

Nisqually Indian Tribe Health Department

COVID-19 Vaccine Patient Acknowledgment

Patient Name (Last, First): _____ DOB: ____/____/____

Phone: _____ Mobile Phone: _____ Email: _____
(This information will be used to contact you for your second dose reminder.)

Address: _____ City, State, Zip Code: _____

Information collected in this section helps ensure we deliver equitable and patient-centered care:

Sex listed at birth (check one):

Male: <input type="checkbox"/>	Female: <input type="checkbox"/>
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Gender identity (check one):

Male: <input type="checkbox"/>	Female: <input type="checkbox"/>	Non-Binary <input type="checkbox"/>	Unspecified/Indeterminant: <input type="checkbox"/>
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Ethnicity (Check one):

Hispanic or Latino (Including Spanish, Mexican, Puerto Rican, Cuban, etc. <input type="checkbox"/>	Not-Hispanic A person not of Spanish culture or origin <input type="checkbox"/>
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Race: (Check all that apply):

Black or African American <input type="checkbox"/>	Asian <input type="checkbox"/>	Hawaiian or Pacific Islander <input type="checkbox"/>
White <input type="checkbox"/>	American Indian or Alaska Native <input type="checkbox"/>	

Vaccine Dose (check one): 1st 2nd **If this is your second dose, what vaccine was your first?** Pfizer Moderna **Don't know** **If this is your second dose, when did you receive your first dose? (date):** _____.

Exclusion Questions: Answering yes to either of these questions excludes you from receiving the vaccine.

Do you have a known history of a severe allergic reaction (e.g. anaphylaxis) to this vaccine or any components of the vaccine such as lipids, potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose? (Full list is available in the <i>Fact Sheet for Vaccine Recipients and Caregivers</i> or from your health care provider.)	Yes	No
Are you under the age of 18 years?	Yes	No

Screening Questions: Immunizer: If patient answers "yes" to any of the below, provide patient counseling or instruct them to consult with their caregiver prior to receiving the vaccine.

In the past two weeks have you tested positive for COVID-19?	Yes	No
In the past two weeks have you had exposure to a person who tested positive for COVID-19 at a distance of six feet or less for a period of 15 or more minutes without wearing appropriate personal protective equipment?	Yes	No
Have you had a new onset of fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, nausea, vomiting or diarrhea?	Yes	No
In the past 90 days have you received passive antibody therapy as part of COVID-19 treatment?	Yes	No
Are you pregnant or breastfeeding or do you plan to become pregnant?	Yes	No
Are you immune compromised or on a medicine that affects your immune system?	Yes	No
Do you have a bleeding disorder or are you on a blood thinner?	Yes	No
Do you have a history of severe allergic reaction (e.g. anaphylaxis) to another vaccine or injectable medication? If yes, what vaccine or injectable medication: _____	Yes	No



Insurance Information:

Insurance company: _____ Are you the primary card holder? Y N

If no, what is the primary card holders name and date of birth? _____

Cardholder ID: _____ Rx Group ID: _____

BIN: _____ PCN: _____

Are you Medicare eligible? Y N If yes, Medicare Part A/B number: _____

If you are not insured and you do not want to pay for administration of the vaccine yourself, you must provide the information below. If you do not provide this information you may be billed for vaccine administration.

I do not have any insurance, including but not limited to Medicare, Medicaid, or any other private or government-funded health benefit plan. In order to have your vaccine administration fee paid for by the United States Health Resources & Services Administration’s COVID-19 Program for Uninsured Patients please provide (a) a valid Social Security number, or (b) state identification number and state of issuance, or (c) a driver’s license number and the state of issuance: _____

Acknowledgements:

- *I made the choice to get the COVID-19 vaccine on my own and freely. I know I have the option to refuse the vaccine. I ask that the vaccine be given to me, or to the person named above for whom I can make this request. I was given the (Fact Sheet for Vaccine Recipients and Caregivers) for this vaccine. The fact sheet has information about side effects and adverse reactions. I read or had read to me the information provided about the COVID-19 vaccine.*
- *I know the Food and Drug Administration (FDA) has authorized the emergency use of this vaccine. I know it is not a fully licensed FDA vaccine. I had the chance to ask questions that were answered to my satisfaction. I now know about the vaccine, alternatives, benefits, and risks, to the extent they are known and unknown at this time.*
- *I know that I must stay in the vaccine area or an area told to me by my health care provider after I receive my immunization so I am near my health care provider if I have any adverse reactions.. If I have a history of severe allergic reaction, (e.g. anaphylaxis), I must stay for 30 minutes. If I do not have a history of severe allergic reaction, I must stay for 15 minutes*
- *I know that if I have a severe allergic reaction, including difficulty breathing, swelling of my face and/or throat, a fast heartbeat, a bad rash all over my body or dizziness and weakness I should call 9-1-1 or go to the nearest hospital. I know I can call my health care provider if I have any side effects that bother me or do not go away.*
- *I was asked to join the V-SAFE program. The program does health checks on the people who get the COVID-19 vaccine. I know I should report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or <https://vaers.hhs.gov/reportevent.html>.*
- *I know I must get two doses of the COVID-19 vaccine and receive the same vaccine each time. I know that with all vaccines there is no promise I will become immune (not get the virus) or that I will not have side effects. I know I may choose to not get the second dose of the vaccine. But if I do not get the second dose, the chance that I will become immune may go down.*

