

# COVID-19 Vaccine Informed Consent Guide

The purpose of this sheet is to be a quick guide to COVID-19 vaccination for children. This does not replace EUA FACT SHEET provided at the time of immunization.

## Risks of Covid-19 in children

- Hospitalization rate of 0.36% for those age 17 and under.<sup>1</sup>
- Statistically 0% mortality rate from Covid in ages 6 months to 4 years, 202 deaths total.<sup>1</sup>
- Children have a 99.995% recovery rate from COVID.<sup>2</sup>
- Children clear the virus more easily than adults.<sup>14</sup>
- Hospitalizations due to Covid-19 are lower than vaccine induced myocarditis hospitalizations.<sup>3</sup>

## Risks of Pfizer Vaccination<sup>4</sup>

- Long-term safety studies are pending
- Remote chance of a **severe allergic reaction** occurring *within a few minutes to one hour* after vaccination. Symptoms may include: difficulty breathing, swelling of the face and throat, fast heartbeat, rash all over the body, dizziness, or weakness. Your child's provider will likely ask you to stay to monitor for a severe allergic reaction after vaccination.
- Mild allergic reactions such as rash, itching, hives, or swelling of the face
- Injection site pain/tenderness
- Tiredness
- Headache

### • Myocarditis/Pericarditis<sup>4</sup>

- Inflammation of the heart muscle called **myocarditis** and inflammation of the lining outside the heart called **pericarditis** have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should **seek medical attention right away if your child has any of the following symptoms** after receiving the vaccine, particularly during the 2 weeks after your child receives a dose of the vaccine:
  - Chest pain
  - Shortness of breath or difficulty breathing
  - Feelings of a fast-beating, fluttering, or pounding heart
  - Fainting
  - Unusual and persistent irritability
  - Unusual and persistent poor feeding
  - Unusual and persistent fatigue or lack of energy
  - Persistent vomiting
  - Persistent pain in the abdomen
  - Unusual and persistent cool, pale skin
- 1 out of 2,700 patients age 12 to 17 were diagnosed with myocarditis after the second vaccine<sup>5,6</sup>
- If your child has one of these or another health issue after vaccination, follow up with your doctor. You can find more information about next steps on the back of this page.
- Multi-System Inflammatory Syndrome in Children (MIS-C) is not listed in the Emergency Use Authorization Fact Sheet for Recipients and Caregivers<sup>4</sup> however it has been listed as an Adverse Event of special interest. If your child experiences signs and symptoms of MIS-C seek medical attention. Symptoms may include fever, rash, red eyes, abdominal pain, sleepiness, or confusion.<sup>7</sup>

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information

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## Alternatives to the vaccine:

- Natural Immunity. In April 2022 the CDC reported that over 75% of children had COVID infection.<sup>8</sup> Children often had mild or undetectable cases. They may not receive any benefit from vaccination. Safety studies have not been completed to determine impacts on children with previous natural infection.
- Talk with your child's pediatrician to optimize their Vitamin D levels.<sup>9, 10</sup>
- Avoid infected individuals.
- Healthy diet & lifestyle including fruits, vegetables, sunshine, and water.
- Provide supportive care if diagnosed including water, rest, and medical attention when needed.
- Carrageenan (Betadine) nasal spray may double the rate of recovery from COVID and influenza infections.<sup>11</sup>

## Other Considerations:

- Pfizer trials failed to meet FDA-specified requirements regarding efficacy of the vaccine.<sup>12, 13, 15, 16</sup>
- The vaccine does not prevent transmission.<sup>4</sup>
- Duration of infection prevention is unknown.<sup>4</sup> Variants may reduce or eliminate infection prevention.
- Families may have many reasons to accept or decline receiving a vaccination. Should you decline the COVID-19 vaccine for your child, it will not change their standard of medical care.

## What if a Reaction Occurs?

- If your child experiences a severe allergic reaction, **call 9-1-1, or go to the nearest hospital.**<sup>4</sup>
- Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child or do not go away.<sup>4</sup>
- Report vaccine side effects to Vaccine Adverse Event Reporting System (VAERS).<sup>4</sup>
  - The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent>
  - Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.
  - Notify your provider and get their help completing the form if needed. For more information you may visit **VAERSproject.com**.
- Report side effects to Pfizer Inc.<sup>4</sup>
  - Website [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com)
  - Telephone number 1-866-635-8337 or 1-800-438-1985.
- At the time of vaccination, you may also be given an option to enroll in **v-safe**. V-safe is a voluntary smart phone based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help the CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).<sup>4</sup>
- Pfizer is **NOT LIABLE** for injury or death. If your child is injured or their death is related to receiving the vaccination you are not able to prosecute the manufacturer. Your child will not be eligible for compensation through the Vaccine Injury Compensation Program (VICP) as with standard childhood vaccinations however they may be eligible under the Countermeasure Injury Compensation Program (CICP). For more information visit [www.hrsa.gov/cicp/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427. **Claims for CICP must be submitted within 1 year of vaccination.**<sup>4</sup>

1. <https://www.medrxiv.org/content/10.1101/2021.11.30.21267048v1.full-text>

2. <https://www.nature.com/articles/s41591-021-01578-1>

3. <https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1>

4. <https://labeling.pfizer.com/ShowLabeling.aspx?id=17228>

5. <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab989/6445179>

6. <https://onlinelibrary.wiley.com/doi/10.1002/pds.5439>

7. <https://www.medpagetoday.com/infectiousdisease/covid19vaccine/97315>

8. <https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e3.htm>

9. <https://link.springer.com/content/pdf/10.1007/s00210-020-01911-4.pdf>

10. <https://pubmed.ncbi.nlm.nih.gov/33017102/>

11. <https://pubmed.ncbi.nlm.nih.gov/34128358/>

12. <https://www.cdc.gov/mmwr/volumes/71/wr/mm7111e1.htm/>

13. <https://www.law.cornell.edu/uscode/text/21/360bbb-3>

14. <https://www.nature.com/articles/s41467-021-22236-7>

15. <https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1>

16. <https://jamanetwork.com/journals/jama/fullarticle/2792525>