safety and Rare Side Effects Questions:

- **Vaccine Safety:** Very safe. Most people get a sore arm for a few days. About half get some general symptoms for about 24 hours, such as feeling tired and achy. A smaller number have a fever. These are the normal side effects seen with most vaccines and they go away quickly. They show your immune system is working. Serious reactions are extremely rare.
- **COVID Arm:** Large red blotchy rash may occur at the injection site. Feels somewhat itchy. Redness can last for a week. It's a harmless local reaction that may or may not occur with next shot. Less than 1 per 100 people have this reaction. Mainly with Moderna vaccine.
- **Blood Clot Concerns:** Very rare. Occur in about 1 person per million vaccinated people. Blood clots occur much more commonly in people who get the natural COVID-19 infection. (Note: have NOT occurred with Moderna or Pfizer vaccines)
- **Myocarditis Concerns:** Myocarditis is inflammation of the heart muscle. Main symptoms are chest pain and shortness of breath. Symptoms start within 1 week of getting the vaccine. Note to triager: If chest pain is the only symptom, refer to PCP or ED urgently. Very rare side effect of the

COVID-19 vaccines. Occurs in about 6 per million vaccinated people. (20 per million in study from Israel) Mainly in teen or young adult males. The symptoms are usually mild and go away quickly. Myocarditis occurs much more commonly in people who get the natural COVID-19 infection and is more severe in them.

4. **COVID-19 Vaccines - Eligibility and Special Patient Questions:**

- **Adults:** Approved for all age groups.
- **Children and Teens:** Currently approved for 6 months and older. Results: strong protection and very safe (normal side effects). Importance: while most children have mild or asymptomatic infections, they can get rare complications such as MIS-C. Also, they can innocently transmit the disease to others.
- **Babies under 6 Months:** During the first 6 months, babies are usually protected by antibodies from their mother. This is true if she is up-to-date on her COVID-19 vaccines.
- **Pregnant Women:** Vaccines are approved and safe.
- **Breastfeeding Mothers:** Vaccines are approved and safe. Studies show that breastmilk passes antibody protection against COVID-19 to the baby.
- **Underlying High Risk Conditions:** Vaccines are approved and safe. These patients need the vaccine protection the most. If you have questions about a specific condition, discuss with your doctor.
- **Person Already had the Disease:** Get the vaccine. It provides higher levels of antibodies and better protection than immunity following a COVID infection. Restriction: not approved until you are over any acute symptoms and the 10 days of isolation have passed.
- Go to CDC website for other questions: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines>

5. **COVID-19 Vaccine - Reasons to Postpone Questions:**

- Any recommended delay in vaccination is to avoid bringing contagious people into a vaccination site.
- **Positive COVID-19 Test with Symptoms:** If your child has a positive COVID-19 test, the vaccine should be postponed for a full 10 days, fever is gone for over 24 hours without fever meds, and the symptoms are resolving (gone or almost gone).
- **Positive COVID-19 Test without Symptoms:** If your child has a positive COVID-19 test without symptoms, the vaccine should be postponed for a full 10 days. The 10 days starts on the day the test sample was collected.
- **Exposed to COVID-19, But No Symptoms:** If your child has been exposed to COVID-19 and is scheduled for the vaccine, the vaccine should be postponed for 10 full days. The 10 days starts on the last day of exposure.
- **Child is Sick and Scheduled for Vaccine:** If your child has symptoms compatible with COVID-19, they should get a test before receiving the vaccine. If negative and mild illness (such as isolated runny nose or mild diarrhea), they can receive the vaccine. For moderate or severe illness (including a fever), the vaccine should be postponed until fever is gone for over 24 hours and symptoms are resolving (gone or mild).
- **Flu and COVID-19 Vaccines:** Can be given at the same time. No waiting period needed between the 2 shots.
- **After Monoclonal Antibody Therapy:** Vaccine should be postponed for a full 10 days after the symptoms started or after positive test.
- **Multisystem Inflammatory Syndrome (MIS-C):** Vaccine must be postponed at least 90 days since MIS-C was diagnosed.

