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 August 2021, the FDA authorized administration of a third dose of mRNA COVID-19 vaccine, at least 28 days following second dose, in moderately and severely immunocompromised individuals. On August 23, 2021, the FDA approved the Pfizer-BioNTech COVID-19 vaccine under the brand name COMIRNATY® for use as a 2-dose primary series in individuals 16 years of age and older. In October 2021, the Pfizer-BioNTech and Moderna COVID-19 vaccines were authorized for emergency use by the FDA and CDC to provide a single booster dose at least 6 months after completing the Pfizer or Moderna primary series in certain people. In November 2021, Pfizer and Moderna booster eligibility was expanded to all individuals 18 years of age and older at least 6 months after completion of the primary series. Subsequently the CDC issued Emergency Use Instructions (EUI) to provide a Pfizer booster and/or additional dose to recipients of a WHO-authorized vaccine. In November 2021, the Pfizer-BioNTech COVID-19 vaccine was authorized for emergency use by the FDA and CDC in children 5 through 11 years old. In December 2021, Pfizer booster eligibility was expanded to individuals 16-17 years old and then was subsequently expanded to individuals 12-15 years of age in the following month. In January 2022, the FDA and CDC authorized shortening the time between completion of primary vaccination of the Pfizer or Moderna COVID-19 vaccine and a booster dose to at least 5 months. Additionally in January 2022, an additional dose of the Pfizer vaccine was authorized for certain immunocompromised children 5 through 11 years of age.

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. On April 13, 2021, the CDC and FDA recommended a pause on the use of Janssen COVID-19 vaccine after reports of U.S. cases of thrombosis with thrombocytopenia syndrome (TTS) among Janssen COVID-19 recipients. ACIP thoroughly reviewed a risk-benefit assessment of TTS events and based on this risk-benefit analysis, ACIP reaffirmed its interim recommendation on April 23, 2021 for the use of Janssen COVID-19 vaccine in all individuals 18 years of age and older. FDA has added a warning to the Janssen COVID-19 vaccine EUA fact sheets regarding rare clotting evens that may occur post-vaccination, primarily in women aged 18-49 years. In December 2021, following an increased incidence of TTS among Janssen COVID-19 recipients and further risk-benefit analyses, the ACIP voted to give preference for the mRNA vaccines over the Janssen vaccine for individuals 18 years of age and older. FDA subsequently added history of TTS as a contraindication to receiving the Janssen COVID-19 vaccine.

In October 2021, the Janssen COVID-19 vaccine was authorized for emergency use by the FDA and CDC to provide a single booster dose at least 2 months after the single-dose primary vaccination in individuals ≥ 18 years old. In October 2021, the CDC and FDA authorized the use of heterologous (or "mix and match") booster doses using any of the currently available (i.e. FDA-authorized or approved) COVID-19 vaccines in eligible individuals following completion of the primary series with any of the currently available COVID-19 vaccines. In December 2021, the CDC updated its recommendations to include a preference for mRNA vaccines as a booster for all vaccine recipients.

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

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

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.*

PROCEDURE (continued)

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
   - 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 12-17 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:
Phuong H Nguyen MD
9097F452E8324B7...

1/20/2022

Phuong H. Nguyen, MD
Chief Medical Officer

Date

AUTHORIZING PROVIDER:

DocuSigned by:
Sh L. Rudman
7AA2AFCB47E274F8...

1/20/2022

Sarah Rudman, MD, MPH
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
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
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
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

ATTACHMENT A

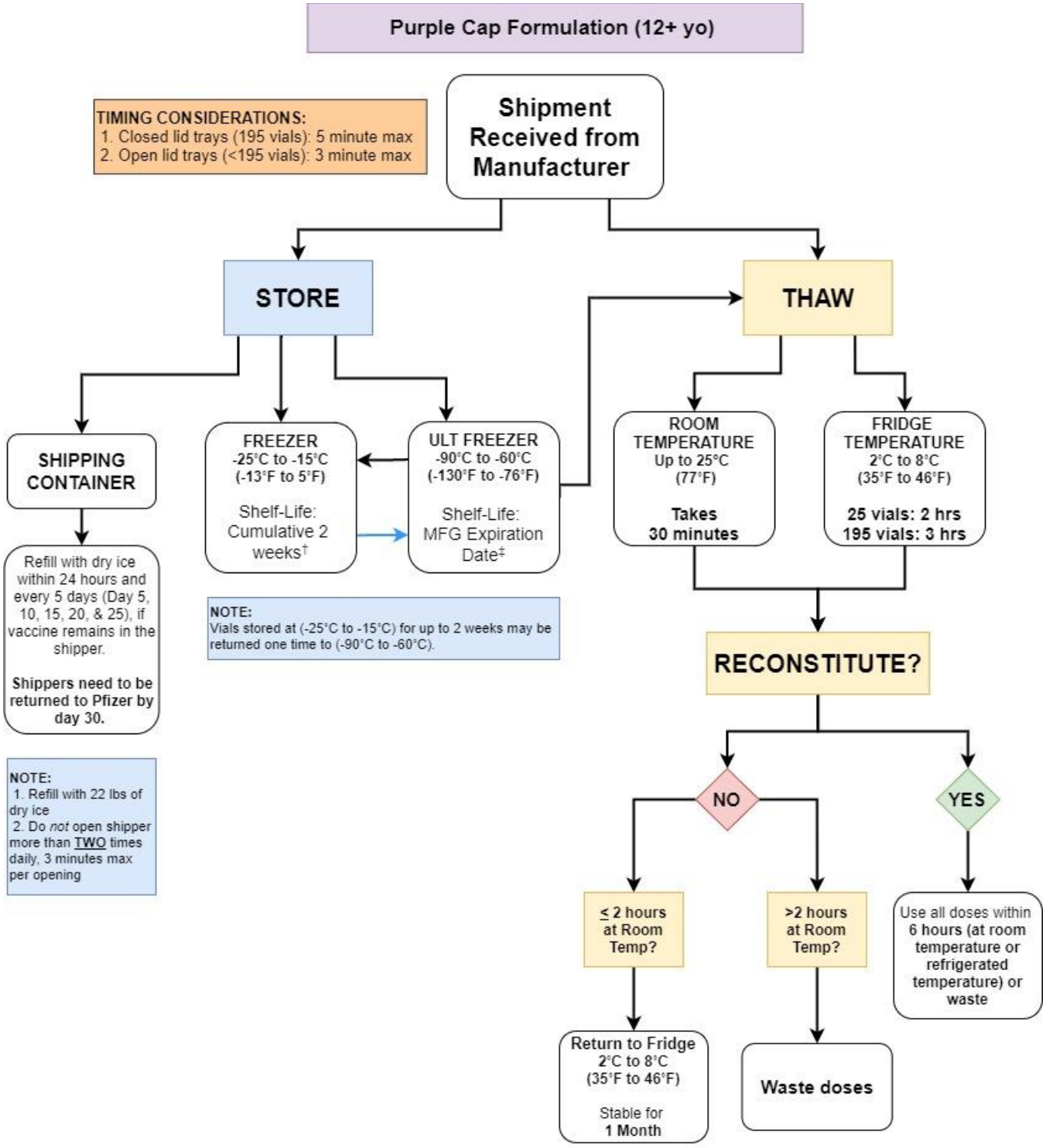
PREPARATION AND STORAGE/HANDLING OF PFIZER-BioNTech COVID-19 VACCINE (PURPLE CAP FORMULATION, ≥12 YO) – NEED RECONSTITUTION

