Answering Your Questions About the New COVID-19 Vaccines

Do clinical trial results show whether vaccines are effective?

Yes. Clinical trials provide data and information about how well a vaccine prevents an infectious disease and about how safe it is. The Food and Drug Administration (FDA) evaluates these data, along with information from the manufacturer, to assess the safety and effectiveness of a vaccine. FDA then decides whether to approve a vaccine or authorize it for emergency use in the United States.

After a vaccine is either approved or authorized for emergency use by FDA, more assessments are done before a vaccine is recommended for public use. The goal of these assessments is to understand more about the protection a vaccine provides under real-world conditions, outside of clinical trials.

After COVID-19 vaccines are approved or authorized for emergency use by FDA and recommended for public use, CDC will further assess their effectiveness. These real-world assessments will compare groups of people who do and don't get vaccinated and people who do and don't get COVID-19 to find out how well COVID-19 vaccines are working to protect people.

Why would the effectiveness of vaccines be different after the clinical trials?

Many factors can affect a vaccine's effectiveness in real-world situations. These factors can include things such as how a vaccine is transported and stored or even how patients are vaccinated. Vaccine effectiveness can also be affected by differences in the underlying medical conditions of people vaccinated as compared to those vaccinated in the clinical trials.

Assessments of vaccine effectiveness can also provide important information about how well a vaccine is working in groups of people who were not included or were not well represented in clinical trials.

How will experts evaluate the COVID-19 vaccines in real-world conditions?

Experts are working on many types of real-world studies to determine vaccine effectiveness, and each uses a different method:

- **Case-control studies** will include cases (people who have the virus that causes COVID-19) and controls (people who do not have the virus that causes COVID-19). People who agree to participate in a case-control study will provide information on whether they received a COVID-19 vaccine or not. Experts will look to see if the cases were less likely to have received the vaccine than controls, which would show that the vaccine is working.
- **A test-negative design study** will enroll people who are seeking medical care for symptoms that could be due to COVID-19. In this special type of case-control study, experts will compare the COVID-19 vaccination status of those who test positive (meaning they have COVID-19) to those who test negative (meaning they do not have COVID-19).

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- **Cohort studies** will follow people who have and haven't had a COVID-19 vaccine for several months to see if getting vaccinated protects them from getting the disease. This can be done in real time (prospectively) or by looking back in time (retrospectively) using data that were already collected, such as information in participants' medical records.
- **Screening method assessments** look at vaccination status among a group of cases (for example, cases detected through ongoing COVID-19 surveillance) and compares those cases with vaccination coverage among the overall population where those cases come from (for example people from the same state). By comparing coverage between these two groups, researchers can get an early estimate of whether a vaccine is working as expected.
- **Ecologic analysis assessments** look at groups of people – such as those in different geographic locations or at different times – to find out how many were vaccinated and how many were diagnosed with COVID-19. These analyses may be hard to interpret because the number of COVID-19 illnesses has changed rapidly over time and in different places.

CDC will use several methods because they can all contribute different information about how the vaccine is working.

Will assessments determine if the vaccines protect people from severe COVID-19 illness?

Yes. Severe illness from COVID-19 is defined as needing care in a hospital or intensive care unit (ICU), needing to be on a ventilator, or dying due to COVID-19.

- Experts will assess how well COVID-19 vaccines protect people against severe illness using case-control studies among hospitalized patients.
- Experts also will use cohort studies of electronic health records to see if people hospitalized with COVID-19 received the vaccine or not.

Will assessments determine if the vaccines protect people against mild illness?

Yes. CDC will use case-control studies to assess how well COVID-19 vaccines protect people against less severe forms of COVID-19 – for example, people with COVID-19 who need to visit a doctor but don't need to be hospitalized.

Will assessments determine if the vaccines protect people who are ill with no symptoms at all?

Yes. Some people can be infected with or "carry" the virus that causes COVID-19, but they don't feel sick or have any symptoms. Experts call this asymptomatic infection. It is important to know whether COVID-19 vaccines can help lower the number of people who have asymptomatic infection. People with asymptomatic infection can unknowingly spread the virus to others.