Authorization to Request Payment: *I authorize the organization providing my vaccine to release information and request payment. I certify that the information given by me in applying for payment under Medicare or Medicaid or the HRSA COVID-19 Program for Uninsured Patients, is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.*

Disclosure of Records: *I understand the organization providing my vaccine may be required to or may voluntarily disclose my vaccine-related health information to my primary care physician, my insurance plan, health systems and hospitals, and state or federal registries or other public health authorities, for purposes of treatment, payment or health care operations. I also understand the organization providing my vaccine will use and disclose my health information as described in its Notice of Privacy Practices which I may receive upon request or find on its website. If I am an employee of Nisqually Tribal Health Department, I understand that it will keep records of this vaccination for me in Greenway Intergy and may keep my vaccination records in Nisqually Tribal Health Department’s employee occupational health records, to the extent required or permitted by law.*

Patient (or Parent/Guardian/Authorized Representative) Signature: _____ Date: _____

Name of Parent, Guardian or Authorized Representative: _____ Date: _____

If you are signing on behalf of the patient, you are stating that you are authorized to make the required decisions on behalf of the patient.



All sections below are for official use only:

Vaccine Administration Information for Immunizer:

Administration date: _____ Administration time: _____
CVX (Product): _____
Dose number: _____
IIS Recipient ID: _____
IIS vaccination event ID: _____
Lot number: _____
Unit of Use MVX (Manufacturer): _____
Sending organization: _____
Vaccine administering provider suffix: _____
Vaccine administering site on the body: Left deltoid Right deltoid Other (indicate location) _____
Vaccine expiration date: _____
Vaccine route of administration: _____
Vaccination series complete (date): _____
Fact Sheet for Vaccine Recipients and Caregivers version date: _____

Notes about this form:

- ***This form should only be provided to a patient if it is accompanied by the Fact Sheet for Vaccine Recipients and Caregivers*** <https://www.cvdvaccine.com/>.
- This form should only be used by clinicians well versed in the CDC's provider education materials who are able to counsel patients who answer "yes" to the screening questions or make referrals for counseling for those patients.
- This form is intended as a resource. It is not a mandatory form.
- This form was developed based on the best available information at the time it was created. Its accuracy is not guaranteed. Organizations and individuals choosing to use this form should do so in consultation with their own clinicians and attorneys.
- This form is subject to update without notice.
- For convenience, some elements in this form may be pre-recorded in electronic health records or other databases.
- Resources used in creating this form:
 - COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals for information about screening questions and *Fact Sheet for Vaccine Recipients and Caregivers* <https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf>
 - Global Information About Pfizer-BioNTech COVID-19 Vaccine (also known as BNT162b2): <https://www.cvdvaccine.com/>
 - V-Safe Program; <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>
 - COVID-19 Vaccination Communication Toolkit: <https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>
 - Washington State's COVID-19 Vaccine Plan for vaccine reporting requirements. <https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/WA-COVID-19-Vaccination-Plan.pdf>
 - For Demographic Information:
 - Washington State CHARS Manual: <https://www.doh.wa.gov/Portals/1/Documents/5300/CHARSManual-UB04-5010.pdf>
 - Race Ethnicity Language Data Collection Best Practices: [http://forces4quality.org/af4q/download-document/6011/Resource-validated final rel data collection best practice guidelines updated 11-28.pdf](http://forces4quality.org/af4q/download-document/6011/Resource-validated%20final%20rel%20data%20collection%20best%20practice%20guidelines%20updated%2011-28.pdf)
 - Collecting Sexual Orientation and Gender Identity Information: <https://www.cdc.gov/hiv/clinicians/transforming-health/health-care-providers/collecting-sexual-orientation.html>



Pre-Vaccination Form for Moderna-NIH COVID-19 Vaccine



Information for Healthcare Professionals about the Pre-Vaccination Form for COVID-19 Vaccine.

For additional information on COVID-19 vaccine recommendations, see:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html>

For additional information on ACIP general recommendations, see:

<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

Are you feeling sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. **Mild illnesses (e.g., upper respiratory infections, diarrhea) are NOT contraindications to vaccination.** Do not withhold vaccination if a person is taking antibiotics. **Vaccination of persons with current SARS-CoV-2 infection should be deferred until the person has recovered from acute illness and they can discontinue isolation.** While there is no minimum interval between infection and vaccination, current evidence suggests reinfection is uncommon in the 90 days after initial infection. Persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

Have you ever received a dose of COVID-19 vaccine?

Two doses of the same COVID-19 vaccine product are recommended. Check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. Those who received a trial vaccine should consult with the trial sponsors to determine if it is feasible to receive additional doses.

Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?

