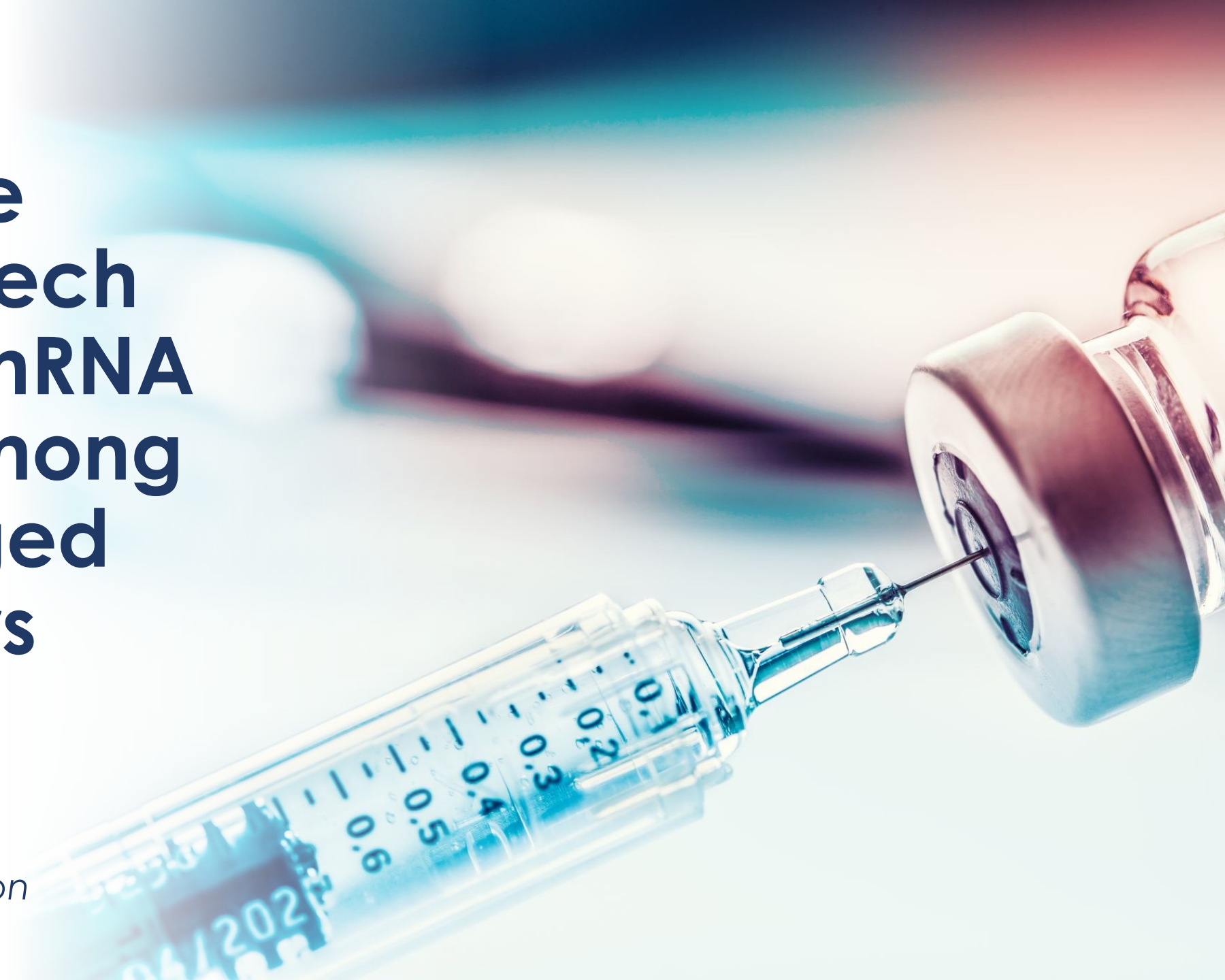
Safety of the Pfizer-BioNTech COVID-19 mRNA Vaccine Among Children Aged 5 to 11 Years



Created by Amy Worthington as a sample slide deck

Safe and effective vaccines have been developed to decrease the severity of COVID-19 symptoms and reduce transmission of the virus.

Many parents, however, remain hesitant to vaccinate their children due to safety concerns about the vaccines.

Here, we review evidence that the Pfizer-BioNTech mRNA vaccine is safe among children aged 5 to 11 years old.

