Assessment, Administration, and Ordering of COVID-19 Vaccines, Emergency Use Authorization, Standardized Procedure

Location (includes Employee Health and all hospital and inpatient, outpatient, and community mass vaccination sites, mobile units and subacute facilities of the hospital, unless otherwise indicated)	
Enterprise Wide	X
O'Connor Hospital	
Santa Clara Valley Medical Center	
St. Louise Regional Hospital	

Who May Perform This Procedure			
RN	X	MUC	
LVN	X	HSR	
HSA		Techs	
MA		MDs, APPs, Residents	X
Other (specify): Pharmacists, pharmacy interns, pharmacy technicians, RPh, dentists, nursing students	X		

Who May Order This Procedure			
RN	X	MUC	
LVN	X	HSR	
HSA		Techs	
MA		MDs, APPs, Residents	X
Other (specify) Pharmacists, pharmacy interns, RPh, dentists	X		

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PURPOSE

To outline the administration process and the healthcare providers' responsibilities for administering, assessing, and ordering the COVID-19 vaccine for individuals who meet the criteria established by the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP).

BACKGROUND

The novel coronavirus (severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2) is a new strain of coronavirus that has been identified as the causative agent of the COVID-19 pandemic. Since the virus first emerged in late 2019, it has spread to 191 countries. The United States has reported over 29 million cases and 500,000 deaths as of early March 2021. Patients infected with SARS-CoV-2 may present with a wide range of clinical manifestations, from being asymptomatic to critically ill which may lead to hospitalization and/or death. Symptoms often appear 2 to 14 days after exposure, which include but are not limited to, fever (≥100°F), cough, shortness of breath, fatigue, muscle aches, and loss of taste or smell. COVID-19 patients 65 years or older, and those with underlying comorbidities (chronic lung disease, cardiovascular disease, diabetes, obesity (BMI ≥ 30 kg/m2), immunosuppression, etc.) are at increased risk of severe disease. Hispanics, Latinx, American Indian or Alaska Natives, and Blacks are disproportionately affected by the disease and have worse prognosis.

In December 2020, the FDA approved two emergency use authorization (EUA) applications for messenger RNA (mRNA) COVID-19 vaccines from Pfizer-BioNTech and Moderna. Both Pfizer and Moderna COVID-19 vaccines utilize mRNA technology to encode the prefusion spike glycoprotein of the SARS-COV-2 virus, which is recognized by the body's immune system to mount an immune response. Large, randomized, double-blind, placebo-controlled Phase 3 clinical trials that enrolled over 30,000 participants demonstrated high vaccine efficacy (94 to 95%) in preventing COVID-19 after completion of a two-dose series of either vaccine. In February 2021, Janssen's COVID-19 vaccine became the first single-dose COVID-19 vaccine to be granted an EUA from the FDA. The vaccine is composed of a recombinant, replication-incompetent adenovirus type 26 (Ad26) vector, constructed to encode a stabilized variant of the SARS-COV-2 spike protein. Transduction of the cell with the vector generates cellular production of the spike protein which instructs the immune system to react defensively and mount an immune response against the SARS-CoV-2 virus. A multicenter, randomized, double-blind, phase 3 clinical trial that enrolled approximately 40,000 participants showed protection against moderate to severe/critical COVID-19 (vaccine efficacy (VE) of 66.1%) and hospitalization, beginning 28 days post-vaccination.

Table 1. Timeline of Authorizations

Date	Pfizer	Moderna	Janssen
August 2021	• Additional dose (3rd dose) authorized for immunocompromised • Receives full FDA approval as COMIRNATY® for 16+ years old	• Additional dose (3rd dose) authorized for immunocompromised	
October 2021	• Booster dose authorized at least 6 months after the primary series for high-risk individuals • Mix-and-match boosters authorized	• Booster dose authorized at least 6 months after the primary series for high-risk individuals • Mix-and-match boosters authorized	• Booster dose authorized for 18+ year olds at least 2 months after the primary dose • Mix-and-match boosters authorized
November 2021	• Booster dose authorized for 18+ years old at least 6 months after primary series • Primary series authorized for 5-11 year olds	• Booster dose authorized for 18+ years old at least 6 months after primary series	
December 2021	• Booster eligibility expanded to 16-17 year olds		• CDC recommends mRNA vaccines over the Janssen vaccine due to risk of TTS
January 2022	• Booster eligibility expanded to 12-15 year olds • Booster dose interval shortened to 5 months • Additional dose authorized for immunocompromised 5-11 year olds	• Booster dose interval shortened to 5 months • Receives full FDA approval as Spikevax® for 18+ year olds	
February 2022			• CDC recommends booster dose for immunocompromised individuals
March 2022	• Second booster dose at least 4 months after the first booster is authorized for 50 + year olds and immunocompromised individuals	• Second booster dose at least 4 months after the first booster is authorized for 50 + year olds and immunocompromised individuals	• Second booster dose at least 4 months after the first booster is authorized for 50+ year olds, 18-49 year olds who received Janssen booster, and immunocompromised individuals
May 2022	• Booster dose authorized for 5-11 years at least 5 months after primary series		• CDC recommends Janssen vaccine should only be used in limited situations due to risk of TTS

LEVEL Interdependent.

SUPPORTIVE DATA This standardized procedure complies with the California Board of Registered Nursing (BRN) Standardized Procedure Guideline and the CDPH's Immunization Branch authorization.

ORDERING AND AUTHORIZING PROVIDER(S) This is a "**per protocol, no co-sign required**" procedure. If using PrepMod, no order is required. If using HealthLink, the system will automatically create a per protocol order authorized by Phuong Nguyen, M.D. for hospital and clinic sites, or Sarah Rudman, M.D., as the authorizing provider for mass and mobile community vaccination sites.

SUPPLIES

- 0.9% Sodium Chloride injection, USP (DO NOT use bacteriostatic 0.9% Sodium Chloride injection)
- 3 mL syringe with 21-gauge needle or narrower (transfer and diluent syringe)
- 1 mL or 3 mL syringe (for administering the vaccine)
- 23 to 25-gauge needles (for administering the vaccine)
- Alcohol wipes
- Pen (to record date and time of dilution, and to fill out vaccination card)
- Band-Aid
- Cotton balls
- Hospital approved germicidal disinfectant
- PPE: Gloves, surgical mask
- Sharps container

The following **emergency supplies must** be **immediately** available to the clinical team assessing and managing anaphylaxis for adult and pediatric patients:

- Adult and pediatric dose epinephrine prefilled syringe or autoinjector (at least THREE doses at each vaccination site at all times)
- H1 antihistamine (e.g., diphenhydramine)
- Blood pressure cuff (adult and pediatric sizes)
- Stethoscope
- Timing device to assess pulse

If feasible, including at sites (not mandatory) for adult and pediatric patients**:**

- Oxygen
- Nasal cannula and face mask(s)
- Oxygen saturation monitor
- Bronchodilator, *e.g.*, albuterol
- H2 antihistamine, *e.g.*, famotidine, cimetidine
- Intravenous fluids
- Intubation kit
- Adult-sized pocket mask with one-way valve (a/k/a cardiopulmonary resuscitation mask)
- Ambu bag (adult and pediatric sizes)
- Scale

REQUIREMENTS FOR VACCINE ADMINISTRATOR

A. **Licensure/Certification**:

1. Licensed/certified providers (e.g., MD, APPs, dentists, pharmacists, RN, LVN, RPh etc.):

a. License/certification in good standing.
b. Completion of a COVID-19 Immunization Training Course given by staff developer which includes the administration of vaccine and emergency management for both adult and pediatric patients.
c. Dentists may independently prescribe and administered COVID-19 vaccines only to persons aged 16 years and older
d. LVNs must be under the direction of physician and surgeon or under standing orders of a supervising physician

2. Intern pharmacists:
   a. Possess a certificate of completion for a pharmacy-based immunization delivery program, a national certification program for pharmacists, developed by the American Pharmacists Association (APhA) or an equivalent Pharmacy-Based Immunization Certificate program approved by the California State Board of Pharmacy.
   b. Intern pharmacists must be under the supervision and control of a pharmacist.
3. Nursing students:
   a. Precepted by instructor from their nursing institution, which must be affiliated with County of Santa Clara Health System.

B. **Training:**
   1. Orientation and competency validation to the standardized procedure of COVID-19 vaccination and administration of vaccines.
   2. Completion of Immunization training course as assigned by staff developer, including management of anaphylaxis.

C. **Experience and Training:** Minimum of completion of orientation.

D. **Initial Evaluation:** Completion of orientation/competency validation to the standardized procedure of COVID-19 Immunization Course.

E. Competency validation for performing this standardized procedure will be documented and maintained in the learning management system.

F. **On-Going Evaluation:** Annual review of competency.

PROCEDURE

A. Prepare vaccines in accordance with **Attachment A** for Pfizer-BioNTech or **Attachment B** for Moderna or **Attachment C** for Janssen.

B. Prior to receiving vaccine individuals will be screened to assess for COVID-19 symptoms. Individuals with the following symptoms should NOT receive the vaccine and should be referred for COVID-19 testing:
   - Fever (≥100°F for HCW and ≥100.4°F for others) or chills
   - Cough
   - New loss of taste or smell
   - Shortness of breath or difficulty breathing
   - New or unexplained in the previous 3 days: fatigue, muscle or body aches, headache, sore throat, congestion or runny nose, nausea, vomiting or diarrhea

PROCEDURE
(continued)

C. Confirm individual using two (2) identifiers.

D. Review individual's date of birth and ensure that individual meets age criteria for vaccine being administered (5 and older for Pfizer; 18 and older for Moderna and Janssen). **Do not vaccinate if age criteria not met.**

E. Review Attestation/consent if required and ensure that it is fully completed and signed, and that the individual meets current vaccine eligibility criteria based on current CDC and CDPH guidelines. If attestation/consent is not available in the individual's preferred language, utilize an interpreter. If interpreter used, document in health record.

F. Ensure that the individual has received (or if not, then provide) the *Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA)* if applicable for the specific COVID-19 vaccine being offered/administered, in the individual's native or preferred language. If the *Fact Sheet for Recipients* is not available in the individual's preferred language, utilize an interpreter. If interpreter used, document in health record. If the individual is receiving an additional or booster dose and completed primary vaccination with a WHO-authorized vaccine that is not authorized/approved in the United States, they may review the *Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers.*

G. Review the individual's responses to COVID-19 vaccine screening questions (PrepMod, HL, paper form, etc.) and review with the individual the contraindications and precautions, using the guidance in **Attachment E and F.**

H. If vaccination is contraindicated, should be deferred, or provider order is required (hospital and clinic setting only) but not provided, do not vaccinate and advise individual to follow up with their primary care provider.

I. Screen individual for allergic reactions to the COVID-19 vaccine components and prior allergic reactions to previous vaccine dose, if applicable. Refer to **Attachment F.**

J. **Co-administration with other vaccines**: COVID-19 vaccines and other vaccines may be administered without regard to timing. This includes simultaneous administration of COVID-19 and other vaccines on the same day, as well as coadministration within 14 days.

If multiple vaccines are administered at a single visit, administered each injection in a different injection site, according to recommendations by age.

- Separate injection sites by 1 inch or more, if possible.
- Label each syringe with name, dosage, lot number, initials of preparer, and exact BUD, if applicable
- For patients 11 years and older, the deltoid muscle can be used for more than 1 intramuscular injection
- For 5-10 years of age:

- If patient has sufficient deltoid muscle mass, the deltoid is the preferred injection site.
- If more than 2 vaccines are injected in a single limb with insufficient deltoid muscle mass, the anterolateral thigh is the preferred site due to greater muscle mass

o Administer the COVID-19 vaccines and vaccines that are more likely to cause a local reaction in different limbs, if possible.

K. Observe individual in accordance with protocols noted in **Attachment F.**

L. Make all efforts to avoid wastage of unused doses. Follow current Hospital Command Center Policy to Avoid Waste of COVID-19 Vaccine Doses About to Expire.

EDUCATION / FOLLOW-UP

A. Advise (and assist as appropriate) the individual to schedule an appointment for the 2nd dose of the vaccine if vaccine requires a 2nd dose. This is very important to achieve the most protection from COVID-19. Advise the individual that COVID-19 vaccine brands are not interchangeable for the initial vaccination. If a 2nd or additional dose is needed, the subsequent dose should utilize the same vaccine product.

For booster dose, the use of an mRNA COVID-19 vaccine is preferred regardless of the primary series vaccine type. Any of the mRNA COVID-19 vaccines can be used if patient is 18+. However, offering the Janssen vaccine as a booster dose is preferable to not providing any COVID-19 vaccine booster in most situations. If a heterologous booster dose is given in 18+, the eligible population and dosing interval are those of the vaccine used for primary vaccination. Only patients 5-17 years old who have completed Pfizer primary series may receive a Pfizer booster dose.

B. Providers should counsel vaccine recipients in accordance with protocols noted in **Attachment G**.

C. Provide the individual with the CDC's "Possible Side Effects After Getting a COVID-19 Vaccine" https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

DOCUMENTATION

A. Document the following information in the required system (e.g., HealthLink, PrepMod, paper form, or other format):

1. Date of *Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA)* given
2. Attestation regarding vaccine eligibility, if applicable
3. Exclusion criteria, if applicable
4. Precaution criteria, if applicable and individual decision to proceed with vaccination
5. Instructions provided, including monitor for allergic reactions and return for second dose of vaccine
6. Any provider notifications, reason for notifications, and follow up / interventions
7. Instructions on follow up appointment (if applicable)

B. Document vaccine administration into CAIR2 within 24 hours of vaccination.
   1. If the patient/guardian declines to have their information in CAIR2 shared with other participating organizations, the patient's vaccination information may still be entered into CAIR2, but the record must be "locked" per CAIR instructions at http://cairweb.org/cair- disclosure-policy/.

DEVELOPMENT & APPROVAL OF THE STANDARDIZED PROCEDURE

A. **METHOD**
Developed and approved by authorized representatives of Administration, Public Health, County Health System Medical Staff, Pharmacy, and Nursing.

B. **REVIEW**
This protocol is to be reviewed whenever new guidance is available and at a minimum annually.

ATTACHMENTS (Click hyperlink to jump to a section. Each attachment will also have a hyperlink to return to this page):

SIGNATURES:

AUTHORIZING PROVIDER:

DocuSigned by:
9097F432E932467...

6/15/2022

Phuong H. Nguyen, MD
Chief Medical Officer

Date

AUTHORIZING PROVIDER:

DocuSigned by:
2AEDCBEB33C14B7...