PROCEDURE:

	STEPS		KEY POINTS
	DOSE PREPARATION		
	FOR MASS VACCINATION SITE, REFER TO PRE-DRAWING INSTRUCTIONS, ATTACHMENT H **FOR MOBILE & HOMEBOUND VACCINATION SITE REFER TO ATTACHMENT I FOR STORAGE AND HANDLING OF COVID-19 VACCINES** **THAWING PRIOR TO DILUTION**		
1.	Gather supplies.		
2.	Perform hand hygiene.		
3.	Don PPE (surgical mask and gloves).	3.1	Required PPE for vaccination include: surgical mask and gloves.
4.	Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has a **purple** plastic cap.		
5.	Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: • Thaw under refrigeration (2ºC to 8ºC (35ºF to 46ºF)): A carton of 25 or 195 undiluted vials may take up to 2 or 3 hours, respectively to thaw. Thawed undiluted vials can be stored in the refrigerator for up to 1 month. • Thaw at room temperature (up to 25ºC (77ºF)): Allow vial(s) to sit at room temperature for 30 minutes. • Using either thawing method, vials much reach room temperature before dilution and must be diluted within 2 hours; otherwise, return to refrigeration 2ºC to 8ºC (35ºF to 46ºF).	5.1 5.2	No more than 2 hours at room temperature, up to 25ºC (77ºF) Once thawed, undiluted vials must be diluted within 2 hours, or returned to refrigeration temperature 2ºC to 8ºC (35ºF to 46ºF).
	DILUTION		

	STEPS		KEY POINTS
6.	• Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Gently invert undiluted vaccine vial 10 times.	6.1	**Do not** use if liquid is discolored or if other particles are observed.
		6.2	**Do not** shake.
	• Clean the sterile 0.9% sodium chloride diluent vial using a single-use antiseptic swab (for 15 seconds). • Cleanse the vaccine vial stopper with a single-use antiseptic swab (for 15 seconds). • Using aseptic technique, withdraw 1.8 mL of 0.9% sodium chloride diluent with the transfer syringe and add to the vaccine vial using 21 gauge or narrower needle. • **Equalize vaccine vial pressure** before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe. • Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.	6.3	**Do not** shake.
	INSPECT THE VIAL		
7.	• Inspect the vaccine in the vial. • The vaccine will be an off-white suspension.	7.1	**Do not** use if vaccine is discolored or contains particulate matter.
		7.2	Each dose is 0.3 mL
8.	Record the expiration date and time of vial (6 hours after dilution) on the Pfizer-BioNTech COVID-19 Vaccine vial label.	8.1	Store between 2°C to 25°C (35°F to 77°F).
		8.2	Discard any unused vaccine 6 hours after dilution.
		8.3	Do not pool excess vaccine from multiple vials.
		8.4	Do not refreeze.

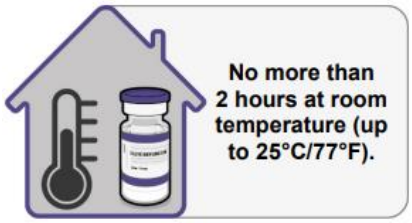
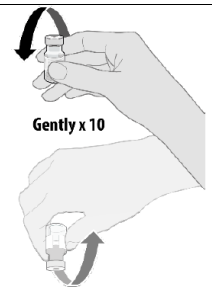
Storage and Handling of Pfizer-BioNTech Vaccine (Purple Cap Formulation)

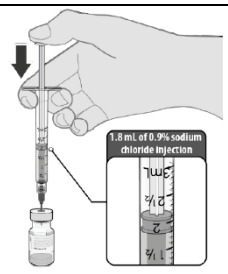
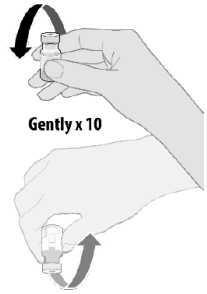


Revised 10.29.2021

Reconstitution of Pfizer-BioNTech Vaccine (Purple Cap Formulation)

VIAL VERIFICATION	
	1. Verify that the vial of Pfizer-BioNTech COVID-19 vaccine has a **purple** plastic cap. Some vials may also have a purple label border

THAWING PRIOR TO DILUTION	
	1. Thaw vials before use by allowing vials to a. Thaw in fridge (2ºC to 8ºC): may take up to 3 hours i. Stable for 1 month at refrigerated temperatures. ii. Label BUD. b. Thaw at room temperature (25ºC): 30 minutes Vials thawed at room temperature must be diluted within 2 hours. 2. Any vials left at room temperature for more than 2 hours must be wasted.
	1. Before dilution, invert vial gently 10 times a. **DO NOT SHAKE** 2. Inspect liquid in vial prior to dilution to ensure that it is: a. White to off-white suspension b. May contain white to off-white opaque amorphous particles 3. Do not use if liquid is discolored or if other particles are observed

DILUTION & PREPARATION	
	1. Withdraw 1.8 mL of 0.9% Sodium Chloride Injection, USP into a transfer syringe 2. Cleanse vaccine vial stopper with a single-use antiseptic swab 3. Add 1.8 mL of diluent into the vaccine vial 4. Equalize the vial pressure before removing the needle by withdrawing 1.8 mL of air
	1. Gently invert vial 10 times to mix a. **DO NOT SHAKE** 2. Inspect liquid in vial prior to dilution to ensure that it is: a. Off-white suspension 3. Do not use if vaccine is discolored or contains particulate matter

 **Record the date and time of dilution.** **Use within 6 hours after dilution.**	1. Record date and time of dilution on the vial or bag label 2. Store between 2ºC to 25ºC 3. Withdraw **0.3 mL** of vaccine for each dose. 4. Do not pool excess vaccine from multiple vials. 5. Discard any unused vaccine 6 hours after dilution

Note: Do NOT use bacteriostatic 0.9% sodium chloride injection or any other diluent.

