COVID CONVERSATION

PREPARING CALIFORNIA FOR INFANT/TODDLER COVID-19 VACCINATIONS

Wednesday, June 22 @ 6:00 pm

Register Today

Yvonne A. Maldonado, MD, FAAP, FPIDS, FIDSA Stanford University School of Medicine

Robert Schechter, MD, MSc Immunization Branch, California Department of Public Health



CALIFORNIA ACADEMY OF FAMILY PHYSICIANS STRONG MEDICINE FOR CALIFORNIA



American Academyof Pediatrics CALIFORNIA

Welcome to COVID Conversations

- All lines are muted during program
- Question-and-Answer box can be utilized to communicate with the moderators
- Webinar will be recorded and posted to the California Immunization Coalition website (<u>https://www.immunizeca.org/</u>) as well as the CIC YouTube page

https://www.youtube.com/channel/UCklkZ1SZQNQLcpmNpeQpDAg

Questions for Presenters?

To ask a question or leave a comment use the question window



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CALIFORNIA ACADEMY OF FAMILY PHYSICIANS STRONG MEDICINE FOR CALIFORNIA

Today's Hosts and Moderators



Dr. Pia Pannaraj

- Associate Professor of Pediatrics, Molecular Microbiology and Immunology, Keck School of Medicine, University Southern California
- Director, Pediatric Immunization Advancement Laboratory, Division of Infectious Diseases, Children's Hospital Los Angeles
- Co-Chair, Emerging Issues Committee, California Immunization Coalition



Dr. Eric Ball

- Primary Care Pediatrician, CHOC Primary Care Network
- Vice Chair, American Academy of Pediatrics, California
- Co-Chair, Emerging Issues Committee, California Immunization Coalition

Today's Speakers



Dr. Yvonne Maldonado

Senior Associate Dean for Faculty Development and Diversity Professor, Departments of Pediatrics and Epidemiology and Population Health Chief, Division of Infectious Diseases Director, Global Child Health Department of Pediatrics Stanford University School of Medicine



Dr. Robert Schechter

Chief, Immunization Branch California Department of Public Health (CDPH)

Evaluation

- At the end of this webinar an Evaluation will pop up on your screen.
- The evaluation should take approximately 2 minutes to complete.
- CIC and AAP-CA utilize the evaluation from our COVID Conversations to guide us in future endeavors.





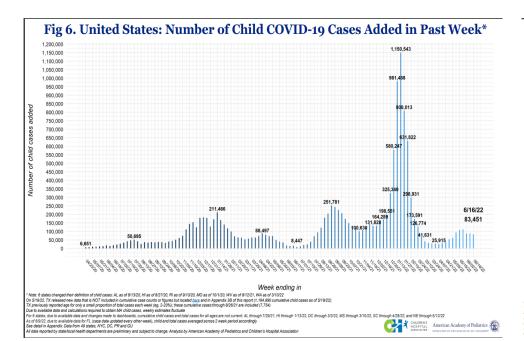
Pediatric COVID-19 vaccines – Clinical considerations

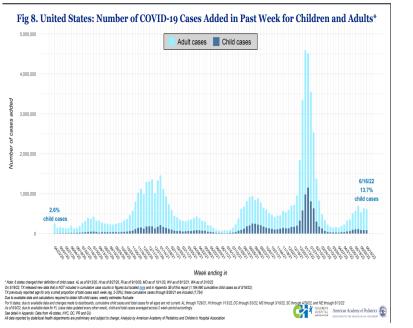
Yvonne "Bonnie" Maldonado, MD, FAAP

Taube Endowed Professor of Global Health and Infectious Diseases

Professor of Pediatrics (Infectious Diseases) and of Epidemiology and Population Health

COVID-19 IN CHILDREN





Appendix Table 1: Case Data Available on 6/16/22

Summary data across the 49 states, NYC, DC, PR, and GU that provided age distribution of reported COVID-19 cases*

Child population, 2019	Cumulative total cases (all ages)	Cumulative child cases	Cumulative percent children of total cases	Cases per 100,000 children
75,266,842	72,342,343	13,624,605	18.8%	18,101.7

https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-

19%20State%20Data%20Report%206.16.22%20FINAL.pdf?_ga=2.2 10166997.1366586198.1655851134-1073158985.1606325707





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COVID-19 IN CHILDREN

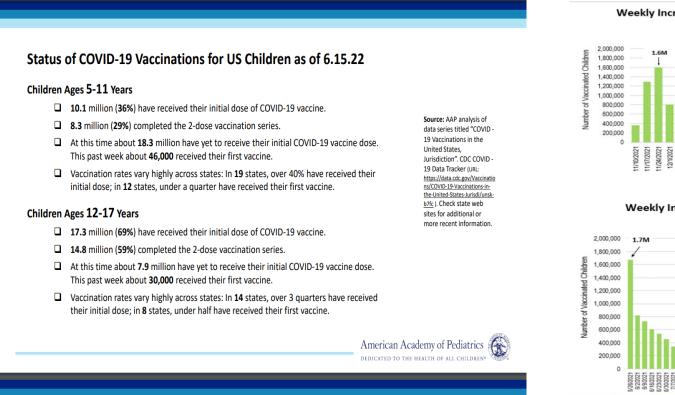
- Since the beginning of the pandemic, among children under 18 there have been:
- Over 43,000 hospitalizations
 - Approximately 85% FOR and not just WITH COVID-19
- Over 1,500 deaths

https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-19%20State%20Data%20Report%206.16.22%20FINAL.pdf?_ga= 2.210166997.1366586198.1655851134-1073158985.1606325707

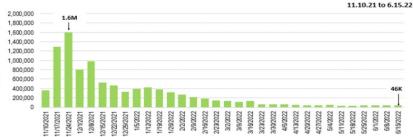
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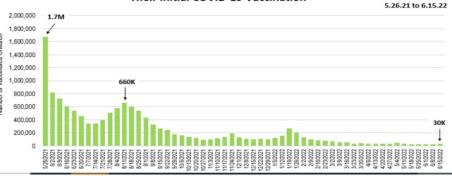
COVID-19 VACCINES IN CHILDREN



Weekly Increase in the Number of US Children Ages 5-11 Receiving Their Initial COVID-19 Vaccination



Weekly Increase in the Number of US Children Ages 12-17 Receiving Their Initial COVID-19 Vaccination



https://downloads.aap.org/AAP/PDF/Child%20Vaccin ations%20Report%20June%2015%20Updated.pdf?_ ga=2.217434966.1366586198.1655851134-1073158985.1606325707

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COVID-19 VACCINES

FDA update

Convenings of the Vaccines and Related Biological Products Advisory Committee (VRBPAC)

- June 14, 2022: VRBPAC meeting to review the request for EUA for the Moderna COVID-19 vaccine in children and adolescents ages 6—17 years
- June 15, 2022: VRBPAC meeting to review requests for EUA for:
 - Moderna COVID-19 vaccine in children ages 6 months—5 years
 - Pfizer-BioNTech COVID-19 vaccine in children ages 6 months—4 years

FDA authorized Pfizer, Moderna COVID-19 vaccines for 6 mo - 4/5 yos; Moderna COVID-19 vaccines from 6 - 17 yos on June 17th





COVID-19 VACCINES

CDC update

Convenings of the CDC Advisory Committee on Immunization Practices (ACIP)

- June 17th and 18th reviewed data on 6 mo 4/5 yos
- June 23rd ACIP will review data on Moderna's COVID-19 vaccine 6
 17 year olds.

CDC endorsed the ACIP recommendation that all children 6 months through 5 years of age should receive a COVID-19 vaccine on June 18th



STATUS OF CDC RECOMMENDATIONS

Child's Age	Pfizer - BioNTech	Moderna
6 months – 4 years old	3 dose primary series	2 dose primary series
5 years old	2 dose primary series	2 dose primary series
6-17 years old	2 dose primary series	Not recommended yet by CDC, reviewing data on Thursday, June 23rd

https://www.cdc.gov/coronavirus/2019ncov/vaccines/vaccines-children-teens.html



UPDATED AAP POLICY STATEMENT

PEDIATRICS

Prepublication Release

COVID-19 Vaccines in Infants, Children, and Adolescents

Committee on Infectious Diseases

Prepublication released on June 18, 2022

DOI: 10.1542/peds.2022-058700

Journal: Pediatrics

Article Type: AAP Policy Statement

Citation: AAP Committee on Infectious Diseases. COVID-19 Vaccines in Infants, Children, and Adolescents. *Pediatrics*. 2022; doi: 10.1542/peds. 2022-058700

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SOURCE: https://doi.org/10.1542/peds.2022-058700



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Efficacy data reviewed by Work Group

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<u>CDC definition</u>: 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

> https://www.cdc.gov/coronavirus/2019ncov/vaccines/vaccines-children-teens.html



Data reviewed by Work Group

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 not met

https://www.cdc.gov/coronavirus/2019ncov/vaccines/vaccines-children-teens.html

¹Seven days after dose 2 to before dose 3

2CDC 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

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Immunocompromised Children

Pfizer-BioNTech COVID-19 Vaccine

- Children ages 6 months—4 years: Should receive a 3-dose primary series. The first and second doses are separated by 3 weeks and the second and third doses are separated by at least 8 weeks. Currently, a booster dose is not authorized for this age group.
- Children ages 5–11 years: Should receive a 3-dose primary series and 1 booster dose. For the primary series, the first and second doses are separated by 3 weeks and the second and third doses are separated by at least 4 weeks. The booster dose is administered at least 3 months after completion of the primary series.

Moderna COVID-19 Vaccine

Children ages 6 months—5 years: Should receive a 3-dose primary series. The first and second doses are separated by 4 weeks and the second and third doses are separated by at least 4 weeks. Currently, a booster dose is not authorized for children in this age group who receive a Moderna primary series.



Prior infection

- People who recently had SARS-CoV-2 infection may consider delaying a primary series dose or their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).
 - <u>Studies</u> have shown that increased time between infection and vaccination may result in an improved immune response to vaccination.
 - Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 <u>severe disease</u>, <u>COVID-19 community level</u>, or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.
- <u>Viral testing</u> to assess for acute SARS-CoV-2 infection or <u>serologic testing</u> to assess for prior infection is <u>not recommended</u> for the purpose of vaccine decision-making.



