



Recommendations for Pfizer-BioNTech and Moderna COVID-19 Vaccine Primary Series in Children 6 Months through 5 Years Old

Clinician Outreach and Communication Activity (COCA) Call
Wednesday, June 22, 2022

**Slides updated post live webinar*

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Objectives

At the conclusion of today's session, the participant will be able to accomplish the following:

1. Review current COVID-19 vaccination recommendations for children ages 6 months through 5 years, including children who are moderately or severely immunocompromised.
2. List key points for healthcare providers to use when talking about COVID-19 vaccination with parents and caregivers of children ages 6 months through 5 years, including children who are moderately or severely immunocompromised.
3. Discuss where to find online resources for clinicians about COVID-19 vaccination for children ages 6 months through 5 years.

To Ask a Question

- Using the Zoom Webinar System
 - Click on the “Q&A” button
 - Type your question in the “Q&A” box
 - Submit your question
- If you are a patient, please refer your question to your healthcare provider.
- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov

Today's Presenters

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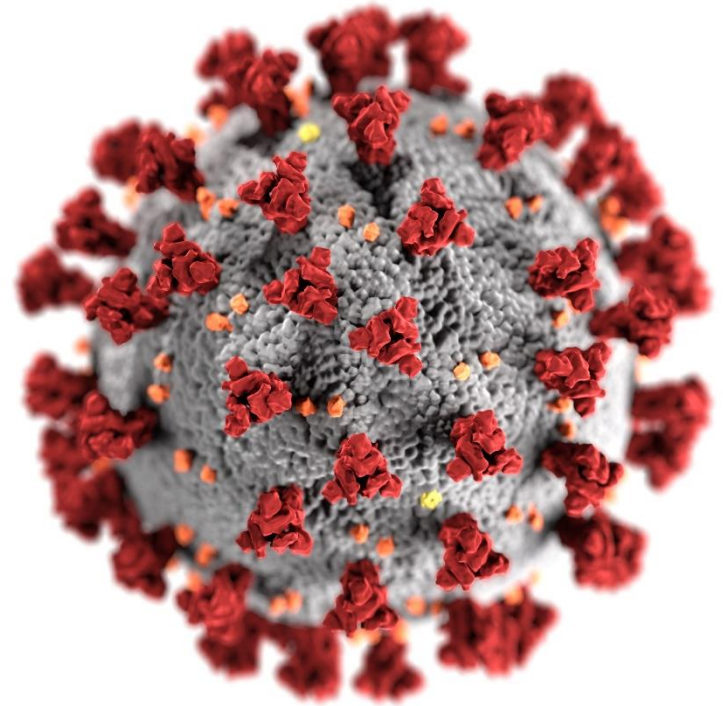
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Recommendations for Pfizer- BioNTech and Moderna COVID-19 Vaccine Primary Series in Children 6 Months through 5 Years Old

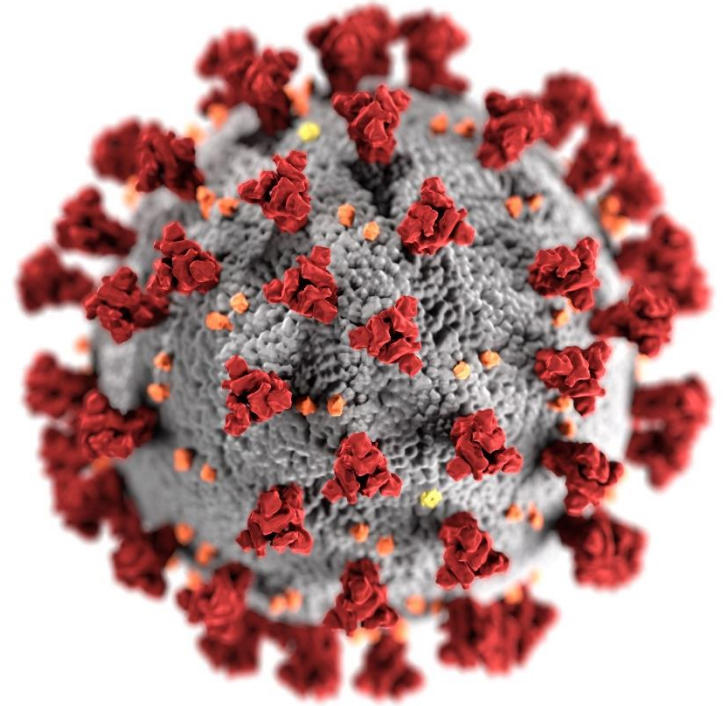
COCA Call
June 22, 2022



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mRNA COVID-19 Vaccines in Young Children

Sara Oliver, MD, MSPH



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U.S. COVID-19 epidemiology in children 6 months–4 years

- COVID-19 has caused **>2 million cases** among children ages 6 months – 4 years
- Children 6 months–4 years of age are **at risk of severe illness** from COVID-19
 - More than half of hospitalized children ages 6 months–4 years had **no underlying conditions**
 - COVID-19 associated hospitalizations among children ages 6 months–4 years have similar or increased severity compared to older children and adolescents
 - Burden of COVID-19 associated death is **similar to** or **exceeds** that of other pediatric vaccine preventable diseases
- Prior infection may not provide broad protection against newer SARS-CoV-2 variants
- COVID-19 pandemic continues to have significant impact on families

Moderna COVID-19 vaccine

Children ages 6 months–5 years



Clinical trial structure

Moderna COVID-19 vaccine: Children ages 6 months–5 years

- Trial conducted from December 2021 through February 2022
- Children ages 6 months–5 years in the United States randomized **3:1** vaccine to saline placebo
- Two doses of 25µg separated by **28 days**
- Median follow-up time post-dose 2: **2.5 months**
- Efficacy and safety populations:
 - 6–23 months: ~**2,300 children**; 1,700 vaccine and 600 placebo
 - 2–5 years: ~**4,000 children**; 3,000 vaccine and 1,000 placebo
 - TOTAL 6 months–5 years: ~**6,400 children**; 4,800 vaccine and 1,600 placebo

Efficacy data

Moderna COVID-19 vaccine: Children ages 6 months–5 years

- Efficacy endpoint^{1,2}: Subjects with or without evidence of prior infection
 - 6–23 months: **50.6%** (21.4–68.6%)
 - 2–5 years: **36.5%** (12.5–54.0%)
 - Overall 6 months–5 years: **41.5%** (23.8–55.0%)
- Higher confidence in the estimate, based on **181** COVID-19 cases in vaccine group and **97** COVID-19 cases in placebo group
- Efficacy in the trial consistent with post-authorization vaccine effectiveness for Moderna COVID-19 vaccine in adults 18–64 years during Omicron
 - Effectiveness against infection 2 months after dose 2 was **35%** (24–45%)

¹**CDC definition:** At least 1 prespecified clinical symptom and a positive RT-PCR

²Efficacy estimates presented represent the manufacturer analysis. For GRADE, estimates based on relative risks will be presented

Immunogenicity data

Moderna COVID-19 vaccine: Children ages 6 months–5 years

- Antibody levels measured 28 days after the second dose for participants without prior infection
- Antibody responses after two 25 μ g doses in children ages 6 months–5 years compared to two 100 μ g doses in individuals ages 18–25 years
 - Ratio for 6–23 months: **1.28** (1.12–1.47)
 - Ratio for 2–5 years: **1.01** (0.90–1.17)
- Immunogenicity population:
 - 6–23 months: **230 children**
 - 2–5 years: **264 children**

Safety data

Moderna COVID-19 vaccine: Children ages 6 months–5 years

- **No deaths** were reported in any trial participants
- Serious adverse events (SAE) **rare** overall
- No cases of myocarditis in any trial participants
- No cases of vaccine-associated anaphylaxis in any trial participants
- **Local** reactions occurring within 7 days were common
 - Pain at the injection site most common
- **Systemic** reactions within 7 days were common
 - Fatigue and headache most common in children ages 2–5 years
 - Irritability and sleepiness more common in children ages 6–23 months

Safety data

Moderna COVID-19 vaccine: Children ages 6 months–5 years

- **Fevers** were more common after vaccine than placebo, and more common after dose 2 than dose 1
- Most fevers were reported on day 1 and 2 after either dose and lasted for a median of 1 day
- Fevers after other routine vaccines given at this age can be ~30%
- One febrile seizure possibly related to vaccine noted (3 days after dose 1)

Fever post-dose 2	Vaccine	Placebo
Any fever	730/4532 (16.1%)	107/1483 (7.2%)
Grade 4 fever (104 ^{oF} or higher)	10/4532 (0.2%)	0/1483 (0%)

Safety data

Moderna COVID-19 vaccine: Children ages 6 months–5 years

- Imbalances were noted with some respiratory infections
 - Overall, events were **rare** (occurred in <1% of trial participants)
- No pattern for respiratory infections noted, and the clinical characteristics were typical and consistent with seasonal respiratory infections
 - Testing not performed systematically; testing for additional respiratory pathogens may have varied by results of COVID-19 testing
- Lymphadenopathy (axillary or groin) noted in 9% of vaccine recipients, compared to 2% of placebo recipients

Conclusions

Moderna COVID-19 vaccine: Children ages 6 months–5 years

- Efficacy seen after two doses of Moderna COVID-19 vaccine in children ages 6 months–5 years of age consistent with real-world vaccine effectiveness in all other ages during Omicron predominance
- Antibody levels after 2 doses in children ages 6 months–5 years produces similar antibody levels after 2 doses in individuals ages 18–24 years
- Reactogenicity post-vaccine consistent with other recommended vaccines in this age group

Pfizer-BioNTech COVID-19 vaccine

Children ages 6 months–4 years

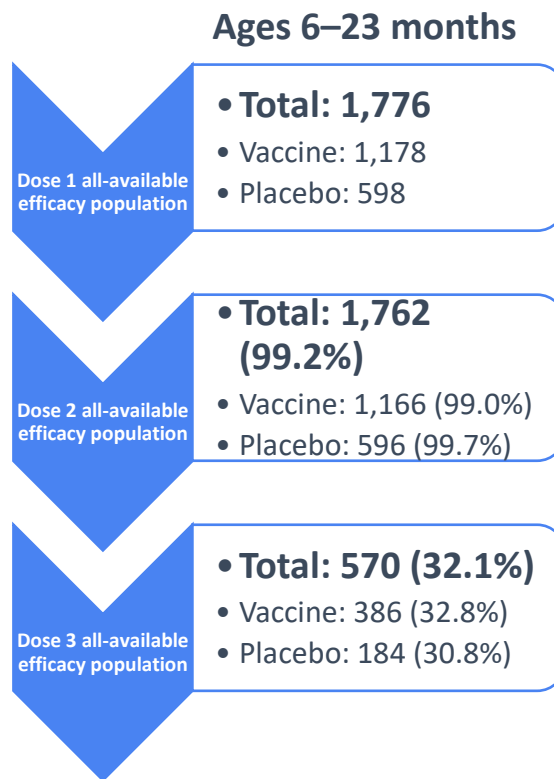
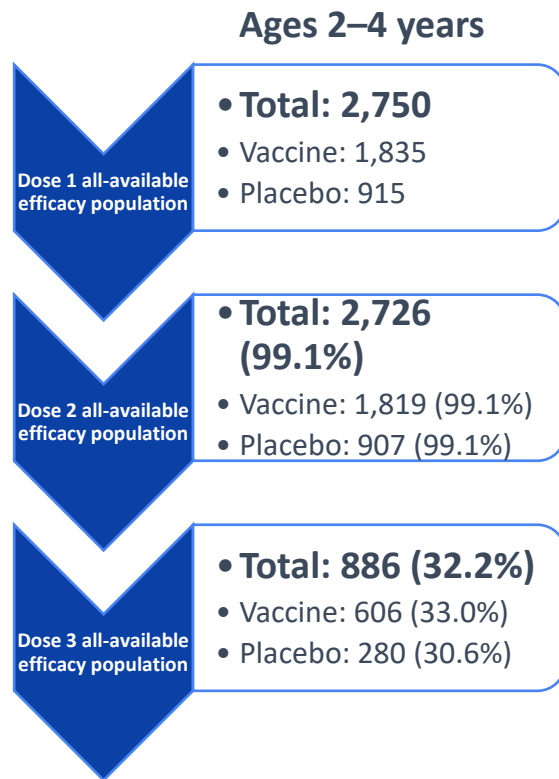