Allergic reactions, including severe allergic reactions, NOT related to vaccines or injectable therapies (e.g., food, pet, venom, environmental, or latex allergies; oral medications) are NOT a contraindication or precaution to vaccination with currently authorized COVID-19 vaccine. HOWEVER, individuals who have had severe allergic reactions to something, regardless of cause, **should be observed for 30 minutes after vaccination.** All other persons should be observed for 15 minutes.

Was the severe allergic reaction after receiving a COVID-19 vaccine?

History of severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of the COVID-19 vaccine product being offered is a contraindication to that COVID-19 vaccine.

Was the severe allergic reaction after receiving another vaccine or another injectable medication?

A history of mild allergic reaction to a vaccine or injectable therapy is not a precaution to vaccination. History of severe allergic reaction (e.g., anaphylaxis) to another vaccine or a component of another vaccine OR anaphylactic reaction to any other injectable medication is a **precaution to currently authorized COVID-19 vaccine.** Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. These individuals should be observed for 30 minutes after vaccination.

Do you have a bleeding disorder or are you taking a blood thinner?

COVID-19 vaccine may be given to these patients, if a physician familiar with the patient's bleeding risk determines that the vaccine can be administered intramuscularly with reasonable safety. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: a fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

Have you received passive antibody therapy as treatment for COVID-19?

Based on the estimated half-life of monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, **vaccination should be deferred for at least 90 days,** as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

» Considerations

Immunocompromise is not a contraindication to current COVID-19 vaccine, including those with cancer, leukemia, HIV/AIDS and other immune system problems or taking medication that affects their immune systems. However, patients should be informed that the vaccine might be less effective than in someone who is immunocompetent.

Pregnancy is not a contraindication to current COVID-19 vaccine. While there are currently no available data on the safety of COVID-19 vaccines in pregnant people, studies and results are expected soon. Pregnant people may choose to get vaccinated. Observational data demonstrate that while the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness.

Lactation is not a contraindication to current COVID-19 vaccine. Lactating people may choose to be vaccinated. There is no data available for lactating people on the effects of mRNA vaccines.

COVID-19 VACCINE HANDOUT

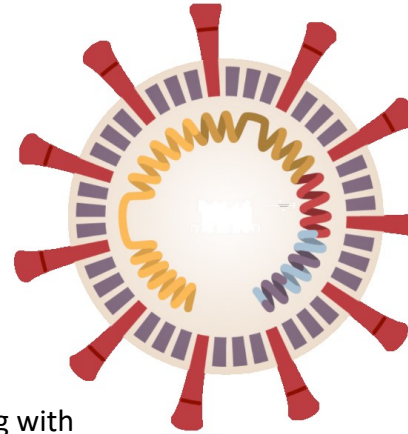
Vaccine Guide: Moderna Vaccine

The Nisqually Tribe is anticipating COVID-19 vaccine to be available to Nisqually Tribal Members, staff, and community according to a phased plan beginning in January 2021.

Vaccine will be administered in 2 doses. One month after your first dose, you'll receive your second and final dose.

The Nisqually Health Department will be administering the vaccine in phases, beginning with essential health personnel at highest risk of exposure, followed by those at highest medical risk and our Elders, and down through populations according to priority based on CDC guidelines.

We are offering the Moderna vaccine, by the National Institutes of Health.



About the Moderna vaccine

You will receive 2 doses (1 month apart)

The first dose provides a partial immune response roughly 2 weeks from receiving the vaccine. The second dose will be administered 28 days later, with full immune response roughly 1 week after receiving the vaccine. The protection resulting from this vaccine has shown to be at minimum as strong as it is for those who get COVID-19, if not better.

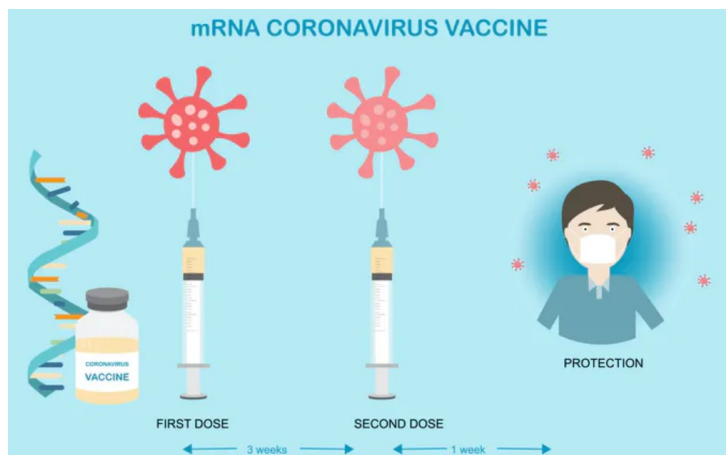
This vaccine has shown 95% efficacy

In clinical trials, roughly 30% of participants were of minority populations (0.8% AI/AN, 0.2% Native Hawaiian, 4.4% Asian, 9.8% African American, 20% Hispanic). This is a huge accomplishment in clinical research, ensuring efficacy and safety across demographics, not just among majority population.

mRNA vaccine

In the vaccine, the person gets a tiny segment of inactive genetic material that does not enter the nucleus of the cell and never reaches the human DNA and then dissolves after a short time— mRNA — that encodes the viral protein to prompt the body to make antigens. When these genetic instructions are injected into the upper arm, the muscle cells translate them to make the viral protein directly in the body.