A special type of cohort study will find out how effective the vaccine is when people are asymptomatic. People who agree to participate will be tested for COVID-19 every week whether they have symptoms or not. Experts will then compare the proportion of people with infection who were vaccinated to the proportion of people with infection who were not vaccinated.

Who will be included in the real-world vaccine assessments?

CDC is working to make sure real-world vaccine assessments include diverse groups of people including the following:

Healthcare personnel and essential workers

Experts will rapidly assess vaccine effectiveness among healthcare personnel working in hospitals, long term care/skilled nursing facilities, or nursing homes in selected sites across the United States. These assessments will show how well COVID-19 vaccines protect healthcare personnel from getting sick or having severe illness. Assessments among healthcare personnel and essential workers will also inform how well COVID-19 vaccines protect them against getting infected, regardless of whether they have symptoms or not.

Older adults and those living in nursing homes

The risk for severe illness from COVID-19 increases with age, so making sure these vaccines protect older adults is critical. People living in nursing homes and long-term care facilities are at especially high risk of getting COVID-19 and severe disease. The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) will

use CMS Medicare billing data to assess COVID-19 vaccine effectiveness among older adults, including those living in nursing homes and long-term care facilities. These data will include information about whether people received a COVID-19 vaccine, whether they got sick with COVID-19, and if they needed hospital care. This information will help inform how well the vaccine works in preventing COVID-19 and severe illness among older adults.

Experts will also use data from CDC and CMS to conduct a case-control assessment. Experts will identify older adults hospitalized for COVID-19 and older adults hospitalized for other reasons. They will then compare how many cases and controls received a COVID-19 vaccine to estimate vaccine effectiveness.

People with underlying medical conditions

To better understand how well COVID-19 vaccines protect people with underlying medical conditions who may be at increased risk for severe illness. Experts are working to make sure various real-world vaccine assessments will include adults with heart conditions, obesity, and diabetes. The real-world vaccine effectiveness assessments will also collect information about other underlying medical conditions. This information will be used to better understand how well COVID-19 vaccines protect people with underlying medical conditions.

People in racial and ethnic minority groups

Long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID-19. CDC is working to ensure that real-world assessments of vaccine effectiveness include diverse populations, such as people from racial and ethnic minority groups disproportionately affected by COVID-19.

CDC also is working with the Indian Health Service (IHS), tribal nations, and other partners to ensure that these real-world assessments include American Indian and Alaska Native populations who have been disproportionately affected by COVID-19. This is important to ensure that COVID-19 vaccines can help achieve health equity, so everyone has a fair opportunity to be as healthy as possible.

These vaccines were produced so quickly. How do we know they are safe?

It is the U.S. vaccine safety system's job to make sure that all vaccines are as safe as possible. Safety has been a top priority while federal partners have worked to make COVID-19 vaccines available for use in the United States.

The new COVID-19 vaccines have been evaluated in tens of thousands of individuals, who volunteered to be vaccinated and to participate in clinical trials. The information from these clinical trials allowed the U.S. Food and Drug Administration (FDA) to determine the safety and effectiveness of the vaccines. These clinical trials were conducted according to rigorous standards set forth by FDA.

FDA has determined that the newly authorized COVID-19 vaccines meet its safety and effectiveness standards. Therefore, FDA has made these vaccines available for use in the United States under what is known as an Emergency Use Authorization.

Will CDC continue to watch for problems with these new vaccines?

Yes. Even though no safety issues arose during the clinical trials, CDC and other federal partners will continue to monitor the new vaccines for serious side effects (known as adverse events) using many vaccine safety monitoring systems.

This continued monitoring can pick up on side effects that may not have been seen in clinical trials. If an unexpected side effect with the new COVID-19 vaccines is seen, experts can quickly study it further to determine if it is a true safety concern. Monitoring vaccine safety is critical to help ensure that the benefits of the COVID-19 vaccines continue to outweigh the risks for people who are vaccinated.