6. **Call Back If:**

- You have other questions or concerns

## FIRST AID

N/A

## BACKGROUND INFORMATION

## Matching Pediatric Handouts for Callers

Printed home care advice instructions for patients have been written for this guideline. If your software contains them, they can be sent to the caller at the end of your call. Here are the names of the pediatric handouts that relate to this topic:

- COVID-19 Vaccines - Answers to Common Questions
- Vaccine Reactions - Normal
- Vaccine Concerns - You're Undecided
- Vaccines - Dangerous Infections They Prevent
- Fever - How to Take the Temperature
- Fever - Myths Versus Facts
- Acetaminophen (Tylenol) Dosage Table - Children
- Ibuprofen (Advil, Motrin) Dosage Table - Children

## Types of Reactions

- **Local Injection Site Reaction:** Most local swelling, redness and pain at the injection begins within 24 hours of the shot (rarely 24 to 48 hours.) Usually lasts 2 or 3 days. Occasionally, localized hives or itching occurs at the injection site. They usually last less than 24 hours. Localized hives do not mean your child is allergic to the vaccine.
- **Systemic (General) Reaction:** Fever with vaccines usually begins within 24 hours (sometimes starts between 24-48 hours). Headache, myalgias, malaise and poor appetite can also be seen. Systemic symptoms usually last 1 to 2 days. Exception: (live vaccines like MMR and chickenpox).
- **Anaphylactic Reaction:** Anaphylactic reactions can occur with any vaccine but they are very rare (1:500,000). In addition, they usually start while the child is still in the office where the injection was given, so calls about them are extremely rare.

## Redness at the Injection Site (Normal Vaccine Reaction) - Rarely Cellulitis

- Local vaccine reactions are normal and a good sign that the vaccine is working.
- Bacterial superinfections (e.g., cellulitis, lymphangitis, abscess) at the injection site are extremely rare. Abscesses are more common than cellulitis. In the 1993 report by Simon, 8 out of 9 abscesses required surgical drainage. These were caused by nonsterile vaccine injections contaminated with Group A Strep bacteria. To further document how rare bacterial cellulitis is following a vaccine, there have been no culture confirmed cases of vaccine associated bacterial cellulitis reported in the medical literature in over 20 years. UpToDate lists vaccine reactions as a masquerader of cellulitis and not as a potential cause. (April 2021 access).
- Clues from Appearance: Local vaccine reactions usually are blotchy red with indistinct borders. Vaccine reactions also are usually mildly tender, sometimes itchy. Cellulitis usually has confluent spreading redness with sharp borders. It also is very tender to the touch.
- Clues from Onset: Redness and fever from a vaccine reaction usually begins within 24 hours following the shot (rarely 24-48 hours). Redness and fever from a bacterial infection usually begins more than 48 hours after the shot (Reason: it takes time for the bacteria to become established and multiply).
- Clues from Duration: Redness that is getting worse after 72 hours also could mean that a bacterial infection has occurred. However, this has been reported as a normal finding after COVID-19 vaccine. It's been called "COVID arm".
- Reassurance if No Redness: Huge swelling without redness is always an atypical vaccine reaction. Cellulitis always has redness.
- Unproven Theory: Excessive redness may occur when an IM vaccine is injected SC rather than IM.

## Vaccine Injection Site Redness and Pain: Advice to Apply Heat Rather than Cold (Author's reasoning to support this care advice change)

- This protocol now recommends applying warm compresses or a heating pad for local vaccine reactions. This advice applies to local reactions from all injected vaccines. Reason: The goal is to increase blood flow to the injection site. Blood brings lymphocytes and other immune helpers. Warmth

may speed up the release of the vaccine into the lymphatic system, making it less concentrated at one site. Heat speeds healing of inflamed tissues.