This gives the immune system a preview of what the real virus looks like without causing disease. This preview gives the immune system time to design powerful antibodies that can neutralize the real virus if the individual is ever infected.



Mild symptoms can occur when you receive the vaccine

There is an immune response to the vaccine when administered. Your body is prompted to make antigens and in response, you might notice symptoms for a day or two as your body adjusts; such as soreness at the injection site or aching muscles and joints, and fatigue.

AFTER VACCINATION

Once you receive your TWO PART vaccination, please remember to continue to practice your 3 Ws –

it is going to take some time for enough people to be vaccinated for risks of this pandemic continuing to spread to be reduced. We can do our part by continuing to practice public health measures to ensure the safety of our community.



WEAR

a cloth face covering.



WAIT

6 feet apart and
avoid close contact.



WASH

your hands often or
use hand sanitizer

Getting the Moderna COVID-19 Vaccine

What to Expect During & After Your Injection

EMERGENCY USE AUTHORIZATION

The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older. There is no FDA-approved vaccine to prevent COVID-19.

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

Before you get the vaccine

Tell your vaccination provider if you:



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

For more information, visit modernatx.com/covid19vaccine-eua/recipients/

After you get the 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

Talk to your vaccination provider if you have side effects that bother you or do not go away.

If you think you're having an allergic reaction to the vaccine, call 9-1-1.

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.

A second dose of the Moderna COVID-19 Vaccine is REQUIRED

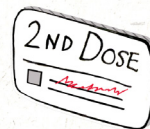
Complete vaccination **1 month** after your first dose of the Moderna COVID-19 Vaccine.

To help remember that appointment:

Immediately schedule your next appointment **after the first dose of your vaccine**



Ask for a **2nd Dose Reminder Card** to display prominently at home



Set a reminder on your mobile phone or calendar



For more information, talk to your vaccination provider or call Moderna Customer Care at: 1-866-MODERNA (1-866-663-3762)

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).

Please see next page for additional Important Safety Information and Fact Sheet for Recipients and Caregivers beginning on page 3 of this document.

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Getting the Moderna COVID-19 Vaccine

What to Expect During & After Your Injection

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Before you get the vaccine

Tell your vaccination provider if you:



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

For more information, visit modernatx.com/covid19vaccine-eua/recipients/

After you get the 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

Talk to your vaccination provider if you have side effects that bother you or do not go away.

If you think you're having an allergic reaction to the vaccine, call 9-1-1.

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.

A second dose of the Moderna COVID-19 Vaccine is REQUIRED

Complete vaccination **1 month** after your first dose of the Moderna COVID-19 Vaccine.

To help remember that appointment:

Immediately schedule your next appointment **after the first dose of your vaccine**



Ask for a **2nd Dose Reminder Card** to display prominently at home



Set a reminder on your mobile phone or calendar



For more information, talk to your vaccination provider or call Moderna Customer Care at: 1-866-MODERNA (1-866-663-3762)

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).

Please see next page for additional Important Safety Information and Fact Sheet for Recipients and Caregivers beginning on page 3 of this document.

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IMPORTANT SAFETY INFORMATION

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 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

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.

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 also report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

See Fact Sheet for Recipients and Caregivers beginning on page 3 of this document.

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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.

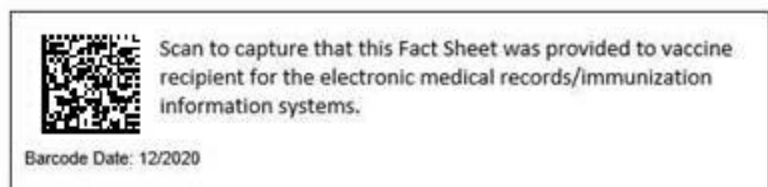
The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of 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).

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Patent(s): www.modernatx.com/patents

Revised: 12/2020





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

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2pm local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.*

*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.



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.



