COVID-19 Vaccination Update For Building Bridges To Healthy & Resilient Communities

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Authorized and Approved COVID Vaccines 2021

Pfizer-BioNTech COVID-19 Vaccine

2-dose primary series

- FDA EUA expanded to 5-11 yrs
- July 2021 – Full FDA approval for
- ages 16+
- May 2021 – EUA for ages 12-15
- Dec 2020 – EUA for ages 16+

Over 236 million doses administered

Moderna COVID-19 Vaccine

2-dose primary series

- Dec 2020 – EUA for ages 18+

Over 154 million doses administered

Janssen (J&J) COVID-19 Vaccine

1-dose primary series

- Booster after 2 months
- EUA 18+ years

Over 15 million doses administered

Vaccination Progress – USA

Total Vaccine Doses

Delivered 503,418,475

Administered 414,302,192

Learn more about the distribution of vaccines.

190.7M
People fully vaccinated

13.3M
People received a booster dose**

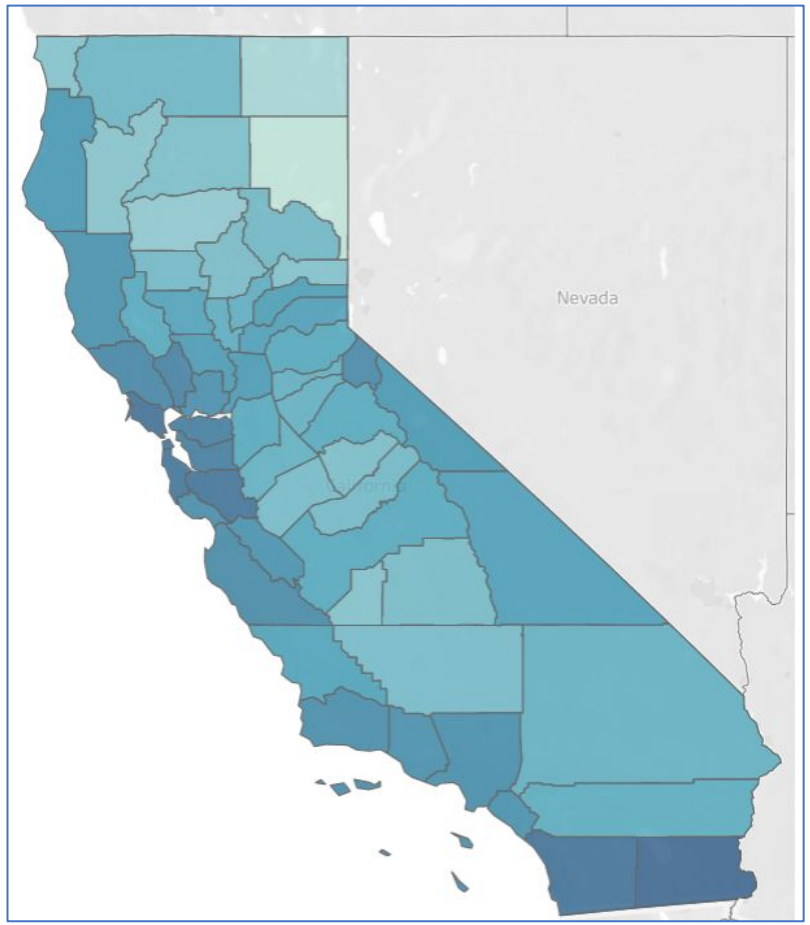
At Least One Dose	Fully Vaccinated	Booster Dose
Fully Vaccinated* People	Count	Percent of US Population
Total	190,699,790	57.4%
Population ≥ 12 Years of Age	190,566,551	67.2%
Population ≥ 18 Years of Age	178,145,538	69%
Population ≥ 65 Years of Age	46,334,975	84.7%

* For surveillance purposes, COVID Data Tracker counts people as being “fully vaccinated” if they received two doses on different days (regardless of time interval) of the two-dose mRNA series or received one dose of a single-dose vaccine.
** The count of people who received a booster dose includes anyone who is fully vaccinated and has received another dose of COVID-19 vaccine since August 13, 2021. This includes people who received booster doses and people who received additional doses.

