

PFIZER COVID-19 VACCINE: Short-Term Efficacy & Safety Data

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1. WHAT IS THE PFIZER COVID-19 VACCINE?

The Pfizer COVID-19 vaccine is made from synthetic genetic material that is immersed in fatty substances, including cholesterol and polyethylene glycol (PEG). More specifically, modified RNA molecules that encode for a mutated spike (S) protein antigen of the Wuhan-Hu-1 SARS-CoV-2 strain, the original virus that caused COVID-19, are immersed in lipid nanoparticles. The drug is administered in two intramuscular doses (30 mcg each for individuals aged 12 or older; 10 mcg each for children aged 5 to 11), 21 days apart.²⁻⁴



2. HOW WAS THE VACCINE STUDIED PRIOR TO OBTAINING FDA APPROVAL?

The Pfizer COVID-19 vaccine was studied through nonclinical data from rats and nonhuman primates, and a human clinical trial comparing approximately 22,000 subjects who received the vaccine with 22,000 subjects who did not receive the vaccine (Table 1).⁵ About 42% of the subjects in the trial were observed for less than four months after the second dose and 51% were observed for four to less than six months after the second dose.⁶

Five times more vaccinated subjects were excluded from the clinical trial compared to subjects who did not receive the vaccine (311 compared to 60). The reason for those exclusions provided by the U.S. Food and Drug Administration (FDA) is “other important protocol deviations.” More specific reasons were not provided.⁷



3. DOES THE VACCINE PREVENT HOSPITALIZATIONS AND DEATHS?

Since the number of hospitalized cases of COVID-19 have not been published in clinical trial documents, the vaccine’s ability to prevent hospitalizations from COVID-19 is unclear.⁸ See Table 1. Regarding deaths, the FDA states, “A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality.”⁸

Of note, a study of a COVID-19 outbreak in July 2021 published in *Eurosurveillance* observed that 100% of severe, critical, and fatal cases of COVID-19 occurred in vaccinated individuals.⁹ A Centers for Disease Control and Prevention (CDC) study of another COVID-19 outbreak in July 2021 observed similar data and found that 80% of hospitalized cases were fully vaccinated.¹⁰



4. HOW EFFECTIVE IS THE VACCINE IN ADULTS?

Vaccine efficacy was calculated by observing the vaccination status of 971 COVID-19 cases (including Alpha and Beta variants of concern¹¹), where a COVID-19 case was defined as the presence of at least one COVID-19 symptom and a positive SARS-CoV-2 test at least seven days after the second dose. In subjects 12 years or older, the vaccine was 93%–98% effective within two months of the second dose. However, between two and four months after the second dose, vaccine efficacy declined to 87%–93%, and between four and six months after the second dose, vaccine efficacy declined to 75%–90%.⁶



5. IS THE VACCINE EFFECTIVE IN CHILDREN?

The vaccine was authorized for use in children 12 to 15 years of age in May 2021, “although limited scientific information is available,” per Pfizer,¹² and was 93%–98% effective over a two-month observation period.⁶ The vaccine was authorized for use in children 5 to 11 years of age in October 2021 and was 67%–98% effective over a two-month observation period.⁴

In the clinical trial, there were zero cases of severe COVID-19 in children who did not receive the vaccine. For adolescents 12 to 15 years of age, the FDA states, “There were no reports of severe COVID-19 cases.”¹³ For children 5 to 11 years of age, the FDA states, “None of these cases met the criteria for severe infection.”⁴ As such, the ability of the vaccine to prevent hospitalizations or deaths from COVID-19 in children 5 to 15 years of age is not known.

SHORT-TERM EFFICACY DATA

Enrolled subjects	Observation period of 2 to 6 months (95% confidence interval)	
Confirmed COVID-19 deaths ^{4,11}	NA*	?
Confirmed COVID-19 hospitalizations ⁸	NA*	?
Confirmed COVID-19 (age 5–11, 0–2 months after second dose) ⁴	67%–98%	✓
Confirmed COVID-19 (age ≥12, 4–6 months after second dose) ⁶	75%–90%	✓ ↓
Confirmed COVID-19 (age ≥12, >6 months after second dose) ⁶	NA*	?
Asymptomatic SARS-CoV-2 infection ⁸	NA*	✗
SARS-CoV-2 spread (transmission) ⁸	NA*	✗