Clinical trial structure

Pfizer-BioNTech COVID-19 vaccine: Children ages 6 months–4 years

- Trial conducted from June 2021 through April 2022
- Children ages 6 months–4 years in the United States randomized **2:1** vaccine to saline placebo
 - Analyses performed separately for 6–23 months and 2–5 years
 - Results pooled for a combined estimate for 6 months–5 years
- Three doses, 3 μ g each: Dose 1 and dose 2 separated by **21 days**
Dose 2 and dose 3 separated by at least **8 weeks**
 - Interval between dose 2 and dose 3 in the trial longer than authorized interval:
 - ~**16 weeks** (range 8–32 weeks) for children ages 6–23 months
 - ~**11 weeks** (range 8–34 weeks) for children ages 2–4 years
- Median follow-up time post-dose 3: **1.3 months**

Number of children contributed *blinded* person-time to efficacy evaluation, by age group



32% of the overall eligible population contributed blinded person-time to the efficacy evaluation due to per-protocol unblinding after dose 2

Efficacy data

Pfizer-BioNTech COVID-19 vaccine: Children ages 6 months–4 years

- Efficacy endpoint^{1,2}: Subjects with or without evidence of prior infection
 - 6–23 months: **75.5%** (-370.1–99.6%)
 - 2–4 years: **82.3%** (-8.0–98.3%)
 - Overall 6 months–4 years: **80.3%** (13.9–96.7%)
- Lower confidence in the estimates, based on **3** COVID-19 cases in vaccine group and **7** COVID-19 cases in placebo group
- Post-authorization vaccine effectiveness (VE) for Pfizer-BioNTech COVID-19 vaccine in adolescents ages 12–15 years during Omicron:
 - VE against infection 2 months after dose 2 was 28.9% (24.5–33.1%)
 - VE against infection 2 months after dose 3 was 42.9% (34.5–50.2%)

¹**CDC definition:** At least 1 prespecified clinical symptom and a positive RT-PCR

²Efficacy estimates presented represent the manufacturer analysis. For GRADE, estimates based on relative risks will be presented

Immunogenicity data

Pfizer-BioNTech COVID-19 vaccine: Children ages 6 months–4 years

- Antibody levels measured 1 month post-dose 3 for participants without prior infection
- Antibody responses after three 3 μ g doses in children ages 6 months–4 years compared to two 30 μ g doses in individuals ages 16–25 years
 - Ratio for 6–23 months: **1.19** (1.00–1.43)
 - Ratio for 2–4 years: **1.30** (1.13–1.50)
 - Overall ratio for 6 months–5 years: **1.26** (1.13–1.40)
- Immunogenicity population:
 - 6–23 months: **82 children**
 - 2–5 years: **143 children**

Data after dose 2

Pfizer-BioNTech COVID-19 vaccine: Children ages 6 months–4 years

- For comparison, results after dose 2 are shown

	Dose 2 ¹ Efficacy ^{2,3}	Dose 2 Immunobridging ⁴
6–23 months	14.5% (-24.9–41.0%)	Non-inferiority criteria <u>met</u>
2–4 years	33.6% (9.1–51.3%)	Non-inferiority criteria <u>not met</u>

¹Seven days after dose 2 to before dose 3

²**CDC definition:** At least 1 prespecified clinical symptom and a positive RT-PCR

³Efficacy estimates presented represent the manufacturer analysis. For GRADE, estimates based on relative risks will be presented

⁴Antibody responses after two 3µg doses in children ages 6 months–4 years compared to two 30µg doses in individuals ages 16–25 years

Safety data

Pfizer-BioNTech COVID-19 vaccine: Children ages 6 months–4 years

- **No deaths** were reported in any trial participants
- Serious adverse events (SAE) **rare** overall
- No cases of myocarditis in any trial participants
- No cases of vaccine-associated anaphylaxis in any trial participants
- **Local** reactions occurring within 7 days were common
 - Pain or tenderness at the injection site most common
- **Systemic** reactions within 7 days were common
 - Fatigue most common in children ages 2–4 years
 - Irritability and drowsiness more common in children ages 6–23 months

*Investigator considered it possibly related; FDA considered the events potentially consistent with symptoms due to viral myositis

Safety data

Pfizer-BioNTech COVID-19 vaccine: Children ages 6 months–4 years

- **Fevers** were reported with similar frequency after both vaccine and placebo, and similar frequencies after doses 1, 2, and 3
- Most fevers were reported on day 1 and 2 after either dose and lasted for a median of 1 day

	Fever post-dose 2		Fever post-dose 3	
	Vaccine N=2926	Placebo N=1469	Vaccine N=917	Placebo N=432
Any fever	173 (5.9%)	82 (5.7%)	53 (5.8%)	21 (4.9%)
Grade 4 fever (104 ^{oF} or higher)	3 (0.1%)	0	1 (0.1%)	0

Conclusions

Pfizer-BioNTech COVID-19 vaccine: Children ages 6 months–4 years

- Antibody levels after 3 doses in children ages 6 months–4 years produces similar antibody levels after 2 doses in individuals ages 16–24 years
- Reactogenicity post-vaccine similar after each of the 3 vaccine doses, and similar to reactions seen in placebo recipients
- Efficacy estimates difficult to interpret given small numbers and limited follow-up time
 - Impact of **longer interval** in the trial between dose 2 and dose 3 on efficacy, reactogenicity or safety are unknown

Summary



Summary

- Since the beginning of the COVID-19 pandemic, among U.S. children ages 6 months – 4 years of age, there have been
 - Over **2 million cases**
 - Over **20,000 hospitalizations**
 - Over **200 deaths**
- COVID-19 can cause severe disease and death among children, including children without underlying medical conditions
- Future surges will continue to impact children, with unvaccinated children remaining at higher risk of severe outcomes

ACIP interpretation:

mRNA COVID-19 vaccines in young children

- mRNA COVID-19 vaccine clinical trials in young children both conducted during Omicron predominance, but different months and incidence levels
 - In addition to differences in number of participants in the efficacy analyses and differences in follow up time, the incidence levels impacted COVID-19 case accrual and certainty in efficacy estimates
- **Efficacy estimates** for these two mRNA vaccines **cannot be directly compared**
- Both vaccines met non-inferiority criteria for neutralizing antibody levels

ACIP interpretation:

mRNA COVID-19 vaccines in young children

- In other age groups during Omicron, mRNA COVID-19 vaccine post-authorization vaccine effectiveness was lower against infection, but **higher** protection against **severe disease**
- Clinical trials were not powered to detect efficacy against severe disease in young children, but similar patterns in this age group are expected to what is seen in everyone ages 5 years and older

Summary

- Current data are for a **2-dose** (Moderna) or **3-dose** (Pfizer-BioNTech) **primary series**
- Post-authorization effectiveness studies can help determine subsequent timing and need of **boosters**
 - Immunocompromised children may also need additional doses for optimal protection

ACIP Recommendation

A **two-dose** Moderna COVID-19 vaccine series (25 μ g) is recommended for children ages **6 months – 5 years**, under the EUA issued by FDA

Two doses of 25 μ g Moderna COVID-19 vaccine, 28-days apart

A **three-dose** Pfizer-BioNTech COVID-19 vaccine series (3 μ g each) is recommended for children ages **6 months – 4 years**, under the EUA issued by FDA

Three doses of 3 μ g Pfizer-BioNTech COVID-19 vaccine
21 days and at least 8 weeks apart

Self-knowledge Check: Current data for COVID-19 vaccines for young children are for a ___-dose (Pfizer-BioNTech) or ___-dose (Moderna) primary series:

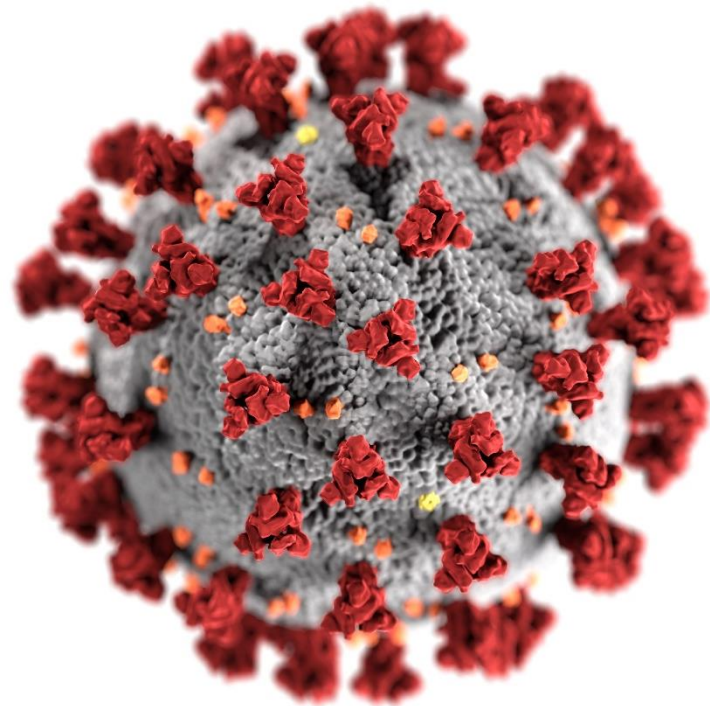
- A. 3, 3
- B. 3, 4
- C. 2, 2
- D. 3, 2
- E. 4, 3

Answer: Current data for COVID-19 vaccines for young children are for a ___-dose (Pfizer-BioNTech) or ___-dose (Moderna) primary series:

- A. 3, 3
- B. 3, 4
- C. 2, 2
- D. 3, 2**
- E. 4, 3

Rationale: A **3-dose** Pfizer-BioNTech COVID-19 vaccine series (3 μ g each) is recommended for children ages 6 months – 4 years. A **2-dose** Moderna COVID-19 vaccine series (25 μ g) is recommended for children ages 6 months – 5 years.

Interim Clinical Considerations Update for Pediatric COVID-19 Vaccines



Elisha Hall, PhD
Clinical Guidelines Lead



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COVID-19 Pediatric Vaccination Schedule



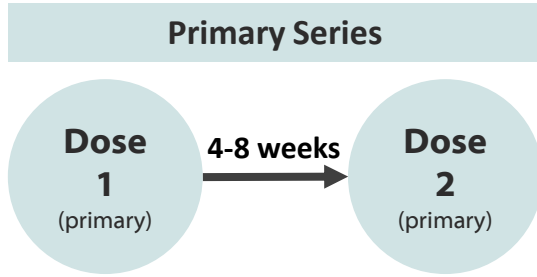
COVID-19 Vaccine Pediatric Age Groups

- Moderna COVID-19 Vaccine
 - Ages 6 months through 5 years
- Pfizer-BioNTech COVID-19 Vaccine
 - Ages 6 months through 4 years
- “Through” means “up to and including” and is denoted by an en dash (–).

