**SAMPLE PROTOCOL for ADMINISTRATION OF Moderna COVID-19 Vaccine**

**Under FDA Emergency Use Authorization (“EUA”) dated December 18, 2020 and as amended**

**Updated May 14, 2021 (Version 7)**

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| The San Francisco Department of Public Health (SFDPH) is sharing this sample protocol for the administration of Moderna COVID-19 vaccine to assist local COVID-19 vaccination providers in developing and implementing their own procedures. This document is based on sources, knowledge, and recommendations current as of the date above, but which are subject to change without notice. We will endeavor to provide updates as new information emerges. Users should regularly consult FDA, CDC, and CDPH sources for initial and updated guidance. |
| 5/14/2021 Updates* Interval between COVID-19 vaccine and other vaccines
* Use in pregnancy and breastfeeding
* Vaccination of persons with prior or current SARS-CoV-2 infection, MIS-C or MIS-A
* Additional warning on syncope; techniques to prevent syncope
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**Vaccine Components**

The vaccine does not contain thimerosal or preservative and the vial stopper does not contain latex.

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| **mRNA:** * Nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized spike glycoprotein (S) of SARS-CoV-2 virus

**Lipids:*** SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
* Polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG]
* Cholesterol
* 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]
 | **Stabilizers:*** Tromethamine
* Tromethamine hydrochloride
* Acetic acid
* Sodium acetate
* Sucrose
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**Authorized Use**

The vaccine is authorized to prevent COVID-19 in persons age **18 years** and older.

**Contraindications**

**Severe allergic reaction** (e.g., anaphylaxis) after a previous dose of mRNA COVID-19 vaccine, or to any of its components (including polyethylene glycol [PEG])

**Immediate allergic reaction of any severity** to a previous dose of mRNA COVID-19 vaccine, or to any of its components (including polyethylene glycol [PEG])

**Warnings and Precautions**

Ensure that medical treatment used to manage immediate allergic reactions (e.g. epinephrine) is immediately available in the event of acute anaphylactic reaction following administration.

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) history of **any immediate allergic reaction to other vaccines or injectable therapies** is a precaution to receiving any COVID-19 vaccine.

**Contraindication to Janssen vaccine** is a precaution to receiving mRNA vaccine; patient may be able to receive mRNA vaccine after consultation with an allergist-immunologist.

**Known polysorbate allergy** is no longer a contraindication to mRNA vaccination; however, known polysorbate allergy is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.

Immunocompromised persons may have a diminished immune response to this vaccine.

Syncope (fainting) may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be in place to avoid injury from fainting.

**Use in Pregnancy**

Data on the safety of COVID-19 vaccines in pregnant people are currently limited. Evidence from pregnancy registries have not identified any safety concerns to date; studies are ongoing. [Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), pregnant women are eligible for and can receive a COVID-19 vaccine.

Routinely testing for pregnancy prior to receipt of vaccine is not recommended.

Pregnant women who experience fever following vaccination may be offered acetaminophen, as fever has been associated with adverse pregnancy outcomes.

**Use during Breastfeeding**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), none of the COVID-19 vaccines can cause infection in either the mother or the infant; therefore, breastfeeding people can receive a COVID-19 vaccine.

**Pediatric Use**

Not authorized for persons younger than age 18 years.

**Use in Persons with Underlying Medical Conditions**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), vaccine may be administered to persons with underlying medical conditions (including those who have received dermal fillers) who have no contraindications to vaccination. This includes persons with auto-immune conditions or a history of Bell’s palsy or Guillain-Barre syndrome.

**Use in Persons with Immunocompromise**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies may receive COVID-19 vaccine unless otherwise contraindicated. Data are not currently available to establish safety and efficacy of vaccination in these groups, and so they should be counseled about the unknown safety and efficacy profile in immunocompromised persons, the potential for reduced immune response to the vaccine, and the need to continue to follow all current guidance to protect themselves against COVID-19. If possible, vaccine should be administered at least 2 weeks prior to initiation of immunosuppressive therapy.