SHORT-TERM SAFETY DATA

Severe systemic reactions (age 5–11) ⁴	1 in 59 to 1 in 143 in vaccinated 6x–7x greater risk in vaccinated 3–8 cases for every 10 non-severe COVID-19 cases	⚠
Severe systemic reactions (age 12–15) ^{22,24}	1 in 9 in vaccinated 6x greater risk in vaccinated 7x more than non-severe COVID-19 cases	⚠
Severe systemic reactions (age 16–55) ^{6,11}	1 in 6 to 1 in 19 in vaccinated 8x–10x greater risk in vaccinated 1x–3x more than COVID-19 cases of any severity	⚠
Severe systemic reactions (age 56 or older) ^{6,11}	1 in 14 to 1 in 30 in vaccinated 9x–11x greater risk in vaccinated 1x–2x more than COVID-19 cases of any severity	⚠
Pregnant/breastfeeding ¹³	NA*	?
Immunocompromised ¹³	NA*	?

✗ Not tested ? Insufficient data to prove efficacy or safety ✓ Evidence of short-term benefit ↓ Evidence of declining efficacy ⚠ Evidence of risk

*No data provided by the FDA.

Table 1: Short-term efficacy and safety data from the Pfizer COVID-19 vaccine clinical trial. The data show the vaccine was effective at preventing COVID-19 cases that did not result in hospitalization. However, vaccine efficacy waned, and there were insufficient data to show vaccine efficacy for hospitalized COVID-19 cases, fatal cases, and asymptomatic cases. In addition, severe systemic reactions were observed.



6. WHAT ABOUT A BOOSTER DOSE?

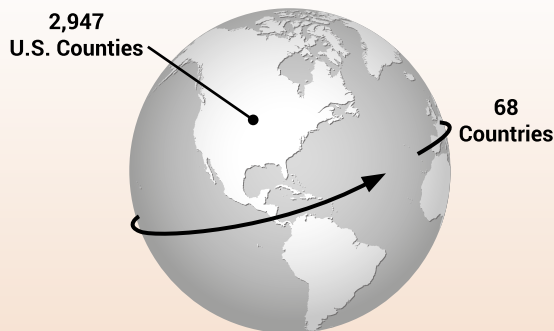
Between September 2021 and January 2022, the FDA granted emergency use authorization (EUA) for a booster dose of the Pfizer COVID-19 vaccine for individuals 12 years of age or older.^{14,15} However, the clinical trial states, “Efficacy was not evaluated for Phase 3 BNT162b2 booster group participants,” and vaccine efficacy was inferred based on antibody levels observed in about 300 vaccinated subjects over a one-month time period.¹⁶



7. DOES THE VACCINE PREVENT INFECTION OR TRANSMISSION?

The Pfizer clinical trial was not designed to observe asymptomatic infection with SARS-CoV-2 or the effect of the vaccine on the spread (transmission) of COVID-19. Consequently, the FDA states that “it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections” and “data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination.”¹⁸ Approximately 33% of SARS-CoV-2 infections are asymptomatic.^{17,18}

Of note, a study of a COVID-19 outbreak in July 2021 published in *Eurosurveillance*⁹ found that “all transmissions between patients and staff occurred between masked and vaccinated individuals, as experienced in an outbreak from Finland.” The authors stated that the study “challenges the assumption that high universal vaccination rates will lead to herd immunity and prevent COVID-19 outbreaks.” A CDC study of another COVID-19 outbreak in July 2021 observed similar data and found that 74% of cases were fully vaccinated.¹⁰ A Harvard study investigating COVID-19 cases across 68 countries and across 2,947 counties in the U.S. found “there also appears to be no significant signaling of COVID-19 cases decreasing with higher percentages of population fully vaccinated.”¹⁹



No decrease in cases with increase in vaccination

reactions occur in 1 in 6 to 1 in 143 vaccinated subjects. See Table 1 and Supplement 1.^{4,6,11,22-24} The clinical trial also found that 1 in about 1,100 vaccinated children 12 to 15 years of age had a grade 4 systemic reaction (fever greater than 104.0° F) after the first dose that required an emergency room (ER) visit and withdrawal from the study.²²



Emergency Room



An ER visit occurred in 1 in about 1,100 kids 12–15 years of age, within one week of being injected with the COVID-19 vaccine.

Of note, approximately 3,400 or 8% of subjects 16 years or older experienced “suspected COVID-19” because they had symptoms but were not confirmed by testing for SARS-CoV-2; two of these cases required hospitalization, both of which were in the vaccinated group. These cases could represent other influenza-like illness and adverse events; 409 such cases occurred in the vaccinated group within seven days of injection whereas 287 such cases occurred in the unvaccinated group in the same time period. Only the cases that were reported as serious were recorded as adverse events.⁸ In the clinical trial, only 5% of all illnesses suspected of being COVID-19 were actually found to be COVID-19.

