

Overview

The County of San Bernardino and Arrowhead Regional Medical Center are committed to implementing a comprehensive COVID-19 vaccination process based on federal, state and local guidelines established by the Centers for Disease Control and Prevention (CDC), California Department of Public Health (CDPH) and the San Bernardino County COVID-19 Vaccination Task Force. The following are Frequently Asked Questions (FAQs) that provide current information about the upcoming COVID-19 vaccinations and phased rollout to communities served by the County.

Topics Covered at a Glance

- Vaccine testing process and current vaccines under development
- Timing of vaccine availability and phases of vaccine allocation
- Safety of the vaccine and administering of shots
- Links to information resources

Vaccine Testing Process and Current Vaccines Under Development

What are the key phases of clinical trials for a COVID-19 vaccine leading to Federal Drug Administration approval?

There are three key phases leading up to limited use and full use approval for a vaccine. According to the [Federal Drug Administration \(FDA\)](#), they are as follows:

Phase 1 – Vaccines are administered by scientists to 20 to 100 healthy volunteers. Researchers answer questions related to how the drug works in the body, the side effects associated with increased dosage, and early information about how effective it is to determine and how best to administer the drug to limit risks and maximize possible benefits.

Phase 2 – Vaccines are administered by scientists to several hundred volunteers. Phase 2 studies provide researchers with additional safety data. Researchers use these data to refine research questions, develop research methods, and design new Phase 3 research protocols.

Phase 3 – Vaccines are administered by scientists to hundreds or thousands of volunteers. Phase 3 studies provide most of the safety data. In previous studies, it is possible that less-common side effects might have gone undetected. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects

FDA licenses a vaccine only if it is successful in each of the three phases, is safe and effective, and benefits outweigh risks.

How many COVID-19 vaccinations are under development?

As of December 5, 2020, there are 58 vaccines in clinical trials on humans. Currently, there are 13 vaccine trials that have reached the final stages of testing, according to the [New York Times Coronavirus Vaccine Tracker](#).

Of these, the FDA will meet on [December 10 in an open session to discuss Emergency Use Authorization for the Pfizer-BioNTech vaccine](#) and on [December 17 for the Moderna Inc. vaccine](#).

Was the vaccine tested among racially and ethnically diverse populations?

[The Pfizer-BioNTech Phase 3 clinical trial concluded](#) with approximately 42% of global participants and 30% of U.S. participants having racial and ethnically diverse backgrounds. This included [Asian \(5% overall, 6% U.S. only\)](#), [Black \(10% overall, 10% U.S. only\)](#), [Hispanic/Latinx \(26% overall, 13% U.S. only\)](#), and [Native American \(1% overall, 1% U.S. only\)](#). Moderna Inc.'s Phase 3 clinical trial had a diverse pool of [U.S. participants that included 37% from racial and ethnic minorities](#).

Timing of Vaccine Availability and Phases of Vaccine Allocation

When will a COVID-19 vaccine be available in the United States?

According to the CDC, the goal is to deliver safe vaccines that work – initial allocations will be available shortly after FDA approvals. When a COVID-19 vaccine is authorized and approved in the United States, there will not be enough doses available right away for all adults, so the first doses will go to front-line health care workers and the most vulnerable. Supplies will increase over time, and all adults who chose to be vaccinated should be able to do so later in 2021.

When is the State of California expected to receive the first FDA-approved vaccinations?

The FDA is meeting on December 10 to approve the first vaccine, which will be from Pfizer-BioNTech. Pre-positioned vaccines are scheduled to arrive in the State of California on December 15, and the remaining early-phase doses are scheduled to arrive later that week. [The Advisory Committee on Immunization Practices \(ACIP\)](#), which is a committee within the CDC that provides advice and guidance on effective control of vaccine-preventable diseases, [will meet in an emergency meeting on December 11 and 13](#) and is expected to recommend use of the first COVID-19 vaccine. On December 17, the FDA is meeting to approve the second vaccine, which will be from Moderna Inc.

Who will be eligible to receive the vaccine?

[The State of California](#) will provide a COVID-19 vaccine to everyone who wants it at no cost. Vaccinations will be allocated in a phased approach as recommended by the Advisory Committee on Immunization Practices (ACIP):

Phase 1: High-risk health care workers, first responders, people of all ages with comorbid and underlying conditions that put them at significantly higher risk, and older adults living in congregate or overcrowded settings.

Phase 2: K-12 teachers and school staff, childcare workers, critical workers in high-risk settings who are in industries essential to the functioning of society, people of all ages with comorbid and underlying conditions that put them at significantly higher risk, people in homeless shelters or group homes for individuals with disabilities, people in prisons, jails, detention centers and similar facilities along with staff who work in such settings and all older adults not included in Phase 1.

Phase 3: Younger adults, children, and workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Phases 1 and 2.

Phase 4: Everyone residing in the United States who did not have access to the vaccine in previous phases.

How will the County of San Bernardino be receiving vaccinations?

The State of California will allocate vaccinations based on a calculation of the number of health care workers within the county. Additionally, San Bernardino County has been designated by the State as a pre-positioning county, which will allow for earlier distribution to our county.

How will the vaccine be distributed?

There will be three primary distribution methods of the vaccine: 1) Direct shipments to providers; 2) Department of Public Health and Office of Emergency Services distribution; and 3) Skilled nursing facilities/long term care facilities in partnership with CVS/Walgreens.