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

OR

Aim your smartphone's camera at this code

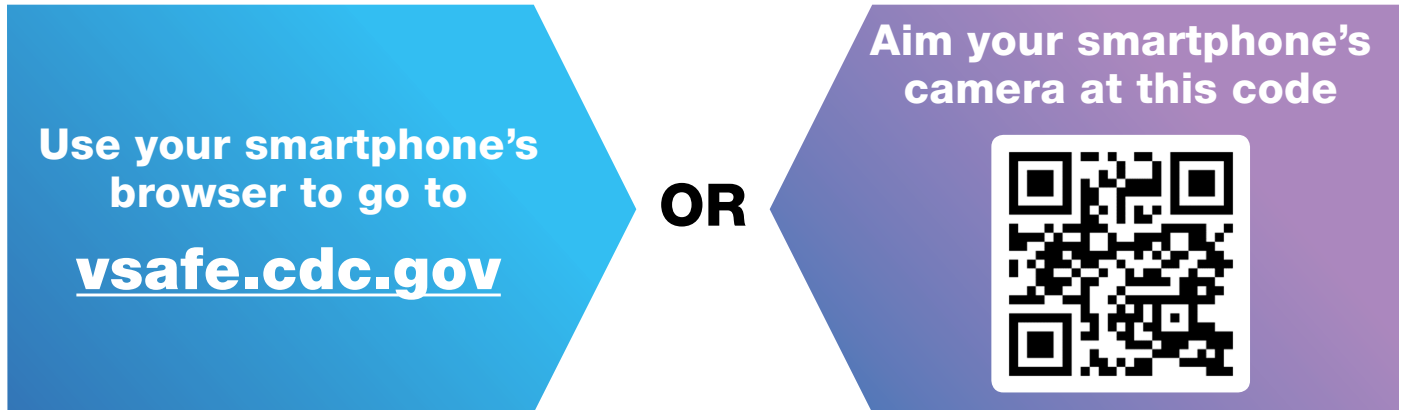


How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the **v-safe** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2pm local time, **v-safe** will start your initial health check-in around 2pm that day. If you register after 2pm, **v-safe** will start your initial health check-in immediately after you register — just follow the instructions.

You will receive a reminder text message from **v-safe** when it's time for the next check-in — around 2pm local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)

TTY 888-232-6348

Open 24 hours, 7 days a week

Visit www.cdc.gov/vsafe



COVID-19 VACCINE FAQs

1. How do the Pfizer-BioNTech and Moderna mRNA vaccines work?

Both the Pfizer and Moderna vaccines are messenger RNA (mRNA) vaccines. Messenger RNA vaccines give instructions for our cells to make a harmless product called a “spike protein.” The spike protein is found on the surface of the virus that causes COVID-19.

COVID-19 mRNA vaccines are given in the upper arm muscle. Once mRNA from the vaccine is inside our cells, they use them to make the spike protein. After the spike protein is made, enzymes in the cell break down the mRNA from the vaccine.

Next, the cell displays this newly made spike protein on its surface. Our immune system recognizes that this is a new, “foreign” protein and begins building an immune response. This response includes making protective antibodies, like what happens during natural infection against COVID-19. At the end of the process, our bodies have learned how to protect against future exposure to the virus.

The benefit of mRNA vaccines, like all vaccines, is that those people who are vaccinated gain protection from infection without ever having to risk the serious consequences of getting sick with the illness, like COVID-19.

2. What are the differences between the Pfizer and Moderna vaccines?

In terms of how they work, the Pfizer and Moderna vaccines are very similar. Both contain messenger RNA within a lipid (fatty or made up of fat) protective layer. Both stimulate our cells to produce the coronavirus spike protein, which in turn stimulates the immune system to produce protective spike protein antibodies. Both vaccines are given as a series of 2 intramuscular shots.

The vaccines differ slightly in how they are stored and administered. The Pfizer vaccine requires long-term storage at -80°C to -60°C , while the Moderna vaccine is stored at -25°C to -15°C . Both should be kept away from the light (sunlight and ultraviolet light).

The timing of the vaccine doses is also slightly different. The second dose of the Pfizer vaccine is given 3 weeks (21 days) after the first dose, while the second dose of the Moderna vaccine is given 4 weeks (28 days) after the first dose.

3. Will we receive one kind of vaccine or will there be different types from different companies?

There are several COVID-19 vaccines in development. The mRNA vaccines from Pfizer and Moderna are the two most likely to be approved and distributed first. In the future, there are likely to be other COVID-19 vaccines. At this point, Operation Ward Speed is organizing vaccine distribution efforts and we don't have the option of selecting what COVID-19 we receive.

COVID-19 VACCINE FAQs

4. What does the vaccine look like?

The vaccine is an off-white suspension. The Pfizer vaccine is diluted in normal saline. The Moderna vaccine does not require dilution.

5. How is the vaccine administered?

The Pfizer and Moderna vaccines are both administered via an intramuscular shot, meaning a shot delivered into a large muscle. The most common site of administration is the upper shoulder muscle (deltoid) because it is a big muscle and it is convenient to access.

6. Is it one shot or a series?

Both the Moderna and Pfizer vaccines require 2 doses. For the Pfizer vaccine, the second dose is given 21 days after the first dose. For the Moderna vaccine, the second dose is given 28 days after the first dose. It is important to note that you must receive the same vaccine for both doses. In other words, if you receive the Moderna vaccine on January 1, you should receive the Moderna vaccine on January 28.

7. Why are two vaccine doses needed? Are the two doses different?

For both the Moderna and Pfizer vaccines, the second vaccine dose is the same as the first dose. The second dose helps boost the immune system to produce a stronger immune response. This means more antibodies to protect against the COVID-19 virus. While the exact amount of antibodies needed to confer protection isn't known, in clinical trials, two doses of the vaccine produced a much more reliable response than one dose. Two doses also help the immune system develop long-lasting immunity, better than just one dose.