The current vaccine safety system is strong and robust, with the capacity to monitor COVID-19 vaccine safety effectively. Existing data systems can rapidly detect if a vaccine has any possible safety problems. These systems are being scaled up to fully meet the needs of the nation. Additional systems and data sources are also being developed to further enhance safety monitoring capabilities.

New vaccine safety monitoring systems and information sources

The following systems and information sources add another layer of safety monitoring, giving CDC and FDA the ability to evaluate COVID-19 vaccine safety in real time and make sure COVID-19 vaccines are as safe as possible:

- **CDC: V-SAFE** — A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. The system also will provide telephone follow up to anyone who reports medically significant (important) adverse events.
- **CDC: National Healthcare Safety Network (NHSN)** — An acute care and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS
- **FDA: Other large insurer/payer databases** — A system of administrative and claims-based data for surveillance and research

Existing Safety Monitoring Systems

The safety of vaccines is monitored all the time with multiple approaches. As people get vaccinated, CDC, FDA, and other federal partners will use the following existing, robust systems and data sources to conduct ongoing safety monitoring in the following groups:

General public

- **CDC and FDA: Vaccine Adverse Event Reporting System (VAERS)** — The national system that collects reports from healthcare professionals, vaccine manufacturers, and the public of adverse events that happen after vaccination; reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with specific studies
- **CDC: Vaccine Safety Datalink (VSD)** — A network of 9 integrated healthcare organizations across the United States that conducts active surveillance and research; the system is also used to help determine whether possible side effects identified using VAERS are actually related to vaccination
- **CDC: Clinical Immunization Safety Assessment (CISA) Project** — A collaboration between CDC and 7 medical research centers to provide expert consultation on individual cases and conduct clinical research studies about vaccine safety
- **FDA and the Centers for Medicare and Medicaid Services: Medicare data** — A claims-based system for active surveillance and research
- **FDA: Biologics Effectiveness and Safety System (BEST)** — A system of electronic health record, administrative, and claims-based data for active surveillance and research
- **FDA: Sentinel Initiative** — A system of electronic health record, administrative, and claims-based data for active surveillance and research

Members of the military

- **Department of Defense (DOD): DOD VAERS data** — Adverse event reporting to VAERS for the DOD populations
- **DOD: Vaccine Adverse Event Clinical System (VAECS)** — A system for case tracking and evaluation of adverse events following immunization in DOD and DOD-affiliated populations
- **DOD: DOD Electronic Health Record and Defense Medical Surveillance System** — A system of electronic health record and administrative data for active surveillance and research

Veterans

- **Department of Veterans Affairs (VA): VA Adverse Drug Event Reporting System (VA ADERS)** — A national reporting system for adverse events following receipt of drugs and immunizations
- **VA Electronic Health Record and Active Surveillance System** — A system of electronic health record and administrative data for active surveillance and research

Tribal nations

- **Indian Health Service (IHS): IHS VAERS data** — Spontaneous adverse event reporting to VAERS for populations served by IHS and Tribal facilities

Learn About the New mRNA COVID-19 Vaccines

The first two COVID-19 vaccines expected to receive authorization for use in the United States are what is known as messenger RNA vaccines—also called "mRNA" vaccines.

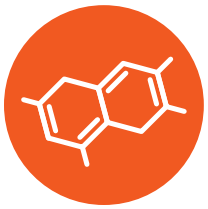
You and your patients may have questions about how mRNA vaccines work and how safe they are.

- Like all vaccines, these COVID-19 mRNA vaccines were tested rigorously for safety before being authorized for use in the United States.
- mRNA technology is new, but not unknown. It has been studied for decades.
- mRNA vaccines do not contain live virus and carry no risk of causing disease in the vaccinated person.
- mRNA from the vaccine never enters the nucleus of the cell and does not affect or interact with a person's DNA.

A new approach to vaccines

mRNA vaccines take advantage of the process that cells use to make proteins in order to trigger an immune response and build immunity to SARS-CoV-2, the virus that causes COVID-19. In contrast, most vaccines use weakened or inactivated versions or components of the disease-causing pathogen to stimulate the body's immune response to create antibodies.