Vaccination Progress – CA

- 73% eligible population fully vaccinated (24,640,044 persons)
- 7.8% partially vaccinated (2,643,884)
  - Achieved June target of 70% vaccination in September
- Over 58% of kids 12-17 years vaccinated
- 1.9 million booster doses administered

Current Adolescent COVID-19 Vaccine Coverage



As of 10/19/21:

- 63.3% of CA's 12-15 year olds have received at least one dose and 57.1% are fully vaccinated.
- 71.45% of CA's 16-17 year olds have received at least one dose and 64.5% are fully vaccinated.
- 34% of CA's 12-17 year olds remain unvaccinated – 1,072,526 individuals
- 80.5% of CA's 12+ population has received at least one dose with 73% fully vaccinated

#relentlessincrementalism

Vaccine Effectiveness

- Challenges in assessing whether increased breakthrough infections due more to waning effectiveness over time vs. delta becoming the dominant strain
- Vaccines reduce risk of infection but more effective at preventing severe disease
- Effectiveness somewhat less in the elderly
  - True with other vaccines also
- Effectiveness much less in some people with weakened immune systems

Vaccine Effectiveness

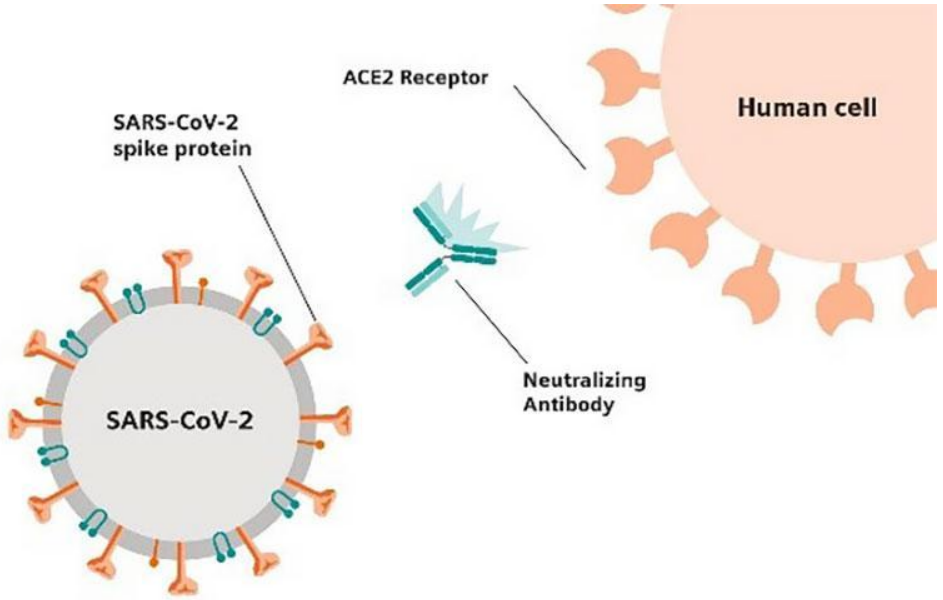
- Effectiveness of mRNA vaccines in particular for preventing severe outcomes (hospitalizations and death) is high and sustained
  - 85-90+%
- Effectiveness at preventing *infection* somewhat less and more evidence of waning over time
- Vaccinated persons are 10-20 times less likely to be hospitalized or die than unvaccinated people
- Risk of infection per se 4-8 times less

Immune System Reaction to Viral Infection or Vaccination

- Central role of lymphocytes
  - B lymphocytes - antibody production (humoral immunity)
  - T lymphocytes - complex roles, multiple subtypes (cellular immunity)
- Lymphocytes work together to learn to recognize and respond to a new threat. Takes some time for mature effective response
- A race between immune system and replicating invading pathogen
- Memory cells (B and T) persist after exposure to pathogen so we can respond better if there is a next time

Antibody Response

- Lag time exists between initial infection and antibody production
- Antibodies are formed against different molecular parts of the invading organism
- Some antibodies more effective than others
- “Neutralizing antibodies” against SARS-CoV-2 block the part of the spike protein that binds to our cells
- Antibody effectiveness at preventing infection depends on the relative amounts (concentrations) of neutralizing antibodies versus the number of virus particles