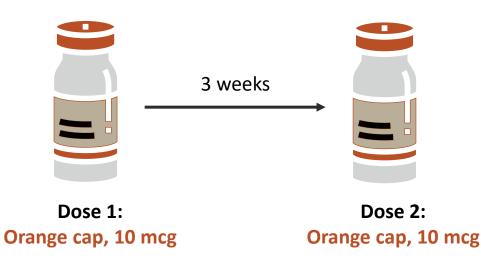
Transitioning from a younger to older age group

- People should receive the recommended age-appropriate vaccine dosage based on their age on the day of vaccination. 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 product and dosage for the older age group for all subsequent doses.
- Pfizer-BioNTech COVID-19 Vaccine
 - Children who will turn from age 4 years to 5 years: <u>FDA authorization</u> of the Pfizer-BioNTech COVID-19 Vaccine allows children who will turn from age 4 years to 5 years between any dose in the primary series to receive:
 - A 2-dose primary series using the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 year, or
 - A 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months—4 years. Each of doses 2 and 3 may be with the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months—4 years, or the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5—11 years.



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

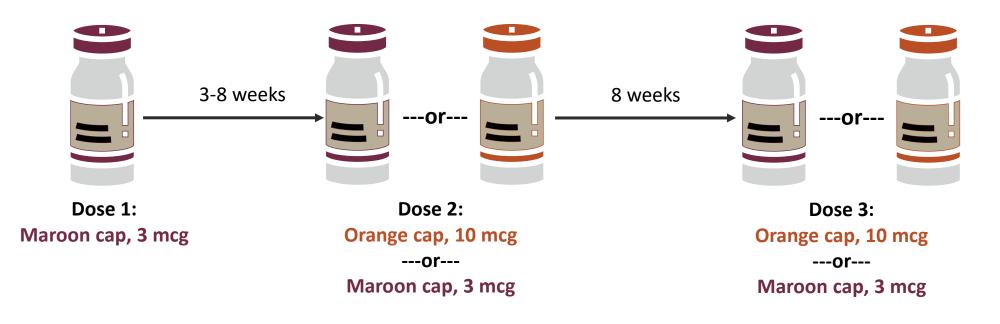
 Scenario 1: A 2-dose primary series using the formulation for people ages 5–11 years (orange cap)





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

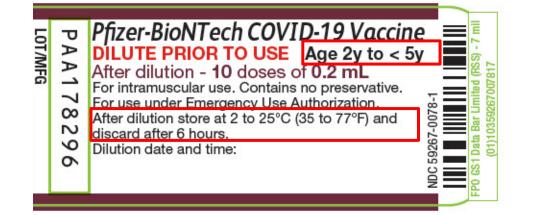
Scenario 2: A 3-dose primary series initiated with the formulation for ages 6 months–4 years. Dose 2 and 3 may be with: the formulation for ages 6 months–4 years or the formulation for ages 6–11 years.





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

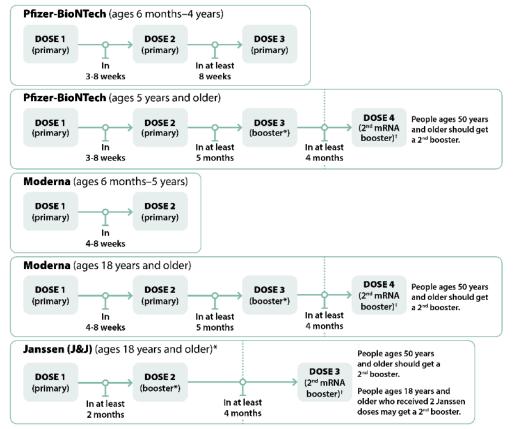
Vaccine may be discarded **12 hours** after dilution rather than **6 hours**.



Vial label states Age 2y to <5y but can be used in individuals age 6 months-4 years.



COVID-19 vaccine schedule



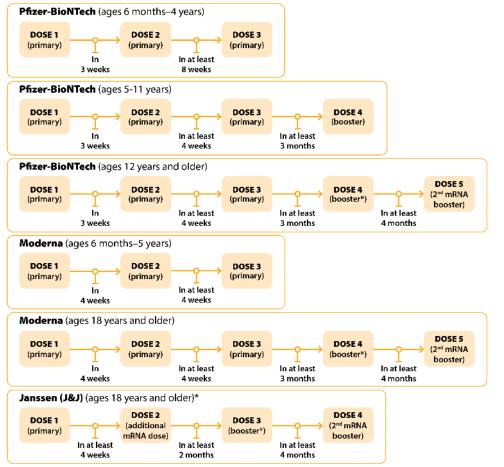
*Age-appropriate mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary and booster vaccination. Janssen COVID-19 Vaccine should only be used in limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinicalconsiderations/interim-considerations-us.html#considerations-Janssen

⁺2nd booster dose for some groups

- Ensure the correct age-appropriate product is administered based on the recipient's age on the day of vaccination
- Vaccine doses should be administered by the intramuscular route and in accordance with the recommended intervals for that age group
- An 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months-64 years, especially for males ages 12–39 years.



Moderate to Severe Immunocompromise



*Age-appropriate mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary and booster vaccination. Janssen COVID-19 Vaccine should only be used in limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us. html#considerations-Janssen

- In addition to COVID-19 vaccination, providers should consult current <u>treatment guidelines</u> for use of monoclonal antibodies as pre-exposure prophylaxis (tixagevimab/cilgavimab [EVUSHELD™]) for people who are moderately or severely immunocompromised and who may be less likely to mount a protective immune response to COVID-19 vaccination.
- Such use of monoclonal antibodies, however, is not a substitute for COVID-19 vaccination.



Revaccination

- Recipients of HCT or CAR-T-cell therapy who received one or more doses of COVID-19 vaccine prior to or during treatment should undergo revaccination for any dose(s) received before and during treatment. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- Revaccination may also be considered for patients who received 1 or more doses of COVID-19
 vaccine during treatment with B-cell-depleting therapies (e.g., rituximab, ocrelizumab) that were
 administered over a limited period (e.g., as part of a treatment regimen for certain malignancies).
 - The suggested interval to start revaccination is about 6 months after completion of the B-cell-depleting therapy.
 - Timing of vaccination for patients who receive B-cell-depleting therapies on a continuing basis (e.g., for treatment of certain autoimmune conditions such as rheumatoid arthritis or multiple sclerosis) is addressed in <u>Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies</u>.



QUESTIONS?







California Department of Public Health CA COVID-19 Vaccination Program

Planning for Infant/Toddler COVID-19 Vaccinations

June 2022





Pediatric COVID-19 Vaccine Products

Age	Brand	Dose	Volume per dose	Primary Series
12+ years	Pfizer	30ug	0.3ml	2 doses
	Moderna	100ug	0.5ml	2 doses
5-11 years	Pfizer	10ug	0.2ml	2 doses
(6-11 years)	<i>Moderna</i>	<i>50ug</i>	<i>0.5ml</i>	2 doses)*
6-59 months	Pfizer	3ug	0.2ml	3 doses
6-71 months	Moderna	25ug	0.25ml	2 doses

*FDA EUA – Potential Recommendation at 6/23 ACIP meeting



Infant/Toddler COVID-19 Vaccine Products

		Moderna (6M – 5Y)	Pfizer (6M – 4Y)
Dose		25 mcg	3 mcg
Schedule	Dose $1 \rightarrow 2$ Dose $2 \rightarrow 3$	4-8 weeks (2-dose initial series)	3 - 8 weeks 8 weeks
Met primary efficacy outcome: Antibody levels equivalent to levels at older ages associated with protection against severe COVID-19?		Yes	Yes
Preliminary clinical data suggesting at least short-term protection against symptomatic infection?		Yes	Yes (based on few cases)
Effectiveness data yet against severe COVID-19?		No	No
Adverse events		Mostly mild-moderate	Mostly mild-moderate
Any fever v. placebo; <i>fever</i> > 104°F v. placebo		16 v. 7%: <i>0.2 v. 0%</i>	6 v. 5%: <i>0.1 v. 0%</i>
Deaths, cases of myocarditis, or new safety concerns identified in trial?		No	No

Vaccinate ACIP Meeting June 17, 2022 – Dr. Oliver, VRBPAC June 14-15, 2022 Meeting Materials - 06/14/2022 | FDA FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age | FDA

Where will Infants/Toddlers Get Vaccinated?

- Pharmacies with a diminished role
- Local health jurisdictions (LHJ) sites
- Pop-up events

accinate

° Childcare, WIC

More Primary Care Providers needed

 Vaccines for Children (VFC) and non-VFC providers

Crucial COVID-19 Conversations Campaign (eziz.org)

Clinical Talking Points IMM-1431.pdf (eziz.org)

- Medical home is a trusted source of care
 - Can counsel hesitant families
 - See linked resources



Figure 1

One In Five Parents Of Children Under 5 Want To Vaccinate Their Child For COVID-19 Right Away When Authorized, But Four In Ten Want To Wait And See

Thinking about your child between the ages of...have they received at least one dose of a COVID-19 vaccine, or not? If not, do you think you will get them vaccinated...?

Child is vaccinated Right away Wait and see Only if required Definitely not					
Ages 12-17 56%					
Ages 5-11	39%		13%	12%	32%
Under 5	18%	38%		11%	27%

NOTE: Asked of parents or guardians of children under 18. For parents of children under 5, question was worded "Thinking about your child under the age of 5, once there is a COVID-19 vaccine authorized and available for your child's age group, do you think you will...?" See topline for full question wording.

KFF COVID-19 Vaccine Monitor

SOURCE: KFF COVID-19 Vaccine Monitor (April 13-26, 2022) • PNG

Co-administration

- COVID-19 vaccine may be given with other vaccines.
- Important to catch-up on routine immunizations. Always check if a patient is up-to-date and, if not, offer catch-up vaccines.
- Integrating COVID-19 vaccination with routine vaccination:
 - Follow best practices to avoid administration errors. See linked resources below.
 - Use the 15-minute observation after COVID-19 vaccination (30 minutes, if at higher risk for anaphylaxis) to encourage families to participate in <u>V-safe</u>, complete health screening questionnaires and counseling.

Coadministration with Other Vaccines California COVID-19 Vaccination Program



COVID-19 vaccines and other vaccines may be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, as well as coadministration within 14 days. The benefits of coadministration and timely catch up on vaccinations outweigh any theoretical risk. New data shows that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.

For detailed guidance, see How to Administer Multiple IM Injections to Adults.

AAP Supports Coadministration

May 12, 2021. The American Academy of Pediatrics (AAP) recommends vaccination for eligible children ages 12 and older with the federally authorized COVID-19 vaccine and supports coadministration of the COVID-19 vaccine with routine immunizations—particularly for children and teens who are behind on their immunizations. Any COVID-19 vaccine authorized through Emergency Use Authorization by the US Food and Drug Administration, recommended by the CDC, and appropriate by age and health status can be used for COVID-19 vaccination in children and adolescents.

AAP recommends that children and adolescents catch up on all vaccinations that may have been delayed during the pandemic. Between the substantial data collected on the safety of COVID-19 vaccines, and the extensive experience with non-COVID-19 vaccines which shows the immune response and side effects are generally similar when vaccines are given together as when they are administered alone, the benefits of coadministration and timely catch up on vaccinations outweigh any theoretical risk.