Mechanism for Action



mRNA vaccines have strands of messenger RNA inside a special coating. That coating protects the mRNA from enzymes in the body that would otherwise break it down. The coating also helps the mRNA enter the muscle cells near the vaccination site.

mRNA vaccines tell our cells to make a piece of the "spike protein" that is found on the surface of the SARS-CoV-2 virus. Since only part of the protein is made, it does not harm the vaccine recipient, but it is antigenic and thus stimulates the immune system to make antibodies.

After the piece of the spike protein is made, the cell breaks down the mRNA strand and disposes of it using enzymes in the cell. As stated above, the mRNA strand never enters the cell's nucleus or affects the vaccine recipient's genetic material. Knowing this helps you respond to misinformation about how mRNA vaccines alter or modify someone's genetic makeup.

Once displayed on the cell surface, the protein or antigen causes the immune system to begin producing antibodies. These antibodies are specific to the SARS-CoV-2 virus spike protein, which means the immune system is ready to protect against future infection.

COVID-19 mRNA vaccines will continue to be rigorously evaluated for safety

These COVID-19 mRNA vaccines went through the same rigorous safety assessment as all vaccines do before the Food and Drug Administration authorizes them for use in the United States. This included large clinical trials and data review by a safety monitoring board.

Often, patients are concerned about live vaccines. mRNA vaccines are not live vaccines and do not use an infectious element, so they carry no risk of causing disease in the vaccinated person.

mRNA vaccines are new, but not unknown

Currently, there are no licensed mRNA vaccines in the United States. However, researchers have been studying them for decades.

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mRNA vaccines have been studied for influenza, Zika, rabies, and cytomegalovirus (CMV). Recent technological advancements in RNA biology and chemistry, as well as delivery systems, have mitigated the challenges of these vaccines and improved their stability and effectiveness.

Beyond vaccines, numerous preclinical and clinical studies have used mRNA to encode cancer antigens to stimulate immune responses targeted at clearing or reducing malignant tumors.

Benefits of mRNA vaccines

mRNA vaccines have several benefits compared to other types of vaccines, including use of a non-infectious element, shorter manufacturing times, and potential for targeting multiple diseases. mRNA vaccines can be developed in a laboratory using readily available materials. This means the process can be standardized and scaled up, making vaccine development faster than traditional methods. In the future, mRNA vaccine technology may allow for one vaccine to target multiple diseases.

Related links

- Talking to Patients about COVID-19 Vaccines
- Patient Information: Understanding mRNA Vaccines
- FDA's Vaccine Development 101
- FDA's Emergency Use Authorization for Vaccines Explained
- FDA Infographic: The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization

Additional resources

- Pardi N, Hogan MJ, Porter FW, Weissman D. mRNA Vaccines—a New Era in Vaccinology. *Nature Reviews. Drug Discovery*. 2018;17(4):261.
- Maruggi G, Zhang C, Li J, Ulmer JB, Yu D. mRNA as a Transformative Technology for Vaccine Development to Control Infectious Diseases. *Molecular Therapy*. 2019;27(4):757–72.
- Jackson NAC, Kester KE, Casimiro D, Gurunathan S, DeRosa F. The Promise of mRNA Vaccines: A Biotech and Industrial Perspective. *Npj Vaccines*. 2020;5(1):1–6.

Quick Answers for Healthcare Professionals to Common Questions People May Ask About COVID-19 Vaccines

When talking to your patients about COVID-19 vaccines, make a strong, effective recommendation and allow time for them to ask questions. Hearing your answers may help them feel more confident about getting vaccinated.

1. Should I get vaccinated for COVID-19?

I strongly recommend you get vaccinated. The vaccine will help protect you from getting COVID-19. If you still get infected after you get vaccinated, the vaccine may prevent serious illness. By getting vaccinated, you can also help protect people around you.