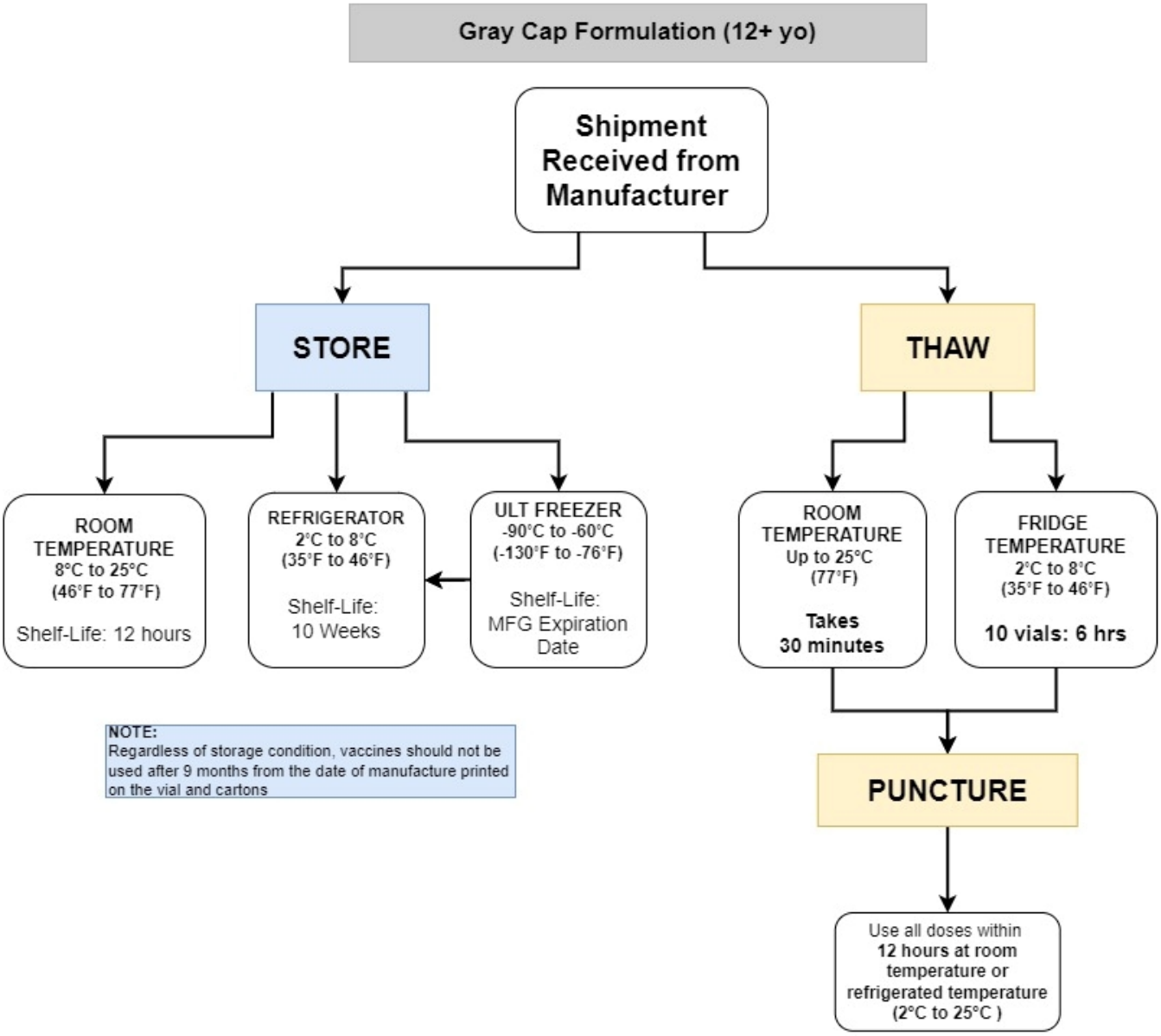
PREPARATION AND STORAGE/HANDLING OF PFIZER-BioNTech COVID-19 VACCINE (GRAY CAP FORMULATION ≥12 YO) – NO RECONSTITUTION

PROCEDURE:

STEPS	KEY POINTS
DOSE PREPARATION	
FOR MASS VACCINATION SITE, REFER TO PRE-DRAWING INSTRUCTIONS, ATTACHMENT H	
FOR MOBILE & HOMEBOUND VACCINATION SITE REFER TO ATTACHMENT I FOR STORAGE AND HANDLING OF COVID-19 VACCINES	
THAWING	
1. Gather supplies.	
2. Perform hand hygiene.	
3. Don PPE (surgical mask and gloves).	3.1 Required PPE for vaccination include: surgical mask and gloves.
4. Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has a **gray** plastic cap and a label with a gray border. Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: • Thaw under refrigeration (2ºC to 8ºC (35ºF to 46ºF)): A carton 10 vials may take up to 6 hours to thaw. Thawed vials can be stored in the refrigerator for up to 10 weeks. • Thaw vials at room temperature (up to 25ºC (77ºF)) for 30 minutes. • Vials may be stored at room temperature (up to 25ºC (77ºF) for up 12 hours.	4.1 No more than 12 hours at room temperature, up to 25ºC (77ºF)
PREPARATION	

	STEPS		KEY POINTS
5.	• Gently invert vial 10 times	5.1	**Do not** dilute
		5.2	**Do not** shake.
		5.3	Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
	• After mixing, inspect the vial. The vaccine should appear as a white to off-white suspension with no visible particles	5.4	**Do not** use if liquid is discolored or if particles are observed after mixing.
6.	• Cleanse the vaccine vial stopper with a single-use antiseptic swab (for 15 seconds) • Using aseptic technique, withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 vaccine	6.1	Each dose must contain 0.3 mL of vaccine.
7.	Record the expiration date and time of first vial puncture on vial label.	7.1	Store between 2°C to 25°C (35°F to 77°F).
		7.2	Discard any unused vaccine 12 hours after first puncture.
		7.3	Do not pool excess vaccine from multiple vials.
		7.4	If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
		7.5	Do not refreeze.
		7.6	Administer immediately.