Antibody Concentrations Matter

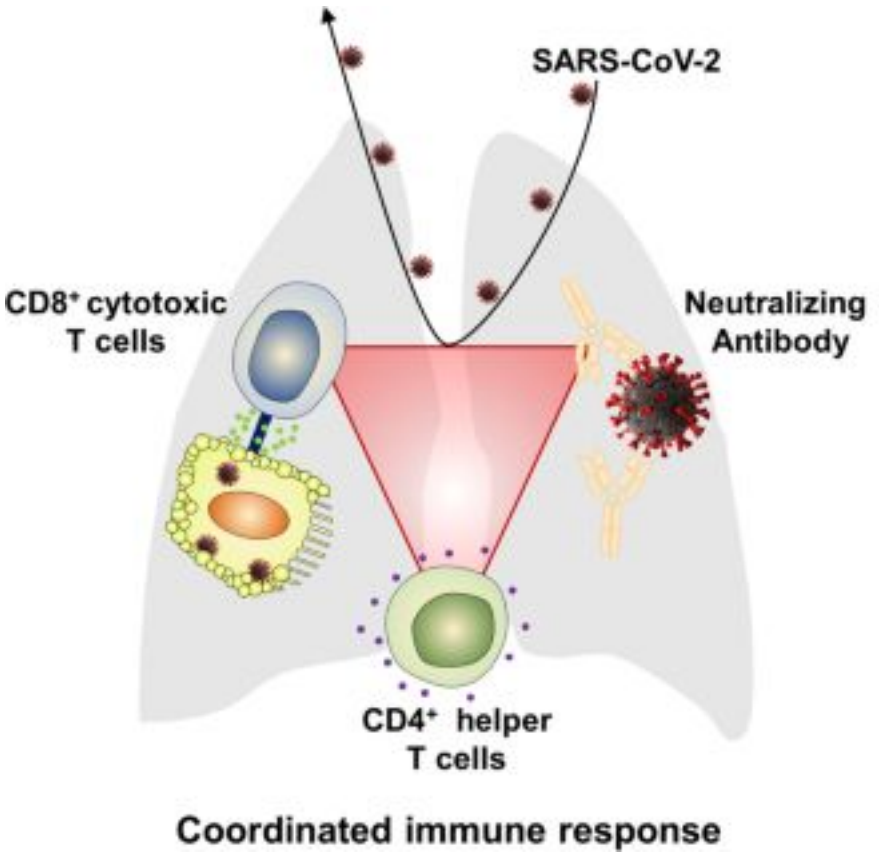
- If neutralizing antibody levels are sufficiently high to bind (attach) to most of the virions (viral particles) infection will be blocked
- Antibody levels peak a few weeks after infection or vaccination and naturally decline over time
  - Most IgG antibodies have half-life of 3 weeks
- Antibody levels in blood generally not the same as antibody levels in tissues such as upper respiratory tract where virus will establish infection
  - Concept of “**compartments**” of the immune system

Memory Cells Expedite Immune Response

- Having B and T memory cells primed by vaccination or prior infection to respond to future SARS CoV-2 infection cuts the time needed to respond effectively
- Antibody production begins more quickly after infection, rapidly augmenting existing antibody levels
- Primed T cells often can attenuate progression of infection, preventing spread of infection into the lungs

Immune System Better at Attenuating Reinfections than Preventing them Completely

- Immune response to natural infection and vaccination are fundamentally similar
- In the absence of ongoing re-exposure our bodies do not continue to produce large numbers of antibodies
- With SARS CoV-2 both vaccination and natural infection produce valuable levels immunity
- Duration of immunity uncertain
  - Individual variation expected, normal
  - May vary by variant strain