**Co-Administration with Other Vaccines**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html/Coadministration), COVID-19 vaccines and other vaccines may now be administered without regard to timing. Consideration should be given regarding administration of two highly reactogenic vaccines (e.g. COVID-19 vaccine plus a tetanus vaccine or an adjuvanted vaccine such as Shingrix, Fluad, or Heplisav-B). If multiple vaccines are administered at a single visit, administer the more reactogenic vaccines at different injection sites, e.g. in different limbs.

**Use in Persons with Prior or Current SARS-CoV-2 Infection, MIS-C or MIS-A**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html%22%20%5Cl%20%22CoV-19-vaccination), vaccination should be offered regardless of history of symptomatic or asymptomatic SARS-CoV-2 infection, including people with prolonged post-COVID-19 symptoms.

In people with known current SARS-CoV-2 infection, vaccination should be deferred until the person has recovered from the acute illness (if symptomatic) and criteria have been met to discontinue isolation.

Viral or serologic testing for acute or prior SARS-CoV-2 infection is not recommended for the purpose of vaccine decision-making.

Persons with a history of multisystem inflammatory syndrome (MIS-C or MIS-A) may be vaccinated after weighing [factors outlined by ACIP.](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#CoV-19-vaccination)

**Use in Persons After Prior Receipt of COVID-19 Passive Antibody Therapy**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), vaccination should be deferred at least 90 days after receipt of COVID-19 monoclonal antibodies or COVID-19 convalescent plasma, due to the possibility that treatment with a COVID-19 antibody-containing product could interfere with development of immune response to the vaccine dose.

**Use in Persons with Recent Known SARS-CoV-2 Exposure**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), recent exposure to COVID-19 is not a contraindication to vaccination. However, individuals should not leave quarantine just to get a vaccine and thereby risk exposing others; if they cannot be vaccinated at their quarantine location, defer vaccination until their quarantine period has ended.

**Dosing and Schedule**

Administer intramuscularly (IM) as a series of two doses (0.5 mL each) given 4 weeks apart

Both doses are necessary for protection; though trial data suggests some protective benefit of a single dose, efficacy of a single dose has not been systematically evaluated.

**Timing.** The second dose should be scheduled and administered as close to 28 days as possible. [Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), second doses administered within a 4-day grace period prior to day 28 (i.e. day 24-27) are considered valid. If it is not feasible to adhere to the recommended interval, the second dose may be given up to 6 weeks (42 days) after the first dose; efficacy data are limited for doses administered beyond this window. Second doses given earlier than the grace period or more than 42 days after the first do not require restarting the series.

**Interchangeability**

Every effort should be made to complete the Moderna series with the same product; doses are not interchangeable with other COVID-19 vaccine products. However, [per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) in ***exceptional situations*** in which the first-dose product cannot be determined or is no longer available, the series may be completed with any available mRNA COVID-19 vaccine given at a minimum interval of 28 days.

In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the 2nd dose (up to 6 weeks) to receive the same product than to receive a mixed series using a different product.

If doses of two different mRNA vaccines are given, no additional doses of either product are recommended.

**Before Administering Vaccine**

Ensure that the recipient or caregiver has received a copy of the [Fact Sheet for Recipients and Caregivers](https://www.fda.gov/media/144638/download) or has been directed to <https://www.modernatx.com/covid19vaccine-eua> to obtain a copy.

Communicate to the recipient:

* That Moderna COVID-19 vaccine is not an FDA-approved vaccine, and has been authorized by FDA for emergency use
* That the recipient or their caregiver has the option to accept or refuse the vaccine.
* The significant known and potential risks and benefits of the vaccine, and the extent to which such risks and benefits are unknown (as outlined in the [Fact Sheet for Recipients and Caregivers](https://www.fda.gov/media/144638/download)).
* Information about available alternative vaccines and the risks and benefits of those alternatives.

Written informed consent is not required in order to receive vaccine under the EUA.

Vial Presentation

Original: multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).

New: multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).

**Instructions for Thawing and Dose Preparation**

The vaccine vial contains a frozen suspension that does not contain preservative and must be thawed prior to administration.