6/14/2022

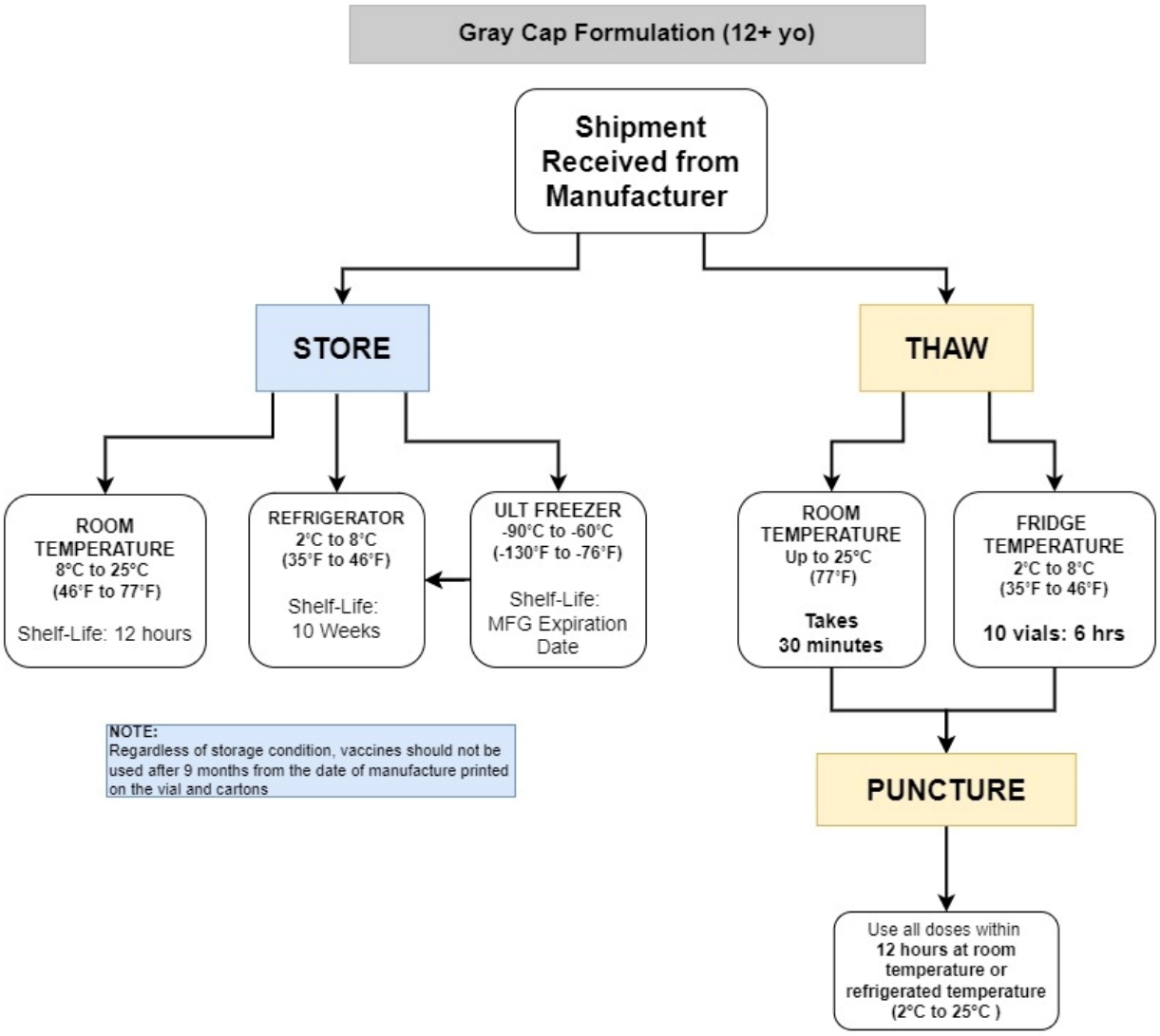
Angela Suarez, MD
Assistant Public Health Officer

Date

Issued: Hospital Command Center 12.29.20, 1.5.21, 1.12.21, 1.26.21,2.2.21, 2.16.21,
Approved: 3.8.21, 4.15.21, 4.21.21, 5.12.21, 5.17.21, 5.20.21, 8.16.21, 9.28.21, 11.10.21, 12.01.21, 12.23.21, 1.20.22, 4.13.22, 6.14.22
Jill Sproul, Chief Nursing Officer, 1.6.21, 1.26.21,2.2.21,2.16.2, 3.8.21, 4.15.21, 4.21.21, 5.12.21, 5.17.21, 5.20.21, 8.16.21, 9.28.21, 11.10.21, 12.01.21, 12.23.21, 1.20.22, 4.13.22
Phuong H. Nguyen, M.D., 1.6.21, 1.26.21,2.2.2, 2.16.21, 3.8.21, 4.15.21, 1.20.22, 4.21.21, 5.12.21, 5.17.21, 5.20.21, 8.16.21, 9.28.21, 11.10.21, 12.01.21, 12.23.21, 1.20.22, 4.13.22, 6.14.22
Sarah Rudman, M.D., 1.6.21, 1.26.21, 2.2.21, 2.16.21, 3.8.21, 4.15.21, 4.21.21, 5.12.21, 5.17.21, 5.20.21, 8.16.21, 9.28.21, 11.10.21, 12.01.21, 12.23.21, 1.20.22, 4.13.22
Angela Suarez, M.D., 6.14.22

ATTACHMENT A

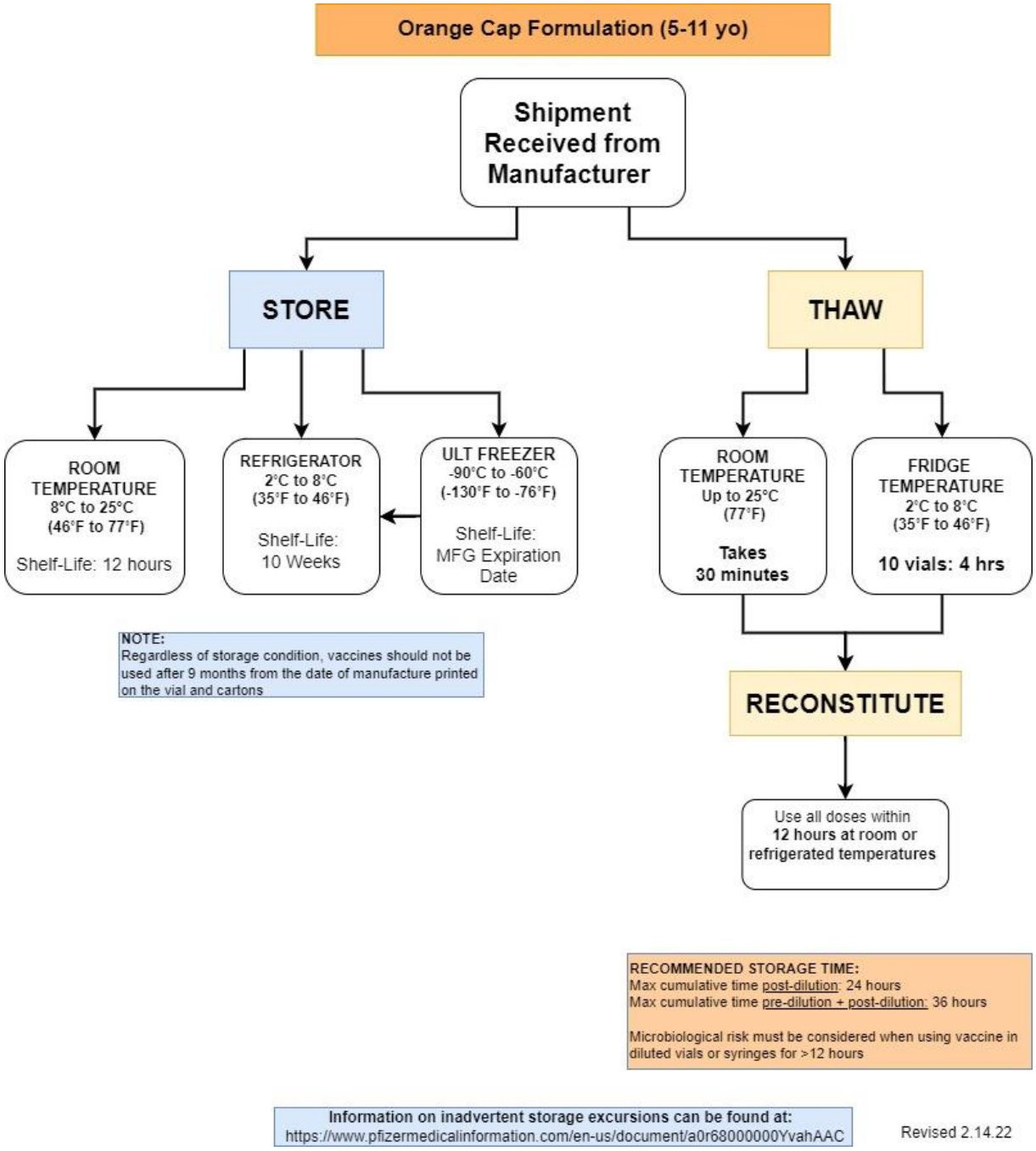
Figure 1. Storage and Handling of Pfizer-BioNTech Vaccine (Gray Cap Formulation)



Revised 12.21.21

For detailed information on storage & handling and preparation of Pfizer-BioNTech Gray Cap formulation, please visit: Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers, Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) For 12 Years of Age and Older [Gray Cap]

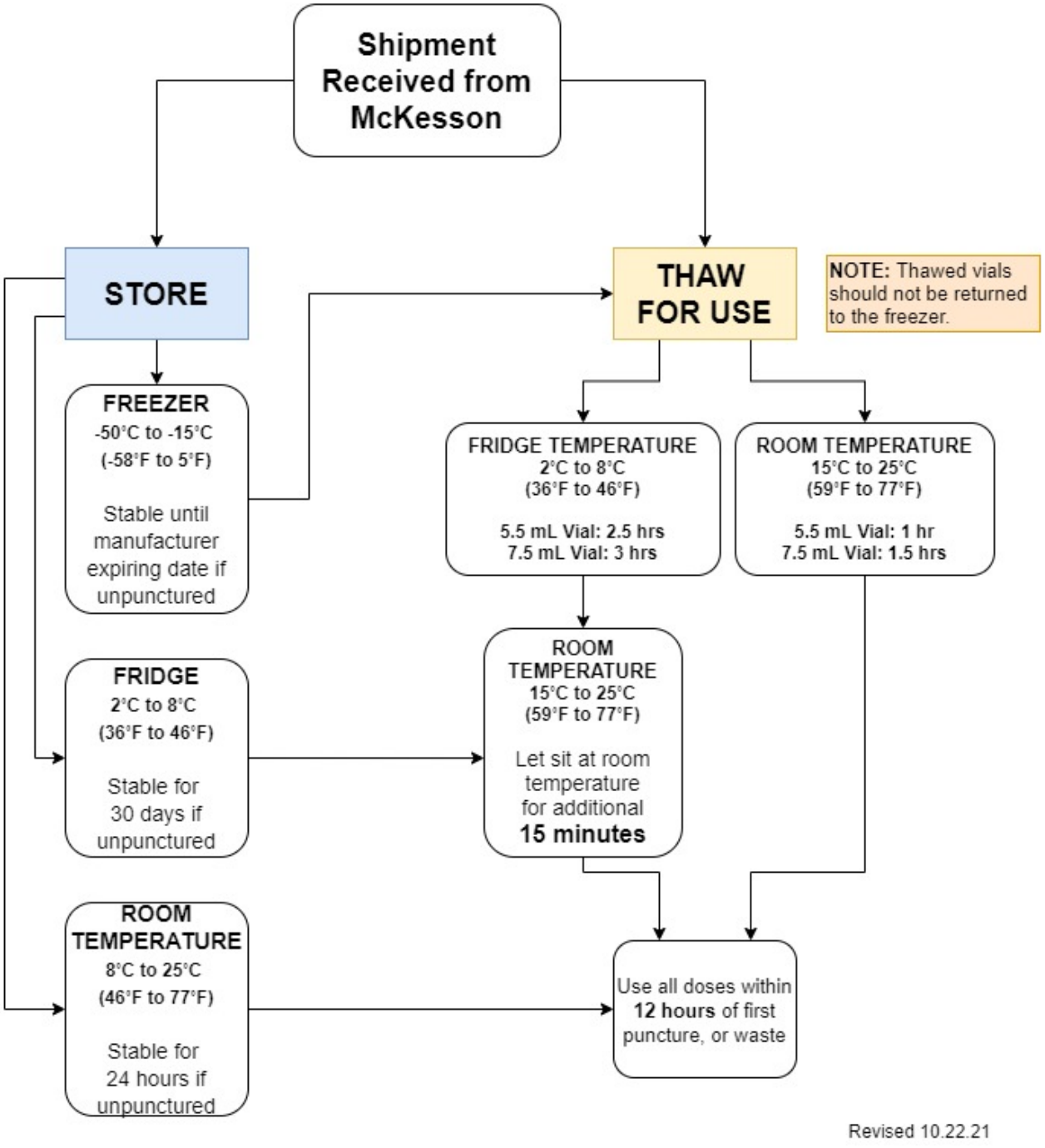
Figure 2. Storage and Handling of Pfizer-BioNTech Vaccine (Orange Cap Formulation)



For detailed information on storage & handling and preparation of Pfizer-BioNTech Orange Cap formulation, please visit: Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers, Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) For 5 Through 11 Years of Age

ATTACHMENT B

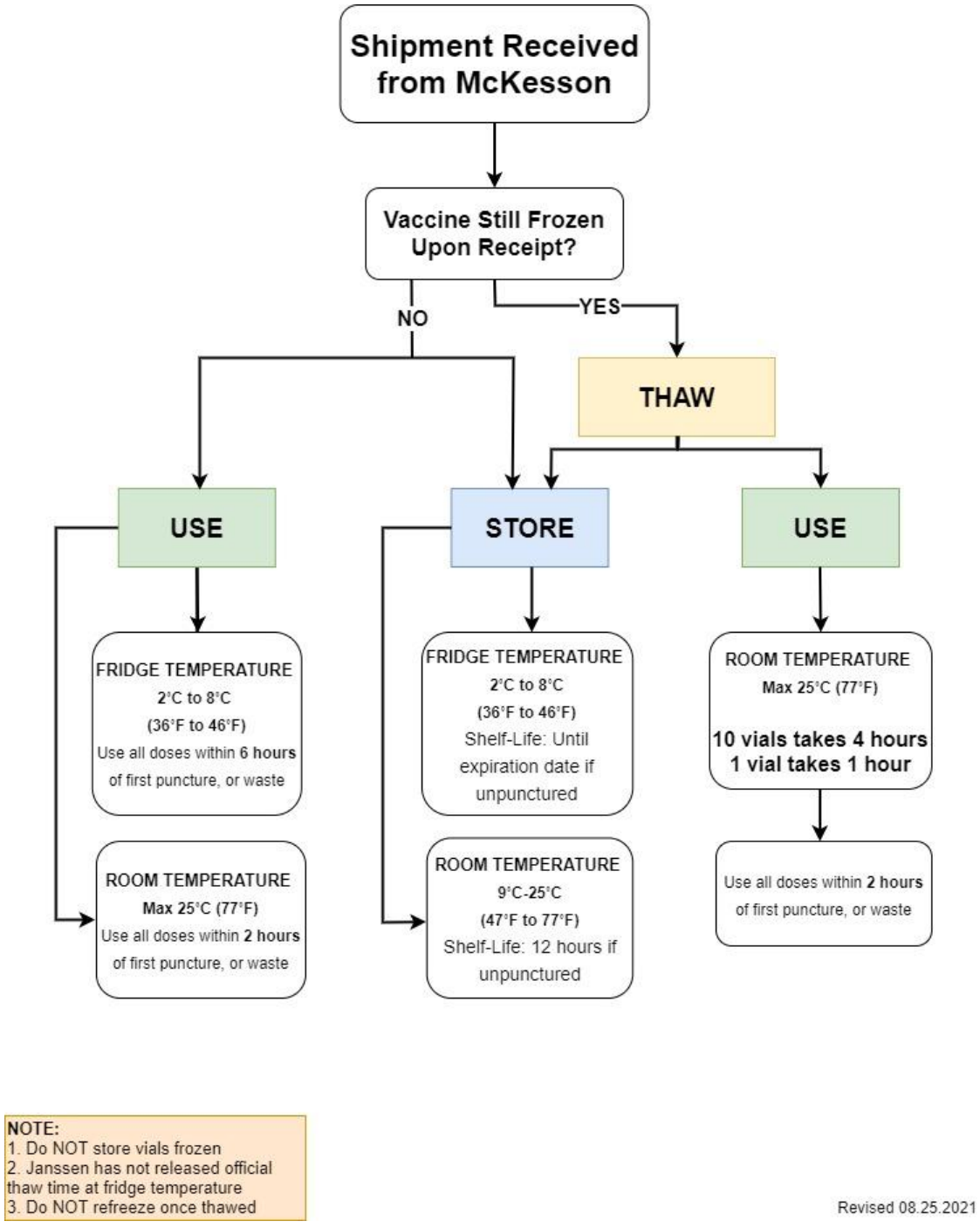
Figure 3. Storage and Handling of Moderna Vaccine