(For details, see Policy Statement, Press Statement, and New HealthyChildren.org article.)

CDC Guidance

When deciding whether to administer an(other) vaccine(s) with COVID-19 vaccine, providers should consider

- · whether the patient is behind or at risk of becoming behind on recommended vaccines,
- their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and
- the reactogenicity profile of the vaccines.

If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection administered at different sites in the muscle.

Consider these best practices for multiple injections:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction
 (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

(Source: Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC.)

California COVID-19 Vaccination Program

IMM-1385 (12/22/21)

IMM-1385.pdf COVID-19 Coadministration

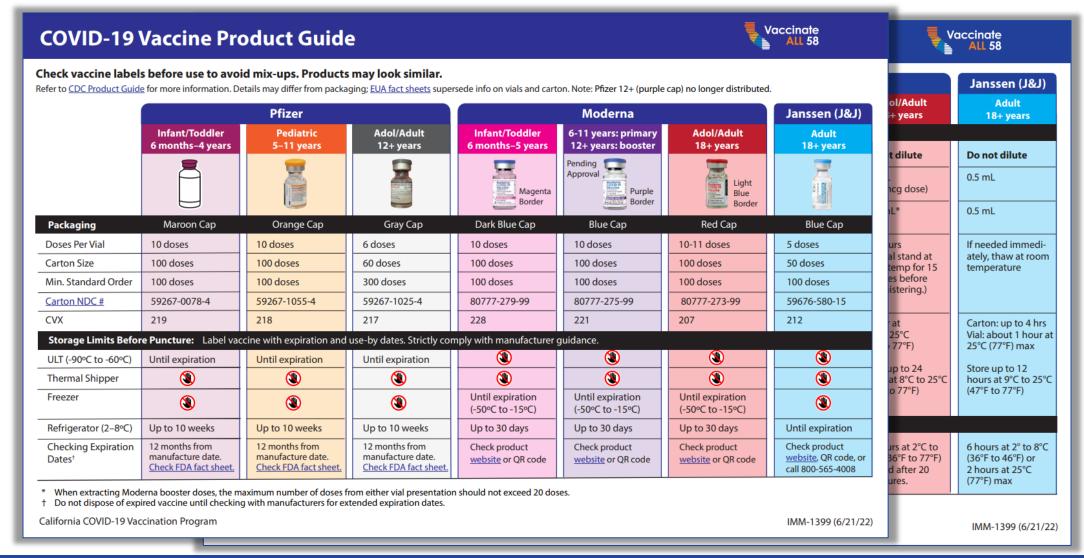


IMM-1385.pdf COVID-19 Coadministration IMM-1398 COVID-19 Vaccine Coadministration Tips IMM-1410 Preventing Administration Errors COVID-19 Vaccine Training (ca.gov) COVID-19 Vaccine Product Guide COVID-19 Vaccine and Coadministration | CDC

Storage and Handling



COVID-19 Vaccine Product Guide



Storage and Handling

- May I safely store the infant/toddler COVID-19 vaccines without an ultracold freezer?
 - Yes! All you need is a refrigerator and a digital data logger
 - Both vaccines can be stored in refrigerated temperature ranges for long periods of time
- Where is storage and handling information on the vaccines?
 - Summarized for all products in the <u>COVID-19 Vaccine Product Guide</u>
 - <u>Vaccine Management EZIZ</u> (see <u>Pfizer | Moderna</u> job aids)
 - The EUAs (next slide) always have up-to-date information





EUA Fact Sheets

- Clinical, administration, and storage/handling information
- Moderna Infant/Toddler 6 months-5 years
 - Provider fact sheet
 - Recipient/caregiver factsheet
- Pfizer Infant/Toddler 6 months-4 years
 - Provider fact sheet
 - Recipient/caregiver fact sheet
 - Pfizer Letter: Vial Mislabeling Explanation



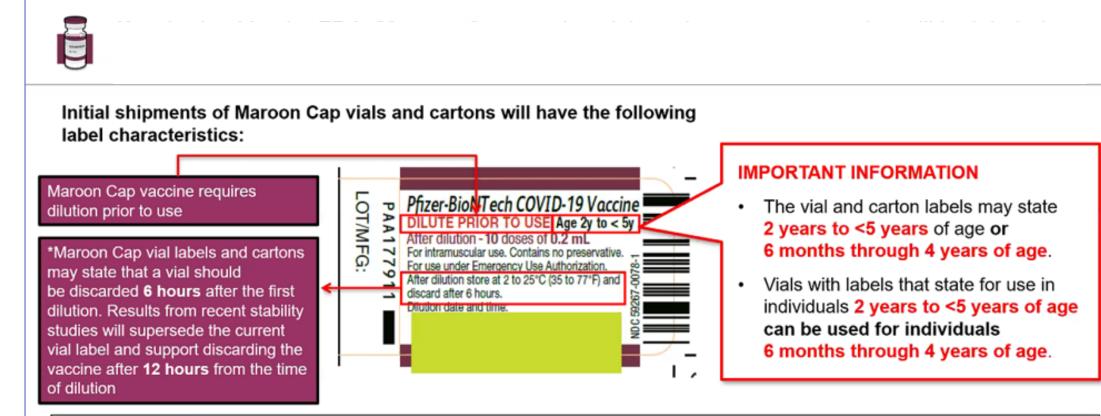


Pfizer Vial Labels

/accinate

Label Characteristics Maroon Cap Ages 6 months through 4 years

(Ages 6 month thru 4)



*Note: Prior to preparation of the vaccine, please review the EUA Fact Sheet (if authorized by the FDA) as the timeframe for use post-dilution has been extended to **12 hours**

Pfizer 6 Months – 4 Years Vaccine Storage and Handling Label

⁵⁸ Pfizer DHCP Maroon Cap and Package Label Discrepancy 06172022 (fda.gov)

Pfizer Infant/Toddler Storage and Handling

- Cap color: Maroon
- 10 dose vial, 10 vial carton, 100 dose minimum direct order
 - Third-party redistributor for orders of 30-90 doses
- Long-term storage
 - -90°C to -60°C Until published expiration date (see the EUA)
- Refrigerated storage (2°C to 8°C) x 10 weeks
- 12 hours prior to puncture at normal room temperature $(8^{\circ} 25^{\circ} \text{ C})$
- 12 hours after puncture at normal room temperature (8° 25° C)
- Requires diluent: 2.2mL normal saline

What's happening with Moderna 6-to-11?

- It's coming! Likely will become available to order in the next few days, pending ACIP
- They are repurposing the Moderna "booster-only" vials for this age group because the concentration is the same as a booster dose.
 - This means the vials will initially arrive mislabeled because they were already manufactured
 - These vials will have a **blue cap** and **purple border**.
- Same storage and handling requirements as the other Moderna vaccines





Preventing Administration Errors

- With multiple vaccine presentations, it is easy for administration errors to take place.
 - Make sure all staff are trained on the specific presentation being used.
- Injection Volume
 - This differs for different age groups, so always double-check!
- Dilution
 - Some vaccines require diluent; Pfizer Infant/Toddler (6 months-4 years, maroon cap) and Pfizer Pediatric (5-11, orange cap)
 - Some do not require diluent; Janssen, Moderna, and Pfizer Tris-sucrose (12+ years, gray cap)
 - The Pfizer Infant/Toddler (6 months-4 years, maroon cap) and Pfizer Pediatric (5-11, orange cap) require different volumes of diluent – make sure staff are aware of this!
- Ensure vaccines are clearly labeled and organized in your fridge so that staff do not accidentally grab the wrong vials.
 - Double check the vial is for the correct age group when you pull the vaccine out of the refrigerator and again before administering.



Preventing Administration Errors Job Aid Vaccine Administration Checklist Job Aid

Pfizer COVID-19 Vaccine Updates & Trainings

Date & Time (linked)	Password			
<u>Thursday, June 23 - 9AM</u>	FKqizmRb735			
<u>Friday, June 24 - 12PM</u>	XZqMY8qQV37			
<u>Monday, June 27 - 12PM</u>	SXpxqFPP265			
<u>Tuesday, June 28 -12PM</u>	vXGkbVDv526			
<u>Wednesday, June 29 - 9AM</u>	3JKnTe4GDx5			
<u>Thursday, June 30 - 9AM</u>	MpBZPFCM635			
<u>Friday, July 01 - 12PM</u>	QMjNKiQX532			
More sessions listed! NOTE: All times listed here are PDT.				

Updated

Audience:

Providers and immunization staff.

Session Topics Include:

- Potential new vaccine presentation (Maroon Cap) for individuals 6 months through 4 years of age** (Starting June 7)
- FDA approvals, authorizations including recent authorizations
- Extended expiry for **Purple**, **Orange**, and **Gray** Cap
- Gray Cap, Comirnaty®
- Use of each vaccine presentation, including storage, handling, preparation, and administration

Moderna Infant/Toddler Storage & Handling

- Cap color: Dark blue
 - Vial label: Magenta border
- 10 doses per vial, 100 dose minimum order
- Long term storage



- -50°C to -15°C until published expiration date (Moderna Vial Expiration Date Lookup)
- Refrigerated storage (2°C to 8°C)
 - ° 30 days
- Room temperature storage for up to 24 hours total (must be discarded within 12 hours of puncture)
- Does not require diluent

Job Aid: Preventing Administration Errors

Preventing Administration Errors

California COVID-19 Vaccination Program

Once an error or deviation has occurred, use this guidance to prevent the administration error from occurring again. Refer to CDC's Interim Clinical Considerations or Revaccination Guidance for next steps.

An administration error is any preventable event that may cause or lead to improper use of vaccine or patient harm. To reduce errors, complete <u>COVID-19 vaccine product training</u> and demonstrate competency for products your site will administer. Report errors to VAERS and ISMP to help prevent future errors.