Pediatric Schedule: Moderna COVID-19 Vaccine

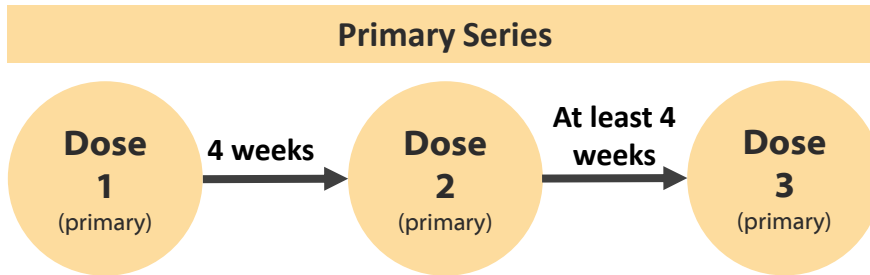
People who are **NOT** moderately or severely immunocompromised

Moderna
(6 months–
5 years)



People who **ARE** moderately or severely immunocompromised

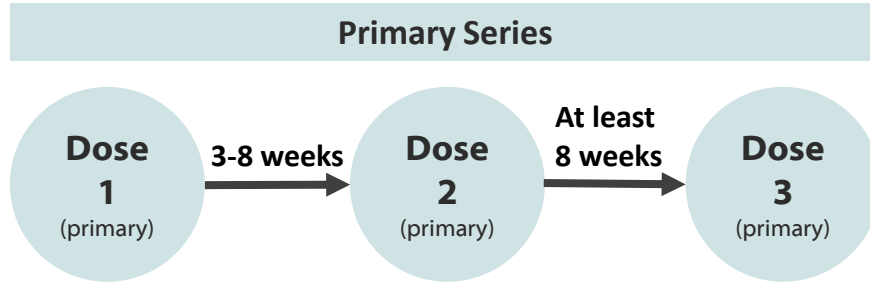
Moderna
(6 months–
5 years)



Pediatric Schedule: Pfizer-BioNTech COVID-19 Vaccine

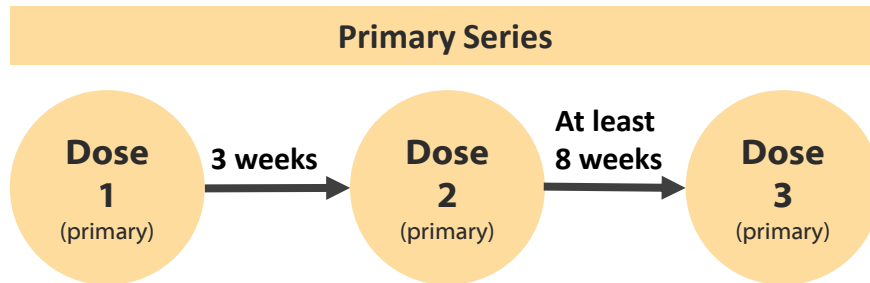
People who are **NOT** moderately or severely immunocompromised

**Pfizer-
BioNTech**
(6 months–
4 years)



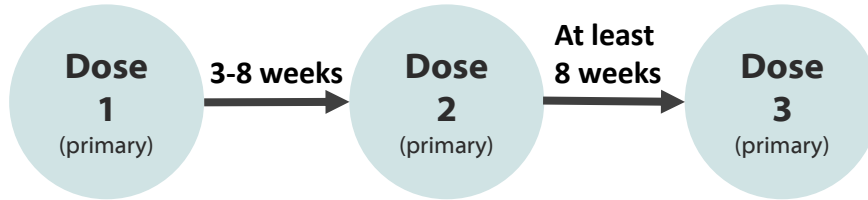
People who **ARE** moderately or severely immunocompromised

**Pfizer-
BioNTech**
(6 months–
4 years)

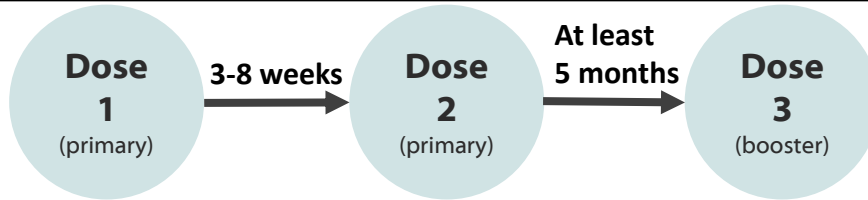


Pediatric Schedule: People Who Are NOT Moderately or Severely Immunocompromised

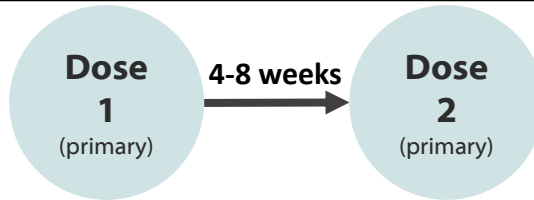
Pfizer-BioNTech
(6 months–
4 years)



Pfizer-BioNTech
(5–17 years)

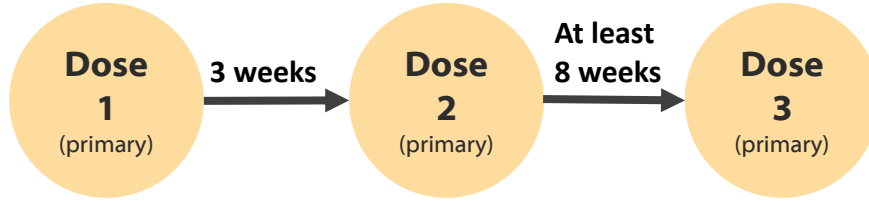


Moderna
(6 months–
5 years)

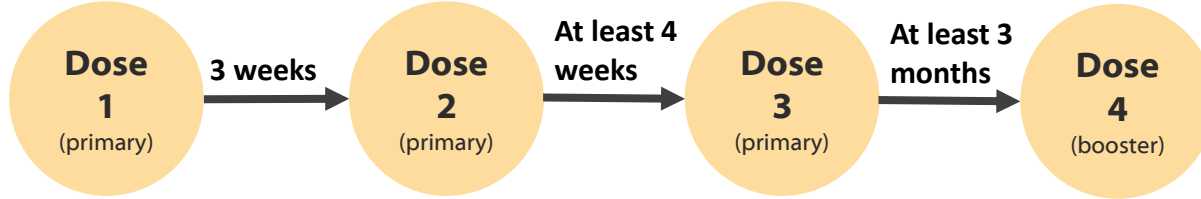


Pediatric Schedule: People Who ARE Moderately or Severely Immunocompromised

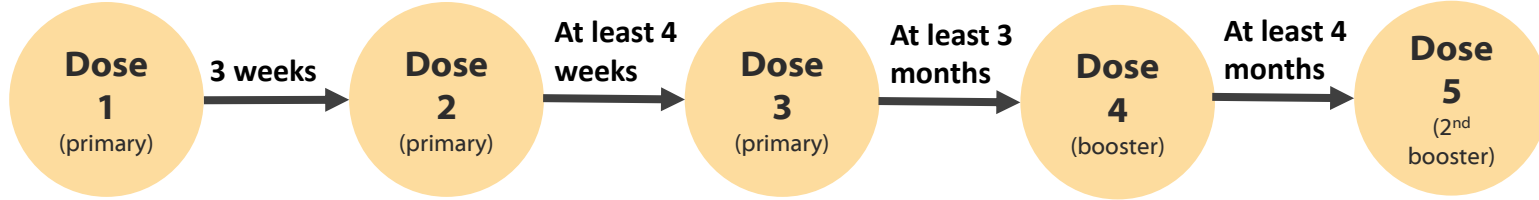
Pfizer-BioNTech
(6 months–
4 years)



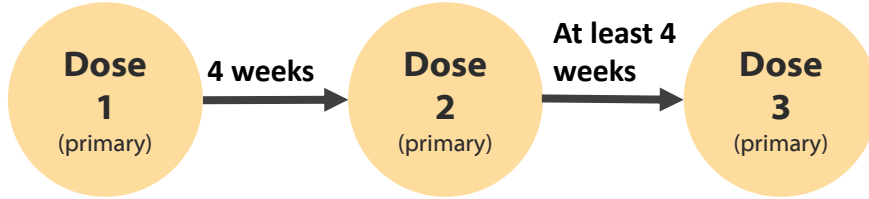
Pfizer-BioNTech
(5–11 years)



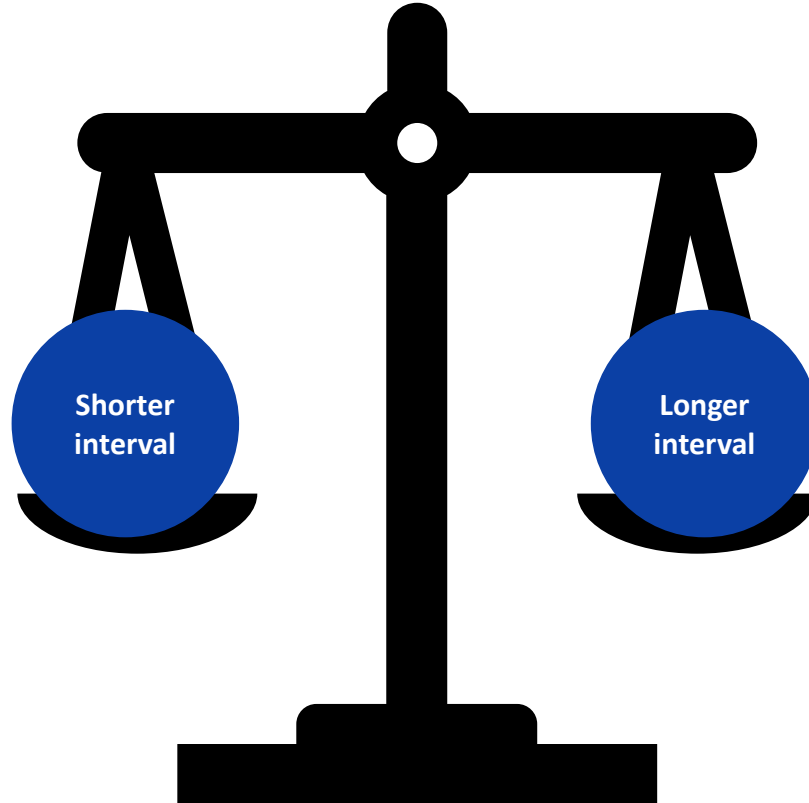
Pfizer-BioNTech
(12–17 years)



Moderna
(6 months–
5 years)

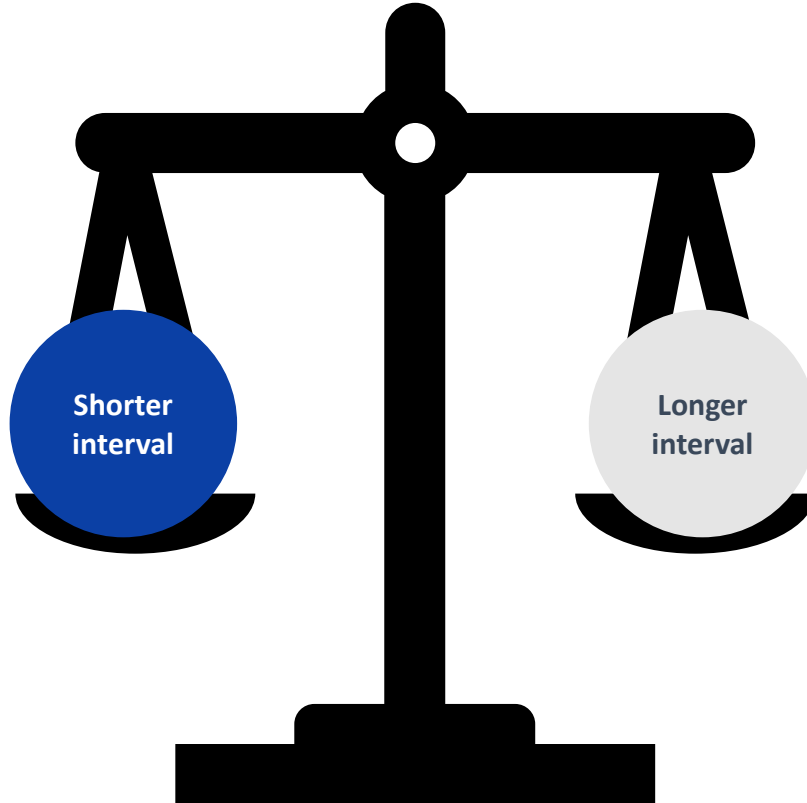


Considerations for Extended Interval Between Dose 1 & 2



Considerations for Extended Interval Between Dose 1 & 2

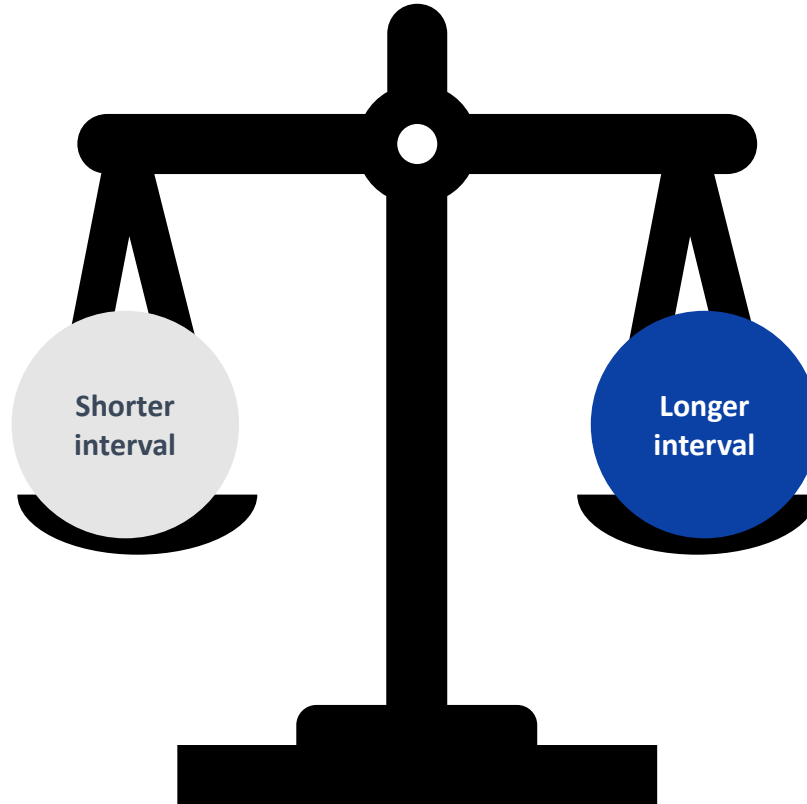
- Immunocompromised
- High risk for severe disease
- Household members with high risk for severe disease
- High COVID-19 community levels