For detailed information on storage & handling and preparation of the Moderna COVID-19 Vaccine, please visit: Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers, Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

ATTACHMENT C

Figure 4. Storage and Handling of Janssen Vaccine



For detailed information on storage & handling and preparation of the Janssen COVID-19 Vaccine, please visit: Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers, Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

ATTACHMENT D

ADMINISTRATION / POST-ADMINISTRATION OF COVID-19 VACCINE

	STEPS		KEY POINTS
	ADMINISTRATION		
1.	Perform hand hygiene.		
2.	Don PPE (surgical mask, gloves)	2.1	If already wearing PPE, perform hand hygiene and change gloves.
3.	Identify individual using two (2) identifiers. If the individual is a patient, check if there is an order for vaccination in HealthLink (HL).	3.1	If no provider order, follow standardized procedures.
	Confirm that the individual meets the age eligibility criteria.	3.2	DO NOT administer Moderna or Janssen vaccine if individual is less than 18 years old. Individuals 5 years of age and older can receive the Pfizer vaccine. Reschedule for Pfizer vaccine if desired.
4.	Confirm with individual verbally and check in HL and CAIR2 to determine if the individual has received a COVID-19 vaccine in the past.	4.1	COVID-19 vaccines and other vaccines may now be administered without regard to timing. If possible, administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction in different limbs.
	Primary Series • If this is the second dose of the **Pfizer** vaccine, review and confirm that it has been 3 weeks* since the first dose AND the first dose was Pfizer. ***Note:** an 8-week interval *may* be optimal for some people 5 years and older, especially for males 12 to 39 years (see **Attachment F: Primary Series** for details).	4.2	The second dose of Pfizer COVID-19 vaccine is to be administered **3 weeks after** the first dose. However, second dose administration within a grace period of 4 days earlier than the recommended date for the second dose is still valid. If individual is within this window, vaccine can be administered.
	• If this is the second dose of the **Moderna** vaccine, review and confirm that it has been 4 weeks* since the first dose AND the first dose was Moderna. ***Note:** an 8-week interval *may* be optimal for some people 5 years and older, especially for males 12 to 39 years (see **Attachment F: Primary Series** for details).	4.3	The second dose of Moderna COVID-19 vaccine is to be administered **4 weeks after** the first dose. However, second dose administration within a grace period of 4 days earlier than the recommended date for the second dose is still valid. If individual is within this grace window, vaccine can be administered.

STEPS		KEY POINTS
Additional Dose (Immunocompromised) • If this is the **additional dose** of an mRNA COVID-19 vaccine primary series, review and confirm that patient meets the CDC criteria for an **additional dose** of mRNA COVID-19 vaccine and that it has been at *least 28 days* (4-day grace period) since the second dose. The vaccine product of the additional should match the initial 2-dose mRNA COVID-19 primary vaccine series. • If this is an **additional dose** of an mRNA COVID-19 vaccine after prior Janssen COVID-19 vaccination, confirm that the patient meets CDC criteria for an **additional dose** and then refer to **Table 7** for dosing protocol.	4.4	If the patient has completed either the Pfizer or Moderna COVID-19 vaccine series in the past and meets the CDC criteria for an additional dose of Pfizer or Moderna (immunocompromised), they may proceed with a third dose at least 28 days after their last mRNA COVID-19 vaccine dose. (At mass and mobile vaccination operations, confirmation that the patient meets CDC criteria may be accomplished by self-attestation from the patient.) The vaccine should match the previous doses (e.g., 3rd dose of Moderna after 2 doses of Moderna already completed), but a different mRNA vaccine may be administered for the 3rd dose if the other mRNA vaccine is not available. If the patient has competed the Janssen COVID-19 dose and meets criteria for an additional dose of Pfizer or Moderna (immunocompromised), refer to **Table 7** for dosing protocol.
Booster Dose • If this is the **<u>first</u> booster** dose of the Pfizer or Moderna COVID-19 vaccine, review and confirm that patient meets CDC criteria for a **booster dose** and that it has been *at least 5 months* since they completed their primary series with the Pfizer or Moderna COVID-19 vaccine, *at least 2 months* since they completed their primary series with the Janssen COVID-19 vaccine, or *at least 3 months* after the third dose of Pfizer and Moderna if they are immunocompromised	4.5	If the non-immunocompromised patient has completed the **Pfizer or Moderna** COVID-19 vaccine series in the past and meets the CDC criteria for a **first** booster dose, they may proceed with a **first** booster dose at least 5 months after completing the primary series. If the non-immunocompromised patient has completed the initial dose of the **Janssen** COVID-19 vaccine in the past and meets CDC criteria for a **first** booster dose, they may proceed with a **first** booster dose of an mRNA vaccine [preferred] at least 2 months after the initial dose.
• If this is the **<u>second</u> booster** dose of the Pfizer or Moderna COVID-19 vaccine, review and confirm that the patient meets CDC criteria for a second booster dose and		If the non-immunocompromised patient has received a first booster dose in the past and meets the CDC criteria for a **second** booster dose, they may proceed with a **second** booster dose at least 4

STEPS		KEY POINTS
that it has been *at least 4 months* since they received their first booster dose		months after receiving the **first** booster dose. If the patient is moderately to severely immunocompromised and has received an mRNA primary series *and* an additional dose of an mRNA COVID-19 vaccine, they may proceed with their **first** booster dose *at least 3 months* after the third dose of an mRNA COVID-19 vaccine. If the patient is moderately to severely immunocompromised and has received a first booster dose in the past, they may proceed with a **second** booster dose of Pfizer (12+ years old) or Moderna (18+ years old) *at least 4 months* after the first booster dose
If this is a **<u>first</u> booster dose** of Janssen COVID-19 vaccine, review and confirm that patient meets CDC criteria for a **booster dose** and that it has been at *least 2 months or 8 weeks* (4-day grace period*)* since the primary dose with Janssen COVID-19 vaccine or the additional mRNA COVID-19 vaccine dose if the patient is immunocompromised. However, an mRNA vaccine is *preferred* as a booster dose	4.6	If the patient has completed a **Janssen** COVID-19 vaccine dose in the past and meets the CDC criteria for a booster dose, they may proceed with a Janssen booster dose at least 2 months (8 weeks) after completing the primary dose or additional dose [mRNA vaccine is preferred as a booster dose] (immunocompromised). (At mass and mobile vaccination operations, confirmation that the patient meets CDC criteria may be accomplished by self-attestation from the patient.)
• For patients 5-17 years of age who have completed primary series with Pfizer COVID-19 vaccine, only an age-appropriate Pfizer product may be used for booster vaccination.	4.7	Mixing and matching of booster is not authorized in patients 5-17 years of age.
• For patients 18+, an mRNA vaccine is preferred for a booster dose, even if the patient received Janssen as their primary series. Any of the mRNA vaccines may be used as booster, regardless of the vaccine product used for primary series.	4.8	Heterologous dosing may be considered for **booster dose** only in patients 18+.
	4.9	If an mRNA vaccine is not available, offering a Janssen vaccine as a booster is preferable to not providing any

	STEPS		KEY POINTS
			COVID-19 vaccine boosters in most situations.
5.	Review the individual's response to COVID-19 vaccine screening questions (PrepMod, HL, paper form, etc.) and review with the individual the contraindications and special precautions in **Attachment F**. If the individual is a minor (under the age of 18) or another individual who is legally unable to provide consent for their vaccination, the legal representative must be either present for the appointment or available by phone at the time of the appointment if discussion is needed with the decisionmaker. If screening questions are not available in the individual's preferred language, utilize an interpreter. If interpreter used, document in health record.	5.1	If individual has contraindication to vaccination (**Attachment F**), do not vaccinate and advise individual to follow up with primary care provider.
		5.2	For any complex COVID-19 vaccine safety question not addressed by the EUA, CDC, or ACIP guidance, the Clinical Immunization Safety Assessment COVIDvax project may be contacted at 800-CDC-INFO (800-232-4636) or via electronic form (https://wwwn.cdc.gov/dcs/ContactUs/Form). In case of an emergent clinical COVID-19 vaccine safety inquiry, call the CDC Emergency Operations Center (EOC) Watch Desk at (770)-488-7100 to be routed to the CISA COVIDvax on-call staff.
6.	Ensure that consent form is signed by individual. If individual is a minor or other individual who is legally unable to provide consent for their vaccination, a person legally authorized to make healthcare decisions for the individual must be present at the appointment to sign the consent form, or the forms must be printed and signed by the legal representative ahead of time and brought to the vaccination appointment. If not, staff shall call the patient's legal representative to obtain verbal consent and document the verbal consent, including the name and relationship of the individual providing consent, and the date and time of the consent, on the consent form. Confirm individual, or the legal representative if the individual is a minor or other person legally unable to consent for vaccine, has reviewed a copy of the *EUA Fact Sheet for Recipients and Caregivers* of the COVID-19 Vaccine being administered. If not, provide a copy either in person (if individual/legal representative is present) or electronically (if not present).	6.1	The individual may also be directed to the website www.cvdvaccine.com to obtain additional information on the Pfizer vaccine.
		6.2	When appointment for COVID-19 vaccine is scheduled in PrepMod, the Fact Sheet will be provided thorough electronic link. Other mechanisms to provide Fact Sheet electronically may be implemented for HealthLink or other mechanisms.
		6.3	The vaccinating entity will retain each patient's COVID-19 Vaccine Screening and Consent Form for 3 years or as long as required by the County's record retention policy, whichever is longer.

	STEPS		KEY POINTS
7.	Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab (15 seconds and allow to dry), and withdraw the COVID-19 vaccine. • Pfizer: 0.3 mL (≥12 yo), 0.2 mL (5-11 yo) • Moderna: 0.5 mL (primary series), 0.25 mL (booster) • Janssen: 0.5 mL	7.1	**Do not** administer if vaccine is discolored or contains particulate matter.
		7.2	If pre-drawn syringes provided, validate correct vaccine type and appropriate dose is in the syringe.
8.	Immediately administer the COVID-19 vaccine intramuscularly.	8.1	For patients 11 years and older, the deltoid muscle can be used for more than 1 intramuscular injection For 5-10 years of age: - If patient has sufficient deltoid muscle mass, the deltoid is the preferred injection site. - If more than 2 vaccines are injected in a single limb with insufficient deltoid muscle mass, the anterolateral thigh is the preferred site due to greater muscle mass
9.	Remove gloves and perform hand hygiene. All sharps and syringes will be disposed in an approved impenetrable sharps container using universal precautions. Pharmacy personnel will dispose of full sharps containers in accordance with California regulations.		
	POST-ADMINISTRATION		
10.	Individual should be observed for immediate adverse reactions to the vaccine. a. Individuals with history of an immediate allergic reaction of any severity to a vaccine or injectable therapy **AND** individuals with a history of anaphylaxis due to any cause: 30 minutes. b. All other individuals: 15 minutes	10.1	If applicable, encourage individual to schedule second COVID-19 vaccine appointment while waiting in the observation area.
		10.2	If applicable, remind the individual of the dosing interval for the second dose of the COVID-19 Vaccine: • Pfizer: needs to be given at **3 weeks after** the first dose. • Moderna: needs to be given at **4 weeks after** the first dose. • **Note:** an 8-week interval *may* be optimal for some people 5 years and older, especially for males 12 to

	STEPS		KEY POINTS
			39 years (see **Attachment F: Primary Series** for details).
11.	Provide a vaccination card to the individual or their caregiver with record of administration. If applicable, provide the date when the individual needs to return for the second dose of the COVID-19 vaccine.		
12.	Provide the v-safe information sheet to vaccine recipient/caregiver and encourage vaccine recipients to participate in v-safe.	12.1	V-safe is a voluntary smartphone-based tool that uses text messaging and web surveys to check in with vaccinated individuals to identify side effects after COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe
13.	For assistance with additional questions/concerns: a. County Health System Healthcare Workers may be directed to the: Santa Clara County Healthcare Worker COVID-19 Vaccine Hotline at 408-283-7444, Mon-Fri 7:30 AM to 4 PM. b. Other individuals	13.1 13.2	Call Santa Clara County Healthcare Worker COVID-19 Vaccine Hotline for additional information. Follow up with primary care provider for further questions/concerns
14.	Document the following information in the designated Immunization Information System (IIS): • Vaccine name and dosage; number (e.g., 1 of 2; 2 of 2); lot #; manufacturer name; expiration date • Body site where injection was given (include preference right/left deltoid; right/left anterolateral thigh) • Date of *EUA Fact Sheet for Recipients and Caregivers* given • Instructions provided, including return for second dose of vaccine • Any provider notifications, reason for notifications, and follow up / interventions • Instructions on follow up appointment (if applicable).	14.1	All vaccination sites need to document vaccine administration into CAIR2 within 24 hours.

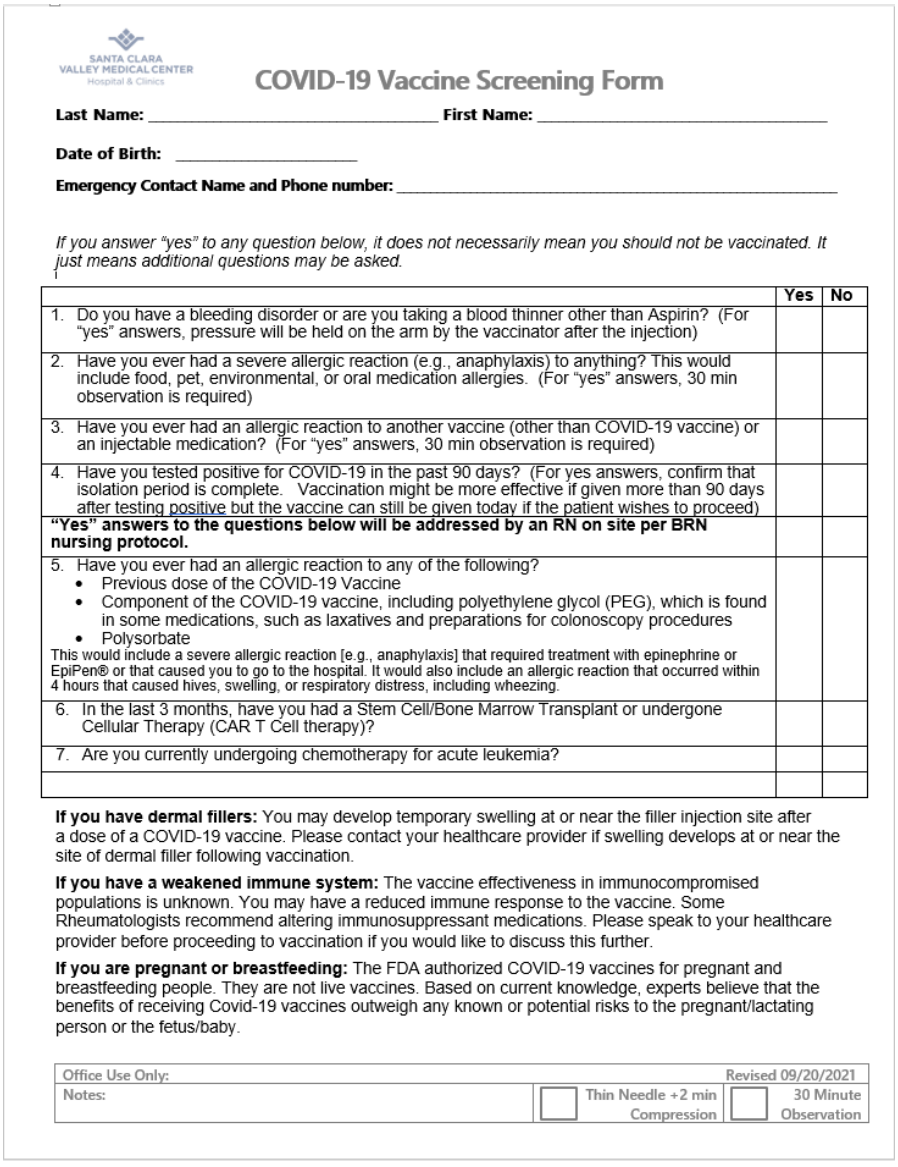
	STEPS		KEY POINTS
	EMERGENCY MANAGEMENT and REPORTING		
15.	**Ambulatory and mass vaccination sites:** • Notify RN / Provider immediately. • Initiate Medical Management of Vaccine Reactions in Patients (**Attachment G**) and submit. **Inpatient:** • Call the Code team AND notify supervisor / provider immediately.	15.1	Report all adverse reactions to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov. 15.2 For hospital and clinic sites, complete and submit an SCVHHS Occurrence Report online.
16.	Instruct individual that if they develop any signs of a severe allergic reaction, to **call 911**, or to go to the nearest hospital.	16.1	Signs of a severe allergic reaction may include: • Difficulty breathing, wheezing • Swelling of the face, lip, throat • Rapid heartbeat • Bad rash all over body • Dizziness and weakness • Feeling of impending doom, anxiety • Abdominal cramping

ATTACHMENT E

INFORMATION FOR CLINICAL REVIEWERS (SCREENERS) AND VACCINATORS

As we roll out vaccines to the public, we are reassigning providers and registered nurses to participate in this effort. This is critical to achieving mass vaccination in a short period of time. Thank you for participating in this incredible effort. We have created this document to help you prepare for your new role and to give you resources that will provide you with additional information. Please remember that you are not the Primary Care Provider for these individuals. You will not have a lot of time to inquire into each individual's personal health care issues nor should you. If the patient has a complex health issue or questions that you do not know how to answer or advise them, please refer them to their Primary Care Provider (PCP)/Health Care System.