2. Can the vaccine give me COVID-19?

No. None of the COVID-19 vaccines currently authorized for use or in development in the United States use the live virus that causes COVID-19. However, it typically takes a few weeks for the body to build immunity after vaccination. That means it's possible you could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick.

3. If I already had COVID-19 and recovered, do I still need to get vaccinated?

Yes. CDC recommends that you get vaccinated even if you have already had COVID-19, because you can catch it more than once. While you may have some short-term antibody protection after recovering from COVID-19, we don't know how long this protection will last.

4. Can my child get vaccinated for COVID-19?

No. More studies need to be conducted before COVID-19 vaccines are recommended for children aged 16 and younger.

5. Is it safe to get a COVID-19 vaccine if I have an underlying medical condition?

Yes. COVID-19 vaccination is especially important for people with underlying health problems like heart disease, lung disease, diabetes, and obesity. People with these conditions are more likely to get very sick from COVID-19.

6. Is it better to get natural immunity to COVID-19 rather than immunity from a vaccine?

No. While you may have some short-term antibody protection after recovering from COVID-19, we don't know how long this protection lasts. Vaccination is the best protection, and it is safe. People who get COVID-19 can have serious illnesses, and some have debilitating symptoms that persist for months

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7. Why do I need two COVID-19 shots?

Currently authorized vaccines, and most vaccines under development, require two doses of vaccine. The first shot helps the immune system recognize the virus, and the second shot strengthens the immune response. You need both to get the best protection.

8. Will the shot hurt or make me sick?

There may be side effects, but they should go away within a few days. Possible side effects include a sore arm, headache, fever, or body aches. This does not mean you have COVID-19. Side effects are signs that the vaccine is working to build immunity. If they don't go away in a week, or you have more serious symptoms, call your doctor.

9. Are there long-term side effects from COVID-19 vaccine?

Because all COVID-19 vaccines are new, it will take more time and more people getting vaccinated to learn about very rare or possible long-term side effects. The good news is, at least 8 weeks' worth of safety data were gathered in the clinical trials for all the authorized vaccines, and it's unusual for vaccine side effects to appear more than 8 weeks after vaccination.

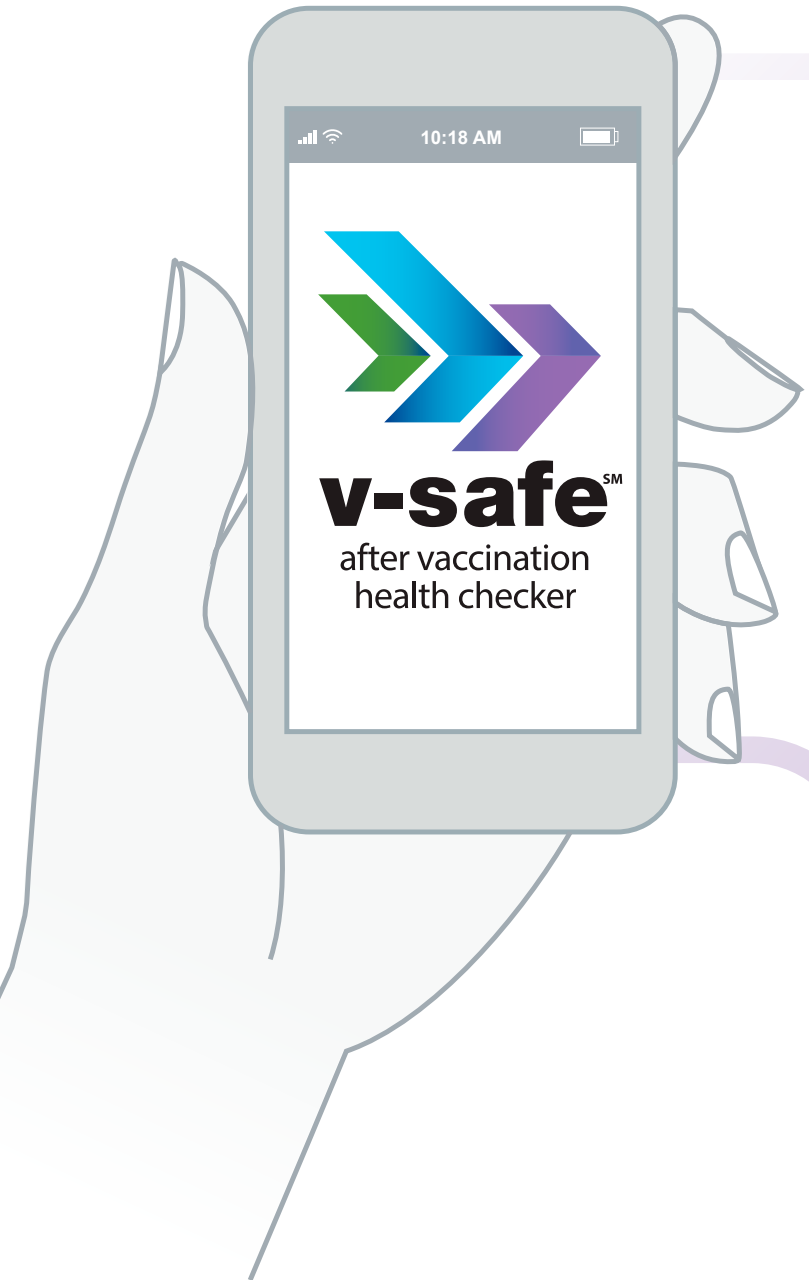
10. How do I know if COVID-19 vaccine is safe?