8. Do I need to get the same vaccine to complete my two doses?

Yes, if you receive a vaccine product that requires two doses, the second dose must be the same brand/manufacturer as the first dose.

9. What are the ingredients and what are their purpose?

The Moderna and Pfizer vaccines both contain messenger RNA, which carries a recipe for a specific SARS-CoV-2 (the virus that causes COVID-19) protein called the spike protein. This mRNA is carried in a fat droplet called a lipid nanoparticle. The lipid nanoparticles protect and transport the active mRNA component of the vaccine to its target site inside our cells.

There's also some buffer solution, which contains electrolytes that balance the pH of the liquid (potassium chloride, sodium chloride, etc.).

There are no additives or preservatives in these vaccines.

COVID-19 VACCINE FAQs

10. Is there any human or animal tissue in the either the Moderna or Pfizer vaccine?

No. The vaccine only contains the messenger RNA code and lipid particles that protect it so it can reach its target cells in the body.

11. Are messenger RNA COVID vaccines made with fetal cells?

No, there are no fetal cells required to manufacture the mRNA COVID-19 vaccines.

12. How effective are the mRNA COVID-19 vaccines?

The vaccines developed by Pfizer and Moderna have reported efficacy of 94%-95%. This efficacy is among the best we have available for any currently used vaccine. For comparison, the efficacy of the MMR vaccine is 97% (2 doses); and chickenpox is 90-92% (2 doses).

13. Is there any chance that a messenger RNA COVID vaccine could give me COVID-19?

No. The mRNA vaccines don't have all of the components necessary to make full copies of the virus that causes COVID-19, so it's not possible to get COVID-19 from a messenger RNA COVID-19 vaccine.

14. Can a person still get the virus even after they've been vaccinated?

It's possible, but much less likely than if you don't receive the vaccine. In clinical trials, both the Moderna and Pfizer vaccines have shown an efficacy of 94% to 95% after the second dose. That means the vaccine might not be fully protective in about 1 in 20 people.

Even when you get the COVID-19 vaccine, it takes a few weeks for the body's immune response to gear up. Keep in mind, one dose of the vaccine isn't good enough. It's important to get 2 vaccine doses. All totaled, it will take about 6 weeks after you receive the first vaccine dose to get the full protection from the vaccine. That means it's important to continue to practice all the measures currently being recommended to reduce the spread of the virus, including:

- Wash your hands regularly with soap and water, or alcohol-based hand rub.
- Cover your mouth and nose with a mask when in public settings or around others.
- Avoid touching your face.
- Cover your mouth and nose when coughing or sneezing.
- Stay home if you feel unwell.
- Practice physical distancing by avoiding unnecessary travel and staying away from large groups of people.

COVID-19 VACCINE FAQs

15. Is there one type of vaccine or different vaccines for different strains of the COVID virus?

Several different strains of the SARS-CoV-2 virus – the virus that causes COVID-19 – have been identified. However, among these strains, there are some common structural elements. One of these is a spike protein on the vaccine’s surface. This protein is crucial to the virus gaining entry into our cells, which allows it to replicate and cause illness. The spike protein stays the same on the different strains of virus.

Both the Pfizer and Moderna mRNA vaccines contain a recipe that allows our cells to produce this specific spike protein. The presence of this new protein causing the immune system to produce antibodies directed against this protein. These antibodies protect against future COVID-19 infection.

16. Does this vaccine act in the same way a flu shot, building up antibodies to help fight the virus?

Yes, basically. The COVID-19 stimulates the body to produce protective antibodies against the virus that causes COVID-19. It also stimulates immune cells called T cells, which help the body to “remember” the virus if exposed to it again. This makes it easier for our immune system to fight off the virus should it come into contact with the virus at a later date.

17. What’s the difference between an immunization and a vaccination?

Vaccination is the process of getting a vaccine into the body. Vaccines stimulate the body’s immune system to protect a person against subsequent infection or disease. Immunization is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine.

18. What are the contraindications to COVID-19 vaccination?

The FDA’s emergency use authorization indicates that the vaccine should not be administered to a person with a history of allergic reaction to a previous dose of COVID-19 vaccine.

19. Is it safe for pregnant or breastfeeding women to get the COVID-19 vaccine?

To date, the COVID-19 vaccines have not been tested on pregnant or breastfeeding women, so there’s no data to answer this question for sure. However, based on how the vaccine works, it is unlikely that vaccination would pose any additional risk to a pregnant or breastfeeding woman.

COVID-19 infection appears to be more dangerous to pregnant women compared to non-pregnant women. For this reason, the CDC is recommending that women in a high-risk

COVID-19 VACCINE FAQs

category (for example, a healthcare worker) get vaccinated even if pregnant or breastfeeding. If you are in this category, you should discuss the pros and cons of vaccination with your healthcare provider.

20. I've heard that the COVID-19 vaccine might interfere with a woman's ability to get pregnant. Is that true?

There's no reason to believe the vaccine is unsafe to use in women trying to conceive. The mRNA used in the COVID-19 vaccine does not integrate into our cell's genetic material. The mRNA in the vaccine shares a code that signals our cells make a protein, which in turn stimulates the production of protective antibodies. Once it does this job, the mRNA is naturally destroyed by enzymes in our cells.