Error Type	Guidance to Prevent Administration Errors
Wrong Site or Route	 Administer COVID-19 vaccines in deltoid muscle (or anterolateral thigh) using IM injection. If multiple vaccines are administered at a single visit, administer each injection in a different injection site. Post this anatomical illustration to help identify recommended injection sites. For people 211 years, the deltoid muscle can be used for more than one intramuscular injection administered at different sites in the muscle. For children (5-10 years), if more than two vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass. For 6 months through 2 years: The injection site is the deltoid muscle can be used for more than one intramuscular injection; For 3 years and older: The injection site is the deltoid muscle. An IM injection given with too short a needle is functionally a subcutaneous injection; post this reference guide and use clinical judgment to adjust needle length for patient weight and gender: COVID-19 vaccines may be administered withhout regard to timing of other vaccines. If coadministering COVID-19 vaccine with routine vaccines, prepare and organize syringes to ensur products are administered in correct site and route. Ask patient to completely expose their shoulder when administering in the deltoid muscle. Ensure vaccinators can locate upper/lower borders of a safe IM injection zone. Incorrect administration into shoulder joint instead of deltoid muscle can trigger inflammation and nignry.
Wrong Age	Do not administer vaccine to an unauthorized age group. Select the correct vaccine product based on patient <u>eligibility and age</u> at date of vaccination.
Wrong Formulation	Select correct vaccine formulation based on patient age at date of vaccination. COVID-19 vaccine dosages are based on patient age—not size or weight; administering the wron formulation may result in a lower-than-authorized dosage and insufficient protection. Double check vial label; always verify patient birthdate. (Early shipments of Pfizer 6M-4Y do not correctly state the age indicators. Please refer to the <u>Pfizer Fordiof Letter.</u>) Refer to <u>COVID-19 Vaccine Product Guide</u> for cap colors and age indicators by product.
Overdosage	Do not administer a higher-than-authorized vaccine injection volume for primary series and additional or booster doses. If too much vaccine is administered, dose may invoke stronger adverse effects; double check injection volume for product & dose before administration. (Report adverse events to <u>VAERS.</u>)

Error Type Guidance to Prevent Administration Errors

Common errors may include overdosing with 0.50 mL instead of 0.25 mL for a Moderna booster.
 Moderna 12Y+ (red cap): Syringes in ancillary kits may require estimating between lines; private stock with appropriate markings may be used instead.

Underdosage Do not administer a lower-than-authorized vaccine injection volume for primary series and additional or booster doses.

- If too little vaccine is administered, dose may not provide sufficient protection; double check injection volume for product & dose before administration.
- Common errors may include underdosing 0.25 mL instead of 0.50 mL for Moderna primary series, leftover vaccine in syringe, vaccine leakage (check for tight fit between needle and syringe), equipment failure (do not use bent or damaged needles) and recipient pulled away (prepare patient in advance).
- Do not exceed number of doses on vial label; resulting volume may not provide sufficient protection.
- Moderna 12Y+ (red cap): When using syringes that have tick marks at 0.2-mL intervals, use best judgment to draw up half-way between 0.24mL and 0.26mL, or use private stock with appropriate markings.

Storage at Do not administer vaccine that has been exposed to improper temperatures (i.e., temperature excursion).

- Administration of vaccine after a temperature excursion may require revaccination.
- Monitor and record storage unit temperatures twice daily. (See sample COVID-19 log.)
- Label affected vaccines DO NOT USE to prevent administration and contact manufacturer to determine if vaccines may be used.
 Report temperature excursions in myCAvax daily and include excursion resolution.
- If manufacturer determines vaccines may not be used, <u>report doses as spoiled</u> in myCAvax and discard using guidance in linked document.

Storage Do not administer expired vaccine.

- Beyond Administration of expired vaccine may require revaccination. Expiration Double check expiration dates before preparation and administration. (See COVID-19 Vaccine Date Product Guide for expiration dates & their location by product.) Rotate stock weekly to ensure vaccines soon to expire are used first; remove expired vaccine from storage units to prevent administration. Report expired doses as "expired" in myCAvax; discard following linked guidance. Storage Do not administer vaccine past recommended beyond-use (i.e., use-by) date/time. Beyond "Use Administration of vaccine past beyond-use limits may require revaccination. By" Date and Double check beyond-use date/time before preparation and administration. Time
 - <u>Storage limits</u> before puncture vary by temperature range; apply beyond-use tracking labels to cartons when vaccine shipments are stored to ensure beyond-use limits are followed.
 Once vial is punctured, label vial with puncture date/time (dilution date/time for Pfizer products); use by time limit printed on vial label.
 - Routinely remove vaccine beyond use-by date/time from storage units to prevent administration.
 - Report doses beyond use-by limits as "expired" in myCAvax; discard following linked guidance.

California COVID-19 Vaccination Program

California COVID-19 Vaccination Program

protection

Guidance to Prevent Administration Errors

recommended date is permitted.)

primary series. (See exceptional situations.)

and Deviations guidance.

recommendations for the immunocompromised.

update the card with additional/booster doses.

immunocompromised. (See Pfizer EUA Fact Sheet.)

Do not dilute Comirnaty (gray cap) formulation.

independent double check of the dilution process.⁺

* Top 10 Errors Related to COVID-19 Vaccination; published June 28, 2021; accessed online November 9, 2021.

Record dilution date/time on vial label.

Pfizer 12Y+ (purple cap): 1.8 mL/vial.

significantly impact intended dose.

Reconstitute Pfizer COVID-19 pediatric vaccine products correctly.

Double check vaccine and diluent labels before reconstituting vaccine.

Reconstitute Pfizer COVID-19 vaccine products with the correct diluent volume.

ONLY use sterile 0.9% Sodium Chloride Injection, USP for diluent.

To prevent a higher-than-authorized dose, ensure diluent is used.

Confirm the correct interval between doses for primary series and additional/booster doses.

Check My Turn, CAIR or your EHR to confirm timing of the patient's next dose.

Check vial label carefully to ensure you're administering the correct product.

Don't administer 2nd dose before its recommended interval. (A 4-day grace period prior to the

Refer to COVID-19 Vaccine Timing by Age for age indicators, timing of primary/booster doses, and

Providers must document administration in My Turn or an EHR connected to CAIR (CAIR2/RIDE)

to help reduce these administration errors. Complete the patient's Vaccination Record Card and

Administer the correct mRNA COVID-19 vaccine product the appropriate dose in 2-dose or 3-dose

Check My Turn, CAIR, or your EHR to confirm vaccine product your patient previously received.

If an incorrect formulation is administered, please refer to CDC's Vaccine Administration Errors

If feasible based on time frame for vaccine stability at room temperature, dedicate a team to dispense prefilled, labeled syringes of the vaccine for daily vaccination clinics. Consider an

Double check diluent volume; if too much diluent is added, doses may not provide sufficient

Diluent volume for Pfizer 6M-4Y (maroon cap) 2.2 mL/vial; Pfizer 5-11Y (orange cap) 1.3mL/vial;

Pfizer recommends use of syringes with appropriate graduations to dilute with the directed 1.3

Use one diluent vial to dilute one vaccine vial; discard the remainder of the diluent in the vial.

mL of saline. Using syringes with 0.2 mL graduations and estimating the volume will not

3-dose primary series of Pfizer maroon cap vaccine applies to infants/toddlers 6M-4Y or for

Administration at an incorrect interval may require revaccination.

Error Type

Given Sooner

Interval

Incorrect

Incorrect

Dilution

Product

Incorrect

Dilution

Volume

IMM-1410 (6/21/22)

Formulation

(Mixed Series)

than Minimum

10.00	 410	(6/21)	(22)



California COVID-19 Vaccination Program

Preventing Administration Errors IMM 1410

IMM-1410 (6/21/22)

Vaccinate

Enrollment and KidsVaxGrant





Before Enrolling in the COVID-19 Vaccine Program



Enrollment kit

- Step 1: Review Program Requirements including CDC Provider Agreement
- ✓ Step 2: Review Provider Enrollment Worksheet
- ✓ Step 3: Enroll in your local IIS
- ✓ Step 4: Review Storage & Handling Guidelines
- ✓ Step 5: Complete Required Training
- Step 6: Complete CDC Provider Agreement in myCAvax





KidsVaxGrant Funding Opportunities

- VFC providers newly enrolled in the California COVID-19 vaccine program (myCAvax) could receive \$10,000 per site to support enrollment and launching a vaccination center. Those that enroll in myCAvax from December 17, 2021, through July 15, 2022, will qualify for the grant.
- VFC providers already enrolled in the California COVID-19 vaccine program (myCAvax), who are expanding operating hours by a minimum of 15 hours, could be eligible for \$15,000, per site. Eligible providers must expand hours of operations by a minimum of 15 hours to provide additional time options for working families.
 - Expanded hours must be outside of normal or existing clinic hours
 - Expanded hours must be completed within 60 days of the application's approval and are not retroactive.





KidsVaxGrant Application Cycle

- The California Department of Public Health has appropriated approximately \$10 million to support the KidsVaxGrant program.
- Application launch: April 1, 2022, at 12:00 a.m. (PDT)
- Application deadline: July 15, 2022, at 11:59 p.m. (PDT)
 - Or once funding is expended



COVID-19 Vaccine Ordering



Infant/Toddler COVID-19 Vaccine Orders





The minimum standard order amount is 100 doses for both products.

- Pre-Order Waves 1 & 2: delivered 6/20-21 (Moderna) and 6/20-22 (Pfizer) and will complete by this week based on provider delivery hours.
- Routine ordering is now open: Orders follow the regular ordering and distribution cadence. (See Ordering Vaccines for guidance.)

Small orders of Pfizer (30-90 doses)

• Via Third-party Redistributor (AmerisourceBergen) starting this week



Order COVID Vaccine through myCAvax



The Product Groupings went live in myCAvax on the evening of Friday, June 3rd. These will be helpful when determining the age group for your desired products!

(Q Reported Inventory (VaccineFin	der)		On-hand	d Inventory		💳 Doses administered	d 📑 Order size		
	"Vaccine product	Quantity	Last updated 👩	*Quantity	Lot number 🌒	Expiration/Beyond use date 👩	"Qty since last order O	Order increments 👩	*Doses requested	
Infant/Toulday	Pfizer (6 Months - 4 years)						+	100 dose min 100 (over 100)	d 🗘	音 Clear Row
Indan	Moderna (6 Months - 5 years)						+	100 dose min 100 (over 100)	0	會 Clear Row
Ductinatedo	Pfizer (5 years - 11 years)					Ë	+	100 dose min 100 (over 100)	0	音 Clear Row
-	Pfizer Tris-sucrose (12 years - 100+ years)						+	300 dose min 300 (over 300)	0	會 Clear Row
Arthonomet / Art In	Moderna (18 years - 100+ years)						+	100 dose min 100 (over 100)	0	會 Clear Row
A	Janssen (18 years - 100+ years))[+	100 dose min 100 (over 100)	0	습 Clear Row



COVID-19 Vaccine Job Aids and Resources



Job Aid: COVID-19 is a Childhood Illness

HOSPITALIZATION RATE Hospitalization rates among unvaccinated children ages 5-11 were 2x as high compared to vaccinated

2X HIGHER

MAKE NO MISTAKE COVID-19 IS A CHILDHOOD ILLNESS



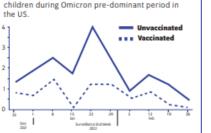
COVID-19 CAN BE SERIOUS FOR KIDS.



OVER 1500 122.000 DEATHS

Over 1500 children have died from COVID-19 in the US since the start of the pandemic. among adults.