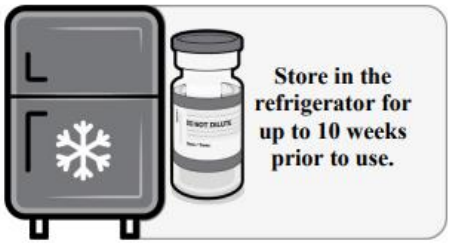
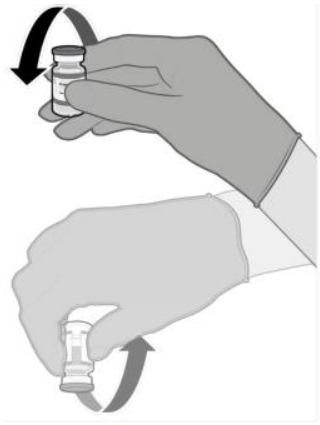
Storage and Handling of Pfizer-BioNTech Vaccine (Gray Cap Formulation)

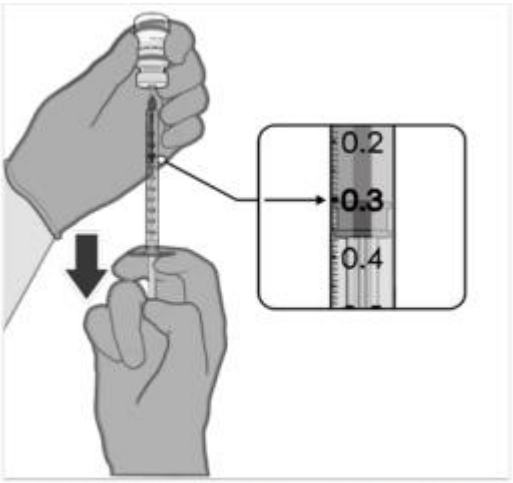
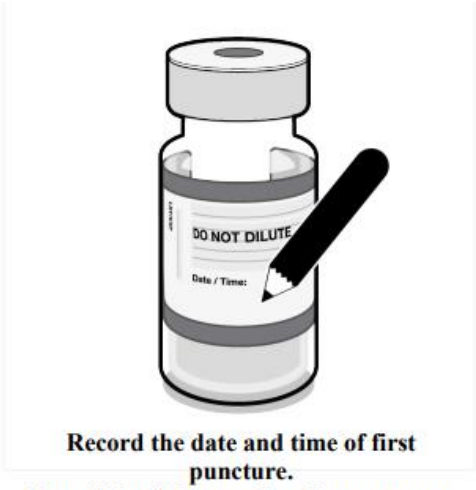


Revised 12.21.21

Preparation of Pfizer-BioNTech Vaccine (Gray Cap Formulation)

VIAL VERIFICATION	
 ✓ Gray plastic cap and label with gray border.	1. Verify that the vial of Pfizer-BioNTech COVID-19 vaccine has a **gray** plastic cap and a label with a **gray** border.

THAWING PRIOR TO USE	
	1. Thaw vials before use by allowing vials to a. Thaw in fridge (2ºC to 8ºC): A carton of 10 vials may take up to 6 hours i. Stable for 10 weeks at refrigerated temperatures. ii. Label BUD. b. Thaw at room temperature (25ºC): 30 minutes 2. Vials may be stored at room temperature [up to 25ºC (77ºF)] for up to 12 hours prior to use
 Gently × 10	1. Before use, invert vial gently 10 times a. **DO NOT SHAKE** 2. Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles. 3. Inspect liquid in vial after mixing to ensure that it is: a. White to off-white suspension with no visible particles 4. Do not use if liquid is discolored or if particles are observed after mixing

PREPARATION	
 **Withdraw 0.3 mL dose of vaccine.**	1. Withdraw **0.3 mL** of the Pfizer-BioNTech COVID-19 Vaccine. 2. Each dose must contain 0.3 mL of vaccine. 3. If the amount remaining in the vial cannot provide the full dose of 0.3 mL, discard the vial and any excess volume. 4. Administer immediately
 **Record the date and time of first puncture.** **Use within 12 hours after first puncture.**	1. Record date and time of first vial puncture on the vial or bag label 2. Store between 2ºC to 25ºC 3. Do not pool excess vaccine from multiple vials 4. Discard any unused vaccine 12 hours after first puncture