Vials may be thawed in the refrigerator or at room temperature. Thawing time depends on the number of doses per vial.



**After thawing, do not refreeze.** **Do not dilute the Moderna vaccine.**

**Swirl vial gently** after thawing, and again between each withdrawal of vaccine from the vial**. Do not shake the vial.**

The Moderna vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the vaccine vials and confirm that there are no other particulates and that there is no discoloration. Discard the vial and do not administer the vaccine if it is discolored or contains other particulate matter.

Each dose is 0.5 mL.

Pierce the stopper at a different site each time a dose is withdrawn.

Depending on the syringes and needles used for each dose, there may not be enough volume to extract more than 10 doses from the maximum of 11 doses vial, or more than 13 doses from the maximum of 15 doses vial.

Irrespective of the type of syringe and needle, each dose must contain 0.5 mL of vaccine.

If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. **Do not pool excess vaccine from multiple vials.**

**Administration**

Ensure the recipient is seated or lying down to receive the vaccine.

Techniques to prevent syncope:

* Ask patients about history of fainting or lightheadedness with needle sticks; if so, have them lie supine on a cot or mat for the injection.
* Ask patients if they’ve eaten today; if not, provide a drink and snack prior to the injection.

The deltoid muscle is the preferred site for IM administration. Inject into the central and thickest portion of the deltoid muscle.

[To avoid injury](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6347325/figure/f1-0650040/), do not inject too high or too low in the deltoid; identify an injection point 2-3 finger widths down from the acromion.

Cleanse the skin of the area to be injected using an alcohol wipe.

Use a sterile 22 to 25-gauge safety needle; 1” length for most adults and 1½” length for adults with very large arms. The needle should be inserted at a 90° angle.

For each dose, draw 0.5 mL into a sterile safety syringe and verify the final dosing volume of 0.5 mL. Cleanse the vial stopper between each withdrawal, using an alcohol wipe.

**Storage and Handling**

See [Fact Sheet for HCP](https://www.fda.gov/media/144637/download) or [CDC Moderna Storage and Handling Resources](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html) for details.

**Storage before vial puncture:**

* Store vials at freezer temperature between -50º to -15ºC (-58º to 5ºF).
* Store in the original carton to protect from light
* Do not store on dry ice or below 50ºC (-58ºF)
* Vials can be stored refrigerated (36° to 46°F) for up to 30 days prior to first use.
* Unpunctured vials can be stored at cool room temperature 8° to 25°C (46° to 77°F) up to 24 hrs.
* Do not refreeze vials once thawed
* During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. However, thawed vials can be handled in room light conditions.

**Storage after first puncture of the vial:**

* Keep the vial at refrigerator temperature or cool room temperature (36° to 77°F)
* Discard vial no later than 12 hours after the first puncture
* Do not refreeze

**After Administering Vaccine**

Observe all recipients after vaccination to monitor for the occurrence of immediate adverse reactions.

**30-min** observation period:

* History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
* History of anaphylaxis due to any cause
* Contraindication to Janssen COVID-19 vaccine, but able to receive Moderna vaccine

**15-min** observation period: All other vaccinees

Counsel recipients:

* That since vaccination is not 100% effective, current guidance on preventing COVID-19 should continue to be followed.
* On the importance of receiving a second dose to achieve full protection, and to return in as close to 28 days as feasible, ideally within 24 to 32 days, for the second dose.  If they develop symptoms after the first dose of vaccine, unless they develop a contraindication to receiving vaccine (e.g. a severe allergic reaction), they should return for the second dose in order to achieve full protection.
* That they may treat post-vaccination symptoms with typical doses of acetaminophen, ibuprofen, or naproxen, but they should not take these medications to try to prevent symptoms

Provide a vaccination document to the recipient or their caregiver with the administration date and brand of the first dose, and the date when the recipient needs to return for the second dose of Moderna vaccine.

**Reported Adverse Reactions**

**Local Reactions.** In clinical studies, redness, swelling, and pain at the injection site were mainly mild-moderate in severity, began on average 1 day after vaccination, and lasted on average for 2-3 days.