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

Considerations for Extended Interval Between Dose 1 & 2

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



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

Products



Pfizer-BioNTech COVID-19 Vaccine Products



Product for ages
6 months–4
years



Product for ages
5–11 years



Product for ages
12 years and
older

	Product for ages 6 months–4 years	Product for ages 5–11 years	Product for ages 12 years and older
Authorized for ages	6 months–4 years	5–11 years	12 years and older
Vial cap color	Maroon	Orange	Gray
Dose (mRNA concentration)	3 mcg	10 mcg	30 mcg
Injection volume	0.2 mL	0.2 mL	0.3 mL
Dilution required	Yes—2.2 mL	Yes—1.3 mL	No
Doses per vial	10 (after dilution)	10 (after dilution)	6

Pfizer-BioNTech COVID-19 Vaccine Products



**Product for ages
6 months–4
years**



**Product for ages
5–11 years**



**Product for ages
12 years and
older**

	Product for ages 6 months–4 years	Product for ages 5–11 years	Product for ages 12 years and older
Authorized for ages	6 months–4 years	5–11 years	12 years and older
Vial cap color	Maroon	Orange	Gray
Dose (mRNA concentration)	3 mcg	10 mcg	30 mcg
Injection volume	0.2 mL	0.2 mL	0.3 mL
Dilution required	Yes—2.2 mL	Yes—1.3 mL	No
Doses per vial	10 (after dilution)	10 (after dilution)	6

Pfizer-BioNTech COVID-19 Vaccine Products



Product for ages
6 months–4
years



Product for ages
5–11 years

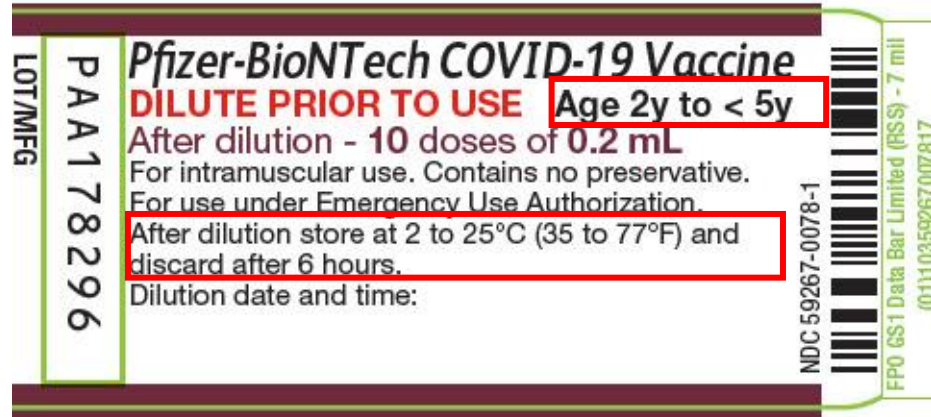


Product for ages
12 years and
older

	Product for ages 6 months–4 years	Product for ages 5–11 years	Product for ages 12 years and older
Authorized for ages	6 months–4 years	5–11 years	12 years and older
Vial cap color	Maroon	Orange	Gray
Dose (mRNA concentration)	3 mcg	10 mcg	30 mcg
Injection volume	0.2 mL	0.2 mL	0.3 mL
Dilution required	Yes—2.2 mL	Yes—1.3 mL	No
Doses per vial	10 (after dilution)	10 (after dilution)	6

Pfizer-BioNTech COVID-19 Vaccine Product for Ages 6 Months–4 Years

Vaccine may be discarded **12 hours** after dilution rather than **6 hours**.



Vial label states Age 2y to <5y but can be used in children ages 6 months–4 years.

Moderna COVID-19 Vaccine Products



**Product for ages
6 months–5 years**



**Product for ages 12
years and older**

Authorized for ages	6 months–5 years	12 years and older
Vial cap color	Dark blue	Red
Label border color	Magenta	Light blue
Dose (mRNA concentration)	25 mcg	100 mcg
Injection volume	0.25 mL	0.5 mL
Dilution required	No	No
Doses per vial	10	Maximum of 11

Moderna COVID-19 Vaccine Products



**Product for ages
6 months–5 years**



**Product for ages 12
years and older**

Authorized for ages

6 months–5 years

12 years and older

Vial cap color

Dark blue

Red

Label border color

Magenta

Light blue

Dose (mRNA concentration)

25 mcg

100 mcg

Injection volume

0.25 mL

0.5 mL

Dilution required

No

No

Doses per vial

10

Maximum of 11

Moderna COVID-19 Vaccine Products



Product for ages
6 months–5 years



Product for ages 12
years and older

Authorized for ages	6 months–5 years	12 years and older
Vial cap color	Dark blue	Red
Label border color	Magenta	Light blue
Dose (mRNA concentration)	25 mcg	100 mcg
Injection volume	0.25 mL	0.5 mL
Dilution required	No	No
Doses per vial	10	Maximum of 11

Moderna COVID-19 Vaccine Product for Ages 6 Months Through 5 Years



703819



STORE FROZEN between
-50° to -15°C (-58° to 5°F).
Protect from light. No preservative.
After first use, hold at 2° to 25°C
(36° to 77°F). Discard after 12 hours.

Record date/time of first use: _____

Scan here for FDA-authorized Fact Sheet
for dosage and administration,
and product expiration dates, or visit
www.modernatx.com/covid19vaccine-eua/

Mfd. for: Moderna US, Inc.,
Cambridge, MA 02139

Moderna COVID-19 Vaccine

Suspension for
Intramuscular Injection
For use under
Emergency Use Authorization

Age 6mo through 5y



Vial contains
10 doses of 0.25 mL

NDC 80777-279-05

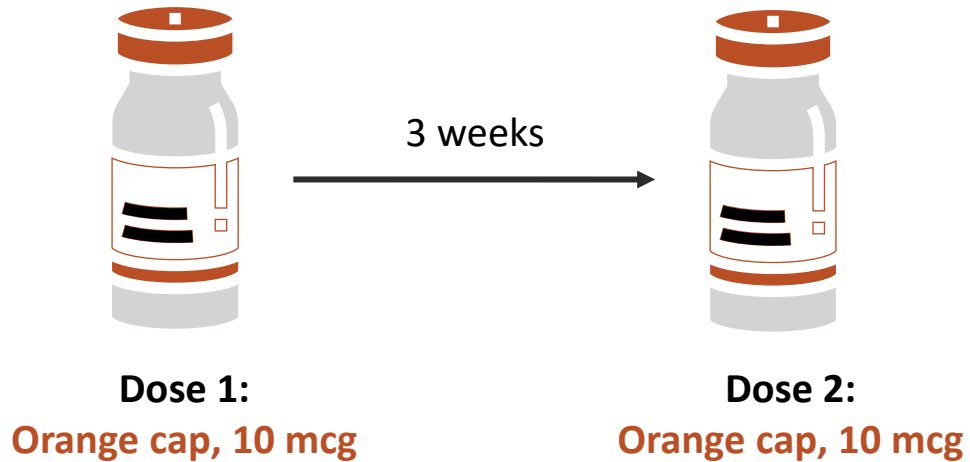
LOT

Vaccine Dosage

- Children should receive the age-appropriate vaccine product and follow the schedule based on their age **on the day of vaccination**, regardless of their size or weight.
- If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine dosage for the older age group for all subsequent doses.

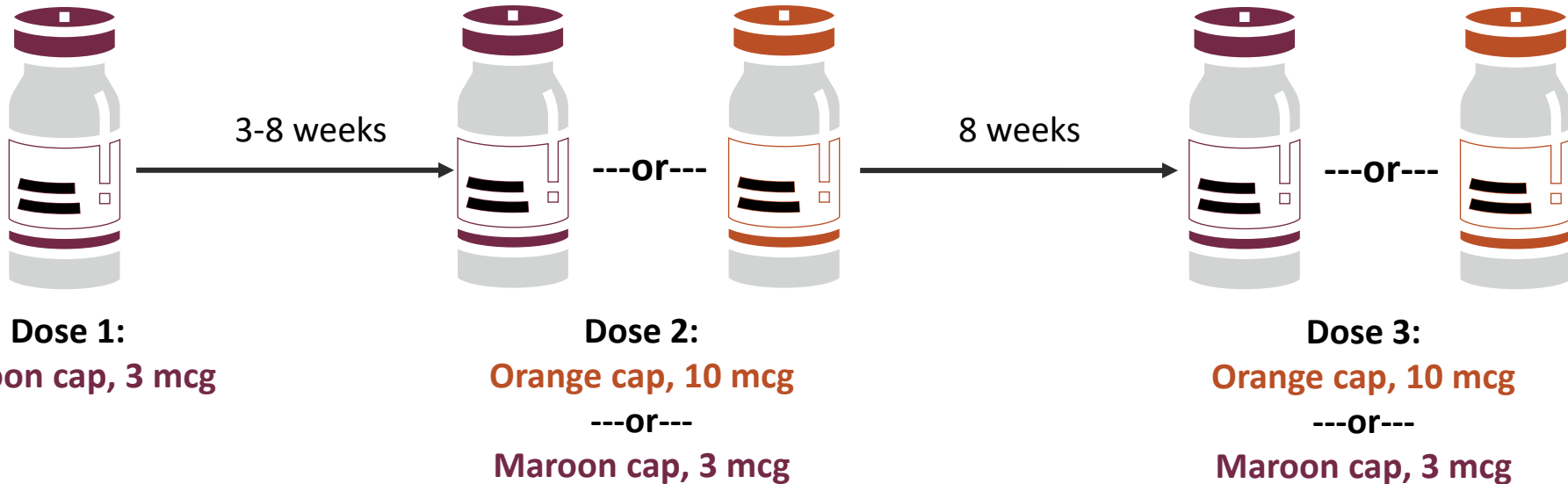
Children Who Turn From Age 4 to 5 years Between Any Dose in the Primary Series May Receive...

- **Scenario 1:** A 2-dose primary series using the product for people ages 5–11 years (orange cap)



Children Who Turn From Age 4 to 5 years Between Any Dose in the Primary Series May Receive...

Scenario 2: A 3-dose primary series initiated with the product for ages 6 months–4 years. Dose 2 and 3 may be with: the product for ages 6 months–4 years or the product for ages 5–11 years.