A. The COVID-19 Vaccine Screening form must be completed by all individuals presenting for a COVID-19 vaccine. Based on the responses to the screening questions, the individual will either: proceed to vaccination or be deferred for vaccination. Refer to the COVID-19 Screening Form Quick Guide and Screening Script and flowchart (What to do when a patient answers YES to the screening questions).



SANTA CLARA VALLEY MEDICAL CENTER
Hospital & Clinics

COVID-19 Vaccine Screening Form

Last Name: _____ **First Name:** _____

Date of Birth: _____

Emergency Contact Name and Phone number: _____

If you answer "yes" to any question below, it does not necessarily mean you should not be vaccinated. It just means additional questions may be asked.

	Yes	No
1. Do you have a bleeding disorder or are you taking a blood thinner other than Aspirin? (For "yes" answers, pressure will be held on the arm by the vaccinator after the injection)		
2. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to anything? This would include food, pet, environmental, or oral medication allergies. (For "yes" answers, 30 min observation is required)		
3. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? (For "yes" answers, 30 min observation is required)		
4. Have you tested positive for COVID-19 in the past 90 days? (For yes answers, confirm that isolation period is complete. Vaccination might be more effective if given more than 90 days after testing positive but the vaccine can still be given today if the patient wishes to proceed)		
"Yes" answers to the questions below will be addressed by an RN on site per BRN nursing protocol.		
5. Have you ever had an allergic reaction to any of the following? • Previous dose of the COVID-19 Vaccine • Component of the COVID-19 vaccine, including polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures • Polysorbate This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.		
6. In the last 3 months, have you had a Stem Cell/Bone Marrow Transplant or undergone Cellular Therapy (CAR T Cell therapy)?		
7. Are you currently undergoing chemotherapy for acute leukemia?		

If you have dermal fillers: You may develop temporary swelling at or near the filler injection site after a dose of a COVID-19 vaccine. Please contact your healthcare provider if swelling develops at or near the site of dermal filler following vaccination.

If you have a weakened immune system: The vaccine effectiveness in immunocompromised populations is unknown. You may have a reduced immune response to the vaccine. Some Rheumatologists recommend altering immunosuppressant medications. Please speak to your healthcare provider before proceeding to vaccination if you would like to discuss this further.

If you are pregnant or breastfeeding: The FDA authorized COVID-19 vaccines for pregnant and breastfeeding people. They are not live vaccines. Based on current knowledge, experts believe that the benefits of receiving Covid-19 vaccines outweigh any known or potential risks to the pregnant/lactating person or the fetus/baby.

Office Use Only:		Revised 09/20/2021
Notes:	☐ Thin Needle +2 min Compression	☐ 30 Minute Observation

What to do when a patient answers YES to three screening questions?

1. Have you ever received a dose of the COVID-19 vaccine? ☐ Yes ☐ No
2. If Yes, which vaccine product? ☐Pfizer ☐Moderna ☐Janssen (Johnson & Johnson) ☐ Other_____
3. Are you here today for an additional dose of vaccine after completing 2 doses of Pfizer or Moderna:
   ☐ Yes ☐ No

Patients seeking a booster dose

- If a non-immunocompromised patient is seeking a first or a second booster dose, please refer to **Attachment F: Table 5** for detailed guidance
- If a moderately to severely immunocompromised patient is seeking a first or a second booster dose and selects Pfizer or Moderna for Question #2, please refer to **Attachment F: Table 6** for detailed guidance
- If a moderately to severely immunocompromised patient is seeking a booster dose and selects Janssen for Question #2, please refer to **Attachment F: Table 7** for detailed guidance

Patients seeking additional vaccine dose (immunocompromised)

- If a patient is moderately to severely immunocompromised is seeking an additional dose selects Pfizer or Moderna for Question #2, please refer to **Attachment F: Table 3** for detailed guidance
- If a moderately to severely immunocompromised patient is seeking a booster dose and selects Janssen for Question #2, please refer to **Attachment F: Table 7** for detailed guidance

People who received COVID-19 vaccination outside the United States

- Please refer to **Attachment F: Table 11** for detailed guidance

1. Do you have a bleeding disorder or are you taking a blood thinner other than Aspirin?

OK to vaccinate. 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.

2. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to anything? This would include food, pet, environmental, or oral medication allergies.

30 minute observation time, place red sticker on patient's chest

*** Any other allergic reaction, not noted above, would require the normal 15 min wait time. This includes non-severe reactions to food, pet, environmental, or oral medication. These are considered to be in the normal 15 min wait time. ***

Common symptoms of anaphylaxis may include: Facial, tongue or throat swelling, difficulty breathing, wheezing, vomiting within 4 hours of exposure. An Epi-Pen may have been administered to treat the symptoms.

3. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication?

30 minute observation time, place red sticker on patient's chest

4. Have you tested positive for COVID-19 in the past 90 days?

If yes: confirm that isolation period is complete
Vaccination might be more effective if given more than 90 days after testing positive but the vaccine can still be given today if the patient wishes to proceed

5. Have you ever had an allergic reaction to any of the following?
   - Previous dose of the COVID-19 Vaccine
   - Component of the COVID-19 vaccine, including polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures
   - Polysorbate

Please reference Table 9: Triage of Persons Presenting for COVID-19 Vaccination

6. In the last 3 months, have you had a Stem Cell/Bone Marrow Transplant or undergone Cellular Therapy (CAR T Cell therapy)?

If Yes: "Have you spoken to your Oncologist about getting the vaccine today?
If Yes- OK to vaccinate (no need to show a letter or proof of this discussion)
If No- Reschedule vaccination

7. Are you currently undergoing chemotherapy for acute leukemia?

If Yes: "Have you spoken to your Oncologist about getting the vaccine today?
If Yes- OK to vaccinate (no need to show a letter or proof of this discussion)
If No- Reschedule vaccination

B. FAQs about the vaccine: Many patients may have questions about the vaccine. Here are two links to provide you with more information about the vaccines and some FAQ's for your reference:

a. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html
b. https://www.scvmc.org/COVID19/Vaccine/12232020%20COVID-19%20Vaccine%20FAQ.pdf

C. COVID-19 Vaccine FAQs (<u>for internal reference only, not for printing/distribution</u>)

What if I can't come to my second dose appointment? What is the latest that I can schedule the second dose?
It is recommended to make your second dose appointment before you leave today (3 weeks after Pfizer dose and 4 weeks after Moderna dose). Ideally, the second dose should be given as close to the

recommended interval as possible. However, if it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered beyond these intervals, there is no need to restart the series.

Does this vaccine contain COVID-19? Will I test positive after I receive the vaccine?
The vaccine doesn't contain the virus. The vaccine should not cause you to test positive. Because the vaccine doesn't provide protection immediately or completely it is still possible that you could contract the infection from other people and test positive from that infection.

Will I need to continue to wear a mask and social distance after I'm vaccinated?
Yes! The vaccine doesn't provide protection immediately or completely so it will be important to continue wearing a face covering and socially distance even after receiving the vaccine.

Will I be immune to COVID after receiving both doses?
The vaccine isn't perfect and so complete immunity isn't expected. Your risk of becoming ill with COVID should decrease after receiving both doses but there is a lot we still need to learn about the effectiveness of the vaccine, particularly with newer strains of the virus emerging.

What happens if I test positive after receiving the vaccine?
A positive test after the vaccine would be due to active infection with the virus and you will need to isolate per instructions from Public Health or your physician.

Will I be more likely to have symptoms after the first or second dose?
The vaccine study participants were more likely to have symptoms after the second dose.

Should I take Ibuprofen or Tylenol when I get home?
Soreness at the injection site or mild achiness can be treated with cool compresses. Tylenol/Advil can help with symptoms as long as you don't have a medical reason not to take those medications. Contact your provider if you for additional guidance.

How long will the vaccine last? Will this be yearly?
We don't yet know if this vaccine will continue to be effective against newer strains of the coronavirus that causes COVID-19. It is possible that repeated vaccine will be needed.

When will my family be vaccinated?
Refer to current vaccination guidance from PHD and our COVID Communication Hub for latest information to share with patient.

ATTACHMENT F

COVID-19 VACCINE INDICATIONS, CONTRAINDICATIONS, PRECAUTIONS, AND SPECIAL POPULATIONS/CONSIDERATIONS

Indications: Patient Inclusion Criteria

1. Age
    a. Pfizer/BioNTech Vaccine: Individuals who are 5 years of age or older.
    b. Moderna Vaccine: Individuals who are 18 years of age or older.
    c. Janssen Vaccine: Individuals who are 18 years of age or older.
2. Individuals who have not completed an FDA approved, FDA authorized, or WHO authorized COVID-19 vaccination series.

Observation period after vaccination

1. Individuals with a history of immediate allergic reaction of any severity to a vaccine or injectable, individuals with a contraindication to a different type of COVID-19 vaccine, and/or individuals with a history of anaphylaxis due to any cause should be observed for **30 minutes**.
2. All other individuals should be observed for **15 minutes**.

Primary Series

1. **People who are not moderately to severely immunocompromised:** *primary series* is defined as a 2-dose series of an mRNA COVID-19 vaccine (Pfizer and Moderna) or a single dose of Janssen vaccine.

Table 2. Primary Series for People Who Are NOT Moderately to Severely Immunocompromised

Vaccine Manufacturer	Age (years)	Vial cap color	Dose (volume)	Number of doses (interval between doses)
Pfizer	5-11	Orange	10 ug (0.2 mL)	2 (3-8 weeks)
Pfizer	11 turning 12 between 1st and 2nd dose	Dose 1: Orange Dose 2: Gray	Dose 1: 10 ug (0.2 mL) Dose 2: 30 ug (0.3 mL)*	2 (3-8 weeks)
Pfizer	≥12	Gray	30 ug (0.3 mL)	2 (3-8 weeks±)
Moderna	≥18	N/A	100 ug (0.5 mL)	2 (4-8 weeks±)
Janssen†	≥18	N/A	5×10^{10} viral particles (0.5 mL)	1 (N/A)

*Children turning 12 years old between 1st and 2nd dose should receive age-appropriate 30 ug Pfizer ≥12 years (gray) formulation as their 2nd dose. However, if 10 ug is given as the 2nd dose, it is not considered an error. Additionally, 10 ug may be administered as the 2nd dose upon parental request if the request is made within 30 days of the child turning 12 years old (if 10 ug for 2nd dose is requested after 30 days, defer patient to pediatrician for appropriate dose assessment).

±An 8-week interval may be optimal for some people ages 5 years and older, especially for males 12 to 39 years. A shorter interval (3 weeks for Pfizer; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults aged 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

†Janssen COVID-19 vaccine should only be used in limited situations; mRNA vaccines are preferred over the Janssen vaccine

2. **People who are moderately or severely immunocompromised** (see **Attachment F: 'Special Populations/Considerations'** for definition of immunocompromised): *primary series* is defined as **a 3-dose series** of an mRNA COVID-19 vaccine *or* a single dose of Janssen COVID-19 vaccine followed by an additional (2nd) dose of an mRNA COVID-19 vaccine at least 4 weeks later (see **Table 7** for dosing guidance).
    - *Additional dose* is defined as a subsequent dose of vaccine administered to people who were less likely to mount a protective immune response after initial vaccination.