Comparing Naturally Acquired Immunity to Vaccination Protection

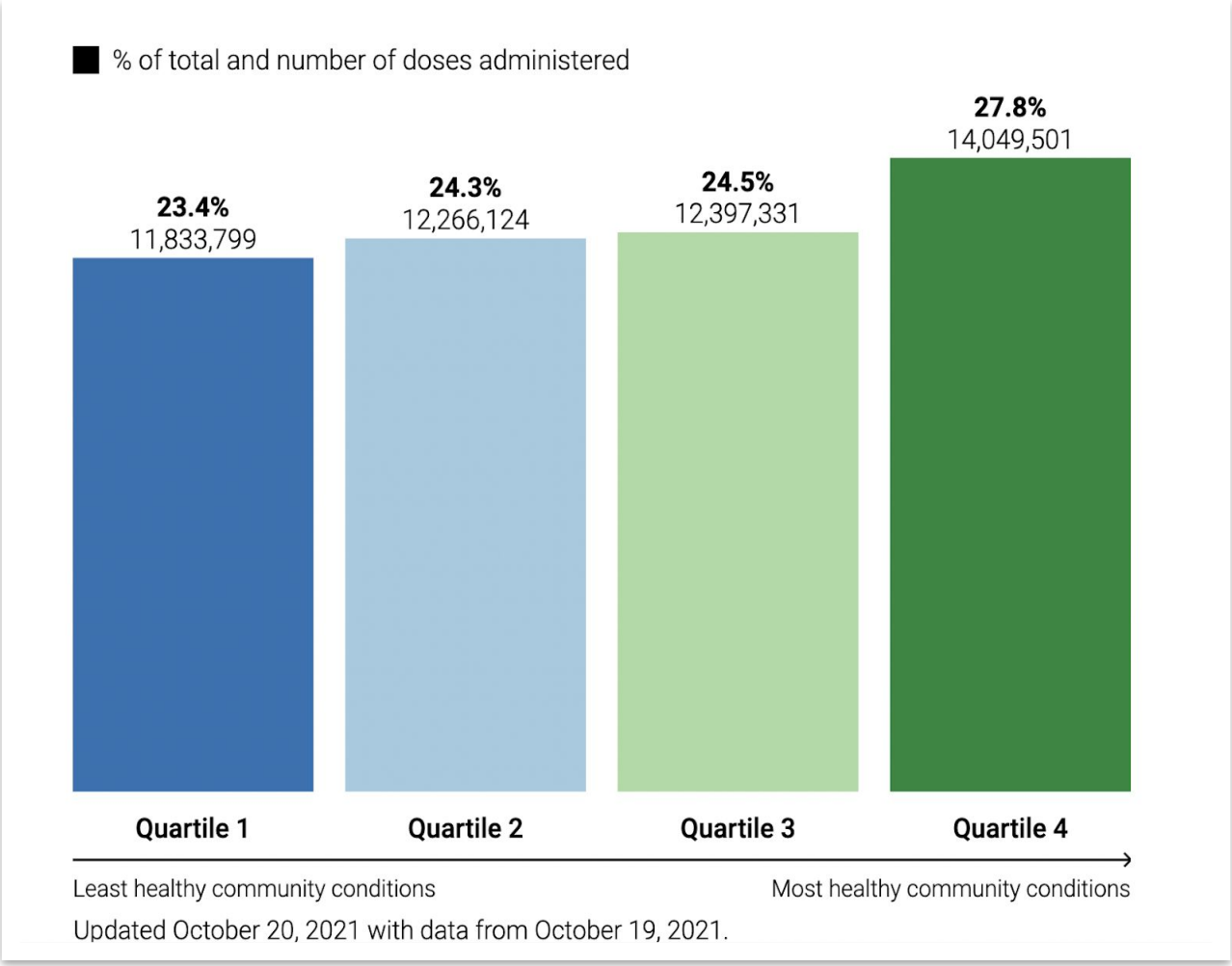
- Challenging. Studies report varying results
- Vaccination appears to produce **more consistent** level of immunity, reduced variation between individuals
- Some evidence that vaccination may provide better protection against variants (**broader** immune response)
- Some countries accept evidence of infection in lieu of vaccination as proof of relative immunity
- CDC and CDPH have yet to embrace this concept

Vaccination Challenges

- Reducing disparities
- Countering hesitancy and misinformation
  - Heterogeneity
- Less dependance on mass vaccination sites

Vaccination Inequities

- Substantial disparities by:
  - Income/Healthy Places Index
  - Race/ethnicity
  - Jurisdiction/geography
  - Health insurance (Medi-Cal gap)
  - Political affiliation
  - Rural vs urban



Pediatric Burden of COVID-19

- Children are about as likely to be infected by the coronavirus but less likely for infections to be recognized
- Rates of severe disease substantially lower
- 6-7 million recognized US pediatric infections to date
- Approaching 9,000 hospitalizations
- Over 790 deaths
- Over 5,000 additional MIS-C cases
  - MIS-C is serious complication of COVID, often resulting in ICU admission
- Uncertain number/percentage of kids with long-lasting symptoms