All COVID-19 vaccines were tested in clinical trials involving tens of thousands of people to make sure they meet safety standards and protect adults of different ages, races, and ethnicities. There were no serious safety concerns. CDC and the FDA will keep monitoring the vaccines to look for safety issues after they are authorized and in use.

11. How do I report problems or bad reactions after getting a COVID-19 vaccine?

I am encouraging all recipients who receive the vaccine to enroll in **v-safe**. This is a smartphone tool you can use to tell CDC if you have any side effects after getting a COVID-19 vaccine. If you report serious side effects, someone from CDC will call to follow up. I will give you instructions for how to enroll.

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



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

When you get your COVID-19 vaccination, ask your healthcare provider about getting started with v-safe

Learn more about **v-safe**
www.cdc.gov/vsafe

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Why Get Vaccinated?

To Protect Yourself, Your Coworkers, Your Patients, Your Family, and Your Community

- Building defenses against COVID-19 in this facility and in your community is a team effort. And **you** are a key part of that defense.
- Getting the COVID-19 vaccine adds **one more layer of protection** for you, your coworkers, patients, and family.

Here are ways you can **build people's confidence** in the new COVID-19 vaccines in your facility, your community, and at home:

- ✓ **Get vaccinated** and enroll in the **v-safe** text messaging program to help CDC monitor vaccine safety.
- ✓ **Tell others why** you are getting vaccinated and encourage them to get vaccinated.
- ✓ **Learn how to have conversations** about COVID-19 vaccine with coworkers, family, and friends.

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12/09/20

State of California—Health and Human Services Agency
California Department of Public Health

Sandra Shewry
Acting Director
Erica S. Pan, MD, MPH
Acting State Health Officer

GAVIN NEWSOM
Governor

December 5, 2020

TO: All Californians

SUBJECT: CDPH Allocation Guidelines for COVID-19 Vaccine During Phase 1A: Recommendations

Recommendation A: Populations for Phase 1a

During Phase 1a of allocation, COVID-19 vaccine should be offered to the following persons in California:

- Persons at risk of exposure to SARS-CoV-2 through their work in any role in direct health care or long-term care settings.

o This population includes persons at direct risk of exposure in their non-clinical roles, such as, but not limited to, environmental services, patient transport, or interpretation.

- Residents of skilled nursing facilities, assisted living facilities, and similar long-term care settings for older or medically vulnerable individuals.