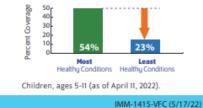
PEDIATRIC VACCINATION COVERAGE IS LOW, ESPECIALLY FOR CALIFORNIA'S MOST VULNERABLE CHILDREN

60% OF KIDS NOT VACCINATED 65% OF KIDS NOT UP-TO-DATE

Over 60% of California children ages 5-11 years have yet to receive 1 dose of COVID-19 vaccine, and over 65% have yet to receive 2 doses, leaving most children vulnerable to Omicron and future variants likely to follow.

SOME COMMUNITIES ARE FAR BEHIND

Only about 23% of California children living in the least healthy conditions are vaccinated against COVID-19 compared to 54% living in the most healthy conditions.



ALL 58 California COVID-19 Vaccination Program

Vaccinate



OF VFC PROVIDERS NOT GIVING COVID-19

VACCINE





Many VFC providers have yet to enroll in the COVID-19 Vaccination Program, leaving many vulnerable children without access in their

Many VFC providers enrolled in the COVID-19 vaccine program haven't ordered vaccine. Once enrolled, start ordering and administering vaccine!

medical home. Enroll today!

More access to vaccine is needed: Pharmacy appointments and school clinics are helpful but not enough to reach many children.

ONLY 1 OF 6 PARENTS SAY THEIR CHILD'S DOCTOR RECOMMENDED THE COVID-19 VACCINE.

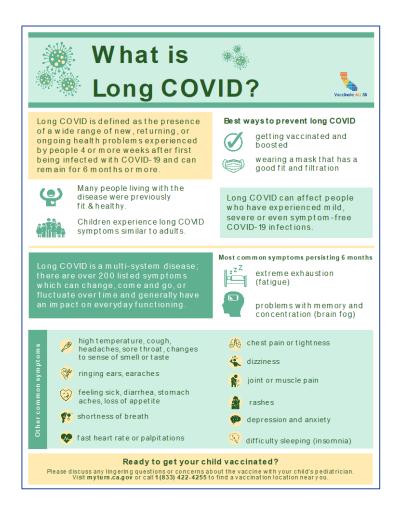
- As a trusted source, your recommendation can influence the decision to vaccinate.
- If you choose not to enroll, have a referral plan in place to ensure that your patients get vaccinated elsewhere.

- MWHR published April 22, 2022 (data from COVID-NET sample of 14 states and 99 counties from December 19, 2021–February 28, 2022)
- COVID-19 Vaccine Progress Dashboard Data National Center for Health Statistics
- Kaiser Family Foundation COVID-19 Vaccine Monitor 2021 Update on Parents'
- Views of vaccines for Kids (figure N)
- CDC COVID Data Tracker: Hospital Admission

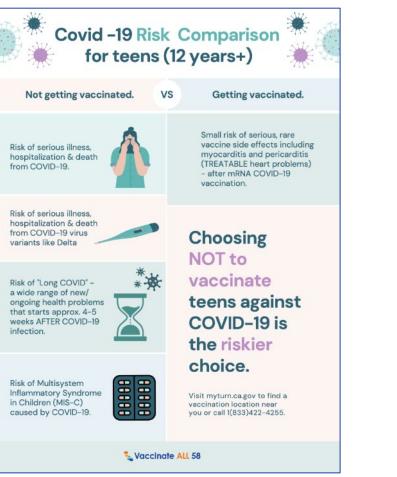
IMM-1415-VFC (5/17/22)



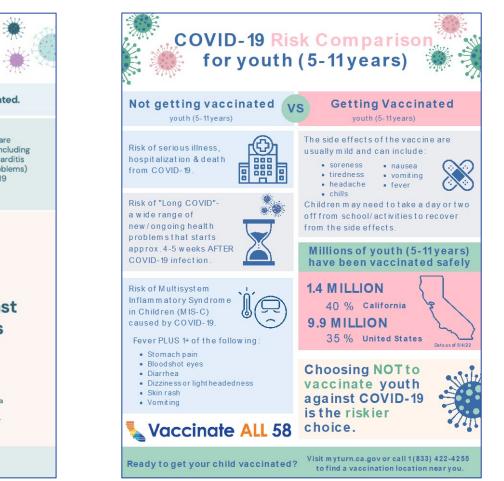
Infographic: COVID-19 is a Childhood Illness







Risk Comparison for Teens



Risk Comparison for Youth

Vaccinate COCA Archived Webinar: Evaluating and Supporting Patients Presenting with Cognitive Symptoms Following COVID-19

Job Aid: Preparing for Infant/Toddler Vaccinations

Preparing for Infant/Toddler Vaccinations

Whenever new vaccine products are introduced into your practice's supply, ensure staff are properly trained on what's new and reinforce the storage and handling basics staff already know. This guide addresses training issues and setup required to support new pediatric vaccine products.

#1. Review Clinical, Safety, and Efficacy Talking Points

We'll share findings from the clinical trials once data are available. In the meantime, review clinical talking points for parents and start talking to families about COVID-19 vaccines now!

#2. Complete the COVID-19 Product Training

CDC's training for any new vaccine products will be posted <u>here</u> once released by CDC. In the meantime, review FDA's EUA Fact Sheets for each product you'll administer.

To ensure everyone is proficient with any new products in your inventory, CDC requires that everyone storing, handling, administering, or managing COVID-19 vaccines complete the <u>COVID-</u> 19 Vaccine Product Training.

CDC training is broken down into separate Preparation & Administration and Storage & Handling summaries so staff and clinicians can review the training appropriate to their roles and print them for reference.

Bookmark the COVID-19 Vaccine Product Guide as a quick reference.

#3. Review Timing for Doses by Age

Ensure staff know how to identify which vaccine is for which age group. <u>This chart</u> includes two schedules (routine and for moderately and severely immunocompromised) for primary and booster doses.

California COVID-19 Vaccination Program

Product Updates

CDC and the California Department of Public Health are updating job aids and communications for the following product authorizations:

 Pfizer-BioNTech COVID-19 boosters for children 5-11Y (recommended)

 Pfizer-BioNTech COVID-19 primary vaccine series for 6M-4Y (Fact Sheet)

 Moderna COVID-19 primary vaccine series doses for 12Y+, boosters for 18Y+ (Fact Sheet updated)

 Moderna COVID-19 primary vaccine series for 6M-5Y (Fact Sheet)

 Moderna COVID-19 primary vaccine series for 6-11Y (Fact Sheet)

COVID Call Center will keep sites posted as new pediatric products or boosters are authorized by FDA and recommended by the Advisory Committee on Immunization Practices (ACIP), CDC, and Western States Scientific Safety Review Workgroup (WSSSRW).



IMM-1432 (6/17/22)

Includes:

- Safety and Efficacy
- Product Training
- Timing for Doses
- Vaccine Organization
- Preparing Staff
- Links to Resources





Recommending COVID-19 Vaccination: Clinical Talking Points for Providers of Pediatric Services



This resource is designed to help you and your staff have effective conversations with families about COVID-19 vaccines, as you are the <u>most trusted source</u> of medical information for families.

Begin to discuss COVID-19 vaccination now.

The top reason parents cite for not vaccinating their children is the need for more information. For families who may be hesitant about the COVID-19 vaccine, begin the conversation by asking, "How do you feel about your child getting the COVID-19 vaccine?" The goals of these conversations are to have a cordial discussion, answer questions, understand and acknowledge any fears they express, and provide accurate information.



Validate parental concerns and answer questions without judgement.

As their child's provider, your guidance is influential. Hearing your opinion that immunization is safe and effective can be reassuring. When parents express hesitation, ask about and acknowledge their concerns. For example, *"If I heard those things, I would be scared, too. Let's talk about your concerns."* Let parents know that you share their goal of keeping their children safe.

Give parents accurate information.

Here are common questions and talking points to help parents. Praise parents who ask questions for wanting to know more. Wrap up the conversation by making a recommendation while acknowledging their authority in deciding for their children. For example, "I think getting vaccinated is best for your child. Ultimately, it's your choice. I'm here to guide you and answer your questions."

Why should my child get the COVID-19 vaccine?

- It's effective. The vaccine does not protect against all COVID-19 infection, but <u>multiple studies</u> have shown it is effective in preventing severe illness and hospitalization, including <u>against the Omicron</u> <u>variant</u>.
 - During the Omicron period, unvaccinated children ages 5-11 were <u>twice as likely</u> to be hospitalized with COVID-19 than vaccinated children.
 - During the Omicron period, <u>1 in 5 children</u> hospitalized with COVID-19 required ICU-level care. Vaccination <u>lowered the risk of critical COVID-19 by 79%</u>.
 - <u>Children with pre-existing conditions</u> are at higher risk for severe COVID-19 outcomes. Vaccination
 is especially recommended to keep children with chronic conditions and disabilities safe and
 healthy.

California COVID-19 Vaccination Program

IMM-1431 (6/1/22) Page 1

Recommending COVID-19 Vaccination: Clinical Talking Points for Providers of Pediatric Services



Healthy children with no pre-existing conditions can have severe COVID-19, too. In fact, <u>almost half</u> of children younger than 18 years hospitalized with COVID-19 have no underlying conditions.

• During the Omicron period, <u>63% of children under 5 years</u> and <u>30% of children 5-11 years</u> hospitalized with COVID-19 did not have any underlying conditions.

 Multisystem Inflammatory Syndrome in Children (MIS-C) is a serious condition that can happen in children after infection with COVID-19, even if they had mild symptoms or no symptoms at all. The COVID-19 vaccine lowers the risk of MIS-C by <u>91%, according to data from July-December 2021</u>.

- In California, there have been over <u>960 cases of MIS-C</u>, many of which were admitted to an ICU (as of 5/9/22).
- The vaccine can shorten time away from school, childcare, and work. Vaccinated children spent less time sick in bed than unvaccinated children, during the Omicron period.
- The vaccine can help protect others at home, including the most at-risk members of your family and community, such as grandparents, babies, and people with compromised immune systems. Vaccinated persons with COVID-19 were one-third less likely to transmit to others in their household in the Omicron period.
- Children infected with COVID-19 were <u>found to be more likely to develop diabetes than those without</u>
 <u>COVID-19</u>. Vaccination may lower this risk.
- We are still learning about long COVID in children. Children have reported <u>ongoing respiratory, cardiac,</u> <u>neurologic and other symptoms</u> following COVID-19 infection. <u>Research in adults</u> suggests that people who are vaccinated against COVID-19 are less likely to develop long COVID.

Is COVID-19 vaccine safe for my child?

- COVID-19 vaccines are safe. Over 220 million people, including over 23 million children, have safely
 received the COVID-19 vaccine in the United States and are now protected against serious COVID-19
 infection. Getting vaccinated is much, much safer than the risks of getting sick with COVID-19.
- Mild to moderate side effects are common and can be a sign that your body is building up its defenses to protect you. It's not unusual for a child to feel sore at the injection site or have a fever, headache, and fatigue for a day or two after vaccination.