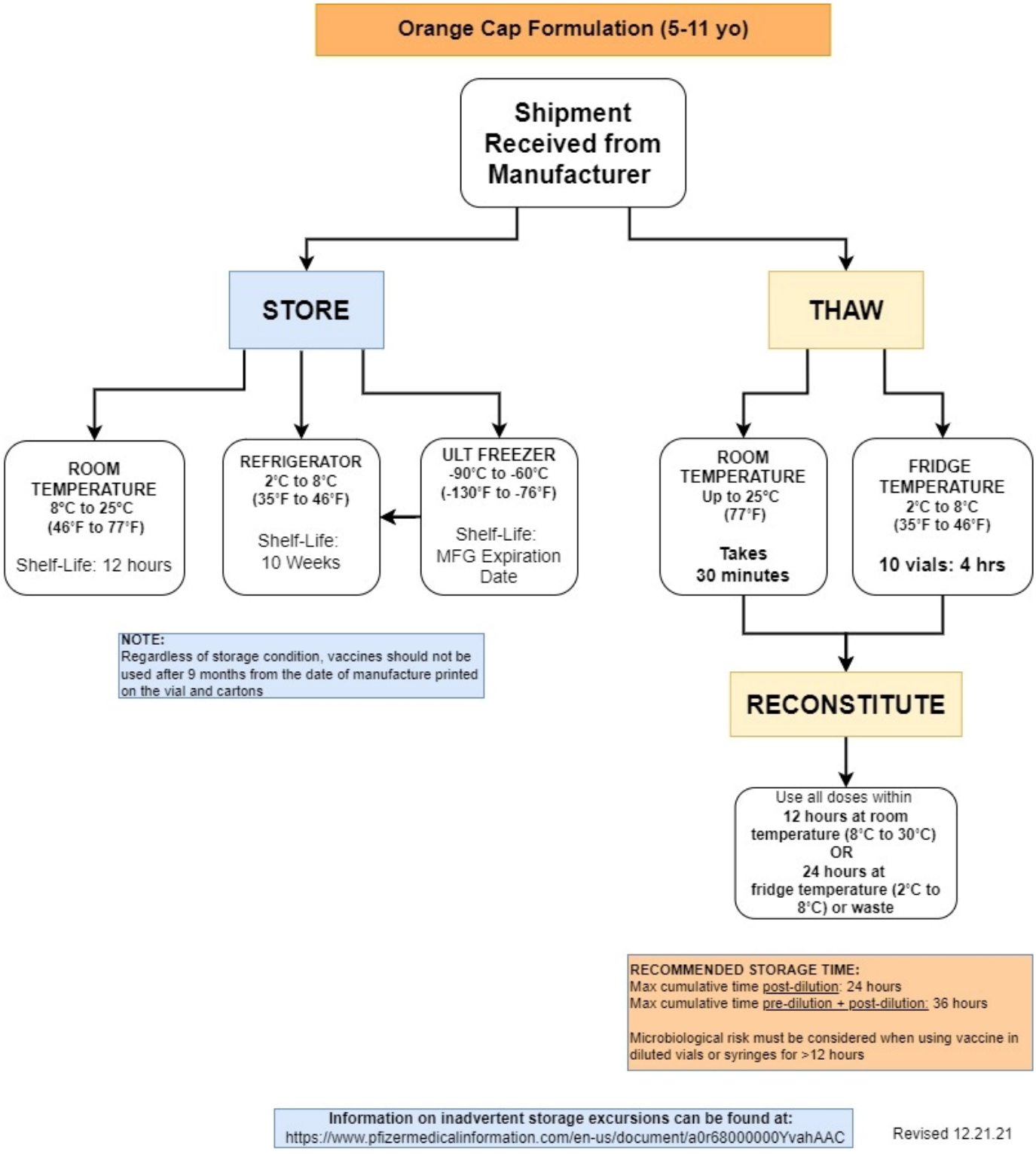
PREPARATION AND STORAGE/HANDLING OF PFIZER-BioNTech COVID-19 VACCINE (ORANGE CAP FORMULATION, 5-11 YO) – NEED RECONSTITUTION

PROCEDURE:

	STEPS	KEY POINTS
	DOSE PREPARATION	
	FOR MASS VACCINATION SITE, REFER TO PRE-DRAWING INSTRUCTIONS, ATTACHMENT H **FOR MOBILE & HOMEBOUND VACCINATION SITE REFER TO ATTACHMENT I FOR STORAGE AND HANDLING OF COVID-19 VACCINES**	
	THAWING PRIOR TO DILUTION	
1.	Gather supplies.	
2.	Perform hand hygiene.	
3.	Don PPE (surgical mask and gloves).	3.1 Required PPE for vaccination include: surgical mask and gloves.
4.	Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an **orange** plastic cap and a label with an orange border and states "Age 5y to <12y" Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:	4.1 Purple cap and gray cap formulations should not be used for individuals **5-11 years old**.
	• Thaw under refrigeration (2ºC to 8ºC (35ºF to 46ºF)): A carton 10 vials may take up to 4 hours to thaw. Thawed undiluted vials can be stored in the refrigerator for up to 10 weeks.	4.2 No more than 12 hours at room temperature, up to 25ºC (77ºF)
	• Thaw at room temperature (up to 25ºC (77ºF)): Allow vial(s) to sit at room temperature for 30 minutes. • Undiluted vials may be stored at room temperature (up to 25ºC (77ºF) for up 12 hours.	4.3 Once thawed, undiluted vials must be diluted within 12 hours, or vials must be wasted.
	DILUTION	
5.	• Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles.	5.1 **Do not** use if liquid is discolored or if other particles are observed.

	STEPS		KEY POINTS
	• Gently invert undiluted vaccine vial 10 times. • Clean the sterile 0.9% sodium chloride diluent vial using a single-use antiseptic swab (for 15 seconds).	5.2	**Do not** shake.
	• Cleanse the vaccine vial stopper with a single-use antiseptic swab (for 15 seconds).		
	• Using aseptic technique, withdraw 1.3 mL of 0.9% sodium chloride diluent with the transfer syringe and add to the vaccine vial using 21 gauge or narrower needle.		
	• **Equalize vaccine vial pressure** before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.		
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.	5.3	**Do not** shake.
	INSPECT THE VIAL		
6.	• Inspect the vaccine in the vial.	6.1	**Do not** use if vaccine is discolored or contains particulate matter.
	• The vaccine will be a white to off-white suspension.	6.2	Each dose is 0.2 mL
7.	Record the expiration date and time of vial (12 hours after dilution) on the Pfizer-BioNTech COVID-19 Vaccine vial label.	7.1	Store between 2°C to 25°C (35°F to 77°F).
		7.2	Discard any unused vaccine 12 hours after dilution.
		7.3	Do not pool excess vaccine from multiple vials.
		7.4	Do not refreeze.
		7.5	Administer immediately.

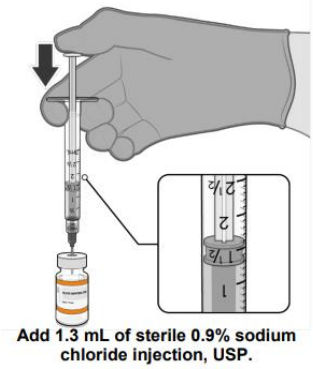
Storage and Handling of Pfizer-BioNTech Vaccine (Orange Cap Formulation)



Reconstitution of Pfizer-BioNTech Vaccine (Orange Cap Formulation)

VIAL VERIFICATION	
	2. Verify that the vial of Pfizer-BioNTech COVID-19 vaccine has an **orange** plastic cap. Some vials may also have an orange label border and states "Age 5y to <12 y."