Table 3. Primary Series for People Who ARE Moderately or Severely Immunocompromised

Vaccine Manufacturer	Age (years)	Dose (volume)	Number of primary series doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose
Pfizer	5-11	10 ug (0.2 mL)	3	At least 3 weeks	At least 4 weeks
Pfizer	≥12	30 ug (0.3 mL)	3	At least 3 weeks	At least 4 weeks
Moderna	≥18	100 ug (0.5 mL)	3	At least 4 weeks	At least 4 weeks
Janssen	≥18	5×10^{10} viral particles (0.5 mL)	1 Janssen followed by 1 mRNA*	At least 4 weeks	N/A

*mRNA vaccine used for additional dose should be Pfizer or full-dose Moderna. See **Table 7** for details

Booster Doses of COVID-19 Vaccine:

- *Booster dose* is defined as subsequent dose of vaccine administered to enhance or restore protection which might have waned over time after primary series vaccination.
    - *Heterologous booster dose (mix-and-match booster)* is a subsequent dose of vaccine that is a different product from the primary series
    - *Homologous booster dose* is a subsequent dose of vaccine that is the same product as the primary series
- *Up to Date:* All recommended primary vaccine series doses and booster doses for which a person is eligible have been received
    - People ages ≥50 years and people ≥12 years who are moderately or severely immunocompromised, should get a second booster dose to be up to date
    - People ages 18 - 49 years who received a Janssen COVID-19 vaccine for both their primary and booster dose may get a second booster dose of either Pfizer-BioNTech or Moderna COVID-19 vaccine, but the second booster dose is not required to be considered up to date

Table 4. Dosing for Boosters

Vaccine Manufacturer	Vial Cap Color	Booster Dose	Injection Volume
Pfizer 5-11 years	Orange	10 ug	0.2 mL
Pfizer ≥12 years old	Gray	30 ug	0.3 mL
Moderna ≥18 years old	Red	50 ug	0.25 mL
Janssen ≥18 years old	Blue	5×10^{10} viral particles	0.5 mL

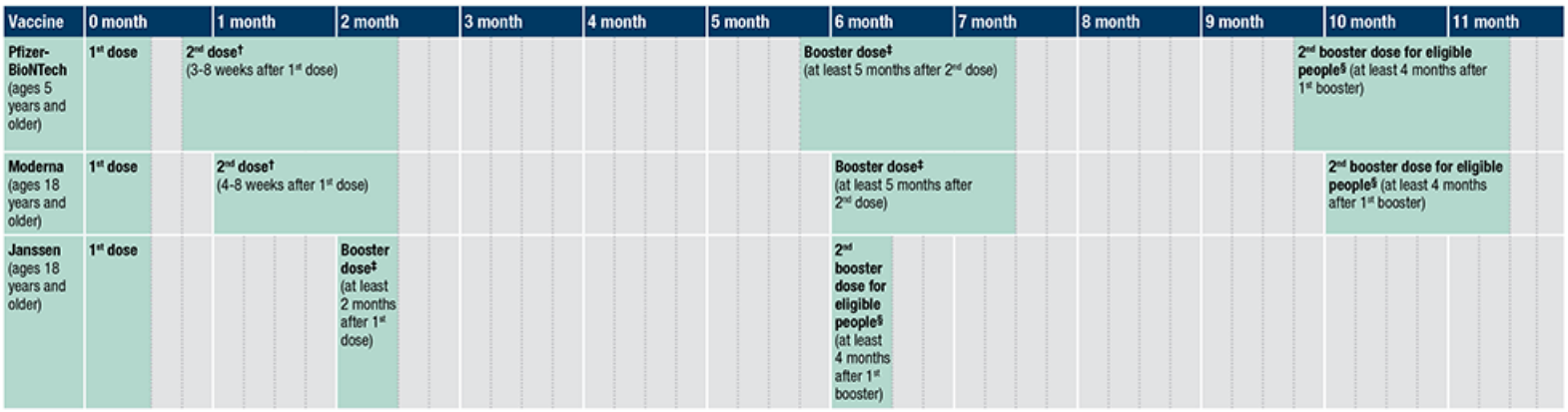
1. People Who are NOT Moderately or Severely Immunocompromised

Table 5. Booster Dose Recommendations for People Who are NOT Moderately or Severely Immunocompromised

mRNA COVID-19 Vaccine Primary Series		
Age Group (years)	**1st Booster Dose***	**2nd Booster Dose**
5-11	Recommended *at least 5 months* after the primary series (Pfizer only)	Not Authorized
12-17	Recommended *at least 5 months* after the primary series (Pfizer only)	Not Authorized
18-49	Recommended *at least 5 months* after the primary series, mRNA preferred over Janssen	Not Authorized
≥50	Recommended *at least 5 months* after the primary series, mRNA preferred over Janssen	Should receive an mRNA booster *at least 4 months* after the first booster dose (total doses= 4)
Janssen COVID-19 Primary Series		
Age Group (years)	**1st Booster Dose**	**2nd Booster Dose**
18-49	Recommended *at least 2 months* after initial dose, mRNA preferred.	People who received Janssen as both their primary series AND booster dose may receive an mRNA booster *at least 4 months* after first booster (total doses= 3)
≥50	Recommended *at least 2 months* after initial dose, mRNA preferred	Should receive mRNA booster *at least 4 months* after the first booster (total doses= 3)

*For dosing, please refer to **Table 4**

Figure 5. Booster Vaccination Schedule for People Who Are NOT Moderately or Severely Immunocompromised



†An 8-week interval may be optimal for some people ages 5 years and older, especially for males ages 12 to 39 years. A shorter interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk for severe disease.

‡ All people ages 5 years and older should receive 1 booster dose of an age-appropriate COVID-19 vaccine. An mRNA COVID-19 vaccine is preferred over the Janssen COVID-19 Vaccine; for people ages 5–17 years, only Pfizer-BioNTech can be used.

§ People ages 18–49 years who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the Janssen booster dose. People ages 50 years and older who received a first booster dose of any FDA-approved or FDA-authorized COVID-19 vaccine should receive a second booster dose using an mRNA vaccine at least 4 months after the first booster dose.

2. **People Who are ARE Moderately or Severely Immunocompromised** (see **Attachment F: 'Special Populations/Considerations'** for definition of immunocompromised)

Table 6. Booster Dose Recommendations for People Who ARE Moderately or Severely Immunocompromised

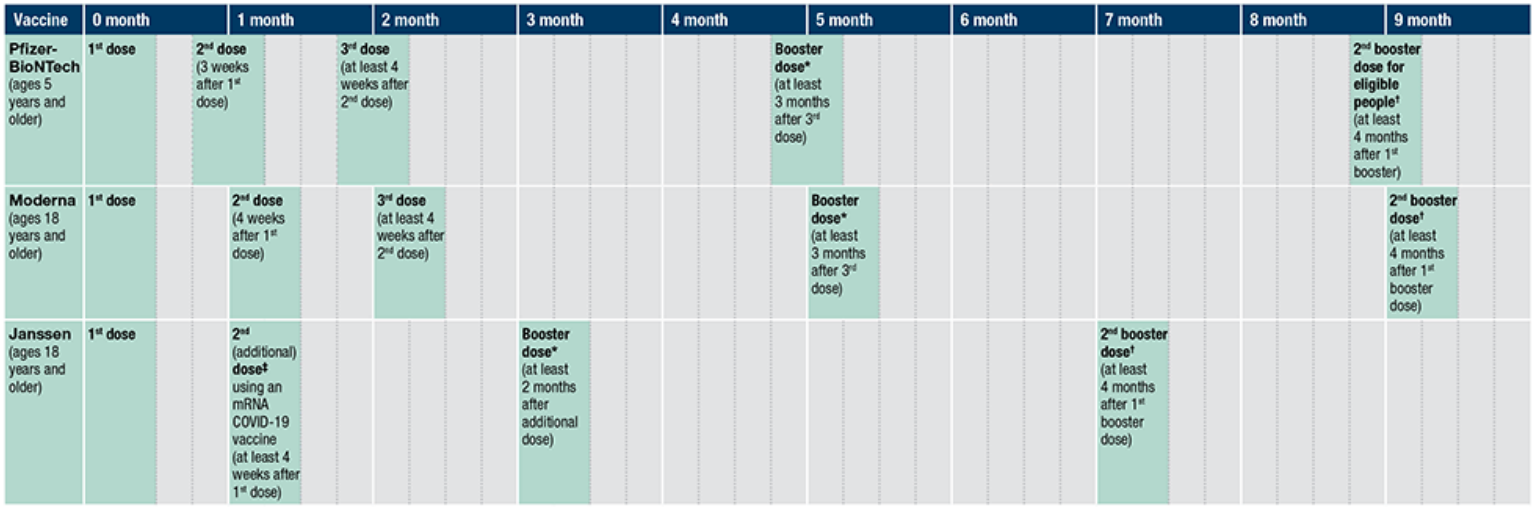
mRNA COVID-19 Vaccine Primary Series		
Age Group (years)	**1st Booster Dose‡**	**2nd Booster Dose**
5-11 (Pfizer only)	Recommended *at least 3 months* after the primary series*	Not Authorized
≥12 (Pfizer= ≥12 years old, Moderna= ≥18 years old)	Recommended *at least 3 months* after the third dose in the primary series, mRNA preferred (total doses= 4)*	Should receive an mRNA booster *at least 4 months* after the first booster dose (total doses= 5)*
Janssen COVID-19 Primary Series		
Age Group (years)	**1st Booster Dose†**	**2nd Booster Dose**
≥18	Recommended *at least 2 months* after the 2nd (additional) dose, mRNA preferred (total doses =3)	Should receive an mRNA booster *at least 4 months* after the first booster (total doses= 4)

*5-17 year olds may only receive age-appropriate Pfizer formulations as booster doses. ≥18 year olds may receive either Pfizer or Moderna as booster doses.

‡For specific scenarios (e.g. people who inadvertently received booster dose before third primary dose), please visit **Appendix D2** in CDC's Interim Clinical Considerations https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-d

†If recipient of Janssen COVID-19 vaccine has already received a booster dose without having the 2nd (additional mRNA dose), please refer to **Table 7** for dosing guidance

Figure 6. Booster Vaccination Schedule for People Who ARE Moderately or Severely Immunocompromised



*All people ages 5 years and older should receive 1 booster dose of an age-appropriate COVID-19 vaccine. An mRNA COVID-19 vaccine is preferred. For people ages 5–17 years, only Pfizer-BioNTech can be used.

†People ages 12 years and older **should** receive a second booster dose using an age-appropriate mRNA COVID-19 vaccine if it has been at least 4 months after the first booster dose. For people ages 12–17 years, only Pfizer-BioNTech can be used.

‡ Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used. See **Table 7** for more information on vaccinating people who are moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine for the primary series.

Table 7. Guidance for People who are Moderately or Severely Immunocompromised and Vaccinated with Janssen COVID-19 Vaccine

COVID-19 Vaccination History	And	Then	Next Dose Due
1 dose	The dose was Janssen	Administer a second (additional) dose at least 28 days after the 1st dose: • Pfizer: 0.3 mL or • Moderna: 0.5 mL	Administer a booster dose at least 2 months after the 2nd dose.*† • Pfizer: 0.3 mL or • Moderna 0.25 mL or • Janssen: 0.5 mL
2 doses	Both doses are Janssen	Administer a third (additional) dose (mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3 mL or • Moderna: 0.5 mL	Vaccination series complete; no additional vaccinations needed†
	1 dose of Janssen and 1 dose of an mRNA vaccine (given as booster dose, i.e. Pfizer 0.3 mL or Moderna 0.25 mL)+	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3 mL or • Moderna: 0.5 mL	Vaccination series complete; no additional vaccinations needed†
	1 dose of Janssen and 1 dose of an mRNA vaccine (given as additional dose, i.e., Pfizer 0.3 mL or Moderna 0.5 mL) +	Administer a booster dose of any COVID-19 vaccine 2 months after the 2nd dose. • Pfizer: 0.3 mL or • Moderna: 0.25 mL or • Janssen: 0.5 mL (mRNA preferred)	Vaccination series complete; no additional vaccinations needed†

*mRNA vaccines are preferred

†See **Table 6** for information on a 2nd booster dose for people who are moderately or severely immunocompromised

+When reviewing vaccination history, doses of the Moderna COVID-19 vaccine received prior to February 7, 2022 should be considered to have been the booster dosage (0.25 mL; 50 mcg)

Table 8. Contraindications and Precautions

Contraindication	**Recommended Action(s)**
History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine	Do not vaccinate with the same type of COVID-19 vaccine (i.e., mRNA or Janssen COVID-19 Vaccine).
History of a known diagnosed allergy to a component of the COVID-19 vaccine	
For the Janssen COVID-19 Vaccine, TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors, e.g., AstraZeneca)*	Do not vaccinate with Janssen COVID-19 Vaccine.
Precaution	**Recommended Action(s)**
History of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])	The benefit of vaccination outweighs the risks for most people.
People with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine (i.e., mRNA or Janssen) have a precaution to the **same type of COVID-19 vaccine**	
People with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to **the other type** of COVID-19 vaccine (e.g., people with a contraindication to an mRNA COVID-19 vaccine have a precaution to Janssen COVID-19 vaccine and vice versa).	
Moderate or severe illness, with or without fever	Defer vaccination until the illness has improved
History of MIS-C or MIS-A	See "COVID-19 vaccination and SARS-CoV-2 infection including MIS-C and MIS-A" in CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection
For mRNA COVID-19 vaccines, history of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine	A subsequent dose of any COVID-19 vaccine should generally be avoided. See "Safety Considerations for MRNA COVID-19 Vaccines: Pfizer and Moderna" in CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#safety-mRNA
For Janssen COVID-19 Vaccine, a history of GBS†	See "Safety Considerations for Janssen COVID-19 Vaccine in CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-Janssen

*People with a history of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT, should not receive Janssen COVID-19 vaccine. These people should receive an mRNA COVID-19 vaccine
†People who develop GBS within 6 weeks after receipt of Janssen COVID-19 vaccine should not receive another dose of Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.

An **immediate allergic reaction** to a vaccine or injectable therapy is defined as any hypersensitivity-related signs or symptoms such as urticaria (hives), angioedema (visible swelling), respiratory distress (e.g., wheezing, stridor), or anaphylaxis that **occurs within four hours following administration**.

Severe allergic reactions include:

- Possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure (see Table 3)
- Any angioedema affecting the airway (i.e., tongue, uvula, or larynx)
- Diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome)

Non-severe allergic reactions include:

- Urticaria beyond the injection site
- Angioedema involving lips, facial skin, or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) is considered a severe allergic reaction (see above).

Healthcare professionals or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project for a complex COVID-19 vaccine safety question not readily addressed by CDC guidance.

See **Appendix F in CDC's Interim Clinical Considerations** for the list of ingredients in COVID-19 Vaccines. Link here: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-f. Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccines. Because PEG and polysorbate are structurally similar, cross-reactive hypersensitivity between these compounds may occur. 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.

To find a **list of medications that contain PEG and/or polysorbate,** review the supplementary materials of Stone CA, et al. "Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." The Journal of Allergy and Clinical Immunology: In Practice 7.5 (2019): 1533-1540. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdfpdf iconexternal icon.
Disclaimer: This is not an all-encompassing list. Information on whether a medication contains PEG, a PEG derivative, or polysorbates as either active or inactive ingredients can be found in the package insert. The National Institutes of Health DailyMed databaseexternal icon may also be used as a resource.

The following considerations may be used to conduct a risk assessment for vaccination of individuals with a precaution to vaccination:

a. Risk of exposure to SARS-CoV-2
b. Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)
c. Unknown risk of anaphylaxis (including fatal)
d. Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis (e.g., in acute care setting) For people with a contraindication due to allergy to one type of COVID-19 vaccines (e.g., mRNA vaccines), who are receiving another type (e.g., Janssen vaccine) and for people with an immediate, non-severe allergic reaction after a

previous dose of COVID-19 vaccine who are receiving vaccination with a subsequent dose of that COVID-19 vaccine type, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions. Consultation with an allergist-immunologist may help to clarify the risk assessment for these individuals.

e. One appropriately counseled, these individuals may receive the vaccine and will need to be observed for 30 minutes post vaccination.

Table 9: Triage of Persons Presenting for COVID-19 Vaccination

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine[1,2] • Known (diagnosed) allergy to a component of a COVID-19 vaccine[1]	**Among people without a contraindication, a history of:** • Any immediate allergic reaction[3] to other vaccines or injectable therapies[4] • Non-severe, immediate (onset <4 hours) allergic reaction[2] after a previous dose of COVID-19 vaccine[6] Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa.[5]	**Among people without a contraindication or precaution, a history of:** • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies
Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative if age appropriate[1,5]	**Actions:** 1. Risk assessment 2. Consider referral to allergist-immunologist 3. 30-minute observation period if vaccinated	**Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

[1] See Appendix F in CDC's Interim Clinical Considerations for list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer or Moderna). However, some of these individuals may be able to receive the Janssen COVID-19 Vaccine after a detailed risk assessment and possibly allergy testing (see footnote # below).

[2] Severe allergic reactions include possible anaphylaxis (e.g. urticaria with wheezing, difficulty breathing, or low blood pressure), any angioedema affecting the airway (i.e. tongue, uvula, or larynx), diffuse rash which also involves mucosal surfaces (e.g. Steven-Johnson Syndrome).

Non-severe allergic reactions may include: urticaria (hives) beyond the injection site, angioedema involving lips, facial skin, or skin in other locations.

[3] Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

[4]People with a history of an immediate allergic reaction to a non-COVID-19 vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction. These individuals may benefit from consultation with an allergist-immunologist who can perform a more detailed risk assessment for COVID-19 vaccine receipt and possibly allergy testing.