Interchangeability

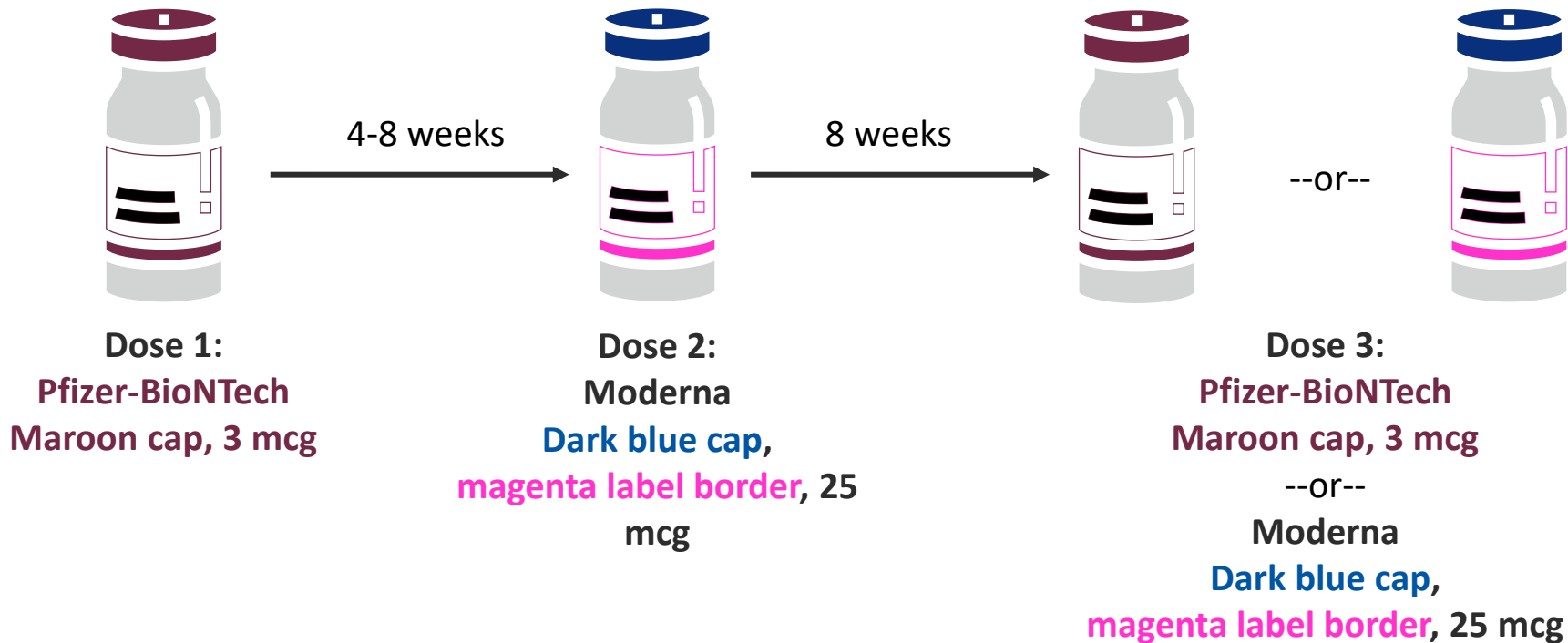
- COVID-19 vaccines are not interchangeable.
- The same mRNA vaccine product should be used for all doses of the primary series.
- In exceptional situations in which the mRNA vaccine product administered for a previous dose(s) of the primary series cannot be determined or is not available, either age-appropriate available mRNA COVID-19 vaccine product may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 primary vaccination series.

Mixed Series For Children Ages 6 months–4 Years

- Children ages 6 months–4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should receive a third dose of either mRNA vaccine 8 weeks after the second dose to complete the 3-dose primary series.

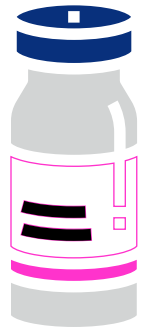
Mixed Series For Children Ages 6 months–4 Years

■ Scenario 1:

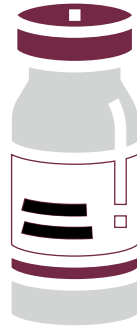


Mixed Series For Children Ages 6 months–4 Years

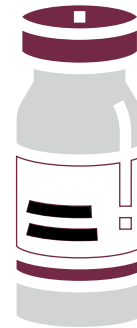
■ Scenario 2:



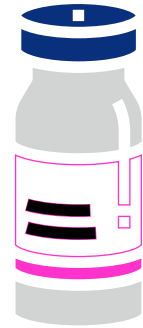
4-8 weeks



8 weeks



--or--



Dose 1:

Moderna

Dark blue cap,

magenta label border,

25 mcg

Dose 2:

Pfizer-BioNTech

Maroon cap, 3

mcg

Dose 3:

Pfizer-BioNTech

Maroon cap, 3 mcg

--or--

Moderna

Dark blue cap,

magenta label border, 25 mcg

Vaccine Administration



Administration

Age	Needle gauge	Needle length	Injection Site
6 months through 2 years	22- to 25-gauge needle	1-inch (25mm) needle*	Vastus lateralis in the anterolateral thigh
3 years and older	22- to 25-gauge needle	5/8- to 1-inch (25mm) needle†	Deltoid muscle

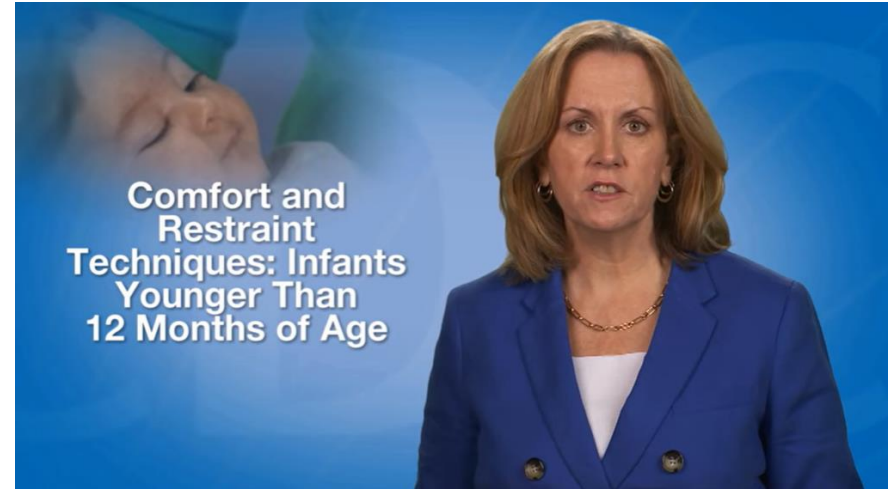
*Use a 5/8- to 1-inch (16 to 5 mm) if using the deltoid muscle. A 5/8-inch needle may be used only if the skin is stretched tightly and the subcutaneous tissue is not bunched.

† Use a 1- to 1.25-inch (25–32 mm) needle if administering vaccine in the vastus lateralis muscle in the anterolateral thigh

- Intramuscular (IM) Injection Infants 11 months of age and younger:
<https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-Infants-508.pdf>
- Intramuscular (IM) Injection Children 1 through 2 years of age:
<https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-1-2-Years-508.pdf>
- Intramuscular (IM) Injection Children 3 through 6 years of age:
<https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-3-6-Years.pdf>

Comfort and Restraint Technique

- Determine the best position for the patient based on comfort, age, activity level, administration site, and safety.
- Instruct the parent on how to help the infant or child stay still so you can administer the vaccine(s) safely.
- Training video:
<https://www.youtube.com/watch?v=r1dGpTCgerE>



Coadministration

- COVID-19 vaccines may be administered without regard to timing of other vaccines.
- Extensive experience with non-COVID 19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.
- Data assessing the outcomes of simultaneous administration of COVID-19 vaccines with other vaccines are limited currently.

Coadministration

- In accordance with [general best practices](#), routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the healthcare visit.
- When deciding whether to co-administer another vaccine(s) with COVID-19 vaccine, providers and parents/guardians may consider:
 - Whether a child is behind or at risk of becoming behind
 - Likelihood of the child returning for another vaccination
 - Their risk of vaccine-preventable diseases
 - The reactogenicity profile of the vaccines

Coadministration

- Best practices for multiple injections include:
 - Label each syringe
 - Administer each injection in a different injection site; separate injection sites by 1 inch or more, if possible
 - Administer the COVID-19 vaccine and vaccines that may be more likely to cause a local reaction in different limbs

Preventing Vaccine Administration Errors

- Clinical guidance for errors:

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-c>

- Handout:

<https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf>

YOU CALL THE SHOTS

Vaccine Administration: Preventing Vaccine Administration Errors

A vaccine administration error is any preventable event that may cause or lead to inappropriate medication use or patient harm.¹ Vaccine administration errors can have many consequences, including inadequate immunological protection, possible injury to the patient, cost, inconvenience, and reduced confidence in the health care delivery system. Take preventive actions to avoid vaccine administration errors and establish an environment that values reporting and investigating errors as part of risk management and quality improvement.

Vaccine administration errors may be due to causes such as:

- Insufficient staff training
- Distraction
- Changes in recommendations
- Lack of standardized protocols
- Patient misidentification
- Using nonstandard or error-prone abbreviations
- Easily misidentified products (e.g. DTaP, DT, Tdap, Td)

If an error occurs, determine how it occurred and take the appropriate actions to put strategies in place to prevent it from happening in the future. The following table outlines common vaccine administration errors and possible preventive actions you can take to avoid errors.

Error(s)	Possible Preventive Actions
Wrong vaccine, route, site, or dosage (amount); or improperly prepared.	<ul style="list-style-type: none"> Circle important information on the packaging to emphasize the difference between the vaccines. Include the brand name with the vaccine abbreviation whenever possible (e.g., PCV13 [Prevnar13]) in orders, medical screens, etc. Separate vaccines into bins or other containers according to type and formulation. Use color-coded identification labels on vaccine storage containers. Store look-alike vaccines in different areas of the storage unit (e.g., pediatric and adult formulations of the same vaccine on different shelves in the unit). Do not list vaccines with look-alike names sequentially on computer screens, order forms, or medical records, if possible. Consider using "name alert" or "look-alike" stickers on packaging and areas where these vaccines are stored. Consider purchasing products with look-alike packaging from different manufacturers, if possible. Establish "Do NOT Disturb" or no-interruption areas or times when vaccines are being prepared or administered. Prepare vaccine for one patient at a time. Once prepared, label the syringe with vaccine name. Do not administer vaccines prepared by someone else. Triple-check work before administering a vaccine and ask another staff member to check. Keep reference materials on recommended sites, routes, and needle lengths for each vaccine used in your facility in the medication preparation area. Clearly identify diluents if the manufacturer's label could mislead staff into believing the diluent is the vaccine itself. Integrate vaccine administration training into orientation and other appropriate education requirements. Provide education when new products are added to inventory or recommendations are updated. Use standing orders, if appropriate.

1. National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors>
01/05/2021 CS 52035A

VAERS website at <https://vaers.hhs.gov/report-event.html>

- At this time, COVID-19 vaccination has additional VAERS reporting requirements, including required reporting of vaccine administration errors. Please see <https://vaers.hhs.gov/faq.html> for more information.

01/05/2021 CS 52035A

Vaccine Administration Errors

Preventive Actions

- Verify patient's identity before administering vaccines.
- Emphasize the importance of avoiding unnecessary distractions or interruptions when staff is administering vaccines.
- Administer vaccines to one patient at a time. If more than one patient needs vaccines during a clinical encounter (e.g., parent with two children), assign different providers to each child. Alternatively, bring only one patient's vaccines into the treatment area at a time, one child and parent name.
- Use color-coded abbreviations to document vaccine administration (e.g., use intranasal route instead of intranasal route—not IN, which is easily confused with IM).
- Use consistent abbreviations.
- Minimize the appearance of look-alike names or generic abbreviations on computer screens, if possible.
- Provide storage and handling training based on manufacturer guidance and/or recommendations.
- Place vaccines with the earliest expiration dates are in the front of the storage unit. Use expiration dates on vaccines/diluents from storage units and areas where viable vaccines are stored.
- Store vaccines exposed to improper temperatures and contact the state or local immunization program or the vaccine manufacturer.
- Use appropriate diluents, if appropriate.
- Use computer systems to obtain a complete vaccination history using the immunization information system (IIS) medical records, and personal vaccination records.
- Provide vaccine administration training, including timing and spacing of vaccines, into orientation and ongoing education requirements.
- Verify that all newborns are vaccinated, especially infants, schedule immunization visits after the birth date.
- Use immunization schedules for children and adults that staff can quickly reference in clinical situations may be prescribed and administered.
- Establish a workspace for timing and spacing in your medication preparation area. CDC has vaccine administration guides for DTaP, Tdap, Hib, PCV13, and polio vaccines to assist health care personnel in catch-up schedule for children.
- Use standing orders and patients on how important it is for them to maintain immunization records.
- Use the VAERS website to report vaccine administration errors to VAERS. To file an electronic report, please see the VAERS website at <https://vaers.hhs.gov/report-event.html>.

H11-2, Medication Errors, 2nd ed., by Cohen, Michael, Washington D.C. American Pharmacists Association; 2007.