California COVID-19 Vaccination Program

IMM-1431 (6/1/22) Page 2



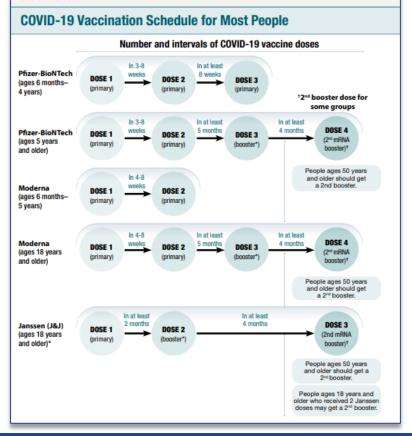
Clinical Talking Points for Providers of Pediatric Services IMM-1431.pdf (eziz.org)

COVID-19 Vaccination Schedules

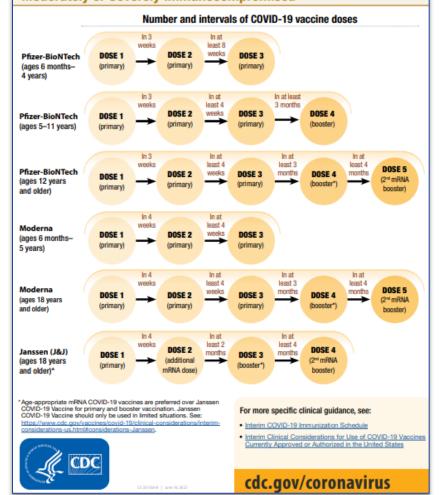
AT-A-GLANCE

COVID-19 Vaccination Schedules

Use the schedules below to determine how many total COVID-19 vaccine doses are recommended based on primary series product, age, and immune status. This schedule does not include clinical details necessary for administering COVID-19 vaccines. For clinical details, see the resources at the end of this document.











your vaccine coordinator may have applied to the carton.

Vaccine Administration Checklist

California COVID-19 Vaccination Program



Use this guidance to help ensure your patients receive sufficient protection after vaccination and to minimize revaccination efforts due to administration errors. Refer to CDC's <u>Interim Clinical Considerations</u> for additional clinical guidance and exceptional circumstances. Ensure check-in staff and vaccinators are properly trained on <u>COVID-19 vaccine timing by age</u>; ensure vaccinators are properly <u>trained to prepare vaccine products</u> your site will administer—paying extra attention to dilution of Pfizer COVID-19 vaccine products.

0	Screen recipients carefully and schedule appointments based on eligibility and age at date of vaccination.	Check-In Staff					
	 COVID-19 vaccine dosages are based on age—not size or weight. Vaccine products may have 2-dose or 3-dose primary series. Refer to <u>COVID-19 Vaccine Timing by Age</u> for age indicators, number/timing of primary and booster doses, recommendations for immunocompromised. For subsequent doses in primary series: Check MY Turn, CAIR or your ENR to confirm the vaccine product your patient previously received AND timing of the next dose; administration at an incorrect interval may require revaccination. Determine if <u>extended dosing interval</u> for Pfizer/Moderna 2nd dose is appropriate. 4-Day grace period: Primary series and booster doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid. Interchangeability of COVID-19 vaccine products: In general, the same mRNA vaccine product should be used for all doses in the primary series. See <u>Interim Clinical Considerations</u> for exceptions. Transitioning from a younger to older age group: People should receive the recommended age-appropriate vaccine dosage based on their age on the day of vaccination. 						
1	Carefully check the vaccine vial label against the prescribed vaccine in My Turn or your EHR.	Vaccinators					
	Administering the wrong formulation may result in a lower-than- For COVID-19 vaccines, use vial cap color to help distingui <u>Product Guide</u> for cap colors and age indicators by produc correctly state the age indicators. Please refer to the <u>Pfize</u>	sh products. Refer to <u>COVID-19 Vaccine</u> :t. (Early shipments of Pfizer 6M-4Y do not					
2	Always check expiration date before preparation and administration.	Vaccinators					
	Administration of expired vaccine may require revaccination (see • See <u>COVID-19 Vaccine Product Guide or EUA Fact Sheets</u> to de • Your vaccine coordinator may have written updated expiration	termine expiration date by vaccine.					
3	Always check beyond-use limits before preparation and administration.	Vaccinators					
	Administration of vaccine past beyond-use limits may require revaccination. See <u>COVID-19 Vaccine Product</u> <u>Guide or EUA Fact Sheets</u> for limits by product.						
Califo	rnia COVID-19 Vaccination Program	IMM-1411 (6/21/22)					

	 For punctured vials: Double check the first-puncture date/time vaccinators have written on the label; use by the limit printed on the vial label then discard. 					
	Pfizer Details:					
	 5-11Y (orange cap) and 6M-4Y (maroon cap): 12-hour limit in labels and cartons. 	EUA Fact Sheet supersedes 6 hours printed on				
4	Prepare vaccine according to the manufacturer fact sheet.	Vaccinators				
	 Prepare vaccines just before administration and in a designated area to avoid contamination. Thaw vials for the day based on number of scheduled appointments and doses/vial. Do not refreeze vaccine. Don't pool vaccine from multiple vials to obtain one dose. Return vaccine product to storage before administration to minimize time exposed to ambient temperatures. COVID-19 vaccines may be administered without regard to timing of other vaccines. If coadministering with routine vaccines, prepare one vaccine at a time then label and organize to prevent mix ups. If vaccinating family members, prepare vaccines for one member at a time to prevent mix ups. 	Resources: • <u>Pfizer 12Y+ (gray cap) Fact Sheet</u> • <u>Pfizer 12Y+ (gray cap) Fact Sheet</u> • <u>Pfizer 6M-4Y (maroon cap) Fact Sheet</u> • <u>Moderna 6M-5Y (red cap) Fact Sheet</u> • <u>Moderna 6M-5Y (dark blue cap) Fact Sheet</u> • <u>Janssen (J&J) Fact Sheet</u> For a chart of thaw times, dosing volume, expiration dates & use-by limits by product: • <u>COVID-19 Vaccine Product Guide</u>				
5	Carefully reconstitute Pfizer COVID-19 vaccine products following manufacturer fact sheets.	Vaccinators				
	If too much diluent is added, doses may be insufficient. Make sure diluent is used to prevent higher-than-authorized doses. • Do not dilute Pfizer 12Y+ (gray cap) formulation. • Double check vaccine and diluent labels. • ONLY use sterile 0.9% Sodium Chloride Injection, USP. • Use one diluent vial to dilute one vaccine vial then discard remaining diluent. • Record dilution date/time on vaccine vial label. From Pfizer: Use syringes with appropriate graduations to dilute with the directed 1.3 mL of saline, or estimate volume.	Tip: To avoid dilution errors, CDC doesn't recommend administering purple and gray cap products in a single clinic. Pficer S-11 Date: 11/10/21 Time Mixed: 2.00 AM Use By Time: 3.00 PM				
6	Select the correct needle for vaccine administration.	Vaccinators				
	Use clinical judgment to <u>adjust length</u> for weight and gender. Use the same needle to withdraw and administer vaccine. Use <u>low dead-volume syringes/needles</u> to maximize Pfizer and Moderna volume. Due to risk of contamination, DO NOT leave a needle inserted into a vial stopper for multiple uses, reuse syringes or needles, or use vial adaptors or spikes to extract doses.					

For unpunctured vials: Don't prepare or administer vaccine past the limits on the beyond-use tracking label

Vaccinators Withdraw the correct vaccine volume. Double check volume for product & dose. Once a vial is punctured, label vial with puncture date/time. Pfizer 5 Years of Age and Older: See <u>Vaccine Dosage Chart</u> for manufacturer guidance by dose. Moderna 12Y+ (red cap): When using syringes that have tick marks at 0.2-mL intervals, use best judgment to draw up half-way between 0.24 mL and 0.26 mL, or use private stock with appropriate markings. Don't exceed the number of doses in the fact sheet. Vaccinators Resulting volume may not provide sufficient protection. Fact sheets supersede label, carton and package insert. Tally doses used on the vial label to ensure you don't administer more than the recommended doses. Moderna 12Y+ (red cap): When extracting only booster doses, or a combination of primary series and booster doses, do not puncture vial stopper more than 20 times to prevent contamination. Follow consistent protocols if prefilling syringes for Vaccinators pharmacies or vaccination clinics. Consider dedicating a team to dispense prefilled, labeled syringes for daily vaccination clinics, and implementing an independent double check of the dilution process. Carefully follow manufacturer guidance. Remove one syringe at a time from wrapper, prefill syringe, and label before proceeding to the next. Each person administering vaccines should draw up no more than one MDV (or 10 doses) at one time. · Predraw reconstituted vaccine into a syringe only when you are ready to administer it. If predrawn vaccine is not used within 30 min of being reconstituted, follow use-by limits & discard. 10 Administer vaccines in the correct site and route. Vaccinators For 6 months through 2 years: The injection site is the vastus lateralis in the anterolateral thigh. For 3 years and older: The injection site is the deltoid muscle. For coadministration, see illustrated guidance. 11 Administer vaccine according to the manufacturer fact sheet. Vaccinators Confirm with recipient (or parent/guardian) which vaccine product and dose you are administering; double check their COVID-19 Vaccination Record Card if previously vaccinated. Distribute Fact Sheet for Recipients BEFORE administration. After administration, observe for 15 min (30 min if has history of allergic reactions or contraindications). Document administration data in My Turn or EHR connected to your local CAIR registry (CAIR2/RIDE). Give recipient Vaccination Record Card for primary series and update it for additional and booster doses. Schedule next appointment for primary series or additional/booster doses before they leave. Recommend y-safe (for wellness check-in and 2nd-dose reminder) and Digital COVID-19 Vaccination Record (for mobile proof of vaccination). In the Event of Administration Errors Refer to CDC's COVID-19 Administration Errors Revaccination Guidance to determine whether revaccination may be recommended and follow CDC's instructions for responding to administration errors.