[5]People with a contraindication to mRNA COVID-19 vaccines (including known PEG allergy) have a precaution to Janssen COVID-19 vaccine. For people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, should wait at least 28 days after the mRNA dose to receive Janssen COVID-19 vaccine. People with a contraindication to Janssen COVID-19 vaccine (including known polysorbate allergy) have a precaution to mRNA COVID-19 vaccine. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

[6] For people with a history of an immediate, non-severe allergic reaction after an mRNA COVID-19 vaccine, vaccination with a subsequent dose of either of the mRNA COVID-19 vaccines should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Similarly, for people with a history of an immediate, non-severe allergic reaction after Janssen COVID-19 Vaccine, vaccination with a subsequent dose of Janssen vaccine should only be undertaken under the supervision of a health care provider experienced in the management of severe allergic reactions. Administering the other vaccine type is another option; this can be done with a 30-minute observation period in a usual COVID-19 vaccination setting.

Neither contraindications nor precautions to vaccination

Allergic reactions (including severe allergic reactions) not related to vaccines or injectable therapies (e.g., food, pet, venom, or environmental allergies; allergies to oral medications [including the oral equivalents of injectable medications]) are **not** a contraindication or precaution to COVID-19 vaccination. The vial stoppers are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for persons with a latex allergy. In addition, as the COVID-19 vaccines do not contain eggs or gelatin, individuals with allergies to these substances do not have a contraindication or precaution.

Delayed-onset local reactions (e.g., erythema, induration, pruritis) around the injection site have been reported after mRNA vaccination in some people starting a few days through the second week after the first dose and are sometimes large. These individuals do not have a contraindication or precaution to the second dose and should complete the original vaccine series, preferably in the opposite arm.

Special Populations/Considerations

Moderately and Severely Immunocompromised People
Moderate and severe immunocompromising conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

Age or place of residence alone (e.g., residence in a long-term care setting), independent of a patient's medical condition, should not be used to determine the level of immune competence, as the balance of benefits and risks of a third primary dose for people who are not moderately or severely immunocompromised is currently unknown.

Other Special Populations
For information on the use of the COVID-19 vaccine in other special populations, please see 'Special Populations' in the CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#special-populations. For information on pregnancy and lactation, visit 'Considerations involving pregnancy, lactation, and fertility' in CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#pregnancy-fertility

Safety Considerations for use of mRNA COVID-19 vaccines
For information on safety of the Pfizer or Moderna COVID-19 vaccines, including guidance on risk of myocarditis/pericarditis, please visit 'Safety Considerations for mRNA COVID-19 Vaccines' in CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#safety-mRNA

Safety Considerations for use of Janssen COVID-19 vaccine
For information on safety of the Janssen COVID-19 vaccine for use in certain populations, including guidance on thrombosis with thrombocytopenia (TTS), please visit 'Safety Considerations for Janssen COVID-19 Vaccine' in CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-Janssen

Deferrals

1. **Individuals with prior or current confirmed COVID-19 infection:** Vaccination (including booster vaccination) should be deferred until recovery from acute illness (if person had symptoms) **and** criteria have been met to discontinue isolation. People who recently had SARS-CoV-2 infection may consider delaying their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Current evidence shows that increased time between infection and vaccination may result in an improved immune response to vaccination.

2. **Individuals with known COVID-19 exposure:** COVID-19 vaccines are not recommended for post-exposure prophylaxis to prevent SARS-CoV-2 infection. Unvaccinated people who were close contacts of a person with SARS-CoV-2 infection should typically not seek vaccination until quarantine has ended.

   In certain circumstances, to avoid missed opportunities for vaccination, vaccination during quarantine could be considered during outreach and contact tracing activities or at the time of post-exposure SARS-CoV-2 testing. In such situations, the person recommended for quarantine can receive vaccination as long as 1) they do not have symptoms consistent with COVID-19 or current SARS-CoV-2 infection, and, 2) appropriate infection prevention and control procedures are employed during vaccination.

   However, they should also be informed that vaccination may not prevent SARS-CoV-2 infection until 2 weeks after the primary series is completed, i.e., will not prevent them from getting COVID-19 from the current exposure but should help protect them from infection after future exposures. In addition, SARS-CoV-2 viral testing may be necessary to differentiate between common post-vaccination symptoms and symptoms of SARS-CoV-2 infection. People who develop signs and symptoms

associated with COVID-19 should isolated and be evaluated for SARS-CoV-2 infection as soon as possible.

3. **History of Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A)** For information on MIS-C and MIS-A, please visit 'COVID-19 vaccination and SARS-CoV-2 infection including MIS-C and MIS-A' in CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection

4. **Individuals currently exhibiting symptoms of COVID-19 like illness**: these individuals should be referred for SARS-CoV-2 testing and not be vaccinated.
   a. Patients with the following symptoms of COVID-19 should be referred for testing:
      i. Fever (≥100°F for HCW and ≥100.4°F for others) or chills
      ii. Cough
      iii. New loss of taste or smell
      iv. Shortness of breath or difficulty breathing
      v. New or unexplained in the last 3 days: fatigue, muscle or body aches, headache, sore throat, nausea, vomiting or diarrhea

People vaccinated with COVID-19 vaccines outside the U.S.

Table 11: People vaccinated with a COVID-19 vaccine outside of the U.S

	Fully Vaccinated	**Partially Vaccinated**
FDA-authorized or approved: **Pfizer-BioNTech** (BNT162b2, COMIRANTY) **Moderna** (mRNA-1273) **Janssen** (Ad26.COV2.S)	Primary series: Completed; Do not re-vaccinate Additional Dose: Moderately or severely immunocompromised patients who have completed a 2-dose mRNA COVID-19 vaccine primary series should receive an additional dose as detailed in **Table 3, Attachment F** Booster Dose[∞]: Patients who have completed an FDA-approved/authorized COVID-19 vaccine primary series should follow the booster dose guidance as detailed in **Table 5, Attachment F**	Primary series: Complete series with 2nd dose as close to the recommended time as possible, preferably with the same mRNA vaccine ; do not restart series Additional Dose: Moderately or severely immunocompromised patients who have completed a 2-dose mRNA COVID-19 vaccine primary series should receive an additional dose as detailed in **Table 3, Attachment F** Booster Dose[∞]: Patients who have completed an FDA-approved/authorized COVID-19 vaccine primary series should follow the booster dose guidance as detailed in **Table 5, Attachment F**
WHO-authorized (but not FDA-authorized/ approved)[#]: **AstraZeneca** (AZD1222 Vaxzevria) **Serum Institute of India** (CoviShield, Covovax) **Sinopharm** (BBIBP-CorV, Vero Cell Inactivated)	Primary series: Completed; Do not re-vaccinate Additional Dose[‡]: Moderately to severely immunocompromised patients should receive an additional dose of an mRNA vaccine* at least 28 days after receiving the last dose of the primary series	Primary series: People who received only the first dose of a WHO-authorized vaccine should receive a single dose of an mRNA vaccine* at least 28 days since receipt of their first dose to complete primary series Additional Dose: Moderately or severely immunocompromised people who received an mRNA vaccine to complete

Sinovac (CoronaVac, Vero Cell Inactivated) **Bharat Biotech** (Covaxin, Vero Cell Inactivated) **Novavax** (NVX-coV2373, Nuvaxovid) **CanSino Biologics Inc.,** (Convidecia, Ad5.CoV2-S)	Booster Dose[∞‡]: Patients should receive a booster dose of an mRNA vaccine at least 5 months after completing primary series Patients who are moderately or severely immunocompromised should receive a booster dose of an mRNA vaccine* at least 3 months after the additional dose for a total of four vaccine doses	the initial series should receive an additional dose of an mRNA COVID-19 vaccine* at least 28 days later Booster Dose[∞]: Patients should receive a booster dose of an mRNA vaccine* at least 5 months after completing primary series Patients who are moderately or severely immunocompromised should receive a booster dose of an mRNA vaccine* at least 3 months after the additional dose for a total of four vaccine doses
Neither FDA nor WHO authorized	Primary series: Re-vaccinate with an FDA-approved or authorized vaccine series[†], preferably with an mRNA COVID-19 vaccine * at least 28 days after the last dose of vaccine Booster Dose[∞]: Administer mRNA booster dose* at least 5 months after completion of the primary series Immunocompromised: People who are moderately or severely immunocompromised should restart the series, following guidance for this group around number and timing of primary series dose(s) and booster vaccination as detailed in Attachment F. Patients who completed a Moderna for Children 6-17 Years Old or Medicago vaccine series are considered fully vaccinated and are eligible for an additional and/or booster dose as detailed in 'People Vaccinated with COVID-19 vaccines as part of a clinical trial in the U.S' below	Primary series: Re-vaccinate with an FDA-approved or authorized vaccine series[†], preferably with an mRNA COVID-19 vaccine* at least 28 days after the last dose of vaccine Booster Dose[∞]: Administer MRNA booster dose* at least 5 months after completion of the primary series Immunocompromised: People who are moderately or severely immunocompromised should restart the series, following guidance for this group around number and timing of primary series dose(s) and booster vaccination as detailed in Attachment F.

[#] This is **NOT** an all-encompassing list. Please be sure to reference https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued for the most updated list of WHO-authorized COVID-19 vaccines.

[*] Pfizer-BioNTech COVID-19 vaccine can be used in individuals 5 years and older and Moderna COVID-19 vaccine can be used in individuals 18 years and older to complete vaccination

[†] The minimum interval between the last dose of a non-FDA-approved or non-FDA-authorized vaccine or a WHO-listed vaccine **and** an FDA-approved or FDA-authorized COVID-19 vaccine is **28 days**

[∞] See **Attachment F** for information on the option of a second booster dose for some people

‡ People who received an additional and/or booster dose of the COVID-19 vaccine after completing a primary vaccination with vaccines not approved/authorized in the United States should receive the following information:

- EUI Fact Sheet for Recipients and Caregivers
- CDC COVID-19 Vaccination Record Card with the lot number and date of administration for the additional or booster dose
- V-safe information sheet

People vaccinated with COVID-19 vaccines as part of a clinical trial in the U.S

People who received a full series of an active (not placebo) COVID-19 vaccination as part of a U.S.-based clinical trial are considered fully vaccinated if:

a. The participant received all recommended doses of a COVID-19 vaccine that is neither FDA-authorized nor FDA-approved but is listed for emergency use by WHO **or**

b. The participant received a vaccine series that is neither FDA-authorized nor FDA-approved nor listed for emergency use by WHO but the participant has been documented to have received the full series of an active COVID-19 vaccine **and** vaccine efficacy has been independently confirmed by a U.S. data and safety monitoring board or equivalent (i.e., Moderna for Children 6-17 Years Old, Medicago for 18+ Years Old)

For details on additional and booster doses, please visit Appendix B 'People who received COVID-19 vaccine as part of a clinical trial' in CDC's Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-b

Laboratory Testing

1. **Tuberculosis (TB) testing**: COVID-19 vaccination should not be delayed because of testing for TB infection. Testing for TB with either the tuberculin skin test or an interferon release assay can be done before, after, or during the same time as COVID-19 vaccination.
2. **Antibody testing**: is not currently recommended to assess the need for vaccination in an unvaccinated person or to assess for immunity to SARS-CoV-2 following COVID-19 vaccination.

ATTACHMENT G

PATIENT COUNSELING AND MANAGEMENT OF VACCINE REACTIONS/ ADMINISTRATION ERRORS IN PATIENTS

Patient Counseling:

Before vaccination, providers should counsel COVID-19 vaccine recipients about expected post-vaccination symptoms. Common local symptoms include pain, swelling, erythema at the injection site, and/or localized axillary lymphadenopathy on the same side as vaccinated arm. Common systemic symptoms include fever, fatigue, headache, chills, myalgia, and/or arthralgia. Overall, side effects are more common younger people compared to older people.

Antipyretic or analgesic medications (e.g., acetaminophen, or non-steroidal anti-inflammatory drugs) can be taken to treat post vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications is not currently recommended.

1. mRNA COVID-19 vaccines (Pfizer and Moderna)
    - Approximately 80-91% of people vaccinated with mRNA COVID-19 vaccine experience at least one local symptom and 48-91% experienced at least one systemic symptom post vaccination.
    - Most systemic post vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1-2 days of onset.
    - Individuals with prior SARS-CoV-2 infection may be more likely to experience systemic symptoms after the first mRNA COVID-19 vaccine dose.
2. Myocarditis and pericarditis
    a. The chance of myocarditis or pericarditis occurring after receipt of an mRNA COVID-19 vaccine is very low.
    b. Individuals receiving mRNA COVID-19 vaccines, especially males aged 12-29 years, should be aware of the possibility of myocarditis or pericarditis following vaccination and the need to seek medical attention right away if any of the following symptoms occur after receiving the vaccine:
        i. Chest pain
        ii. Shortness of breath
        iii. Feelings of having a fast-beating, fluttering, or pounding heart
    c. Extending the interval between the first and second mRNA vaccine dose to 8 weeks may reduce the risk for some people ages 12 and older, especially for males ages 12-39 years old
3. Viral vector COVID-19 vaccine (Janssen)
    a. Approximately 50% of people vaccinated with the viral vector COVID-19 vaccine experienced at least one local symptom and 55% experienced at least one systemic symptom post vaccination.
    b. Most systemic post vaccination symptoms are mild to moderate in severity and resolve within 1-2 days after vaccination.

- Thrombosis with Thrombocytopenia (TTS) WARNING:
    a. Very rarely, recipients of the Janssen COVID-19 vaccine experienced blood clots involving blood vessels in the brain, abdomen, and legs accompanied with low platelet levels approximately 1-2 weeks post-vaccination. To date, most of these individuals who developed these blood clots were women aged 18-49 years. People should seek medical attention right away if they experience any of the following symptoms after receiving Janssen COVID-19 vaccine:

        - Shortness of breath
        - Chest pain
        - New or severe leg swelling
        - Persistent or severe abdominal pain
        - Severe or persistent headaches or blurred vision
        - Easy bruising or tiny blood spots under the skin beyond the site of the injection
    - It is critical to educate patients about the TTS warning signs to ensure that women aged <50 years are aware of the increased risk for TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized or FDA-approved COVID-19 vaccines (i.e., mRNA vaccines).
- Guillain-Barré Syndrome
    a. Reports of adverse events following use of the Janssen COVID-19 vaccine under EUA suggest an increased risk of GBS during the 42 days post-vaccination. Although the chance of GBS occurring is very low, vaccine recipients should seek medical attention right away if they experience any of the following symptoms after receiving Janssen COVID-19 vaccine:
        i. Weakness or tingling sensations, especially in legs or arms, that is worsening and spreading to other parts of the body
        ii. Difficulty walking
        iii. Difficulty with facial movements, including speaking, chewing, or swallowing
        iv. Double vision or inability to move eyes
        v. Difficulty with bladder control or bowel function

Emergency Medical Management Documentation:

1. Vaccination providers are required by the Food and Drug Administration to report the following that occur after COVID-19 vaccination under Emergency Use Authorization:
    a. Vaccine administration errors
    b. Serious adverse events
    c. Cases of Multisystem Inflammatory Syndrome
    d. Cases of COVID-19 that result in hospitalization or death
2. Report all adverse reactions to the federal VAERS at www.vaers.hhs.gov or call (800) 822-7967. Reports may also be faxed to (877) 721-0366.
    a. Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event.
3. Report all vaccine errors to ISMP Vaccine Error Reporting Program (VERP) at https://www.ismp.org/report-medication-error.
4. Keep a copy of all submitted reports on record.