- Boils and Cellulitis: Skin infections are examples where applying heat is standard advice.
- Sports Injuries and Ice: The advice to treat with ice or cold compresses comes from how sports injuries are generally treated. But injuries are different. Usually there is some bleeding and cold is thought to prevent the bleeding from recurring. Injuries cause muscle or other tissue damage. Cold is thought to reduce swelling of the damaged tissue. Neither of these reasons apply to vaccine injections. In addition, sports medicine specialists and athletic trainers recommend switching to heat after the first 24 to 48 hours to speed healing.
- Research: There is no study comparing the application of heat versus cold for local vaccine reactions. Facts from pathophysiology and the normal inflammatory response would support the use of heat.
- Physician Preferences: If the caller states that their PCP recommends treating with cold, the triage nurse should support the PCP's preferred advice. Also, office-based pediatricians and call center medical directors can customize the care advice in this protocol for their facility.

### **Consultants for Heat versus Cold for Vaccine Injection Site Reactions:**

This approach of applying heat to local vaccine reactions was reviewed and is supported by the following vaccine specialists:

- Paul Offit MD, Professor of Pediatrics, pediatric infectious disease specialist, medical director of the Vaccine Education Center at Children's Hospital of Philadelphia.
- Sean O'Leary MD, Professor of Pediatrics, pediatric infectious diseases specialist, Children's Hospital Colorado, and Vice Chair of the Committee on Infectious Diseases, American Academy of Pediatrics

### **Rare Adverse Reactions for COVID-19 Vaccines**

- **Severe allergic reactions** with the COVID-19 vaccine are very rare. Moderna vaccine: 2.5 cases per million doses. Pfizer vaccine: 11 cases per million doses. (CDC report, January 2021). Usually occur within 20 minutes.
- **Blood clot concerns:** Very rare. Occur in about 1 person per million vaccinated people. (Note: have NOT occurred with Moderna or Pfizer vaccines)
- **Myocarditis Concerns:** Myocarditis is inflammation of the heart muscle. Main symptoms are chest pain and shortness of breath. Symptoms start within 1 week of getting the vaccine. Note to triager: If chest pain is the only symptom, refer to PCP or ED urgently. Very rare side effect of the COVID-19 vaccines. Occurs in about 6 per million vaccinated people. Mainly in teen or young adult males. The symptoms are usually mild and go away quickly. Myocarditis occurs much more commonly in people who get the natural COVID-19 infection and is more severe in them.

### **Prophylactic Acetaminophen Causes Reduced Vaccine Response - AVOID**

- In 2009, a Czech Republic study looked at prophylactic acetaminophen administration after vaccinations. (Pyrmula 2009)
- The study included 460 healthy children 9-16 weeks and 12-15 months receiving booster vaccinations.
- Children were randomly assigned to 2 groups: those who were given acetaminophen in 3 doses during the 24 hours post-vaccine versus no post-vaccine antipyretic treatment.
- Blood samples were drawn to determine the immunogenicity of vaccinations at 1 month after the injection.
- The study concluded that acetaminophen led to reduced immunogenic responses regardless of the presence of fever.
- In 2018, an Australian study on 3300 children confirmed the Czech study results. Children who received antipyretics after an influenza vaccine had a lower antibody response. (Li-Kim-Moy, *Pediatr Infect Dis J*, 2018).
- Application: This Immunization Reaction guideline has never recommended giving antipyretics prophylactically before receiving vaccines. Antipyretics are only recommended for fever over 102 F or for severe pain following immunizations. Furthermore, it is only recommended as needed based on

symptoms, not dosed at regular intervals.

- Summary: No national organization (e.g., the AAP) has changed their recommendations for pre- or post-immunization care based on these 2 studies. For now, this protocol is in compliance with the findings. More research is needed to further confirm that these findings are valid and clinically important.

### **Vaccines on the Go - a Free App from CHOP**

- This is a consumer app for vaccine facts.
- This free app answers any vaccine question a parent might have.
- It is evidence-based and up-to-date.
- Source: Children's Hospital of Philadelphia (CHOP)
- Recommend it to your worried callers.

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