Adverse Events and Patient Counseling



Patient and Parent/Guardian Counseling: Side Effects

- Children may experience fewer side effects than adolescents or young adults.
- Local side effects
 - Pain, swelling, and redness at the injection site,
 - Axillary or inguinal lymphadenopathy
- Systemic side effects
 - Fever, fatigue, headache, chills, myalgia, arthralgia
 - Irritability, crying, sleepiness, loss of appetite in infants and younger children

Febrile Seizures

- Febrile seizures were rare in COVID-19 vaccine clinical trials for young children.
 - The impact of coadministration with COVID-19 vaccines on risk of febrile seizures has not been specifically studied.
- Febrile seizures are not uncommon generally and can occur in infants and young children with any condition that causes a fever, including COVID-19.
 - Nearly all children who have a febrile seizure recover quickly and do not have any permanent neurological damage.
- CDC will closely monitor for febrile seizures following COVID-19 vaccination in young children.

Resources



Interim Clinical Considerations

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html>
- FAQs for the Interim Clinical Considerations: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html>
- At-A-Glance COVID-19 Vaccination Schedule: <https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vacc-schedule-at-a-glance-508.pdf>

The image shows a screenshot of the CDC website. The top left section is titled 'Vaccines & Immunizations' and contains a sidebar with links to 'COVID-19 Vaccination', 'Product Info by U.S. Vaccine', 'Interim Clinical Considerations', 'Use of COVID-19 Vaccines in the US', 'Aids for the Interim Clinical Considerations', 'Managing Anaphylaxis', 'Meningitis and Pericarditis Considerations', 'Lab Tests After Severe Allergic Reactions', 'Clinical Care', 'Provider Requirements and Support', 'Training and Education', 'Vaccine Recipients Education', 'Health Departments', 'Planning & Partnerships', and 'Vaccine Effectiveness Research'. The main content area is titled 'Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States'. It includes a 'Summary of recent changes (last updated May 20, 2022):' with bullet points: 'New guidance for use of a Pfizer-BioNTech COVID-19 Vaccine booster dose in children ages 5-11 years', 'Updated guidance that the following people should receive a second COVID-19 booster dose: People ages 12 years and older who are moderately or severely immunocompromised; People ages 50 years and older', 'Updated guidance for people who are moderately or severely immunocompromised and are treated with B-cell-depleting therapies', 'Clarification of COVID-19 vaccination guidance for multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A)', and 'Updated guidance for primary series vaccination after SARS-CoV-2 infection'. Below this is a 'Reference Materials' section with links to 'Summary Document for Interim Clinical Considerations', 'Interim COVID-19 Immunization Schedule', 'At-A-Glance COVID-19 Vaccination Schedule (NEW 5/24/2022)', 'Administration Error Revaccination Guidance', and 'Administration Error Revaccination Guidance - Poster'. There is also a 'Get Email Updates' section with a 'Get Email Updates' button. The right side of the screenshot shows the 'Vaccination Schedules' section, which includes a 'Vaccination Schedule for Most People' and 'Intervals of COVID-19 vaccine doses'. The schedule for most people shows three rows of doses: 1) Dose 1 (primary) in 3-8 weeks, Dose 2 (booster) in at least 5 months, Dose 3 (2nd mRNA booster) in at least 4 months, and Dose 4 (2nd mRNA booster) in at least 4 months. 2) Dose 1 (primary) in 4-8 weeks, Dose 2 (booster) in at least 5 months, Dose 3 (booster) in at least 4 months, and Dose 4 (2nd mRNA booster) in at least 4 months. 3) Dose 1 (primary) in at least 2 months, Dose 2 (booster) in at least 4 months, and Dose 3 (2nd mRNA booster) in at least 4 months. Text boxes specify that people ages 50 years and older should get a 2nd booster, and people ages 18 years and older who received 2 Janssen doses may get a 2nd booster. The bottom right corner of the screenshot shows the CDC logo and the URL 'cdc.gov/coronavirus'.

Clinical Resources

- US COVID-19 Vaccine Product Information:
<https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>

The screenshot displays the CDC's 'Vaccines & Immunizations' website for COVID-19. The page title is 'U.S. COVID-19 Vaccine Product Information'. A navigation menu on the left includes 'Product Info by U.S. Vaccine' (expanded to show Pfizer-BioNTech Vaccines, Moderna Vaccine, Janssen/J&J Vaccine, EUA, EUI, and FAQs for Healthcare Professionals), 'Interim Clinical Considerations', 'Clinical Care', 'Provider Requirements and Support', and 'Training and Education'. The main content area features a 'Español' link and a text box stating: 'Find a suite of information and materials that are needed for each specific COVID-19 vaccine that cover administration, storage and handling, safety, and reporting.' Below this are three tabs for 'Pfizer-BioNTech', 'Moderna', and 'Janssen/J&J'. The 'Pfizer-BioNTech' tab is active, showing 'Interim COVID-19 Immunization Schedule for Ages 5+' with a sub-heading 'Find guidance for COVID-19 vaccination schedules based on age and medical condition.' The 'Janssen/J&J' tab is active, showing 'Prevaccination Screening Form' with a sub-heading 'Download a prevaccination checklist in multiple languages.' and a list of language options: Arabic, Dari, English, French (Canada), Haitian Creole, Korean, Pashto, Portuguese (Portugal), Simplified Chinese, Spanish, Ukrainian, and Vietnamese.

Resources for Vaccine Recipient Education

- Recipient Education:
<https://www.cdc.gov/vaccines/covid-19/hcp/index.html>
- COVID-19 Vaccination for Children:
<https://www.cdc.gov/vaccines/covid-19/planning/children.html>

COVID-19 Vaccines for Children and Teens
What Parents and Caregivers Need to Know

Everyone ages 5 years and older should get vaccinated against COVID-19

If infected with COVID-19, children and teens can:

- Get really sick
- Have both short- and long-term health problems
- Spread COVID-19 to loved ones and people at school and in the community

There is no way to tell in advance how children or teens will be affected by COVID-19. Although uncommon, even healthy children can get really sick from COVID-19. Children and teens can also experience ongoing health problems after getting COVID-19 that can include physical and mental health complications that can affect their quality of life.

Getting children vaccinated can help keep them from getting really sick if they do get COVID-19. Vaccination can also help keep children in school or daycare and safely participating in group activities.

Help protect children and teens by getting them vaccinated against COVID-19.

COVID-19 vaccines are safe for children and teens

The benefits of COVID-19 vaccination outweigh the known and potential risks.

COVID-19 vaccines are monitored under the most intense safety monitoring in U.S. history. Before recommending COVID-19 vaccination for children, scientists conducted clinical trials with thousands of children to make sure vaccination was safe and effective. The safety of COVID-19 vaccines continues to be monitored, including the low risk of myocarditis and pericarditis in children and teens. Serious reactions after COVID-19 vaccination are rare and are most frequently reported the day after vaccination.

Children cannot get COVID-19 from getting vaccinated and COVID-19 vaccines do not alter DNA in any way. There is also no evidence that COVID-19 vaccination causes any problems with fertility or becoming pregnant in the future.

Through ongoing safety monitoring, COVID-19 vaccination continues to be found safe for children and teens.

Children and teens who have already had COVID-19 should still get vaccinated

Emerging evidence indicates that people can get added protection by getting vaccinated after having been infected with the virus that causes COVID-19. So, even if a child has had COVID-19, they should still get vaccinated.

Get started with v-safe

After getting your child vaccinated, enroll them in the v-safe After Vaccination Health Checker. v-safe provides personalized and confidential health check-ins after COVID-19 vaccination.

www.cdc.gov/covid-19/children-teens.html

www.cdc.gov/covid-19/children-teens.html

Self-Knowledge Check

What is the interval between the second and third primary doses for children ages 6 months–4 years that receive Pfizer-BioNTech COVID-19 Vaccine?

- a) At least 4 weeks
- b) At least 8 weeks
- c) At least 4 months
- d) At least 5 months

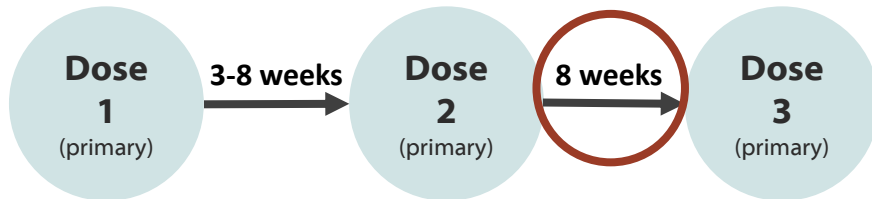


Self-Knowledge Check: Answer

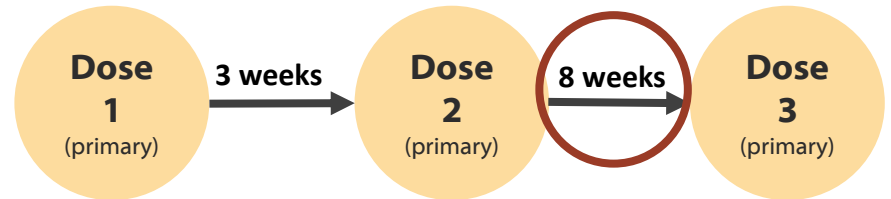
What is the interval between the second and third primary doses for children ages 6 months–4 years that receive Pfizer-BioNTech COVID-19 Vaccine?

- a) At least 4 weeks
- b) At least 8 weeks**
- c) At least 4 months
- d) At least 5 months

Schedule: People who are NOT Immunocompromised



Schedule: People who ARE Immunocompromised

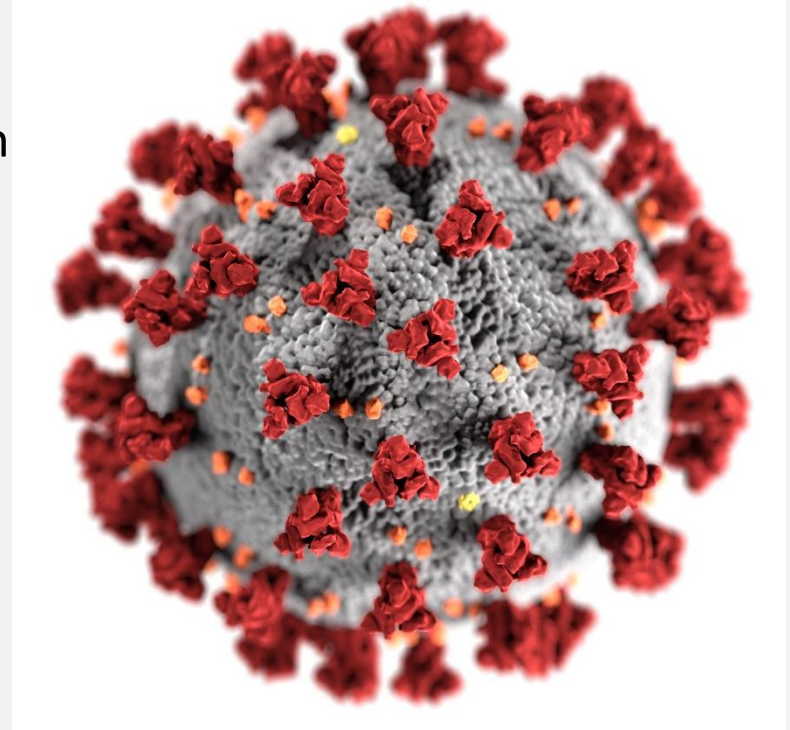


Pediatric COVID-19 Vaccine Planning for Children 6 Months–4 Years

Kevin Chatham-Stephens, MD, MPH, FAAP
Pediatric Vaccine Planning and Implementation
Lead