Can the County purchase more COVID-19 vaccines than currently allotted?

Unfortunately, not at this time. The CDC is responsible for distributing the vaccines and determines how many doses each state receives based on the size of the state. California received an initial allotment of 327,000 doses. Counties in California were allotted doses based on their percentage of health care workers, who are the first to receive the vaccinations as part of the Phase 1a rollout. San Bernardino County has approximately 112,000 healthcare workers in the state. This translates to the county receiving 15,600 initial doses on December 15. Weekly distributions will continue thereafter.

More vaccines are expected to be approved by the FDA in 2021 that will increase the availability for more segments of the population. The County's Vaccination Task Force is working diligently to ensure that there are no delays in procuring vaccinations for its residents.

How has the County of San Bernardino prepared for receiving and distributing the vaccine?

The County of San Bernardino has prepared a Standard Operating Guide to address and guide its response to the COVID-19 vaccination process, which includes a plan for inspections of vaccine shipping containers within five minutes of receipt as well as storage protocols. Important to note is that the Pfizer-BioNTech vaccine requires ultra-cold freezer refrigeration. The Moderna Inc. vaccine requires standard freezer refrigeration. The County and transport partners are prepared to handle these cold storage requirements.

The County actively engages the San Bernardino County Vaccination Task Force to ensure thorough vaccination planning and preparation is taking place and that all the steps necessary to begin the vaccination process are being taken.

Safety of The Vaccine and Administering of Shots

How do we know if the COVID-19 vaccine is safe?

The San Bernardino County Department of Public Health will review information regarding the safety and efficacy of vaccine candidates and follow guidance provided by [California's Scientific Safety Review Workgroup](#).

This workgroup consists of California scientists with expertise in immunization and public health that will independently review the safety and efficacy of any vaccine that receives FDA approval.

These top health experts – guided by the principles of safety, equity and transparency – will review and verify a vaccine's safety before California makes a COVID-19 vaccine available.

How will COVID-19 vaccines work?

COVID-19 vaccines will protect people from the virus that causes COVID-19 without having to get the illness. Different vaccines work in different ways, but they all help the immune system fight infections in the future.

It typically takes a few weeks after the last dose in a series to become fully protected. Sometimes vaccination can cause mild fever, cold-like symptoms or a sore arm from the shot, but these are not harmful.

How many shots of the COVID-19 vaccines will be needed?

All but one of the COVID-19 vaccines currently in Phase 3 clinical trials in the United States need two shots to be effective, given approximately 21 to 28 days apart. The Pfizer and Moderna vaccines will require two shots.

Who will administer the COVID-19 vaccinations?

The County of San Bernardino is working in partnership with health providers in the county to administer the vaccinations as they become available.

Where will the COVID-19 vaccinations be administered?

Many county locations currently being used for COVID-19 testing will also eventually offer the COVID-19 vaccination when it is ready for the community. Additionally, a network of health providers in the county will administer vaccinations throughout the various allocation phases.

Will I be able to choose which COVID-19 vaccine to get?

According to the CDC, because of the limited supplies of the vaccine that will be initially available to [healthcare workers and residents of long-term care facilities](#), they may not have a choice of which vaccine they can take between Pfizer-BioNTech or Moderna Inc., which are expected to receive FDA approval in December 2020. By the time that the general public has an opportunity to get vaccinated in approximately spring of 2021, there could be a number of additional vaccines approved by the FDA. At this point, there is not enough data to determine if a particular vaccine candidate should be used by certain groups. The CDC will be monitoring the data closely to determine if recommendations need to change.

Is it mandatory to get a COVID-19 vaccination?

There is currently no requirement for people to get a COVID-19 vaccination. This is an individual's choice to help protect themselves from contracting COVID-19 and helping stop the spread of the virus.

If I already had COVID-19 and recovered, do I still need to get vaccinated with the COVID-19 vaccine when it becomes available?

There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19. As more data is collected, this information will be updated to reflect the latest scientific findings.

Why would a vaccine be needed if we can do other things, like social distancing and wearing masks, to prevent spreading COVID-19?

Stopping a pandemic requires using all the tools available. Vaccines work with your immune system so your body will be ready to fight the virus if you are exposed. Other steps, like covering your mouth and nose with a mask and staying at least 6 feet away from others, help reduce your chance of being



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exposed to the virus or spreading it to others. Together, COVID-19 vaccination and following CDC's recommendations [to protect yourself and others](#) will offer the best protection from COVID-19.

Do I need to wear a mask and avoid close contact with others if I have received two doses of the COVID-19 vaccine?

Yes. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue practicing social distancing, wearing a mask covering your mouth and nose and washing hands often. Experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on steps everyone should take to slow the spread of the virus that causes COVID-19. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

Will I be required to provide personal information when receiving a vaccination shot?

Health authorities need this information to help you stay safe and healthy. The CDC is implementing a new smartphone-based tool called V-SAFE to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a V-SAFE information sheet telling you how to enroll in V-SAFE. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

Links to Information Resources

San Bernardino County COVID-19 Response – www.SBCOVID19.com

State of California COVID-19 Response – www.COVID19.ca.gov

Centers for Disease Control and Prevention COVID-19 – www.cdc.gov/coronavirus/

World Health Organization COVID-19 – www.who.int

Federal Drug Administration – www.fda.gov

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