Social and Mental Health Impacts on Children

- Epidemic loss of parents and caregivers
  - Over 140,000 children have lost a parent or secondary caregiver
- Mental health toll is high
  - Growing number of studies assessing the adverse mental health effects of pandemic on children's mental health

Expected Benefits of Pediatric Vaccination

- Reduce child morbidity and mortality
- Children have highest case-rate in recent months
- Children of all ages transmit infection to others
- Reducing infections in children will benefit children and those around them
- Reducing infection rates in children better enable school operations

Vaccine Availability For Children: Pfizer

- Pfizer fully approved for 16 years and older
- Pfizer EUA expanded in May for 12-to-15-year-olds
  - Two 30 mcg doses 21 days apart
- Pfizer EUA just expanded a few days ago for 5-to-11-year-olds
  - CDC/ACIP recommendations pending – Nov 2, 2021
  - Two 10 mcg doses 21 days apart
  - Separate formulation with different storage and mixing requirements

What We Anticipate

- Next steps for EUA of 5-11-year-old COVID-19 vaccine **today**:
  - Advisory Committee on Immunization Practices (ACIP) | CDC
  - CDC Director announcement of recommendations
  - Western States Scientific Safety Review Workgroup
- 3.6 Million 5-11 year olds in California
- Probably about 1/3 of parents will rapidly seek immunization
- Rest will be slower to embrace
- Primary care provider community essential
- School mandate

Pediatric COVID Vaccination is Effective and Safe

- Vaccine effectiveness in kids is comparable to that seen in adults
- Recent real-world studies demonstrate effectiveness in adolescents (in delta context)
- Pfizer trial results presented to FDA shows 90-91% short-term vaccine effectiveness in 5-11year olds
- Trial data reflects delta predominance
- No safety signals in the primary trials
  - Trials small for evaluating rare risks

COVID Vaccine Safety in Children

- Transient “reactogenic” side effects are relatively common and expected
  - Local and systemic symptoms in the day or days following vaccination (sore arms, fatigue, headache, etc)
  - Generally not severe
  - Reflect normal immune reaction
- Myopericarditis-cardiac inflammation

Myocarditis

- Inflammation of heart muscle (myocardium) recognized as a safety issue and is being closely monitored
- Myocarditis occurs naturally but not commonly, often as a complication of viral and other infections
  - Young males, adolescents and young adults, are most likely to experience myocarditis
  - Severity varies from mild to life-threatening
  - More commonly seen with COVID infection than vaccination
- Severity after COVID vaccination is generally mild but evaluation is continuing
  - Most people recover quickly with minimal treatment
  - Many admitted to hospital for observation

Myocarditis Associated with mRNA COVID Vaccines

- Rare; Usually associated with second dose
- Israeli study cited in Pfizer application to FDA found highest rate in males 20-24 years old
- Rate among adolescents in Israel around 1/100,000 persons
- Rate in U.S. study about 5/100,000 among 12-17 year olds
- Rates in kids 12-15 y.o. half the rate in older adolescents

Is Myocarditis a Risk in 5-11 year olds?

- Unknown but less risk may exist
- Myocarditis less common naturally in this age group
- Risks appear to decrease from early/mid 20s toward younger ages among vaccine recipients
  - Rate in 12-15 year olds is lower than in older teenagers
- Dose in younger kids is 2/3 lower
- No cases seen in Pfizer trial of approximately 4500 children
- Close monitoring is planned

FDA estimated benefits and risks in 5-11year olds

- Assuming that: COVID rates similar to September 2021 and risk of myocarditis identical to that seen in 12-15 year olds in Israel:
- For every 1 million 5-11 year olds immunized
- 33,600 COVID cases prevented
- 170 hospitalizations prevented
  - Plus MIS-C cases prevented (half occur in this age group)
- 21 cases of myocarditis expected (double that if analysis excludes girls and focuses on 1 million boys)

Immediate Hypersensitivity Reactions

- Risk of anaphylaxis with COVID shots exists
- In real world use has proven very rare, only slightly more common than is seen with vaccines in common use, e.g. flu shots
- Federal rules stipulate that people be observed for at least 15 minutes after vaccination
- Vaccinators should be familiar with treatment of anaphylactic reactions and have access to epinephrine