Medical Management of Vaccine Reactions in Patients:

1. TTS is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin. Clinicians should consult the Health Alert Network (HAN) notification and guidance from the American Society of Hematology (ASH) for information on the diagnosis and treatment of suspected TTS:
    a. HAN: https://emergency.cdc.gov/han/2021/han00442.asp
    b. ASH: https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

2. Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported following COVID-19 vaccination. Although this complication is rare every health care provider administering the vaccine should be knowledgeable about the management of anaphylaxis. Please review the link below for guidance on the **management of allergic reactions after COVID 19 vaccination**:

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fanaphylaxis-management.html

Reaction	Symptoms	Management
Mild		
Localized	The injection site is swollen, sore, red, or itchy	▪ Recommend application of a cold compress or ice to the injection site. ▪ Recommend an analgesic agent or antipruritic medication. ▪ Ask the patient to be observed for 30 minutes if possible. If not further symptoms, send the patient home.
Localized	Slight bleeding	▪ Affix an adhesive bandage over the injection site.
Psychological fear and syncope	Fright, fear, or anxiety before receiving injection.	▪ Request the patient to lie down or sit during vaccination. **Do not** vaccinate if the patient is combative.
Moderate		
Localized	Continuous bleeding	▪ Place a thick layer of gauze pads over injection site, maintaining direct and firm pressure; elevate the bleeding injection site (e.g., arm) such that it is above the heart level.
Psychological fear and syncope	Extreme pallor, sweating, cold extremities (hands, feet), nausea, dizziness, weakness, or disturbances in vision.	▪ Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. ▪ Apply cool, damp cloth to patient's face and neck.
	Fall, without loss of consciousness	▪ Examine the patient to determine if injury is present before attempting to move the patient. ▪ Place patient flat on back with feet elevated. ▪ Notify designated provider of the event.
Severe		
	Loss of consciousness	▪ Call 911 ▪ Assess the patient for signs of injury before any attempt to move the patient. If there is any indication of cervical spine involvement, **DO NOT** move the patient. ▪ Try to have the patient lying flat on his/her back with feet up, if pulse, respiration, BP are steady. ▪ Continuously observe and monitor until EMS arrives and the patient is transported to the ED for evaluation. ▪ Notify designated provider of the event.
Anaphylaxis	Sudden or gradual onset including:	**Outpatient clinic sites:**

Reaction	Symptoms	Management
	Respiratory: sensation of throat closing or tightness, stridor (high-pitched sound while breathing), hoarseness, respiratory distress (such as shortness of breath or wheezing), coughing, trouble swallowing/drooling, nasal congestion, rhinorrhea, sneezing **Gastrointestinal:** nausea, vomiting, diarrhea, abdominal pain, or cramps **Cardiovascular:** dizziness; fainting, tachycardia; hypotension; weak pulse; cyanosis; pallor; flushing **Skin/mucosal:** generalized hives; widespread redness; itching; conjunctivitis; or swelling of eyes, lips, tongue, mouth, face, or extremities **Neurologic:** agitation; convulsions; acute change in mental status; sense of impending doom **Other:** sudden increase in secretions (from eyes, nose, or mouth); urinary incontinence **IMPORTANT:** Anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than 1 body system is involved) or are serious or life-threatening in nature, even if they involve a single body system (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips).	▪ Follow Ambulatory Services BRN 1, Anaphylaxis Standardized Procedure. **Community mass vaccination sites** (May be initiated by the RN): ▪ **Call 911** (preferably by another person). ▪ Initiate the following treatment at the first sign of symptoms. ▪ **The first-line AND most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis.** ▪ In adults, administer epinephrine auto-injector (0.3mg/dose) IM, preferably in the mid-outer thigh through clothing if necessary. ▪ In pediatrics, follow the medication dosage chart for anaphylaxis for weight-based dosing. ▪ Epinephrine dose **may be repeated 2 <u>additional</u> times** every 5-15 minutes as necessary if anaphylactic symptoms persist, while waiting for EMS to arrive. ▪ The number and timing of epinephrine doses should be recorded and communicated to EMS. ▪ If patient is wheezing, generalized hives, or in respiratory distress: o Have patient sit up ▪ If patient has low blood pressure or pulse is weak: o Have patient lie down flat on back with feet elevated o Monitor blood pressure and pulse every 5 minutes ▪ If patient is unresponsive and pulseless: o Initiate CPR ▪ For <u>non-life-threatening</u> reaction: if available, administer supplemental oxygen at 2 to 6 liters per minute via nasal cannula to maintain oxygen saturation greater than 94%. ▪ For <u>life threatening reaction</u>: if available, administer supplemental oxygen at 8 to 10 liters per minute via face mask, up to 100% to maintain oxygen saturation greater than 94%. ▪ **Optional pharmacologic treatment**: Diphenhydramine can be considered to provide relief for itching and urticaria (hives). In adults, administer 50 mg orally, x1, (max single dose: 50 mg) or 50 mg IM x1. In pediatrics, follow the medication dosage table for weight-based dosing. **NOTE:** This does not relieve upper or lower

Reaction	Symptoms	Management
		airway obstruction, hypotension, or shock. Administer other medications as ordered. ▪ Notify designated provider of the event. ▪ Record/document: o Signs/symptoms observed by the staff and/or described by the patient. o All vital signs o Medications (time, dosage, response) o name of the medical personnel who administered the medication o other relevant clinical information ▪ Any allergic response that requires intervention with epinephrine should be followed up with an ED visit, then by the patient's primary care provider or other health care provider for a medical evaluation. ▪ Any new allergy should be added to the EHR by the provider. RNs may only document symptoms. ▪ **Inpatient setting:** follow inpatient anaphylaxis protocol.

Medication Dosage Chart for Anaphylaxis

EPINEPHRINE 1 mg/mL Injectable

FIRST-LINE TREATMENT: Epinephrine 0.01 mg/kg (max 0.5mg) administered intramuscularly. May repeat every 5 - 15 minutes for a total of 3 doses.

NOTE:
Dosing by weight is preferred. If weight is unknown or not readily available, dosing by age is appropriate.
* Rounded weight at the 50th percentile for each age range.
Child is defined as prepubertal patient weighing less than 35-40 kg (not defined by age)

	Weight Range (kg)*	Age Group	Epinephrine Auto-injector Dosing IM injection	Epinephrine 1 mg/mL Vial or Ampule Dosing IM injection
Infants and Children	4 - 8.5 kg	1 - 6 **months**	X	Calculate 0.01 mg/kg
	9 - 14.5 kg	7 - 36 **months**	X	Calculate 0.01 mg/kg
	15 - 17.5 kg	37 - 59 **months**	0.15 mg/dose	Weight-based dosing = **0.01 mg/kg (0.01 mL/kg)** not to exceed maximum single dose of 0.5 mg (0.5 mL)
	18 - 25.5 kg	5 - 7 years	0.15 mg/dose	
	26 - 29.9 kg	8 - 10 years	0.3 mg/dose	
Teens / Adults	30 - 45 kg	11 - 12 years	0.3 mg/dose	
	46+ kg	13 + years	0.3 mg/dose	

DIPHENHYDRAMINE (Benadryl)

SECOND-LINE TREATMENT: Diphenhydramine 1 to 2 mg/kg per DOSE (up to 50 mg / dose)

NOTE:
Child is defined as prepubertal patient weighing less than 35-40 kg (not defined by age)

Infants, Children, and Adolescents: Do not exceed 5 mg/kg or max of 300 mg in 24 hours
Adults: Do not exceed max of 400 mg in 24 hours

	Weight Range (kg)	Diphenhydramine Dose 12.5mg/5 ml oral liquid 25 mg or 50 mg tablet 50 mg/mL injectable (IV or IM)
Infants and Children	9 -14.5 kg	10 mg – 15 mg
	15 - 17.5 kg	15 mg – 20 mg
	18 - 25.5 kg	20 mg – 25 mg
	26 - 45 kg	25 mg - 50 mg
Teens / Adults	46 + kg	50 mg/dose (Adolescent max dose = 50 mg. May consider doses up to 100 mg for adults.)

Table 10. Management of Vaccine Administration Errors and Deviations in Patients

Type	Administration error/ deviation	Interim Recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid [preferred site] or anterolateral thigh [alternate site])	• Do **not** repeat dose.
	• Incorrect route (e.g., subcutaneous)	• Do **not** repeat dose. • Inform recipient of the potential for local and systemic adverse events.
Age	• Unauthorized age group (ages 4 years and younger)	• Do not give another dose at this time.*
	• Unauthorized age group (ages 5-17 years old)	• If Moderna vaccine administered: o As the first dose, administer a single dose of the age-appropriate Pfizer-BioNTech vaccine at least 28 days after the Moderna vaccine dose. Administer a Pfizer-BioNTech booster dose at least 5 months later. o As the second dose, or as both the first and second dose, the primary series is complete. Administer a Pfizer-BioNTech booster dose at least 5 months later. • If Janssen vaccine administered: o Because the efficacy of this vaccine in this age group has not been established, administer a single dose of the age-appropriate Pfizer-BioNTech vaccine at least 28 days after the Janssen vaccine. Administer a Pfizer-BioNTech booster dose at least 5 months later.
Formulation and Dosage	• If aged 5-11 years and Pfizer ≥12 years formulation (**gray cap**) was inadvertently administered, resulting in a higher than authorized dose.	• If 0.1 mL administered, in general, do not repeat dose. - However, based on clinical judgement (e.g., child received 2 doses of incorrect formulation), a repeat dose of Pfizer 5-11 years formulation (**orange**) may be administered at an interval of ≥21 days after the dose given in error.[§] • If >0.1 mL administered, resulting in a higher than authorized dose, do **not** repeat dose.[†]
	• If aged 12-17 years and Pfizer 5-11 years formulation (**orange**) was administered, resulting in a lower than authorized dose.[‡]	• In general, do not repeat the dose. - However, based on clinical judgement (e.g., adolescent received 2 doses of incorrect formulation), a repeat dose of Pfizer ≥12 years formulation (**gray**) may be given at least 21 days after the dose given error.[§]
	• If aged ≥18 and Pfizer 5-11 years formulation (**orange**) was	• **Repeat dose immediately** with age-appropriate dose and formulation.[§]

	administered, resulting in a lower than authorized dose.	
	• Higher-than-authorized dose volume administered of the **correct formulation**	• Do **not** repeat dose.[†] • Common errors include: - 100 ug (full dose) administered for a Moderna COVID-19 vaccine booster dose
	• Lower-than-authorized dose volume administered of the **correct formulation**	• **Repeat dose immediately** (no minimum interval).[§] • However, if a half-volume formulation of vaccine is administered on the same clinic day to a patient recommended for the full volume formulation, another half-volume dose can be administered, and the two doses can count as one full dose. • Common errors include: - 0.25 mL administered for Moderna COVID-19 vaccine primary series - 0.2 mL Pfizer ≥12 years formulation administered to an individual older than 12 years.
Storage and handling	• Dose administered after improper storage and handling	• Contact manufacturer for guidance. If manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).[§]
	• Dose administered past the expiration/beyond-use date	• Contact manufacturer for guidance. If manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).[§]
Intervals[¶]	• An mRNA primary series or additional dose administered prior to the recommended interval[#]	• Repeat dose after the invalid dose by at least the minimum interval (i.e., no sooner than 21 days if Pfizer or 28 days if Moderna).[§]
	• Any COVID-19 vaccine dose administered at any interval after the recommended interval	• Do **not** repeat dose • There is no maximum interval • VAERs reporting is **not** required
	• Booster dose administered prior to the recommended interval (i.e. prior to 2 months after Janssen primary series or 3 months after mRNA primary series)	• Repeat dose if this is the first booster dose. Space repeat dose after the dose given in error by at least the minimum interval.[§] o 2-month minimum booster interval after Janssen vaccine primary series o 3-month minimum booster interval after mRNA vaccine primary series • Do **not** repeat dose if this is the second booster dose. •
	• Incorrect mRNA COVID-19 vaccine administered for second dose in 2-dose primary series or as an additional primary dose.	• Do **not** repeat dose

	• Tixagevimab/cilgavimab (EVUSHELD™) administered less than 14 days after COVID-19 vaccination	• In general, do **not** repeat dose. However based on clinical judgment, a repeat dose of vaccine may be administered at an interval of at least 28 days after the dose of vaccine[§]
Mixed series	Incorrect MRNA COVID-19 vaccine product inadvertently administered as part of a 2- or 3-dose primary series	• Do **not** repeat dose
Diluent (Pfizer only [purple cap and orange cap])	• Only diluent administered (i.e. sterile 0.9% sodium chloride)	• Administered authorized dose immediately (no minimum interval)
	• No diluent, resulting in higher than authorized dose (i.e., 0.3 ml of undiluted vaccine administered)	• Do **not** repeat dose.[†] • Inform recipient of potential local and systemic adverse events.
	• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	• Contact manufacturer for guidance. • If manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).[§]
	• Vaccine is mixed with too little diluent	• Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events[†]
	• Vaccine is mixed with too much diluent	• Repeat dose immediately (no minimum interval)[§]
	• Single-use vial of diluent is used to mix multiple vials of vaccine	Do not repeat dose. Inform patient of the potential for bacterial infection
Diluent (Pfizer-COVID-19 formulation that should not be mixed with diluent [gray cap]	• Vaccine is mixed with any diluent (i.e. any type or volume of diluent)	• Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval)[§]

[*]Do not administer the second dose until the person becomes eligible to receive vaccination (either by reaching the authorized age or if the authorization is extended to include additional age groups), even if this results in the second dose being administered after the recommended interval between doses.

[†]If the administration error resulted in a higher-than-authorized vaccine dose, in general the subsequent dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the subsequent dose, this dose might be delayed, but this decision should be assessed on a case-by-case basis.

[‡] Individuals who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 µg) (orange cap); or (2) COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 µg (purple or gray cap). This dosing is in accordance with the FDA EUA and if such dosing occurred, this is not considered an error and VAERS reporting is not indicated.

[§] Some experts suggest further delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccine, particularly in adolescent boys and young adult men. Individual risks for COVID-19 and the likelihood for an adverse event following vaccination should be taken into consideration when recommending a longer interval.

¶For the purpose of the public health definition of fully vaccinated, doses administered with an interval error prior to October 25, 2021 do not need to be repeated.

#Vaccine administered up to 4 days before the minimum interval may be counted and do not need to be repeated.

For up-to-date guidance on vaccine administration errors, please visit *Appendix C* in CDC's Interim Clinical Considerations, which can be found at the following link: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-c.

Printable References:
CDC's Administration Errors Revaccination Guidance – PDF
CDC's Administration Errors Revaccination Guidance – Poster

ATTACHMENT H

PRE-DRAWING OF COVID-19 VACCINE AT MASS VACCINATION CLINICS

Reference:

Immunization Action Coalition, IAC Express, Special Edition: Ask the Experts; Issue 1,518: September 29, 2020. Accessed 1/14/2021 from: https://www.immunize.org/express/issue1518.asp#IAC24

USP COVID-19 Vaccine Handling Toolkit. Version 3.0. Last revised: March 2021. Accessed 5/14/2021 from: https://www.usp.org/covid-19/vaccine-handling-toolkit

Although the Centers for Disease Control and Prevention (CDC) discourages the practice of pre-drawing vaccines, a limited amount of vaccine may be pre-drawn in a mass-immunization clinic setting under the following conditions:

- Only a single type of vaccine (for example, influenza) is administered at the mass-immunization clinic setting
- Vaccine is not drawn up in advance of its arrival at the mass-vaccination clinic site
- These pre-drawn syringes are stored at temperatures appropriate for the vaccine they hold
- No more than 1 vials worth is drawn into syringes
- Clinic staff monitor patient flow carefully and avoid drawing up unnecessary doses or delaying administration of pre-drawn doses.
- At the end of the clinic day, any remaining vaccine in syringes prefilled by staff should be discarded.