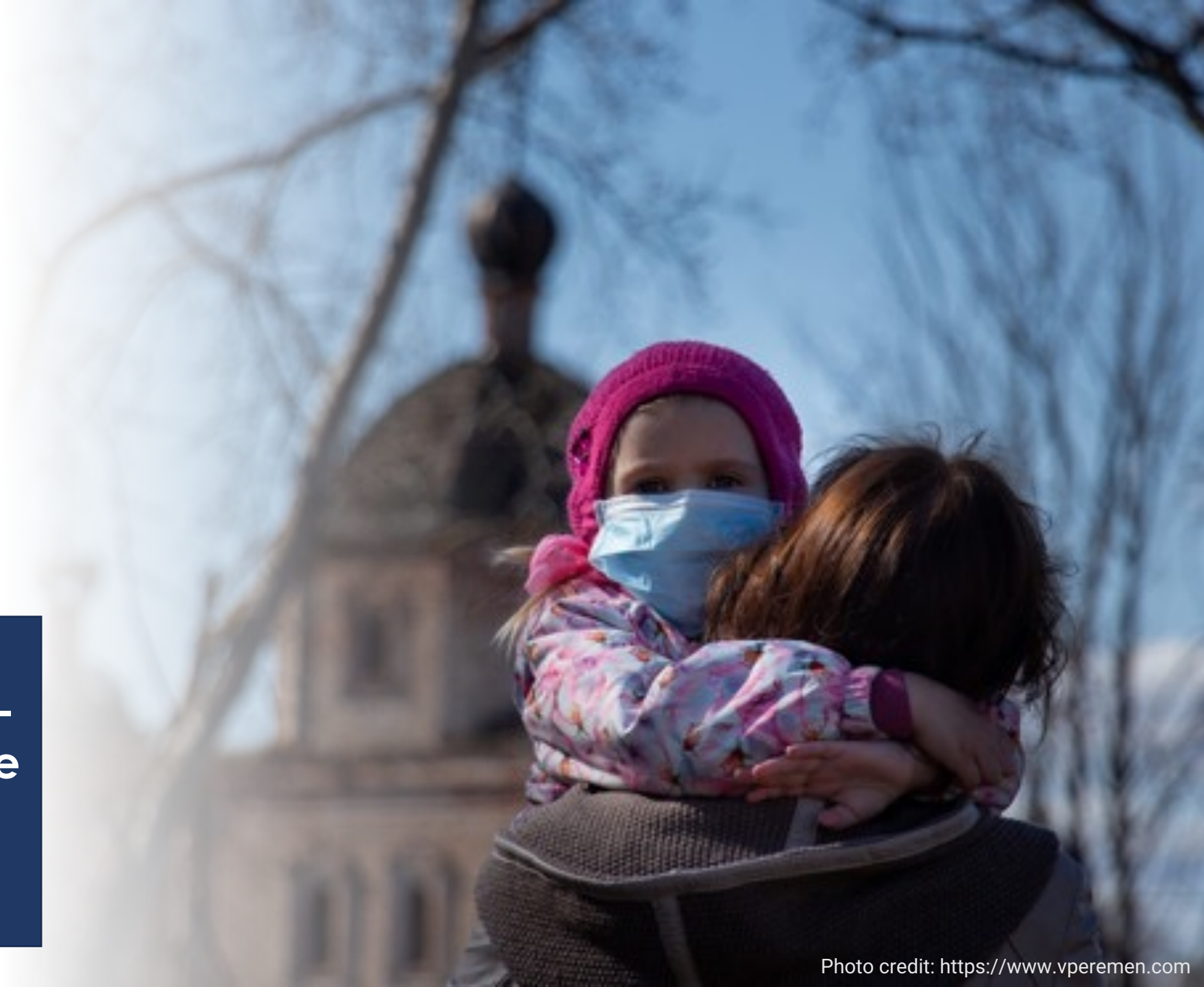


Photo credit: https://www.vperemen.com

Timeline of Key Vaccine Approval Events

Preauthorization clinical trials deemed the Pfizer-BioNTech 2-dose vaccine safe and effective at preventing COVID-19 in children aged 5–11 years.

On October 29, 2021 the Food and Drug Administration (FDA) expanded the use of the Pfizer-BioNTech COVID-19 vaccine to children aged 5–11 years.

Between November 3 – December 19, 2021, approximately **8.7 million doses** of the Pfizer-BioNTech COVID-19 vaccine were administered to children aged 5–11 years.

The CDC reviewed data from two sources monitoring adverse events after child COVID-19 vaccination from November 8 – December 4, 2021

1. **Vaccine Adverse Event Reporting System (VAERS)** – a vaccine safety surveillance system co-managed by the CDC and FDA
   - Reports are from health care providers, vaccine manufacturers, and the public.
   - Limitations:
     - passive surveillance reporting system subject to reporting biases and underreporting
     - data on ethnicity/race not provided in >40% of VAERS reports
2. **v-safe** – a smartphone-based safety surveillance system
   - Reports are from parents and guardians of vaccinated children.
   - Limitations:
     - voluntary reporting program
     - data may not be representative of vaccinated population

Safety data from VAERS

During the study period, VAERS had 4,249 reports of adverse events in children 5–11 years of age.

97.6% of reports were nonserious events

- The most common issues were no adverse event (27.9%) and incorrect vaccine preparation (22.3%) or dosing (16.3%).

2.4% of reports were serious events

- The most common issues were fever (29.0%), vomiting (21.0%), and increased troponin (15.0%).