21. I'm trying to conceive. Should I get a pregnancy test before receiving the COVID-19 vaccine?

Pregnancy testing before COVID-19 vaccination is not recommended.

22. Can I get the COVID-19 vaccine if I have a history of Guillain-Barre or other neurological condition?

We don't know for sure, but there's no data to suggest that people with a history of Guillain-Barre or other neurological condition should be excluded from COVID-19 vaccination.

The cause of Guillain-Barre is unclear, but it seems to be related to an overactive immune response from our body. Infections are thought to be one of the triggers that may provoke this immune response. Approximately two-thirds of patients with Guillain-Barre give a history of a recent respiratory tract or gastrointestinal infection. While Guillain-Barre has followed vaccinations, the risk of Guillain-Barre after receiving a vaccination is much smaller than the risk of Guillain-Barre after having an infection such as influenza.

23. Is this vaccine safe for older people who might have chronic health conditions?

Among the 30,000 participants in the Moderna trial, more than 7,000 Americans were over the age of 65. It also included more than 5,000 Americans who are under the age of 65 but who have high-risk chronic diseases that put them at increased risk of severe Covid-19, such as diabetes, severe obesity and cardiac disease. About 40% to 45% of the participants in the Pfizer study were between the ages of 56 and 85.

Based on currently available information, the vaccine is just as safe and effective in older people with chronic diseases as it is in younger, healthy people.

COVID-19 VACCINE FAQs

24. Should I be vaccinated if I have a condition or take medication that weakens my immune system (for example, HIV infection, treatment for cancer or rheumatologic illness)?

People whose immune systems are weak are at greater risk of developing severe COVID-19 infection. For this reason, the COVID-19 vaccine is recommended for people with conditions that suppress their immune system. Although the vaccine is recommended, people with immunosuppression may have a diminished response to the COVID-19 vaccine.

25. Does the COVID-19 vaccine cause people with autoimmune conditions to have a flare up?

In clinical trials with the COVID-19 vaccines, there were a small number of people with autoimmune conditions, and there was no evidence that receiving the COVID-19 vaccine caused their autoimmune conditions to flare up.

26. Is the vaccine safe for children?

The Pfizer vaccine has been given emergency use authorization for use in people 16 years of age and older. That's mainly because early vaccine trials did not include children. However, studies are now enrolling children, so we will have more information about the safety and effectiveness of the COVID-19 vaccines in this age group soon.

27. What are the vaccines' side effects?

The most common side effects are at the site of injection, such as localized tenderness, redness, swelling, or pain. Less commonly, people may have chills, fatigue, fever, muscle/joint pain, or nausea. Most people experience mild side effects that don't interfere with everyday activities, and most symptoms don't last longer than 2 days. Some people experience, symptoms might be moderate and last up to 5 days.

In Moderna's latest trials, about 10 percent of participants experienced fatigue, roughly 9 percent reported muscle aches and about 5 percent had joint pain and headaches. In Pfizer's analysis of its latest trials, fatigue was reported in 3.8 percent of participants and headaches in 2 percent. Injection site pain was noted with both vaccines.

The good news is that all these effects are signs that the vaccine is working and none of them produced long-term consequences.

There is a remote chance that the vaccine could cause a severe allergic reaction. These reactions usually happen minutes to one hour after getting a dose of the vaccine. Signs of a severe allergic reaction include:

- Difficulty breathing

COVID-19 VACCINE FAQs

- Swelling of the face and throat
- Fast heartbeat
- Rash all over the body
- Dizziness and weakness

If you experience any of these side effects, call 911 or go to the nearest hospital.

28. Have there been any deaths so far from people taking the COVID vaccine?

There have been no deaths reported in either the Moderna or Pfizer vaccine trials.

29. It seems that some people are experiencing some possible long-term symptoms from COVID. I understand that the vaccine is also new but is there any data regarding possible long term reactions from the vaccine?

Trials with the Moderna and Pfizer vaccines began in March, so we only have 6 to 9 months of data on the safety of these vaccines. Based on this data, the vaccines have not been associated with any long-term effects. Usually if you have a serious side effect from a new product, you'll find it out within the first few weeks, and no serious side effects have been identified in any of the Pfizer or Moderna vaccine trials. However, there is the remote possibility that a rare, serious side effect doesn't become apparent for some time after a vaccine is being used in large numbers of people. That's why participants in the vaccine clinical trials will continue to be tracked for at least two years, and there are several comprehensive national systems to monitor vaccine safety in the United States (for example, the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD)).

30. I have allergies and carry an Epi-pen. Is it safe for me to receive the COVID-19 vaccine?

The CDC considers a history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution but not a contraindication to vaccination. Persons who have a history of anaphylaxis to another vaccine or injectable therapy should discuss the pros and cons of COVID-19 vaccination with their health care provider.

There's no evidence that people with non-drug allergies (for example, shellfish, nut, latex allergy) have an increased risk of allergic reaction to the COVID-19 vaccine. Therefore, COVID-19 vaccination is recommended for these individuals.