CDC COCA Call

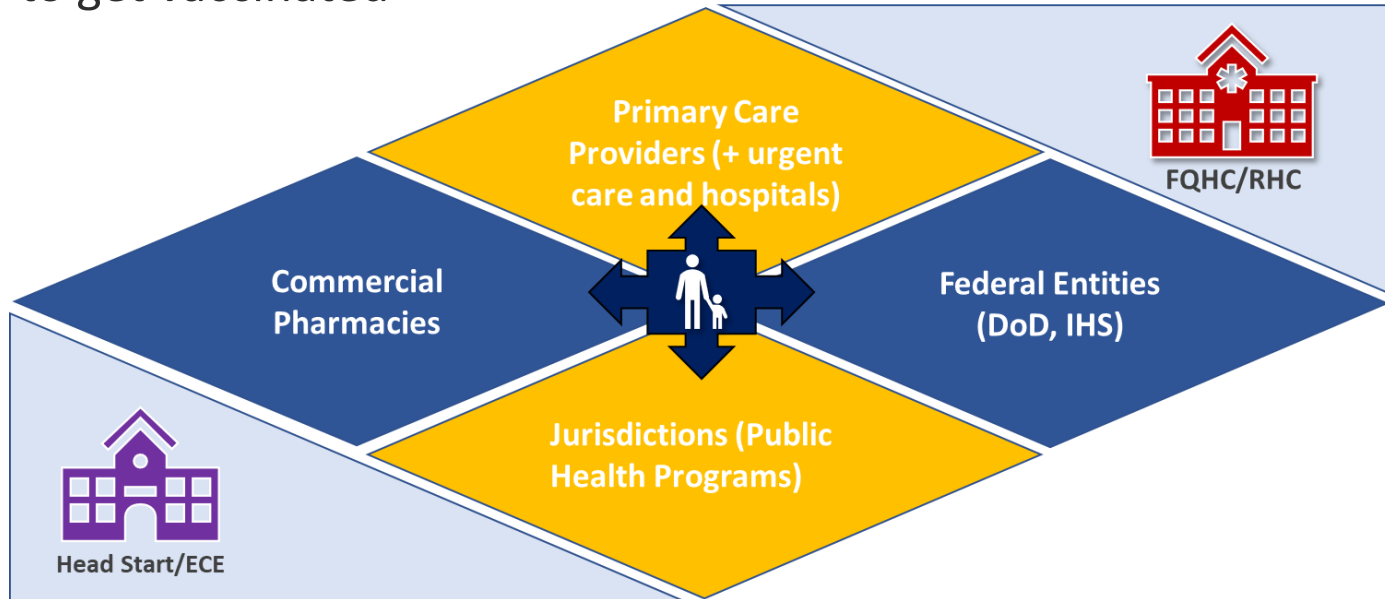
June 22, 2022



cdc.gov/coronavirus

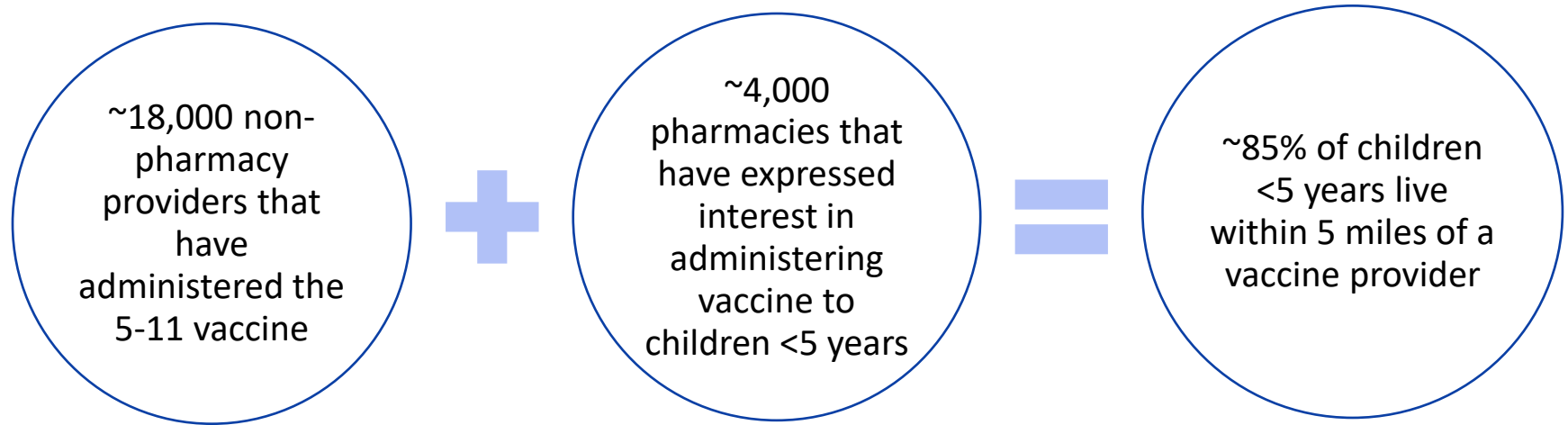
Approach to Reaching All Children Aged 6 Months–4 Years

- Goal: Ensure all eligible children <5 years old (~20 million) have access and ability to get vaccinated*



*ECE: Early care and education, DoD: Department of Defense, IHS: Indian Health Service, FQHC: Federally Qualified Health Center, RHC: Rural Health Clinic

Possible Network of Vaccine Providers for Children Aged 6 Months–4 Years



Vaccination by Regular Health Care Provider in the Medical Home

- Doctors' offices are common locations for vaccination
 - During the 2020-2021 flu season*:
 - ~80% of children 6 months–4 years old were vaccinated in a doctor's office
 - ~4% of children 2–4 years old and <1% of children <2 years old were vaccinated in a pharmacy
- Well-patient visits are an opportunity for clinicians to provide recommended vaccines and:
 - [Conduct recommended screenings](#) (such as development, autism, vision, iron deficiency, lead poisoning)
 - Provide counseling on nutrition, injury prevention, and chronic disease management



*National Immunization Survey-Flu (NIS-Flu), 2020-21 Influenza Season

COVID-19 Vaccine Practices and Intention to Vaccinate Children Aged <5 Years Among Vaccines for Children (VFC) Providers*

	All providers N=2,246** n (%)	Urban providers N=1,551 n (%)	Rural providers N=678 n (%)
Have administered COVID-19 vaccine to children aged 5–17 years	1,915 (85%)	1,338 (86%)	562 (83%)
Intend to offer COVID-19 vaccine to children aged <5 years who are current patients	1,641 (73%)	1,175 (76%)	454 (67%)
Intend to offer COVID-19 vaccine to children aged <5 years who are not current patients	1,165 (52%)	760 (49%)	395 (58%)

*Unpublished CDC data from March 2022; 15,000 of approximately 38,000 VFC provider practices randomly selected and invited to complete an online survey during February 28–March 11, 2022 (response rate = 19%)

**Limited to practices enrolled in the COVID-19 Vaccination Program. Urban/rural status could not be determined for some practices.



How CDC is Supporting Health Departments, Clinicians, and Other Partners

- Operational Planning Guide
 - <https://www.cdc.gov/vaccines/covid-19/downloads/Pediatric-Planning-Guide.pdf>
- Dear Colleague letter to VFC providers
- Vaccine confidence bootcamps (such as with childcare partners)
- Jurisdiction-specific maps of likely vaccine providers for children aged <5 years
- Resources to promote the COVID-19 vaccine for children and teens
 - <https://www.cdc.gov/vaccines/covid-19/planning/children/resources-promote.html>



Communication Resources for Vaccine Providers & Partners

- Website on vaccinating children with disabilities
- Updated quick conversation guide for talking with families
- Medscape commentary on routine pediatric and COVID-19 vaccination
- Customizable materials that align with key messages
- Updated information for schools to include content for childcare partners

Vaccinating Children with Disabilities Against COVID-19

Information for Vaccine Providers and Partners Planning Vaccination
<https://www.cdc.gov/vaccines/covid-19/planning/children/disabilities.html>

Quick Conversation Guide on *Pediatric COVID-19 Vaccination*

Now that COVID-19 vaccination is available for everyone ages 5 years and older, parents may have questions for you. Hearing your answers to their questions can help parents feel more confident vaccinating their children and teens.

<https://www.cdc.gov/vaccines/covid-19/downloads/talking-to-parents.pdf>



Communicating with Parents and Caregivers

- Redesigned websites
 - [COVID-19 Vaccines for Children and Teens](#)
 - [Frequently Asked Questions about COVID-19 Vaccination in Children](#)
 - [6 Things to Know About COVID-19 Vaccination for Children and Teens](#)
 - *short videos in development*
- New website content for [COVID-19 Vaccination for Children with Disabilities](#)
- Culturally and linguistically appropriate materials including [printable fact sheets](#)
 - Available in Amharic, Arabic, Chinese, English, French, Korean, Portuguese, Spanish, Vietnamese

About Vaccination for Children and Teens

CDC recommends COVID-19 vaccines, including boosters, for everyone ages 5 years and older. Use [CDC's COVID-19 booster tool](#) to learn if and when your child or teen can get boosters to stay up to date with their COVID-19 vaccines.

[Vaccines for Children and Teens](#)

[Why Children and Teens Should Get Vaccinated](#)

[Vaccine Safety in Children and Teens](#)



Requesting accommodations at COVID-19 vaccination sites

When making an appointment or arriving for vaccination, parents and caregivers can let staff and/or volunteers know your child might need some accommodations.

[COVID-19 Vaccine Disability Information and Access Line \(DIAL\)](#)

Call 888-677-1199 Monday-Friday from 9 a.m. to 8 p.m. (EST) or email DIAL@usaginganddisability.org to help:

- Find local vaccination locations
- Make appointments
- Connect to local services such as accessible transportation

Home visits: If a child under your care is unable to leave the home, contact your [state](#), [territorial](#), [local](#) [health department](#) to request an in-home vaccination.



Children with service animals are allowed by law to have them accompany them at COVID-19 vaccination sites.

Additional resources: www.cdc.gov/vaccines/covid-19/planning/children/resources-promote.html



Vaccines.gov Planning

- Vaccines.gov enables the **public** to identify nearby providers with vaccine in stock, and enables **providers** to report COVID-19 vaccine inventory
- For the <5-year rollout, the minimum age (months and years) of vaccination at the location will be displayed in search results
 - Providers can report this data now
 - Example screenshot on right

[← Back to COVID-19 Search](#)

COVID-19 vaccine locations near 98102

with any COVID-19 vaccine and appointments available

- Show all locations
- Hide appointments **unavailable**

Powered by **VaccineFinder**

1. [Rite Aid #RA105207](#)
201 Broadway E, Seattle, WA 98102
✔ COVID-19 appointments available
✔ Able to vaccinate kids 3+
2. [QFC Pharmacy #70500887](#)
417 Broadway E, Seattle, WA 98102
✔ COVID-19 appointments available
📞 Call for provider's age policies



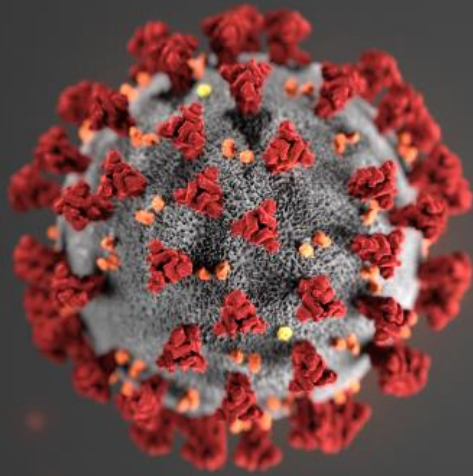
Self-knowledge Check: How is CDC supporting health departments, clinicians, and other partners in vaccine planning for children 6 months–4 years?

- A. Operational Planning Guide
- B. Dear Colleague letter to VFC providers
- C. Vaccine confidence bootcamps (such as with childcare partners)
- D. Jurisdiction-specific maps of likely vaccine providers for children aged <5 years
- E. All of the above

Answer: How is CDC supporting health departments, clinicians, and other partners in vaccine planning for children 6 months–4 years:

- A. Operational Planning Guide
- B. Dear Colleague letter to VFC providers
- C. Vaccine confidence bootcamps (such as with childcare partners)
- D. Jurisdiction-specific maps of likely vaccine providers for children aged <5 years
- E. All of the above**

Rationale: The goal to ensure all eligible children <5 years old (~20 million) have access and ability to get vaccinated.