Symptom, sign, diagnostic result, or condition (MedDRA PT)	No. reporting	% Reporting
Nonserious reports (n = 4,149)		
No adverse event†	1,157	27.9
Product preparation issue	925	22.3
Incorrect dose administered	675	16.3
Underdose	324	7.8
Vomiting	316	7.6
Fever	291	7.0
Headache	255	6.2
Syncope	255	6.2
Dizziness	244	5.9
Fatigue	201	4.8
Nausea	192	4.6
Urticaria	186	4.5
Rash	166	4.0
Pallor	151	3.6
Product storage error	146	3.5
Serious reports§ (n = 100)		
Fever	29	29.0
Vomiting	21	21.0
Troponin increased	15	15.0
Chest pain	12	12.0
Echocardiogram normal	12	12.0
Blood test	11	11.0
C-reactive protein increased	11	11.0
SARS-CoV-2 test negative	11	11.0
Appendicitis	10	10.0
Electrocardiogram normal	10	10.0
Headache	10	10.0
Rash	10	10.0
Seizure	10	10.0
Intensive care	9	9.0
Full blood count normal	8	8.0

Abbreviations: MedDRA PT = Medical Dictionary for Regulatory Activities preferred term; VAERS = Vaccine Adverse Event Reporting System.

Safety data from VAERS

A closer look at serious adverse events:

- **10 confirmed seizures**
  - Three children had histories of or potentially evolving seizure disorder.
  - One child had a febrile fever.
  - Five children experienced new-onset seizures.
- **11 verified cases of myocarditis**
  - All children recovered or were in the process of recovering at the time of the report.
- **2 reports of death**
  - Both children had complicated medical histories and were in fragile health prior to vaccination.
  - There is no data to suggest causation with vaccination.

Take-away

Serious adverse events to COVID-19 vaccination in children aged 5–11 are **rare**.

Safety data from v-safe

During the study period, v-safe enrolled 42,504 children aged 5–11 years that received their 1st dose and 29,899 that received their 2nd dose.

More than half of children had local reactions at the injection site.

Systemic reactions to vaccination were common (34.7%) and were more likely after the second dose.

- most commonly fatigue, fever, and headache

A small percentage of children were unable to perform normal activities the day after vaccination (5.0–7.4%).

- hospitalizations were rare and often unrelated

Event	% of v-safe enrollees reporting reaction or health impact*	
	Dose 1 (N = 42,504)	Dose 2 (n = 29,899)
Any injection site reaction	54.8	57.5
Itching	3.8	3.7
Pain	52.7	55.8
Redness	3.7	4.4
Swelling	3.9	4.9
Any systemic reaction	34.7	40.9
Abdominal pain	5.1	6.4
Myalgia	7.1	10.2
Chills	3.9	6.8
Diarrhea	2.6	2.2
Fatigue	20.1	25.9
Fever	7.9	13.4
Headache	13.9	19.8
Joint pain	2.1	2.9
Nausea	5.0	6.9
Rash	1.2	1.0
Vomiting	2.3	2.7
Any health impact	10.9	15.1
Unable to perform normal daily activities	5.1	7.4
Unable to attend school	7.9	10.9
Needed medical care	1.2	1.1
Telehealth	0.3	0.2
Clinic	0.6	0.6
Emergency visit	0.1	0.1
Hospitalization	0.02	0.02

* Percentage of enrollees who reported a reaction or health impact at least once during days 0–7 post-vaccination.

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Take-away

Mild local and systemic reactions to COVID-19 vaccination in children aged 5–11 are **common**.

Key Findings

1. The Advisory Committee on Immunization Practices (ACIP) recommends the Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years for the prevention of COVID-19.

2. Parents and guardians should be advised that mild to moderately severe reactions are expected in the days following vaccination.

3. The CDC and FDA will continue to monitor vaccine safety and provide updates on COVID-19 vaccination recommendations.

Thank you!

I am happy to take your questions.

Supplementary VAERS data on child demographic characteristics and reported symptoms

TABLE 1. Adverse event reports among children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine, by selected demographic characteristics and reported symptoms (N = 4,249) — Vaccine Adverse Event Reporting System, United States, November 3–December 19, 2021

Characteristic	Total, % (N = 4,249)	Nonserious, % (n = 4,149)	Serious, %* (n = 100)
Sex			
Female	45.0	45.1	39.0
Male	44.6	44.2	61.0
Unknown	10.4	10.7	0
Age range, yrs (median)	**5–11 (8)**	**5–11 (8)**	**5–11 (9)**
Ethnicity			
Hispanic or Latino	11.0	10.9	16.0
Non-Hispanic or Latino	40.0	39.7	56.0
Unknown ethnicity	48.9	49.4	28.0
Race			
American Indian or Alaska Native	0.6	0.6	0
Asian	4.0	4.0	7.0
Black	4.1	4.2	2.0
Native Hawaiian or Other Pacific Islander	0.2	0.2	0
White	39.5	39.2	52.0
Multiracial	2.2	2.1	9.0
Other	7.1	7.1	4.0
Unknown race	42.3	42.7	26.0

Abbreviation: VAERS = Vaccine Adverse Event Reporting System.