If you have a history of anaphylaxis, it's recommended that you be monitored for 30 minutes after receiving the COVID-19 vaccine.

COVID-19 VACCINE FAQs

31. How long does immunity last?

We don't know for sure because the studies with the vaccines have only followed patients for less than a year. However, we know from other mRNA vaccines that immunity usually lasts for several years, often even decades. A "booster" vaccine dose may be necessary some time after the initial 2-dose regimen, but we're not certain about this right now. The CDC will make more specific recommendations once we have more information about the long-term immunity produced by the vaccines.

32. Can I get the COVID-19 vaccine at the same time as I get my influenza vaccine?

There's no information on the COVID-19 vaccine being administered with other vaccines. So, at this point, the CDC is recommending that the COVID-19 vaccine be administered separate from any other vaccine and preferably at least 14 days before or after another vaccination, such as the flu shot. However, if you inadvertently receive the COVID-19 vaccine less than 14 days after another vaccination, re-dosing is not recommended.

33. Will people have to get a two-part vaccine every year or will it become one-part vaccine every year?

We don't know yet. Vaccine studies are ongoing to help answer this question.

34. Who will be first in line to get the vaccine?

Priority groups for vaccination haven't been fully established; however, at the current time we know that the Phase 1A priority group will be healthcare workers and people living in long-term care facilities. The CDC Advisory Committee on Immunization Practices (ACIP) will be making recommendations as to who should be prioritized to receive COVID vaccine.

35. Will the vaccine be mandatory for federal employees?

Vaccination will be voluntary but will be made available to all employees.

36. Will I need to take the vaccine if I already had COVID-19?

Although many people who have COVID-19 develop protective antibodies, it's uncertain how long those antibodies last. There's evidence to suggest that the antibody response produced by the vaccine may be stronger and last longer than the antibody response mounted by the body in response to a natural infection. For this reason, COVID-19 vaccine is recommended for people regardless of whether or not they have had COVID-19 (symptomatic or asymptomatic) in the past.

COVID-19 VACCINE FAQs

37. If I have recently recovered from COVID-19, should I wait to get the vaccine?

The best information we have suggests that antibodies to COVID-19 that are produced by the body last for at least a few months. However, there's no way to determine whether that's true for everyone. There's also evidence to suggest that the antibody response produced by the vaccine may be stronger and last longer than the antibody response mounted by the body in response to a natural infection. For this reason, COVID-19 vaccine is recommended regardless of whether you have had COVID-19 or not.

That being said, if vaccine doses are very limited, it might make sense first to vaccinate people with no history of COVID-19, who definitely don't have antibodies to the virus and vaccinate individuals with a history of recent COVID-19 infection when more vaccine doses become available.

38. I received monoclonal antibody treatment (bamlanivimab, casirivimab, imdevimab) for COVID-19. Am I still eligible to get the vaccine?

You can still receive the COVID-19 vaccine if you were treated with monoclonal antibody therapy for COVID-19 infection. However, it's recommended that the vaccine be administered no less than 90 days after you received treatment to avoid interference of the treatment with the vaccine-induced immune response.

39. I received convalescent plasma for the treatment of COVID-19. Am I still eligible to get the vaccine?

You can still receive the COVID-19 vaccine if you were treated with convalescent plasma for COVID-19 infection. However, it's recommended that the vaccine be administered no less than 90 days after you received treatment to avoid interference of the treatment with the vaccine-induced immune response.

40. I understand the vaccine requires very strict temperature control. What are the possible negative consequences of receiving a vaccine where somewhere along the line temperature control wasn't optimal?

We don't have a lot of information to answer this question. However, based on previous experience, the most likely consequence is that the vaccine will be less effective or not effective at all. That's because the messenger RNA in the vaccine breaks down very easily, particularly if exposed to warm temperatures or light.

COVID-19 VACCINE FAQs

41. Does the vaccine work hand-in-hand with any of new treatment medications that have been authorized for use by the FDA?

Several medications such as bamlanivimab have been granted by the Food and Drug Administration (FDA) emergency use authorization (EUA) for patients with COVID-19. These drugs are used *to treat* patients who are confirmed to be COVID-19 positive through a laboratory test. They are not used to prevent infection.

Vaccines are intended to be used on healthy people *to prevent* infection. They stimulate our immune system to create protective antibodies. Vaccines work alone. No other medications need to be given for a vaccine to work.

42. Once we have the vaccine, will we still have to wear masks in public?

Remember, it takes about 6 weeks after the first dose of COVID-19 vaccine for the body to develop a protective immune response. It will also take several months for everyone who is eligible to get vaccinated. For these reasons, it's unlikely we'll see any changes to current recommendations for some time. The CDC will continue to modify recommendations based on COVID-19 case rates and trends throughout the world.

43. Will the COVID-19 vaccine affect results of SARS-CoV-2 nucleic acid amplification (PCR) or antigen tests?

No. Results of PCR or antigen tests for SARS-CoV-2 infection are not affected by the COVID-19 mRNA vaccines.

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