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

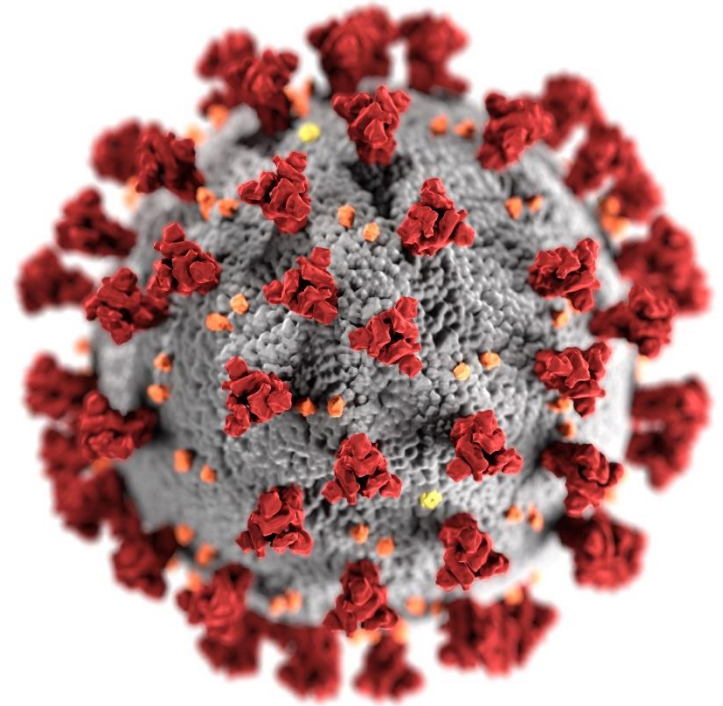


Early Safety Monitoring for COVID-19 Vaccine Doses: Reports to VAERS and v-safe

Clinician Outreach and Communication Activity
(COCA) Call

June 22, 2022

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Immunization Safety Office

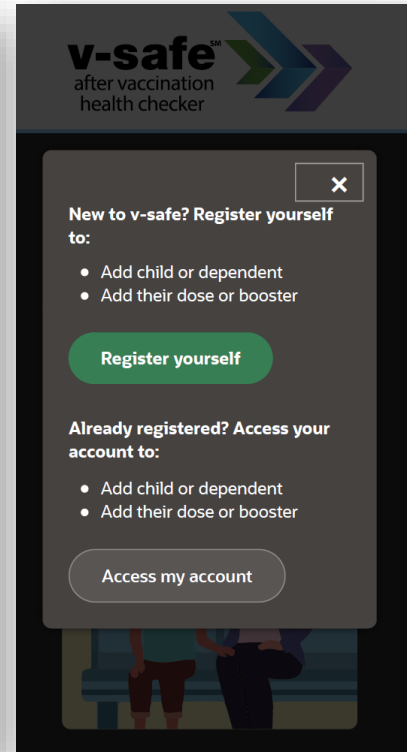
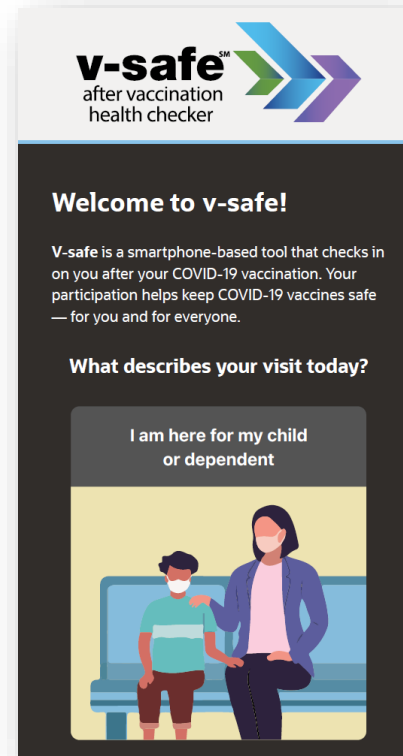


cdc.gov/coronavirus

Smartphone-based safety monitoring for COVID-19 vaccines

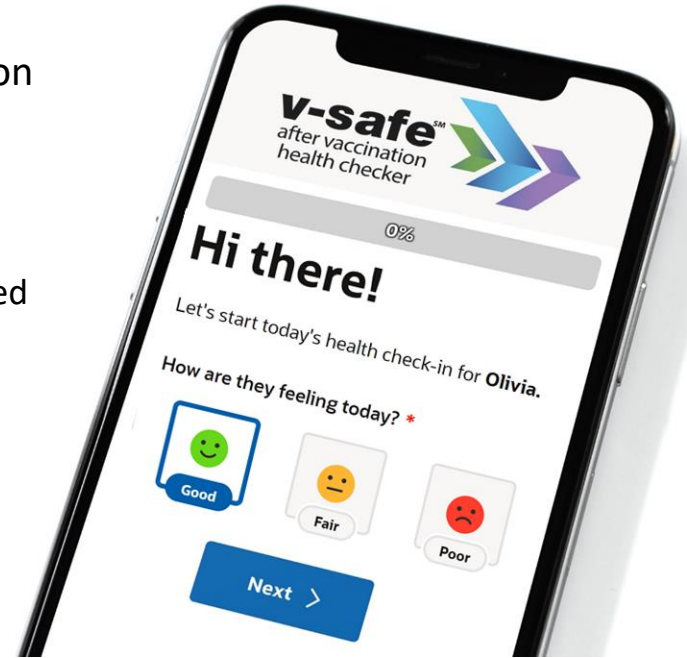
v-safe is a CDC smartphone-based monitoring program for COVID-19 vaccine safety in the U.S.

- A parent must be registered with v-safe in order to add a child to their account
- If a parent is already registered, they can access their account to add a child
- To register or access your account go to <https://vsafe.cdc.gov/en/>



v-safe uses text messages and web surveys to check in

- Parents complete surveys on behalf of their child
- Surveys solicit how the child feels after COVID-19 vaccination
 - Local injection site reactions (i.e., pain, redness, swelling)
 - Systemic reactions (i.e., fatigue, headache, joint pain)
 - Health impacts (unable to perform normal daily activities, missed school or work, or received care)
- Surveys have specific questions for young, non-verbal children



Promoting v-safe in practice– we need help!

How:

- Direct patients to <https://vsafe.cdc.gov/en/>
 - Ideally this should occur before vaccination
- Provide **v-safe** information sheet to patients
- Display posters about **v-safe**

<https://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/vsafe/printresources.html>



**Get vaccinated.
Get your smartphone.
Get started with v-safe.**

What is v-safe?
v-safe provides personalized and confidential health check-ins via text messages and web surveys so you can quickly and easily share with CDC how you or your dependent feel after getting a COVID-19 vaccine. It takes just a few minutes to enroll and your participation in v-safe helps us monitor the safety of COVID-19 vaccines for everyone.

v-safe features:

- Enroll your dependents and complete check-ins on their behalf
- Enter and report how you feel after first, second, additional, and booster doses

How can I enroll and how does it work?
You can enroll in v-safe after any dose of COVID-19 vaccine by using your smartphone and going to vsafe.cdc.gov.

During the first week after each vaccination, v-safe will send you a text message each day to ask how you are feeling. After that, you will receive occasional check-ins, which you can opt out of at any time. Depending on your answers, someone from CDC may call to get more information. Your personal information in v-safe is protected so it's safe and private*.

How can I enroll my child or dependent?
You can enroll any family member (or friend) who is eligible to be vaccinated in v-safe. Children under 16 years old must be enrolled using a parent or guardian's v-safe account. You can add a dependent to your existing account or create a new account if you don't have one yet. Creating an account to enroll a dependent does not require that you enter your own vaccination information or complete health check-ins for yourself.

Need step-by-step instructions? Go to: www.cdc.gov/vsafe

v-safe uses existing information systems managed by CDC, FDA, and other federal agencies. These systems use strict security measures to keep information confidential. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

v-safe
after vaccination
health checker

Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code



Need help with v-safe?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe


CS24195-L 06/10/2022

Self knowledge check: True or False? A parent or guardian must be registered with v-safe in order to add a child to their account.

- A. True
- B. False

Answer: True or False? A parent or guardian must be registered with v-safe in order to add a child to their account.

A. True

B. False

Rationale: To complete v-safe health surveys on behalf of a child, a parent or guardian must be registered with v-safe. Children aged 15 years and younger must be registered by a parent or guardian. To register or access your account go to <https://vsafe.cdc.gov/en/>.

VAERS is the nation's early warning system for vaccine safety



VAERS

Vaccine Adverse Event Reporting System

<http://vaers.hhs.gov>



Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the downloadable PDF. *New!*

Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.



Reporting requirements for healthcare providers administering COVID-19 vaccines



REPORT AN ADVERSE EVENT

Review reporting requirements and submit reports.



SEARCH VAERS DATA

Download VAERS Data and search the CDC WONDER database.



REVIEW RESOURCES

Find materials, publications, learning tools, and other resources.

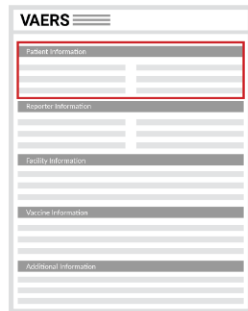


SUBMIT FOLLOW-UP INFORMATION

Upload additional information related to VAERS reports.

Completion Status

- Patient Information
- Reporter Information
- Facility Information
- Vaccine Information
- Additional Information



Click to preview VAERS form

Report an Adverse Event - Patient Information

[Instructions](#) | [en Español](#)

Note: Fields marked with an * are essential and should be completed.

Item 1

Patient first name: Patient last name:

Street address:

City: State: County:

Zip code: Phone: Email:

Item 2

* Date of birth mm/dd/yyyy or mm/yyyy

Item 3

* Sex:
 Male Female Unknown

Item 4

* Date of vaccination mm/dd/yyyy or mm/yyyy Time: AM PM

Item 5

* Date adverse event started mm/dd/yyyy or mm/yyyy Time:



<https://vaers.hhs.gov/esub/index.jsp>

Self knowledge check: A VAERS report may be submitted by:

- A. Healthcare provider
- B. Vaccine manufacturer
- C. Member of the public
- D. All of the above

Answer: A VAERS report may be submitted by:

- A. Healthcare provider
- B. Vaccine manufacturer
- C. Member of the public
- D. All of the above**

Rationale: Anyone can submit a VAERS report regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event.

To Ask a Question

- Using the Zoom Webinar System
 - Click on the “Q&A” button
 - Type your question in the “Q&A” box
 - Submit your question
- If you are a patient, please refer your question to your healthcare provider.
- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov

Continuing Education

- All continuing education for COCA Calls is issued online through the CDC Training & Continuing Education Online system at <https://tceols.cdc.gov/>.
- Those who participate in today's COCA Call and wish to receive continuing education please complete the online evaluation by **July 25, 2022**, with the course code **WC4520-062222**. The access code is **COCA062222**.
- Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation between **July 26, 2022**, and **July 26, 2024**, and use course code **WD4520-062222**. The access code is **COCA062222**.
- Continuing education certificates can be printed immediately upon completion of your online evaluation. A cumulative transcript of all CDC/ATSDR CEs obtained through the CDC Training & Continuing Education Online System will be maintained for each user.

Today's COCA Call Will Be Available to View On-Demand

- **When:** A few hours after the live call ends*
- **What:** Video recording
- **Where:** On the COCA Call webpage
https://emergency.cdc.gov/coca/calls/2022/callinfo_062222.asp

**A transcript and closed-captioned video will be available shortly after the original video recording posts at the above link.*

Upcoming COCA Calls & Additional COVID-19 Resources

- Continue to visit <https://emergency.cdc.gov/coca/> to get more details about upcoming COCA Calls, as COCA intends to host more COCA Calls to keep you informed of the latest guidance and updates on COVID-19.
- Subscribe to receive notifications about upcoming COCA calls and other COCA products and services at emergency.cdc.gov/coca/subscribe.asp.
- Share call announcements with colleagues.

Join Us on Facebook



The screenshot shows the Facebook profile for "CDC Clinician Outreach and Communication Activity - COCA". The profile picture features a group of six diverse healthcare professionals. The cover photo shows a group of five healthcare professionals. The page includes a navigation menu on the left with options like Home, About, Posts, Photos, Events, and Community. The main content area shows a status update from October 31, 2017, about a free CE event. The right sidebar displays page information, including the location "Government Organization in Atlanta, Georgia", and engagement statistics: 21,420 likes and 21,217 followers. A map shows the location of the CDC in Atlanta.

COCA
CDC Clinician Outreach and Communication Activity - COCA ✓
@CDCClinicianOutreachAndCommunicationActivity

Home
About
Posts
Photos
Events
Community
Create a Page

Liked Following Share ... Sign Up

Status
Write something on this Page...

Posts
CDC Clinician Outreach and Communication Activity - COCA shared their event.
October 31 at 1:18pm · 🌐
Clinicians, you can earn FREE CE with this COCA Call Join us for this COCA Call November 7, 2017 at 2:00PM.

Government Organization in Atlanta, Georgia
Community See All
21,420 people like this
21,217 people follow this
About See All

Thank you for joining us today!



emergency.cdc.gov/coca