THAWING PRIOR TO DILUTION	
	3. Thaw vials before use by allowing vials to a. Thaw in fridge (2ºC to 8ºC): A carton of 10 vials may take up to 4 hours i. Stable for 10 weeks at refrigerated temperatures. ii. Label BUD. b. Thaw at room temperature (up to 25ºC): 30 minutes 4. Undiluted vials may be stored at room temperature for up to 12 hours prior to use
	1. Before dilution, invert vial gently 10 times a. **DO NOT SHAKE** 5. Inspect liquid in vial prior to dilution to ensure that it is: a. White to off-white suspension b. May contain opaque amorphous particles 6. Do not use if liquid is discolored or if other particles are observed

DILUTION & PREPARATION	
	5. Withdraw 1.3 mL of 0.9% Sodium Chloride Injection, USP into a transfer syringe 6. Cleanse vaccine vial stopper with a single-use antiseptic swab 7. Add 1.3 mL of diluent into the vaccine vial 8. Equalize the vial pressure before removing the needle by withdrawing 1.3 mL of air

 Gently × 10	1. Gently invert vial 10 times to mix a. **DO NOT SHAKE** 2. Inspect liquid in vial prior to dilution to ensure that it is: a. Off-white suspension 3. Do not use if vaccine is discolored or contains particulate matter
 Use within 12 hours after dilution.	5. Record date and time of dilution on the vial or bag label 6. Store between 2ºC to 25ºC 7. Withdraw **0.2 mL** of vaccine for each dose. 8. Do not pool excess vaccine from multiple vials. 9. Discard any unused vaccine 12 hours after dilution

Note: Do NOT use bacteriostatic 0.9% sodium chloride injection or any other diluent

ATTACHMENT B

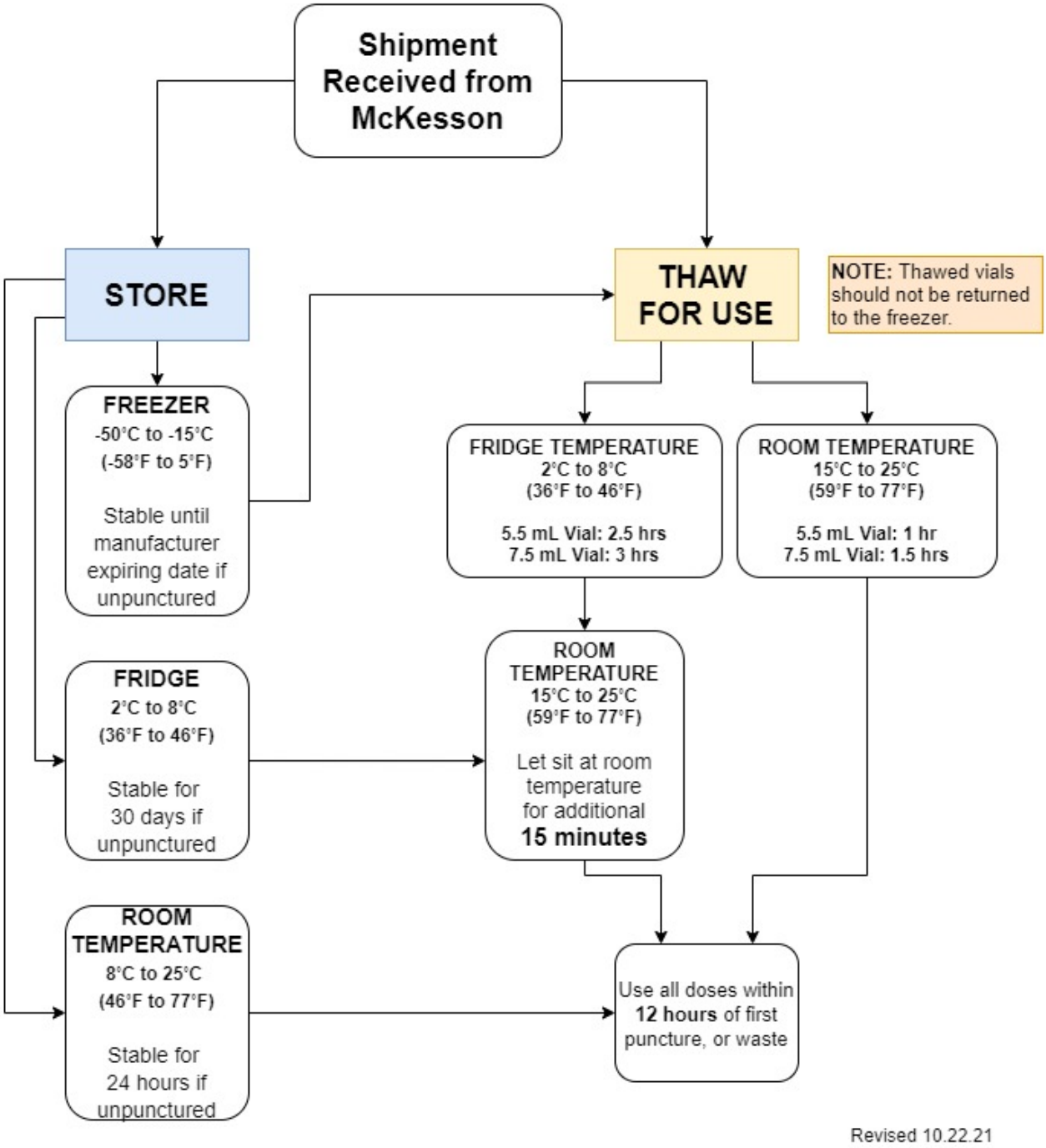
PREPARATION AND STORAGE/HANDLING OF MODERNA COVID-19 VACCINE

PROCEDURE:

	STEPS		KEY POINTS
	DOSE PREPARATION		
	FOR MASS VACCINATION SITE, REFER TO PRE-DRAWING INSTRUCTIONS, ATTACHMENT H **FOR MOBILE & HOMEBOUND VACCINATION SITE REFER TO ATTACHMENT I FOR STORAGE AND HANDLING OF COVID-19 VACCINES**		
	THAWING		
1.	Remove the required number of vial(s) from storage and thaw each vial before use.		
2.	Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes 5.5 mL vial) or 3 hours (7.5 mL vial) Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour (5.5 mL vial) or 1 hour and 30 minutes (7.5 mL vial).	2.1	Unpunctured vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to **first** use. Unpunctured vials may be stored at room temperature between 8° to 25°C (46° to 77°F) for up to 24 hours. **Do not** refreeze once thawed.
3.	Once thawed, allow the vial to stand at room temperature for 15 minutes before administering.		
4.	Perform hand hygiene.		
5.	Don PPE (surgical mask and gloves).	5.1	Required PPE for vaccination include: surgical mask and gloves.
	INSPECT THE VIAL		
6.	Swirl vial gently after thawing and between each withdrawal.	6.1	**Do not** shake. **Do not** dilute the vaccine.