After mass vaccination with the Pfizer COVID-19 vaccine began, the CDC recorded about 5,000 “health impact events” among 215,000 vaccinated subjects (1 in 43) that, similar to the definition of severe systemic reactions in the clinical trial, prevented the ability to perform normal daily activities, including work, and required medical attention.²⁵

Concerningly, post-EUA safety surveillance reports have identified serious risks for myocarditis and pericarditis in subjects under age 40, within seven days of vaccination. In boys aged 16 or 17, after the second dose of the Pfizer COVID-19 vaccine, the risk of myocarditis or pericarditis is 1 in 5,000.¹⁶ Additionally, since the clinical trial observed only about 1,100 vaccinated children aged 12 to 15¹² and 1,500 vaccinated children aged 5 to 11,⁴ there were not enough children included in the trial to be able to show the vaccine is safer than the disease. As of Nov. 3, 2021, the chance of a child 17 years or younger contracting SARS-CoV-2 and dying from COVID-19 was 1 in 126,000 or 0.0008%.²⁶

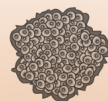
Moreover, per the FDA, there are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as pregnant and lactating individuals, and immunocompromised individuals.¹³ Per Pfizer, the vaccine “has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility.”¹¹ And, because all subjects were observed for only two to six months, the long-term safety of the vaccine for any age group is not known.



8. WHAT IS THE RISK OF A SEVERE SIDE EFFECT FROM THE VACCINE?

The Pfizer COVID-19 vaccine clinical trial found that the vaccine causes severe (grade 3) systemic reactions, which include fever greater than 102.1° F; vomiting that requires IV hydration; diarrhea of six or more loose stools in 24 hours; and severe fatigue, severe headache, severe muscle pain, or severe joint pain that prevents daily activity.^{11,20} Trial data²¹ demonstrate that severe systemic

No safety studies for:



Cancer



Damage to genes



Impaired fertility

Supplement 1 and all references are available at physiciansforinformedconsent.org/covid-19-vaccines.

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SUPPLEMENT 1: RISK OF SEVERE SYSTEMIC REACTIONS FROM THE PFIZER COVID-19 VACCINE

The Pfizer COVID-19 vaccine clinical trial found that the vaccine causes severe (grade 3) systemic reactions, which include fever greater than 102.1° F; vomiting that requires IV hydration; diarrhea of six or more loose stools in 24 hours; and severe fatigue, severe headache, severe muscle pain, or severe joint pain that prevents daily activity. Trial data²¹ demonstrate the following:

Children 5 to 11 years of age

- A range of 1 in 59 to 1 in 143 vaccinated children suffered severe systemic reactions within seven days of the second dose.
- There was a 6 to 7 times greater risk of a severe systemic reaction from the vaccine.
- There were 3 to 8 cases of severe systemic reactions observed in the vaccinated group for every 10 cases of non-severe COVID-19 in the unvaccinated group.

Adolescents 12 to 15 years of age

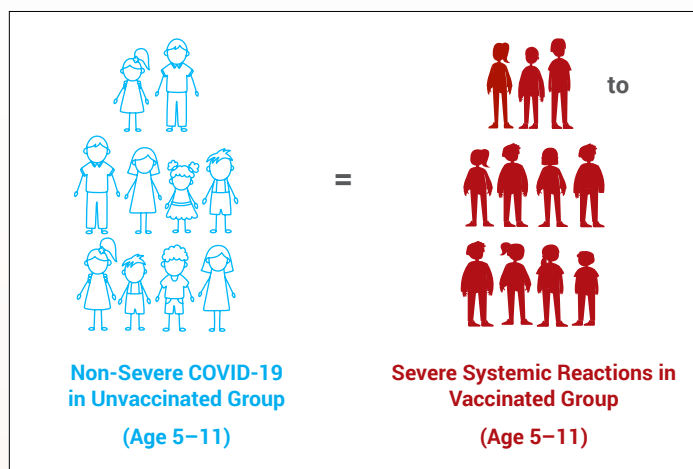
- 1 in 9 vaccinated adolescents suffered severe systemic reactions within seven days of the second dose.
- There was a 6 times greater risk of a severe systemic reaction from the vaccine.
- There were 7 times more severe systemic reactions observed in the vaccinated group than non-severe COVID-19 cases in the unvaccinated group.