Fainting and anxiety reactions

- Fainting after shots or blood draws is more common among teenagers than other persons
- Recommended that vaccinators serving this age group be prepared to deal with scenario of kid feeling faint after administration
- Have someplace where someone can easily lie down
- See "Tips to Ease Anxiety During Vaccination" job aid

Pediatric Vaccine Formulations

- 12-17 year olds receive adult formulation
- Different vial/formulation, not to be interchanged
  - Color coded vials to reduce confusion
- Different diluent volumes
  - Future formulation for older kids and adults won't require mixing/dilution
- 30 mcg (0.3 ml)
- 5-11 year olds receive 10 mcg (0.2 cc)

Storage and Handling

- Shipped at ultralow temps and may stored in ULT freezer for entire shelf life
- After removal from ULT storage rules differ between little kid and adolescent/formulations
  - Concerns about error potential
- For both/all formulations vial is good for only 6 hours after being punctured/mixed
- Wastage is unavoidable in many situations

COVID-19 Vaccine Product Guide

Vaccinate ALL 58

Check vaccine products before use to ensure administration to appropriate ages.

Refer to CDC product info for more details.

	5-11 years old	12+ years old		18+ years old	
	Pfizer	Pfizer	Pfizer (Comirnaty)	Janssen (J&J)	Moderna
	Pending Approval	Currently Available	Pending Approval		
					
	subject to change		subject to change		
Packaging					
Cap color	Orange cap	Purple	Gray cap	Blue cap	Red cap
Doses per vial	10 doses	6 doses	6 doses	5 doses	14 (or 10) doses
Package size	100 doses	1170 (or 450) doses	TBD	50 doses	140 (or 100) doses
NDC # in VTrckS	95267-1055-04	59267-1000-02	TBD	59676-0580-15	80777-0273-98
Administration					
Diluent	1.3 mL per vial	1.8 mL per vial	Do not mix	Do not mix	Do not mix
Injection Volume–Primary	0.2 mL	0.3 mL	0.3 mL	0.5 mL	0.5 mL
Injection Volume–Booster	N/A	same	TBD	same	0.25 mL*
Storage Limits**	(Store products on different shelves, labeled by age, to avoid mix-ups.)				
ULT (-90 to -60ºC)	Up to 6 months†	Up to 9 months	Up to 6 months†	N/A	N/A
Thermal Shipper	N/A	Up to 30 days	N/A	N/A	N/A
Freezer	N/A	Up to 14 days (-25 to -15ºC)	N/A	N/A	Until expiration (-50 to -15ºC)
Refrigerator (2º to 8ºC)	Up to 10 weeks†	Up to 31 days	Up to 10 weeks†	Until expiration	Up to 30 days

* When drawing up half-doses for Moderna boosters, note that Moderna vials cannot be punctured more than 20 times.
** Do not dispose of expired vaccine until checking with manufacturers for extended expiration dates.
† Regardless of storage condition, do not use vaccine after 6 months from manufacture date printed on vial/cartons.

California COVID-19 Vaccination Program

IMM-1399 (10/22/21)

Link to job aid

Access to Pediatric COVID-19 Vaccine in CA

- Ongoing effort to recruit more pediatric vaccination providers into myCAvax COVID vaccination program
  - Over 4000 vaccinators of children enrolled
  - Focus on Vaccines For Children (VFC) providers
  - Ensuring equitable distribution of new pediatric vaccine
- Local Health Departments will play key role in many areas
- Encouraging pharmacies to provide vaccination services to younger children
- Promotion and support of School-located Vaccination Events

Immunizing Kids In Schools

- Important strategy to facilitate pediatric vaccination
- Potential to improve both equity and vaccination coverage
- Best practice is to offer immunization to students, family and staff
- Co-administer flu and other appropriate vaccines when possible
- Varied approaches to immunizing in school settings

Immunizing Kids in Schools

- Pop-Up vaccination events
  - Some schools/districts have capacity to implement
  - Others conducted in partnership with local health departments, medical practices/clinics, pharmacies, schools of nursing or pharmacy, state vaccination contractors
  - State-funded vaccination contractors are available for school-located vaccination upon request
- School-Based Health Centers

Support For School-Located Vaccination

- State or LHD may provide team to conduct SLV event at your school
- Request mobile clinic or pop-up
- Toolkits, webinars and communication resources
- Receive incentives by enrolling as a COVID-19 vaccination provide through the CalVaxGrant Program
- MyTurn.com for scheduling, registration and reporting to registry
- Future funding for school vaccination staff

Consent for Pediatric COVID-19 Vaccination in CA

- Parents not required to be physically present if signed consent is provided.
- Must receive vaccine information
- MyTurn permits electronic consent
- CA permits parents to consent verbally via digital video platforms, e.g., FaceTime, WhatsApp, etc.