Up to 90% of vaccinees reported at least one local injection site reaction. Pain at the injection site was by far the most frequent, while axillary swelling or tenderness was reported less frequently, and redness and swelling at the injection site were less frequent still.

**Systemic Reactions.** In clinical studies, systemic adverse reactions were mainly mild to moderate in severity, began within 1-2 days of vaccination, and lasted on average for 2 days.

Between 50% and 82% of vaccinees reported at least one systemic reaction. The frequency of systemic adverse reactions was higher after the second dose of vaccine compared with the first dose, and higher in recipients age 18 to 64 years compared with those age 65 years and older.

Fatigue, headache, and myalgia were the most common systemic reactions, occurring in 20% to 67% of recipients depending on age and dose sequence.

Fever was uncommon after the first dose of vaccine, but were reported in up to 17% of recipients after the second dose. Chills were also uncommon after the first dose, were reported in up to 48% of recipients after the second dose.

Joint pain was reported in up to 16% of recipients after the first dose, and in up to 35% of recipients after the second dose. Nausea and vomiting were reported in up to 21% of recipients.

See [Fact Sheet for HCP](https://www.fda.gov/media/144637/download) or this [CDC page](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/reactogenicity.html) for data on rates of reported adverse reactions.

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), infrequently persons who have received dermal fillers may develop temporary swelling at or near the site of filler injection (usually face or lips) following a dose of an mRNA COVID-19 vaccine. Corticosteroid therapy may help; advise such persons to contact their healthcare provider for evaluation.

**Evaluating and Managing New-Onset Systemic Post-Vaccination Symptoms**

Post-vaccination signs and symptoms might be challenging to distinguish from signs and symptoms of COVID-19 or other infectious diseases.

Note that cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms, and instead may be symptoms of SARS-CoV-2 or another infection.

CDC has posted approaches to evaluating and managing new onset post-vaccination signs and symptoms [in healthcare providers](https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html) and in [long-term care facility residents](https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html). Additional guidance for other persons or settings may be forthcoming.

**Mandatory Reporting to the Vaccine Adverse Event Reporting System (VAERS)**

Vaccination providers are responsible for reporting certain types of events in vaccine recipients.

* All vaccine administration errors, whether or not the error is associated with an adverse event.
* Serious adverse events, whether or not the event is attributable to vaccination.
	+ Serious adverse events are defined as: death; a life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; a congenital anomaly/birth defect; an important medical event that may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes above).
* Cases of multisystem Inflammatory Syndrome (MIS) in adults or children

Refer to the [Fact Sheet for HCP](https://www.fda.gov/media/144637/download) for details of reporting to VAERS.

**Reference Documents**

EUA Fact Sheet for Recipients/Caregivers <https://www.fda.gov/media/144638/download>

EUA Fact Sheet for Healthcare Providers <https://www.fda.gov/media/144637/download>

FDA website: Moderna Vaccine

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine>

CDC Interim Clinical Considerations for Use of COVID-19 Vaccines <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

CDC Moderna Vaccine Page

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>

Moderna COVID-19 vaccine Website <https://www.modernatx.com/covid19vaccine-eua/>

**Update History**

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| 1/2/2021 Updates* ACIP revisions to contraindications and precautions; a few other clarifications
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| 1/10/2021 Updates* Reflects ACIP 1/6/2021 clarifications on 4-day grace period for second doses, vaccine co-administration, and passive antibody therapy
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| 1/23/2021 Updates* Reflects ACIP 1/21/2021 clarifications re: dermal fillers, timing of 2nd doses, persons with history of SARS-CoV-2 infection, and interchangeability of vaccine products.
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| 3/8/2021 Updates* Contraindications and precautions
* Interchangeability of vaccines
* Vaccination prior to initiation of immunosuppressive therapy
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| 4/20/2021 Updates* Transition to new vial capacity of 13-15 doses
* Thawing time extended for the 13-15 dose vials
* Storage conditions updated for unpunctured and punctured vials
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