People 16 to 55 years of age

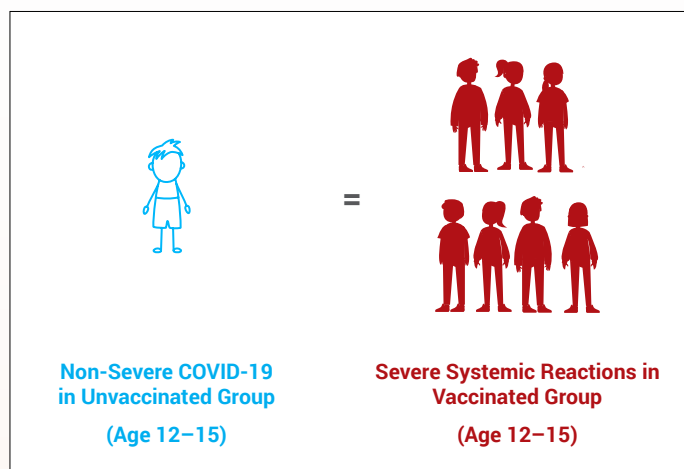
- A range of 1 in 6 to 1 in 19 vaccinated subjects suffered severe systemic reactions within seven days of the second dose.
- There was an 8 to 10 times greater risk of a severe systemic reaction from the vaccine.
- There were 1 to 3 times more severe systemic reactions observed in the vaccinated group than COVID-19 cases of any severity in the unvaccinated group.

People 56 years or older

- A range of 1 in 14 to 1 in 30 vaccinated subjects suffered severe systemic reactions within seven days of the second dose.
- There was a 9 to 11 times greater risk of a severe systemic reaction from the vaccine.
- There were 1 to 2 times more severe systemic reactions observed in the vaccinated group than COVID-19 cases of any severity in the unvaccinated group.



In the Pfizer COVID-19 vaccine clinical trial, zero unvaccinated children 5 to 11 years of age suffered a severe case of COVID-19. In contrast, for every 10 cases of non-severe COVID-19 in the unvaccinated group, there were 3 to 8 cases of severe (grade 3) systemic reactions in the vaccinated group.



In the Pfizer COVID-19 vaccine clinical trial, zero unvaccinated adolescents 12 to 15 years of age suffered a severe case of COVID-19. In contrast, for every 1 case of non-severe COVID-19 in the unvaccinated group, there were 7 cases of severe (grade 3) systemic reactions in the vaccinated group.

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21. For children 5 to 11 years of age, the overall incidence of severe systemic reactions within seven days of the second dose was 0.7% to 1.7%, or 1 in 143 to 1 in 59, respectively, in the vaccinated group compared to 0.1% to 0.3% in the unvaccinated group, resulting in a 6 to 7 times greater risk of a severe systemic reaction from the vaccine.⁴ In addition, the incidence of COVID-19 in the unvaccinated group was 2.2%;⁴ therefore, there were 0.3 to 0.8 times as many severe systemic reactions observed in the vaccinated group than there were non-severe cases of COVID-19 in the unvaccinated group.
For adolescents 12 to 15 years of age, the overall incidence of severe systemic reactions within seven days of the second dose was 10.7%, or 1 in 9, in the vaccinated group compared to 1.9% in the unvaccinated group, resulting in a nearly 6 times greater risk of a severe systemic reaction from the vaccine.^{22,23} In addition, the incidence of COVID-19 in the unvaccinated group was 1.6%;²⁴ therefore, there were almost 7 times more severe systemic reactions observed in the vaccinated group than there were non-severe cases of COVID-19 cases in the unvaccinated group.
For subjects 16 to 55 years of age, the overall incidence of severe systemic reactions within seven days of the second dose was 5.3% to 16.4%, or 1 in 19 to 1 in 6, respectively, in the vaccinated group compared to 0.7% to 1.6% in the unvaccinated group, resulting in an 8 to 10 times greater risk of a severe systemic reaction from the vaccine.¹¹ In addition, the incidence of COVID-19 in the unvaccinated group was 4.9%;⁵ therefore, there were 1 to 3 times more severe systemic reactions observed in the vaccinated group than there were COVID-19 cases of any severity in the unvaccinated group.
For subjects 56 years or older, the overall incidence of severe systemic reactions within seven days of the second dose was 3.3% to 7.3%, or 1 in 30 to 1 in 14, respectively, in the vaccinated group compared to 0.3% to 0.8% in the unvaccinated group, resulting in a 9 to 11 times greater risk of a severe systemic reaction from the vaccine.¹¹ In addition, the incidence of COVID-19 in the unvaccinated group was 3.2%;⁶ therefore, there were 1 to 2 times more severe systemic reactions observed in the vaccinated group than there were COVID-19 cases of any severity in the unvaccinated group.
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