School-Based Health Centers and Schools/Districts Encouraged to Enroll in myCAvax

- myCAvax is CA's COVID-19 vaccine management system
- Application/enrollment takes a little time and effort
  - Both federal and state requirements
- CDPH staff available to provide assistance via COVID-19 Provider Call Center at (833) 502-1245
- Grant program (administered by Physicians For A Healthy California) provides funds to offset costs of enrollment and providing COVID vaccination. Deadline extended – now December 17th.
  - $10,000 per site up to 5 sites for a practice
- EZIZ.org/COVID provides information about myCAvax and grant program

Resources

- Resources for School-located Vaccination Against COVID-19 and Other Diseases (turnkey options, staffing, equipment, technical assistance, etc.).
- Toolkit, created in partnership with California Immunization Coalition.
- Schools eligible for CalVaxGrant program! (effective 8/13/21 - deadline extended to December)
- Technical assistance webinars and availability of subject matter experts.
- Many more long-term supports (IZ Champions, ShotsforSchool.org and CAIR enhancements, training resources).
- Safe Schools for All Hub

ShotsforSchool.org

ShotsforSchool

Child Care | K-12 | 7TH Grade | College | Laws

School-located Vaccination

- Shots Required for K-12
- Transitional Kindergarten FAQs
- Tools for Schools
- Kindergarten School Reporting Data
- School-located Vaccination
- How Is Your School Doing?
- All Required Vaccines Rate FAQs
- Audit

ShotsForSchool > Shots Required for K-12 > School-located Vaccination

Resources for School-located Vaccination Against COVID-19 and Other Diseases

Local Health Jurisdictions, school districts and individual schools all play a significant role in the collective effort to keep students healthy and in school. The California Department of Public Health (CDPH) continues to build resources to support school-located vaccine (SLV) clinics for COVID-19 vaccine, seasonal influenza vaccine and other routine immunizations.

Benefits of SLV clinics include:

- the ability to immunize large numbers of children in a short timeframe
- increasing access to underserved students and their families by making vaccination more convenient
- decreasing illness-specific school absences and lowering disease transmission and hospitalization rates in surrounding communities
- maximizing opportunities for students and families to stay up-to-date on recommended vaccines

Resources for schools and local health jurisdictions:

- Request a team of personnel (vaccinators, admin, data entry) to put on a vaccine event at your school.* Schools should contact their local health jurisdiction and ask them to request staff via MHOACs.
- Request a mobile or pop-up clinic to come to a school to administer vaccines.*
- Request a pharmacy to come to a school to administer vaccines.
- Request volunteers for your COVID-19 vaccination site.
- Schools may consider enrolling as a COVID-19 Vaccine Provider and receive incentives from the CalVaxGrant Program.
- Reach out to your local health department to discuss planning of a school-located vaccine clinic.
- School-Located Influenza Vaccination Toolkit (NACCHO)
- School COVID-19 Vaccination Toolkit (HHS)
- Tips for Successful Vaccine Partnerships (School Based Health Alliance)
- "Shoo the Flu" Campaign Toolkit

For general guidance (including equipment needs) for planning school-located vaccine clinics, email SchoolVaxTeam@cdph.ca.gov.

*At no cost to school or local health jurisdiction, for school located events only, until funding limit is reached.

CDPH California Department of Public Health

This website contains information about immunizations required for school entry in California.
View CDPH's privacy policy

Acknowledgments/Information Sources

- CDC.gov
- CDPH.ca.gov
- EZIZ.org/covid
- FDA VRBPAC briefing document for Pfizer application to expand EUA to 5-11 y.o. https://www.fda.gov/media/153409/download

Thank you for listening

Questions?