Recommendation B: Subprioritization During Phase 1a

- During Phase 1a, if there are not enough doses of COVID-19 vaccine for all who choose to receive them, then health departments should subprioritize doses as needed to match the level of available supplies in a sequential fashion using the following ranked categories:

o Persons exposed though work in health care or long-term care settings, by:

1. Type of facility or role
2. Location of facility
3. Attributes of individuals

- Health departments may reprioritize temporarily under limited circumstances described in Recommendation C.

Recommendation B1: Subprioritization by type of facility or role

- If supplies are limited during Phase 1a, COVID-19 vaccines should be directed to as many tiers, and categories in each tier (e.g., hospitals) as possible to reach the prioritized populations.
- The tiers and categories in each tier are presented in ranked order.
- Persons immunizing the prioritized populations in a tier should be offered immunization during or before the same tier.

Tier 1

- Acute care, psychiatric and correctional facility hospitals
- Skilled nursing facilities, assisted living facilities, and similar settings for older or medically vulnerable individuals
- Also, in concordance with ACIP, residents in these settings
- Paramedics, EMTs and others providing emergency medical services
- Dialysis centers

Tier 2

- Intermediate care facilities for persons who need non-continuous nursing supervision and supportive care
- Home health care and in-home supportive services
- Community health workers, including promotoras
- Public health field staff
- Primary Care clinics, including Federally Qualified Health Centers, Rural Health Centers, correctional facility clinics, and urgent care clinics

Tier 3

Other settings and health care workers, including

- Specialty clinics
- Laboratory workers
- Dental and other oral health clinics
- Pharmacy staff not working in settings at higher tiers

Recommendation B2: Subprioritization by location of facility

- When there are inadequate doses to reach all workers in a tier or facility category (e.g., acute care hospitals), doses should be prioritized to facilities serving the greatest proportion of vulnerable persons in their catchment area, as measured by the HPI or comparable health department knowledge, followed by facilities serving fewer vulnerable persons.

Recommendation B3: Subprioritization by attributes of individual health care workers

If there are not enough doses to reach all workers at risk in a facility, then

- Health departments may allocate doses for facilities—if information is available—to protect workers at higher risk of occupational exposure to SARS-CoV-2 before those at lower risk.
- Local facilities should consider offering doses of vaccine to workers using the following risk factors, in sequence: o Occupational risk of exposure to SARS-CoV-2
    - Descending age, in the following age groups:

        (1) 65 years and older

        (2) 55-64 years

        (3) Younger than 55 years

    - Other attributes supported by evidence, including but not limited to underlying medical conditions, race, and ethnicity
    - To support immunization of these workers, facilities should provide extensive information and counseling.

Recommendation C1. Evolving information about COVID-19 vaccine characteristics

Health Departments may adjust prioritization to reflect or comply with available vaccine characteristics. However, prompt measures should be taken to revert to the original prioritization criteria and immunize persons delayed by these restrictions as soon as circumstances permit, such as:

- Additional formulations become available
- Changes in authorized indications from FDA or in recommendations from ACIP or CDPH

Recommendation C2. Minimizing disuse of scarce COVID-19 vaccine

To avoid wastage or disuse of scarce supplies and maximize their benefit to Californians:

- Health departments may allocate doses on the assumption that immunization will be accepted by some but not all who are offered the vaccine, and then adjust later allocations based on the number of doses that are accepted.
- After intensive and appropriate efforts to reach the groups prioritized at that moment, health departments and facilities may offer vaccine promptly to persons in lower priority groups when:
    - Demand subsides in the current groups, or
    - Doses are about to expire according to labeling instructions.
- Health Departments may temporarily adjust prioritization based on other resource constraints while continuing efforts to immunize higher priority groups as soon as feasible.

California Department of Public Health
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Page Last Updated : December 5, 2020

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?
Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe. V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?
- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Patent(s): www.modernatx.com/patents
Revised: 12/2020

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

WHO SHOULD <u>NOT</u> GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?
The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

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Currently, there is no approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

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If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

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Global website	Telephone number
www.cvdvaccine.com 	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

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The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-1.1

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