California COVID-19 Vaccination Program

IMM-1411 (6/21/22)

IMM-1411 (6/21/22)

California COVID-19 Vaccination Program



Vaccine Administration Checklist IMM 1411

Job Aid: Reporting Inventory to VaccineFinder

Back to Inventory				
Add Vaccines to Your Inventory				
any vaccines you add to your inventory will appear automatically in your m	nost recent .csv file as well as on your manual dashboard.			
. Choose vaccines to add (select all that apply):				
Select all vaccines				
Moderna, COVID-19 Vaccine, 100mcg/0.5mL 10 dose Pfizer-BioNTech, COVID-19 Vaccine, 30 mcg/0.3mL (Moderna 12Y+ red cap) (Pfizer 12Y+ purple cap)				
Janssen, COVID-19 Vaccine, 0.5 mL	nL D Pfizer-BioNTech, COVID-19 Vaccine, 30 mcg/0.3mL, tris-sucrose (Pfizer 12Y+ gray cap)			
 Pfizer-BioNTech, COVID-19 Vaccine, 10 mcg/0.2 mL, tris-sucrose (Pfizer 5-11Y orange cap) 	Pfizer-BioNTech, COVID-19 Vaccine, 3 mcg/0.2 mL, tris-sucrose (Pfizer 6M-4Y maroon cap)			
 Pfizer-BioNTech, COMIRNATY, 30 mcg/0.3 mL, tris-sucrose (Pfizer 16Y+ gray cap) 	Moderna, COVID-19 pediatric vaccine, 25mcg/25 ml (Moderna 6M-5Y dark blue cap)			
. Choose locations where you'd like to add your selected vaccines (select a	all that apply):			
Select all locations				
Vour Clinic Name Your address				

Begin reporting infant/toddler inventory once vaccines arrive at least weekly on Fridays by close of business.

	Pfizer 6M-4Y (maroon)	Pfizer 5-11Y (orange)	Pfizer 12Y+ (gray)	Pfizer 12Y+ (purple)	Moderna 6M-5Y (dark blue)	Moderna 12Y+ (red)	Janssen (blue)
NDC	59267- 0078-4	59267- 1055-4	59267- 1025-4	59267- 1000-2	80777- 279-99	80777- 273-99	59676- 580-15
Max Doses Reported	10	10	6	6	10	10	5

Report these maximum quantities for unpunctured vials.



CDPH: Training & Resources

CDPH Immunization Branch Training and Resources

Includes:

- Program Training Requirements
- COVID-19 Vaccine Product Training
- Technical Training for New Vaccinators
 - Includes video and job aids for IZ Techniques and Patient Care for children under 5

California Department of	
PublicHealth	

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Iome | Programs | Center for Infectious Diseases | Division of Communicable Disease Control | COVID-19 Vaccine Training

IMMUNIZATION BRANCH

Vaccination Program

Program Enrollment

Vaccine Management

Vaccine Administration

Reporting Requirements

Training

Training and Resources

Required Training for Participation in the California COVID-19 Vaccination Program

Providers and key practice staff storing, handling, managing, or administering vaccines must complete the required training to meet federal and state program requirements.

Program Training

This training prepares sites to incorporate program requirements into clinic protocols and identifies key resources for use on the job. Organization & Location Coordinators must complete the required program training in myCAvax during enrollment but may access the lessons below. Review times are approximate.

Interactive Lessons	Organization* Coordinator	Location+ Coordinator
Program Requirements (15 mins) (PDF)	~	~
Orders and Distribution (5 mins) (PDF)	-	~
Storage and Handling (15 mins) (PDF)	-	~
Vaccine Management (10 mins) (PDF)	-	~
VaccineFinder (5 mins) (PDF)	\checkmark	\checkmark

* Organization Coordinators complete Section A of the provider enrollment application and are responsible for implementing vaccination program requirements for their provider organization.

† Location Coordinators complete Section B (location enrollment) and act as vaccine coordinators for their provider location.

COVID-19 Vaccine Product Training

This training shows staff how to prepare, administer, store, and handle COVID-19 vaccine products and report adverse events to VAERS. To prepare in advance of initial vaccine shipments, print and review summary sheets– only for products your location will be ordering. Review times vary by learner role & technical experience.

Highlight: Technical

Highlight includes:

- Supplies
- Immunization Techniques
 - Intramuscular (IM) injections
- Patient Care
- Patient Education

The following resources provide technical instruction for COVID-19 vaccine administration that is not included in the required program training. New vaccinators should work with their supervisors to obtain hands-on training and arrange for supervision until proficiency is demonstrated.

Topic	Resources	
Supplies	 Preparing Multi-dose Vials video Low Dead-Volume Syringes/Needles: Optimizing Preparation and Safety job aid VanishPoint[®] Syringe video Safe and Proper Sharps Disposal job aid Strategies During Supply Shortages job aid Needle Gauge and Length job aid 	
Immunization Techniques	Intramuscular (IM) Injections	
	Identifying IM Injections Sites for All Ages: 5-minute Video	
	Adults	
	 Adults 19 years of age and older: PDF Video 	
	Older Children & Teens	
	Children: 7 – 18 years (PDF) Vaccinating Adolescents (PDF)	
	Coadministration Tips: Ages 5+ Years (PDF)	
	Infants & Young Children	
	 Babies: PDF Video Giving All the Doses Under 12 Months 12 Months and Older (PDF) 	
	 Infants 11 months of age and younger (PDF) 	
	Children 1 through 2 years of age (PDF) Children 3 through 6 years of age (PDF)	
	Proficiency	
	Skills Checklist for Vaccine Administration job aid (PDF)	
	 Injection Safety job aid (PDF) 	
	Vaccine Administration Checklist (PDF)	
	Preventing Administration Errors (PDF)	
Patient Care	 Tips to Ease Anxiety During Vaccination: 	
	Babies & Toddlers Older Children & Adults (PDF)	
	 How to Hold Your Child During Vaccination Pre-vaccination Screening Questionnaires (multiple languages on CDC 	
	COVID-19 Vaccine Product Information website by product)	
	Medical Management of Vaccine Reactions in Children and Teens in a	
	Community Setting (PDF)	
Patient Education	EUA Vaccine Fact Sheet for Recipients:	
	Pfizer-BioNTech Moderna (PDF) Janssen (PDF)	

Coming Soon: COVID-19 Vaccine Product Training*

See highlighted links to CDC product summary sheets, which summarize EUA fact sheets.

Training includes COVID-19 Vaccine

- Preparation & Administration
- Contraindications and Precautions
- Reporting Doses & Adverse Events
- Storage & Handling

COVID-19 Vaccine Product Training

This training shows staff how to prepare, administer, store, and handle COVID-19 vaccine products and report adverse events to VAERS. To prepare in advance of initial vaccine shipments, print and review summary sheets only for products your location will be ordering. Review times vary by learner role & technical experience.

Pfizer-BioNtech	Location Coordinator	Vaccinator	Provider
 Vaccine Preparation & Administration Ages 6M-4Y Ages 5-11 Ages 12+ (PDF) Mixing Diluent & Vaccine (PDF) Storage & Handling: Ages 6M-4Y Ages 5-11 Ages 12+ (PDF) 	~		
Delivery Checklist (PDF)	1	-	H
Moderna	Location	Vaccinator	Provider
	Coordinator		Provider

Tips: Ease Vaccine Anxiety

Distract-Reduce stress and ease pain. **Comfort**-Remain calm and stay positive Educate-Manage pain and side effects.

Tips to Ease Anxiety During Vaccination

People of all ages may experience stress or anxiety when getting vaccinated. It's important to give patients adequate opportunity to express fears and ask guestions. Health care staff can help by suggesting these strategies or encouraging them to use their existing coping skills to reduce anxiety.



DISTRACT: Reduce stress and ease pain.

- Interact warmly with the patient throughout the appointment.
- Point out interesting things in the room or ask them to count all the blue items they see. Tell a story. Ask them to wiggle their toes or tighten and release muscles in their face, hands, or legs.
- Suggest they play a game, watch a video, listen to music, or imagine their favorite place. Parents can try talking or singing to their child.
- Tell them to take slow, deep breaths during vaccination. Children can blow bubbles (imaginary or real) to help them take big breaths.
- Remind them to stay focused on the distraction strategy if their attention wanders.



COMFORT: Remain calm and stay positive.

- Reassure them that it may sting, but it will only last a few seconds. (Consider using topical anesthetic before vaccination, if appropriate. Allow for time to take effect.)
- Though a seated position is preferred for vaccination, those with anxiety may lie down. Remind them to relax their arms and shoulders.
- Adults may wish to bring a support person or have a friendly hand to squeeze. Parents may hold their child on their lap during vaccination and cuddle them after.
- Allow children to cry don't force them to "be brave."
- Reward young patients with a sticker or colorful Band-Aid. Parents may offer to take them to the park or to get a treat.
- Give positive reinforcement-tell them they did something good by protecting themselves and those around them.

California COVID-19 Vaccination Program



Vaccinate ALL 58

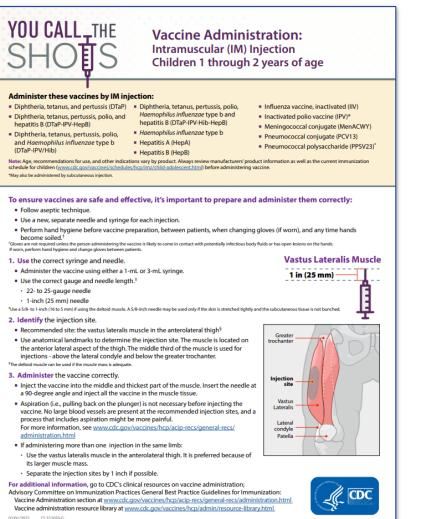
EDUCATE: Manage pain and side effects.

- Inform patients or their parents that they may experience mild side effects that should go away within a few days. This is a normal sign that their body is building immunity.
- Common side effects include soreness, redness or swelling where they got the shot, feeling tired, headache, muscle pain, chills, fever, or nausea.
- Apply a cool, wet cloth to the area to reduce any soreness where the vaccine was administered. Use or exercise the arm
- Advise on what pain relievers can be used to help alleviate soreness or other side effects. Aspirin is not recommended for children and adolescents. Instead, use acetaminophen (e.g., Tylenol) or ibuprofen (e.g., Advil, Motrin).