During the COVID-19 pandemic, COVID-19 vaccines may be pre-drawn under the conditions set forth by the CDC:

- Only a single type of vaccine (COVID-19) is administered at the mass-immunization clinic setting
- Vaccine is not drawn up in advance of its arrival at the mass-vaccination clinic site
- These pre-drawn syringes are stored at temperatures appropriate for the vaccine they hold
- No more than 1 vials worth is drawn into syringes
- Clinic staff monitor patient flow carefully and avoid drawing up unnecessary doses or delaying administration of pre-drawn doses
- At the end of the clinic day, any remaining vaccine in syringes prefilled by staff will be transferred to other locations to prevent wastage.
- Individual syringes will NOT be labeled.

The pre-drawn syringes will be placed in a Ziploc baggie. The Ziploc baggie will contain a label with the following information:

- Facility name and phone number
- Quantity of syringes
- Name and amount of vaccine
- The exact beyond-use date (BUD) and time
- Lot number
- Initials of preparer(s) – drawer and quality assurance (QA)

Documentation of vaccine administration will occur in the appropriate record (HealthLink or PrepMod) AND the vaccinator will document their name/title on the Ziploc baggie label.

Example of Labeled Pre-Drawn COVID-19 Vaccine

ATTACHMENT I

This document applies to the following site(s):

MEDICAL CENTER	
O'Connor	X
Santa Clara Valley	X
St. Louise Regional and DePaul	X

Division	
Ambulatory Clinic	X
Inpatient	X
Outpatient	X
Custody	X
Public Health	X

County of Santa Clara Health System

DEPARTMENT OF PHARMACY SERVICES

TITLE: Pharmacy COVID-19 Vaccine Safety

POLICY: This policy is to outline and implement pharmacy practice standards when multiple COVID-19 vaccines are available for use to ensure patient safety at COVID-19 vaccine. operations. Standard procedures for clinic opening, vaccine storage and handling, quality assurance, and vaccination stations as well as the responsibilities of vaccine drawers, vaccinators, and pharmacy runners are included.

PURPOSE: Pharmacy COVID-19 vaccine operations shall implement the practice standards outlined in this policy when multiple COVID-19 vaccines are available for use. The aim is to ensure all sites have measures in place to vaccinate patients with the correct vaccine manufacturer and correct dose.

POLICY OWNER: Jennefer Yoon

DATE OF ORIGIN/REVISION: 11/21. 01/22

DEFINITIONS (if applicable):

1. Primary dose series:
    a. Pfizer 2-dose series
        i. Pfizer 2-dose series- **Gray Cap** (12 years and older, doses given 21 days apart)
        ii. Pfizer 2-dose series- **Purple Cap** (12 years and older, doses given 21 days apart)
        iii. Pfizer 2-dose series- **Orange Cap** (5- to 11-year-olds, doses given 21 days apart)
    b. Moderna 2-dose series (18 years and older, doses given 28 days apart)
    c. Johnson & Johnson single-dose series (18 years and older)
2. Additional doses – patients with moderately to severely compromised immune systems:
    a. Pfizer 3rd dose (5-years and older, 28 days after receiving 2nd dose)
    b. Moderna 3rd dose (18 years and older, 28 days after receiving 2nd dose)
3. Booster doses:
    a. Pfizer boosters (12-years and older, at least 5 months after completing primary dose series)
    b. Moderna boosters (18 years and older, at least 5 months after completing primary dose series)
    c. Johnson & Johnson booster (18 years and older, 2 months after

completing series)

d. Johnson & Johnson booster (18 years and older, 2 months after completing series)

TABLE 1. COVID-19 VACCINE DOSING FOR EACH VACCINE TYPE

Vaccine Type	Age Range	Dose/Injection Volume
Pfizer Primary Series – **Orange** Cap(1st & 2nd and/or 3rd dose)	5- to 11-year-olds	10 mcg/0.2 mL
Pfizer Primary Series and Additional Dose – **Gray** and **Purple** Cap (1st, 2nd, and/or 3rd dose)	12 years and older	30 mcg/0.3 mL
Pfizer Booster - **Gray** and **Purple** Cap	12 years and older	30 mcg/0.3 mL
Moderna Primary Series and Additional Dose(1st, 2nd, and/or 3rd dose)	18 years and older	100 mcg/0.5 mL
Moderna Booster	18 years and older	50 mcg/0.25 mL
Johnson & Johnson (Single Primary Dose & Booster)	18 years and older	$5x10^{10}$ viral particles/0.5 mL

PROCEDURE:

Objective 1	**Standardize clinic opening and closing procedures to identify and communicateto clinic staff factors essential to vaccine safety**
1.1	Prior to the start of clinic, the pharmacist and/or pharmacy technician will review theclinic schedule to confirm the number of patients receiving COVID-19 vaccines to ensure sufficient vaccine/ancillary supplies are on-site
1.2	The pharmacist and/or pharmacy technician will regularly review with drawers thevaccination preparation steps, including but not limited to the following: a. Appropriate aseptic technique and vaccine dilution b. Appropriate safety and vaccine handling c. Appropriate dose based on vaccine manufacturer type and age d. Correct use of the needles and syringes included in the ancillary kits (Example:doses < 0.5 mL must use a 1 mL syringe, doses ≥0.5 mL may use a 3 mL syringe)
1.3	Clinic lead will review vaccine administration steps with vaccinators (see Attachment A)

Objective 2	**Standardize all labeling and signage related to vaccine manufacturer type to communicate to patients and staff at multiple points in the clinic workflow which vaccine is being handled and administered**
2.1	All labels and signage related to vaccine manufacturer type will follow this standardized color-coding: a. Blue = Pfizer vaccine 1st, 2nd, 3rd dose, and booster (12 years and older) b. Orange = Pfizer vaccine 1st, 2nd,3rd dose (5- to 11-year-olds) c. Green = Moderna vaccine 1st, 2nd, 3rd dose (18 years and older) d. Purple = Moderna vaccine booster (18 years and older) e. Pink = Johnson & Johnson single-dose series and booster (18 years and older) Color-coding for additional vaccines that receive FDA Emergency Use Authorizationwill be determined as needed
2.2	The following items or areas must be labeled, color-coded, and/or visible to patientsand staff: a. Vaccinator stations b. Vaccine syringes will be stored in labeled bags. Bag labels shall correspond tothe appropriate color-coding and include: i. Clinic name and phone number ii. Name of vaccine iii. Quantity of syringes iv. Lot number v. Expiration date and time vi. Name of vaccine preparer
Objective 3	**Vaccine vial storage and handling prior to drawing must meet safety standards**
3.1	The pharmacist or pharmacy technician will store each vaccine manufacturer type in separate color-coded bins in the refrigerator/freezer
3.2	The pharmacist or pharmacy technician will remove the vaccine vials from the refrigerator/freezer and document on physical inventory log
3.3	The pharmacist or pharmacy technician will continue to keep each vaccine manufacturer type in a separate basket at preparation station
Objective 4	**Vaccine drawers must meet safety and quality standards**
4.1	Each vaccine drawer shall demonstrate appropriate aseptic technique and proper vaccine preparation steps (Refer to Assessment, Administration, and Ordering of COVID-19 Vaccines, Emergency Use Authorization, Standardized Procedure)
4.2	Each vaccine drawer shall ensure the vaccine bag label matches the vaccine vial
4.3	Each vaccine drawer will have the following supplies at the drawing station: a. Appropriate syringes for dilution and administration of vaccine b. Alcohol wipes c. Tray d. Color-coded sign on bins e. Sharps container f. Trash container

4.4	Each vaccine drawer will draw all doses of a consistent volume (e.g. once 0.5 mL doses are drawn from a Moderna vial, all remaining doses drawn will be 0.5 mL). All doses must be drawn up at once and no doses shall remain inside the vial.
4.5	Mass vaccinations: For the Pfizer 5- to 11-year-old series, the vaccine drawer will label each individual syringe with the appropriate color-coded label. Mini vaccinations, office visits (pediatric/family practice clinics): The vaccine drawer will label each individual syringe with the appropriate color-coded label. The syringe labels will include vaccine information. Barcode scanning is required and recommended when available.
4.6	The vaccine drawer must prepare one vaccine manufacturer type at a time. All doses must be prepared and a quality assurance check must be completed prior to switching to preparation of a different vaccine manufacturer type.
Objective 5	**Pharmacists and pharmacy technicians/interns (or other designated licensed healthcare professionals) involved in quality assurance (QA) must ensure safety standards are met**
5.1	If necessary, Pharmacy Lead will select other designated licensed healthcare professionals to complete QA. Pharmacy is responsible for completing training and competency with designees, and supervision of QA.
5.2	Pharmacists, pharmacy technicians, and/or healthcare licensed designee will ensure the appropriate volume is drawn and large air bubbles are absent
5.3	Pharmacists, pharmacy technicians, and/or healthcare licensed designee will ensure the correct number of doses are drawn from each vial
5.4	Pharmacists, pharmacy technicians, and/or healthcare licensed designee will ensure appropriate color and consistency (e.g., no particulates) of each vaccine dose
5.5	Pharmacists, pharmacy technicians, and/or healthcare licensed designee will verify the correct label is affixed to the syringe and bag, as appropriate
Objective 6	**Vaccinator stations, as the critical location for vaccine administration, must meet additional safety standards**
6.1	Each vaccinator station must be clearly labeled and color-coded to indicate the station number and vaccine manufacturer type (e.g. laminated colored vaccine name & dose at vaccination table)
6.2	Each vaccinator station shall only have one vaccine manufacturer type present at any given time. At no point shall multiple vaccine manufacturer types (e.g., both Pfizer and Moderna vaccines) be present at the same vaccinator station.
6.3	Under ideal circumstances, each vaccinator station is dedicated to one vaccine manufacturer type and only administers one vaccine manufacturer type for the entire duration of clinic each day

6.4	For clinics with limited staffing but vacant vaccinator stations, such that vaccines need to be shared between stations, the vaccinator will physically move to a new vaccinator station if needed to administer the secondary vaccine manufacturer type. It is preferred that only a limited number of vaccinators are designated to switch vaccinator stations per day.
6.5	For clinics with limited space such that vaccinator stations need to be converted between vaccines: a. Pre-determined vaccinator station(s) and vaccinator(s) are dedicated for conversions and are identified during the daily huddle b. All operations for that vaccinator station are paused c. All vaccinator station labels are changed d. Only one vaccine manufacturer type is at the vaccinator station at any given time e. A time-out will be performed with the vaccinator to verify new vaccinator station setup and vaccine manufacturer type f. An announcement is made to all staff regarding the conversion Refer to Attachment A for an additional sample checklist
Objective 7	**Vaccinators or pharmacy runners retrieving vaccine must meet safety standards**
7.1	Pharmacy runners will fill out the Pharmacy Runner Distribution Log (see Attachment B) before delivering vaccines to designated vaccinator station(s)
7.2	Pharmacy runners will ensure the vaccine bag label matches the corresponding sign at the vaccinator station
7.3	If pharmacy runners are not present, vaccinators will bring their color-coded sign to retrieve their own vaccines and fill out the Pharmacy Runner Distribution Log (see Attachment B) before returning to their designated vaccination station(s)
Objective 8	**Standardize patient queueing and line management process**
8.1	Under ideal circumstances, each vaccine manufacturer type will have a separate line leading to the vaccination area. Patients are directed by a staff member to the appropriate line based on what vaccine manufacturer type the patient is receiving.
8.2	For clinics with limited space such that there can only be one line for all vaccine manufacturer types, a staff member is responsible for directing patients to the appropriate vaccinator station based on what vaccine manufacturer type the patient is receiving
Objective 9	**Incorporate a standard procedure for the vaccinator to verify the manufacturer and dose with the patient and verify patient age**
9.1	Prior to administration, the vaccinator will review vaccine information with each patient and verbally confirm the manufacturer type and dose, e.g., “This is the Pfizer vaccine, the dose is 30mcg/0.3 mL”
9.2	Prior to administration, the vaccinator will show the vaccine-labeled bag along with the syringe to the patient, while verbally reviewing the information listed in Objective 9.1.
9.3	Prior to administration, the vaccinator will verify the patient’s name and date of birth and confirm the patient’s age to ensure he/she is eligible to receive the vaccine

9.4	Prior to administration, the vaccinator will check the physical product to ensure the needle is firmly connected to the syringe, in order to prevent needle detachment or leakage during vaccine administration

REGULATORY REFERENCES: CDC Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

RELATED POLICIES: Assessment, Administration, and Ordering of the COVID-19 Vaccines, Emergency Use Authorization, Standardized Procedure

APPENDICES:

1. Appendix A: Vaccinator Checklist to Prevent Medication Errors
2. Appendix B: Pharmacy Runner Distribution Log
3. Appendix C: Vaccine Holding Log

REFERENCES

1. CDC COVID-19 VACCINE CODES – Preview Posting of COVID-19 Vaccine Codes andCrosswalk for Currently Authorized Vaccines and Anticipation of Potential Vaccine Availability under Emergency Use Authorization. Accessed 01/06/2022 from: https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html

2. CDC COVID-19 VACCINE– COVID-19 Vaccination Clinical & Professional Resources. Accessed 01/07/2022 from: https://www.cdc.gov/vaccines/covid-19/index.html

APPENDIX A

Vaccinator Checklist to Prevent Medication Errors

1. **Vaccinator Checks PRIOR to administration: (REMEMBER to check the "7 rights of medication administration")**
   - Verify correct patient — ask for full name and date of birth
   - Verify vaccine with patient — ask which vaccine manufacturer type they arereceiving, 1st, 2nd, 3rd, or booster dose
     - **For 2nd & 3rd doses:**
       - Verify patient's CDC immunization card — Pfizer vs. Moderna
       - If no card, verify patient's chart/immunization record — Pfizer vs. Moderna
     - **For booster doses:**
       - Verify patient's CDC immunization card to review appropriate schedule – Pfizer vs. Moderna vs. J&J
       - If no card, verify patient's chart/immunization record – Pfizer vs.Moderna vs. J&J
   - Verify the vaccine bag label — correct vaccine and dose for the patient? (see Table1)
   - Do NOT remove syringes from bag until ready to administer the patient. Only removeone syringe from the bag at a time.
   - Before administering the vaccine, show the patient the syringe and state the volumeto let them know what vaccine you are about to give (see Table 1)
2. **"Time-Out" BEFORE Changing Vaccine Tables:**
   - Must announce "time-out" before changing the vaccine manufacturer type orchanging the vaccinator
   - Change only one vaccinator station at a time. Changes should be limited to only afew, pre-determined vaccinator stations
   - Before changing the vaccinator station, ensure all appropriate individuals are notifiedand are on the same page
   - Double-check to make sure no other vaccines are on the table. If there are leftovervaccines, turn-in to pharmacy first
   - Double-check the new vaccines given—check vaccine bag label and dose (seeTable 1)
   - Only one labeled bag of vaccine is allowed per table
3. **Before Vaccinator goes on break:**
   - Do NOT leave any vaccine bags at vaccinator station
   - Must turn-in labeled vaccine bags and fill out the vaccine holding log (see attachmentC) at the pharmacy medication preparation table before leaving their designated vaccinator station to go on break
   - Clean the vaccinator station in the event that another vaccinator is available to coveryour vaccinator station
4. **Site leads / charge RNs**
   - Make rounds to ensure there is only one labeled vaccine bag per vaccinator

station,no vaccines are left unattended, and vaccinators are not removing syringes from thelabeled vaccine bag until they vaccinate

APPENDIX B – PHARMACY RUNNER DISTRIBUTION LOG

_____ CLINIC: VACCINE DISTRIBUTION LOG

Time	Bag#	Station#	Vaccinator Name

APPENDIX C : VACCINE HOLDING LOG

COVID-19 Vaccine Temporary Holding Log

Date	Bag#	#doses in bag	Vaccinator Name	Time In	Signature	Time Out	Signature