Under 3 Years:

Vastus Lateralis



Deltoid YOU CALL_THE Vaccine Administration: Intramuscular (IM) Injection Children 3 through 6 years of age Administer these vaccines by IM injection: Diphtheria, tetanus, and pertussis (DTaP) Diphtheria, tetanus, pertussis, polio, Influenza vaccine, inactivated (IIV) Haemophilus Influenzae type b and Diphtheria, tetanus, pertussis, and polio Inactivated polio vaccine (IPV)* hepatitis B (DTaP-IPV-Hib-HepB) (DTaP-IPV) Meningococcal conjugate (MenACWY) Haemophilus Influenzae type b Diphtheria, tetanus, pertussis, polio, and Pneumococcal conjugate (PCV13) hepatitis B (DTaP-IPV-HepB) Hepatitis A (HepA) Pneumococcal polysaccharide (PPSV23)* Diphtheria, tetanus, pertussis, polio, and Hepatitis B (HepB) Haemophilus Influenzae type b (DTaP-IPV/Hib) Note: Age, recommendations for use, and other indications vary by product. Always review manufacturers' product information as well as the current immunization schedule for children (www.cdc.gov/vaccines/schedu dolescent.html) before administering vaccine. *May also be administered by subcutaneous injection. To ensure vaccines are safe and effective, it's important to prepare and administer them correctly: Follow asentic technique Use a new, separate needle and syringe for each injection. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.[†] Gioves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands If worn, perform hand hygiene and change gloves between pa Use the correct syringe and needle. 5/8 in (16mm) -1 in (25 mm) -Administer the vaccine using either a 1-mL or 3-mL syringe Use the correct gauge and needle length.[‡] If the skin is stretched tightly and the subcutaneous 22- to 25-gauge needle tissues are not bunched 5/8- to 1-inch (16 to 25 mm) needle ⁸Use a 1- to 1.25-inch (25-32 mm) needle if administering vaccine in the vastus lateralis muscle in the anterolateral third 2. Identify the injection site. Preferred site: the deltoid muscle in the upper arm⁵ Use anatomical landmarks to determine the injection site. The deltoid muscle is Scapula a large, rounded, triangular shape. Find the acromion process, which is the bony point at the end of the shoulder. The injection site will be below the hone and Acromion above the axillary fold/armpit. Injection process ⁵The vastus lateralis muscle in the anterolateral thigh can also be used. site Deltoid muscle Inject the vaccine into the middle and thickest part of the muscle. Insert the Axillary fold/ armpit Humerus For more information, see www.cdc.gov/vaccines/hcp/acip-recs/general-recs/ This muscle is preferred for young children because of its larger muscle mass. For additional information, go to CDC's clinical resources on vaccine administration SC CDC

3 Years and Over:

Preferred Injection Sites

Vaccinate

CDPH Training and Resources: Immunization Techniques, Infants & Young Children

11 months of age and younger

1 through 2 years of age

3 through 6 years of age

11/01/2021 CS 322033-H

Administer the vaccine correctly.

- needle at a 90-degree angle and inject all the vaccine in the muscle tissue. Aspiration (i.e., pulling back on the plunger) is not necessary before injecting the vaccine. No large blood vessels are present at the recommended injection sites, and a process that includes aspiration might be more painful.
- administration.htm
- If administering more than one IM injection:
- Use the vastus lateralis muscle in the anterolateral thigh for young children. Separate the injection sites by 1 inch if possible.

Advisory Committee on Immunization Practices General Best Practice Guidelines for Immunizations: Vaccine Administration section at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.htm Vaccine administration resource library at www.cdc.gov/vaccines/hcp/admin/resource-library.html

Comforting Restraint Positions

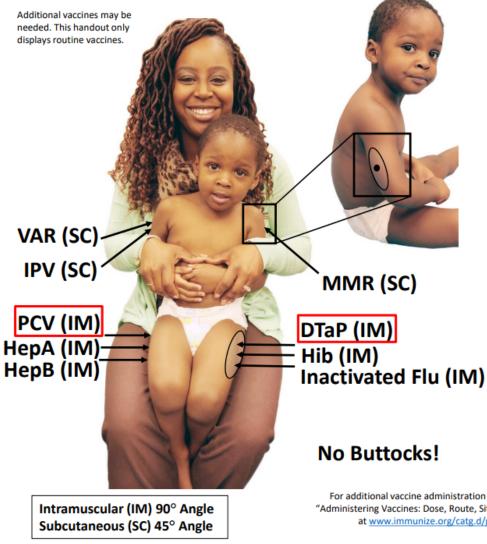


Infants and Toddlers



Older Children

Giving All the Doses 12 Months and Older



- **IM** injections are given in the anterolateral thigh (preferred site for 12 mos.-2 yrs.) using a 1" needle
 - Separate IM injection sites by a minimum of 1"
 - Deltoid is preferred IM site for 3 yrs. and older
 - · Anterolateral thigh is an alternative site if deltoid cannot be used
- **SC** injections are given in the upper outer triceps area or thigh using a 5/8" needle (see • to the left for placement in triceps area)
- Using combination vaccines decreases the number of injections
 - IPV must be given IM when given as a combination vaccine (e.g., DTaP-IPV/Hib, DTaP-IPV-HepB)
- Give vaccines likely to cause greater local reaction (e.g., DTaP, PCV) into separate limbs
- Give the most painful injections last (e.g., MMR, PCV)

For additional vaccine administration information see: "Administering Vaccines: Dose, Route, Site, and Needle Size" at www.immunize.org/catg.d/p3085.pdf





CDPH Training and Resources: Immunization Techniques, Infants & Young Children

How to Hold Your Child during Vaccinations | CDC

Giving All the Doses (aimtoolkit.org)

Archived: COVID-19 Crucial Conversations

Talking with Parents About COVID-19 Vaccines for Children

Eric Ball, MD, FAAFP

#ThisIsOurShot, American Academy of Pediatrics (AAP-CA), Children's Immunization Coalition (CIC)





Crucial Conversations: Talking With Parents About COVID-19 Vaccine

Language to Use with Parents

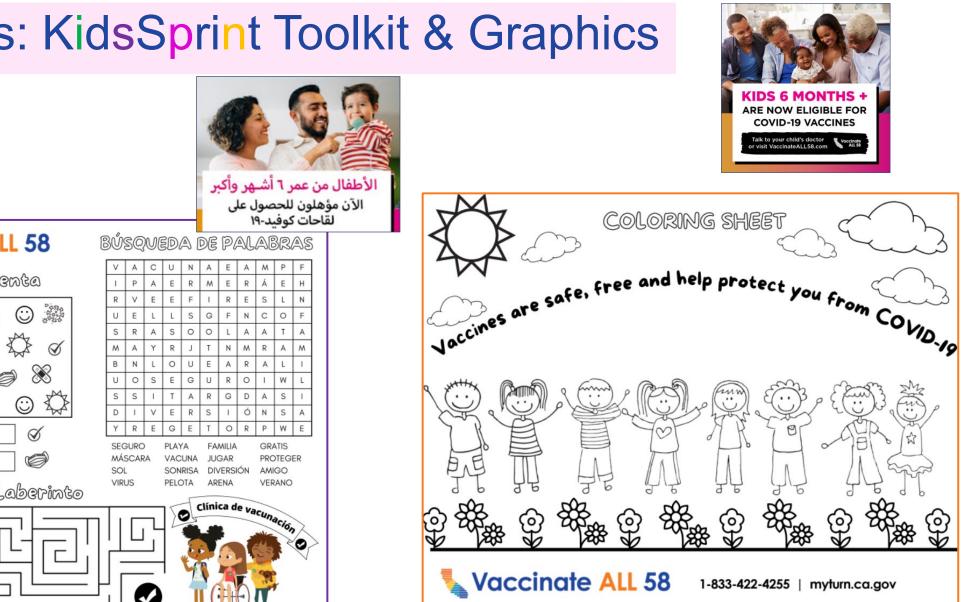
Do Say	Don't Say		
Vaccination	Injection or shot		
A safe and effective vaccine	A vaccine developed quickly		
Authorized by FDA based on clinical testing	Approved by FDA; Operation Warp Speed; Emergency Use Authorization*		
Get the latest information.	There are things we still don't know.		
Keep your family safe; keep those most vulnerable safe.	Keep your country safe.		
Public Health	Government		
Health/medical experts and doctors	Scientists		
People who have questions	People who are hesitant, skeptical, resistant, or "anti- vaxxers"		

* The perceived speed of vaccine development is a current barrier among many audiences. These recommendations are based partly on research conducted by the de Beaumont Foundation.

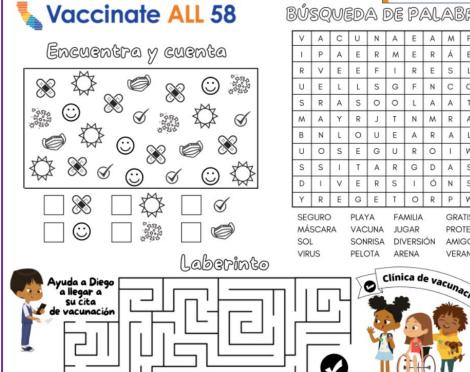


American Academyof Pediatrics CALIFORNIA





Resources: KidsSprint Toolkit & Graphics



Infant/Toddler Toolkit

ДЕТИ ОТ 6 МЕСЯЦЕВ И СТАРШЕ

ТЕПЕРЬ ИМЕЮТ ПРАВО НА ПОЛУЧЕНИЕ ВАКЦИН ОТ КОВИД-19

Vaccinate

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Youth and KidsSprint Resources

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Additional Support

Type of Support		Support	Description	Updated 6.6.22
K		COVID-19 Provider Call Center	The COVID-19 Call Center for Providers and Local Health Departments is dedicated to medical provider their COVID-19 response, specifically addressing questions about State program requirements, enrollmed distribution, including the Vaccine Marketplace.	
(\sim γ		Email: <u>covidcallcenter@cdph.ca.gov</u>	
			Phone: (833) 502-1245, Monday through Friday from 8AM–6PM	
	\mathcal{A}	Enrollment Support	For Provider enrollment support, please contact myCAvax Clinic Operations at	
			Email: myCAvaxinfo@cdph.ca.gov	
			Dedicated staff provide up-to-date information and technical support on the myCAvax system.	
		myCAvax Help Desk	Email: myCAvax.HD@Accenture.com	
	\Box^{\prime}		 Phone: (833)-502-1245, option 3, Monday through Friday 8AM–6PM 	
			For training opportunities: <u>https://eziz.org/covid/education/</u>	
		My Turn Clinic Help Desk	For onboarding support (those in the process of onboarding): <u>myturnonboarding@cdph.ca.gov</u>	
			For technical support with My Turn Clinic for COVID-19 and flu vaccines: <u>MyTurn.Clinic.HD@Accentur</u> (833) 502-1245, option 4: Monday through Friday 8AM–6PM	<u>e.com</u> or
			For job aids, demos, and training opportunities: flu at <u>https://eziz.org/covid/myturn/flu/</u> and COVID at <u>https</u>	://eziz.org/covid/myturn/
		Archived Communications	For archived communications from the COVID-19 Provider Call Center about the California COVID-19 V visit Website: EZIZ Archived Communications 	accination Program





Thank you for protecting California's children!

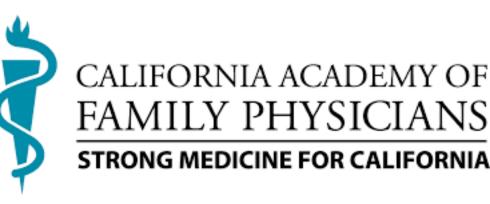




American Academyof Pediatrics CALIFORNIA Incorporated in California

Stay tuned for future COVID Conversations





Thank you for your support and your participation!

You can find all previous Covid Conversations on our YouTube channel

https://www.youtube.com/channel/UCklkZ1SZQNQLcpmNpeQpDAg

www.ImmunizeCA.org/Covid-19-Updates