	STEPS		KEY POINTS
7.	Visually inspect the vaccine vials for other particulate matter and/or discoloration prior to administration.	7.1	The Moderna COVID-19 vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates.
		7.2	**Do not** use if there is other particulate matter and/or discoloration.
	Note the expiration date and time of the vial	7.3	After first puncture, keep the vaccine between 2°C and 25°C (36°F and 77°F) for up to 12 hours.
		7.4	Discard any unused vaccine from punctured vial after 12 hours.
8.	Moderna COVID-19 Vaccine is supplied in two multiple-dose vial (MDV) presentations: • A MDV containing 5.5 mL ▪ Primary Series: maximum 11 doses (0.5 mL each) ▪ Booster Dose: maximum 20 doses (0.25 mL each) • A MDV containing 7.5 mL ▪ Primary Series: maximum 15 doses (0.5 mL each) ▪ Booster Dose: maximum 20 doses (0.25 mL each)	8.1	When extracting the **primary series doses only**, depending on the syringe and needles used for each dose, a maximum of 11 doses (range: 10-11 doses) may be extracted from the 5.5 mL vial or a maximum of 15 doses (range: 13-15 doses) may be extracted from the 7.5 mL vial
9.	Primary series dose of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation. Booster dose vials are the *same* formulation/NDC as the primary series. When extracting only booster doses or a combination of the primary series and booster doses, no more than 20 doses may be extracted from a single vial.	9.1	Each dose for the **primary series** and **additional dose** must contain 0.5 mL
		9.2	Each dose for the **booster** dose must contain 0.25 mL
		9.3	Do not pool excess vaccine from multiple vials.
		9.4	Pierce stopper at a different site each time
		9.5	Do not puncture the vial stopper more than 20 times. If the vial stopper has been punctured 20 times, discard the vials and contents.

Storage and Handling of Moderna Vaccine



ATTACHMENT C

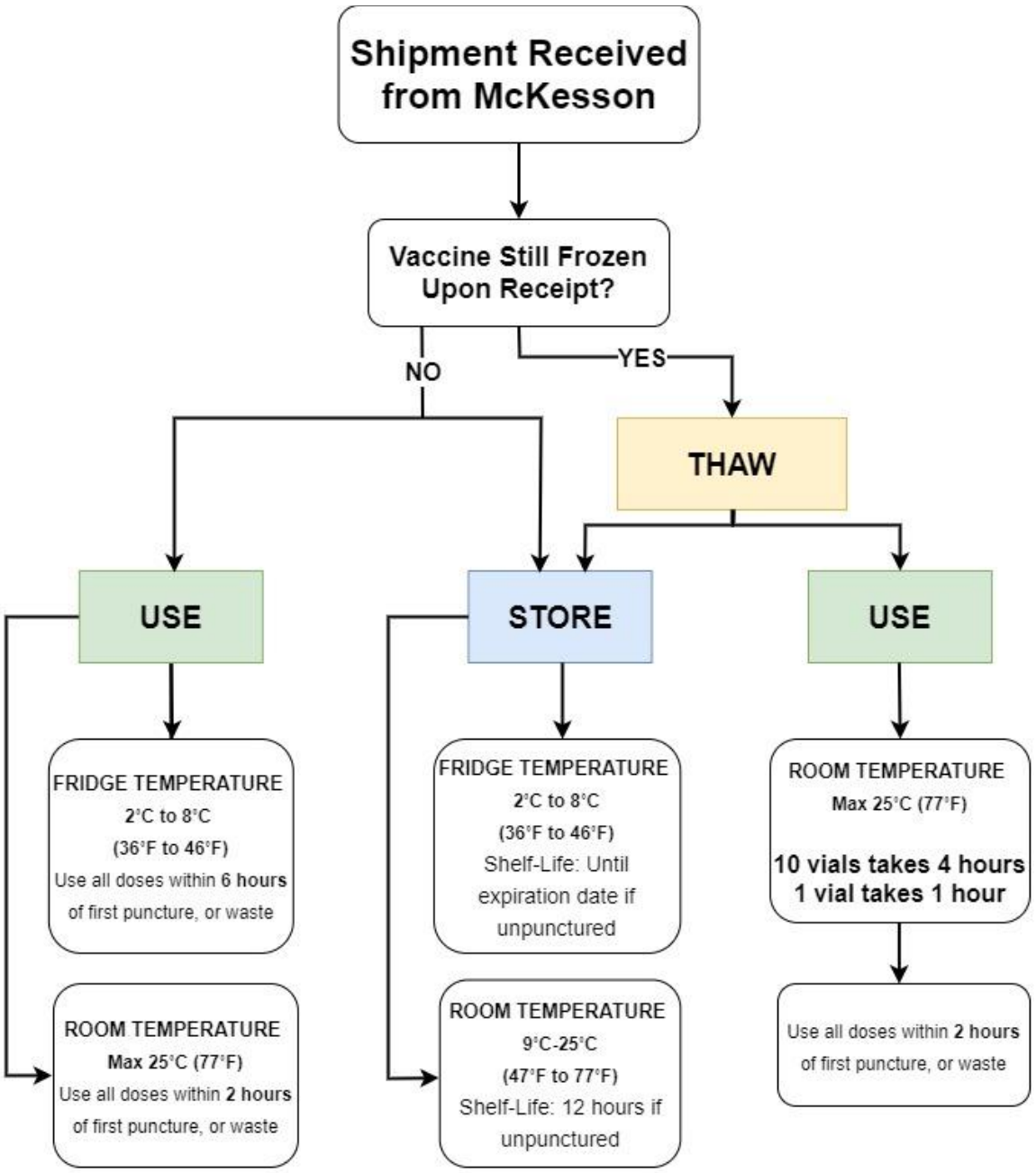
PREPARATION AND STORAGE/HANDLING OF JANSSEN (JOHNSON & JOHNSON) COVID-19 VACCINE

PROCEDURE:

	STEPS		KEY POINTS
	DOSE PREPARATION		
	FOR MASS VACCINATION SITE, REFER TO PRE-DRAWING INSTRUCTIONS, ATTACHMENT H **FOR MOBILE & HOMEBOUND VACCINATION SITE REFER TO ATTACHMENT I FOR STORAGE AND HANDLING OF COVID-19 VACCINES**		
	THAWING		
1.	Remove the required number of vial(s) from storage and thaw each vial before use.		**Do not** refreeze upon receipt of the vials or once vials have been thawed.
2.	If vaccine is still frozen upon receipt, thaw at 2˚C to 8˚C (36° to 46°F) If vaccine is needed for immediate use, thaw at room temperature (max 25˚C / 77°F) • A 10-vial carton takes around 4 hours to thaw • A single vial takes around 1 hour to thaw	2.1	Storage prior to first puncture: • Store unpunctured multi-dose vials at 2˚C to 8˚C (36° to 46°F) for up to 3 months and protect from light. Do not store frozen. • Unpunctured vials may be stored between 9˚C to 25˚C (48° to 77°F) for up to 12 hours.
3.	Perform hand hygiene.		
4.	Don PPE (surgical mask and gloves).	4.1	Required PPE for vaccination include: surgical mask and gloves.
	INSPECT THE VIAL		
5.	Visually inspect the vaccine vials for other particulate matter and/or discoloration prior to administration.	5.1	The Janssen COVID-19 vaccine should be colorless to slightly yellow.
		5.2	**Do not** use vaccine if there is discoloration or if it contains particulate matter.

	STEPS		KEY POINTS
6.	Before drawing up a dose, carefully swirl the multi-dose vial in an upright position for 10 seconds.	6.1	**Do not** shake. Vaccine **does not** require reconstitution.
7.	Record the date and time of first use on the Janssen COVID-19 Vaccine vial or bag label	7.1	Storage after first puncture: Keep punctured vial between 2°C to 8°C (36°F and 46°F) and use all doses within 6 hours, or waste. **OR** Keep punctured vial at room temperature (max 25˚C / 77°F) and use all doses within 2 hours, or waste.
		7.2	Discard any unused vaccine from punctured vial if doses are not used within these timeframes.
8.	Each vial contains five doses	8.1	Each dose is 0.5 mL
		8.2	Do not pool excess vaccine from multiple vials

Storage and Handling of Janssen Vaccine



NOTE:
1. Do NOT store vials frozen
2. Janssen has not released official thaw time at fridge temperature
3. Do NOT refreeze once thawed

Revised 08.25.2021

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, 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.
	• If this is the second dose of the **Pfizer** vaccine, review and confirm that it has been 21 days since the first dose AND the first dose was Pfizer.	4.2	The second dose of Pfizer COVID-19 vaccine is to be administered **21 days 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 28 days since the first dose AND the first dose was Moderna.	4.3	The second dose of Moderna COVID-19 vaccine is to be administered **28 days 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
	4.4	Per CDC recommendation, second dose should be administered as close to the recommended interval as possible. However, if it is not feasible to adhere to the recommended interval, the second dose should be administered within 6 weeks (42 days) of the first dose. Effectiveness of administration outside of this window is unknown. If individual is outside of the 6 weeks window, inform the individual of the unknown benefit. Recommend to individual to proceed with second dose. Do not restart the series. If individual has additional questions, discuss with clinical advisor on site or refer individual to their primary care provider.
• If this is the third dose of an mRNA COVID-19 vaccine, 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.	4.5	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 this is the **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.	4.6	If the patient has completed the **Pfizer or Moderna** COVID-19 vaccine series in the past and meets the CDC criteria for a booster dose, they may proceed with a booster dose at least 5 months after completing the primary series.

	STEPS		KEY POINTS
	If this is a **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.		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 booster dose at least 2 months (8 weeks) after completing the primary dose. (At mass and mobile vaccination operations, confirmation that the patient meets CDC criteria may be accomplished by self-attestation from the patient.)
	• For patients 12-17 years of age who have completed primary series with Pfizer COVID-19 vaccine, only the Pfizer product may be used for booster vaccination.	4.7	Mixing and matching of booster is not authorized in patients 12-17 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 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.

	STEPS		KEY POINTS
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.
7.	Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, 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.		

	STEPS	KEY POINTS
	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 **21 days after** the first dose. • Moderna: needs to be given at **28 days after** the first dose.
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 Call Santa Clara County Healthcare Worker COVID-19 Vaccine Hotline for additional information. 13.2 Follow up with primary care provider for further questions/concerns

	STEPS		KEY POINTS
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.
	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 15.2	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. 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: _____ **Patient Weight (12 years and under):** _____

Emergency Contact Name and Phone number: _____

Have you ever received a dose of the COVID-19 Vaccine? ☐ Yes ☐ No

If yes, which vaccine product? ☐ Pfizer ☐ Moderna ☐ Janssen (Johnson & Johnson) ☐ Other _____

Are you here today for an additional dose of vaccine after completing ☐2 doses of Pfizer, ☐2 doses of Moderna, ☐1 dose of Janssen, or ☐3 doses of Pfizer or Moderna Vaccine?

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)		
"Yes" answers to the questions below will be addressed by an RN on site per BRN nursing protocol.		
4. 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.		
5. In the last 3 months, have you had a Stem Cell/Bone Marrow Transplant or undergone Cellular Therapy (CAR T Cell therapy)?		
6. Are you currently undergoing chemotherapy for acute leukemia?		
7. Have you received antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19 in the last 90 days?		

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 11/08/2021
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)
   ☐ Others (List Name of Vaccine Received)_____
3. Are you here today for an additional dose of vaccine after completing ☐ 2 doses of Pfizer, ☐ 2 doses of Moderna, ☐ 1 dose of Janssen, or ☐ 3 doses of Pfizer or Moderna Vaccine?

Patients seeking a booster dose

- If 18+ patient answers YES to Questions #1 and #3, AND selects Pfizer or Moderna in Question #2, AND meets CDC criteria for a **booster dose**, they should proceed with a booster dose at **least 5 months** after their 2nd or 3rd Pfizer or Moderna COVID-19 vaccine dose.
- If 18+ patient answers YES to Questions #1 and #3, AND selects Janssen in Question #2, AND meets CDC criteria for a **booster dose**, they should proceed with a booster dose at **least 2 months** after their initial Janssen COVID-19 vaccine dose.
- If 12-17 yo patient answers YES to Questions #1 and #3, AND selects Pfizer in Question #2, AND meets CDC criteria for a **booster dose**, they should proceed with a booster dose (Pfizer) at **least 5 months** after their 2nd or 3rd Pfizer COVID-19 vaccine dose.
- If 18+ patient received a mixed primary dose series (e.g., 1st dose Pfizer, 2nd dose Moderna) and is seeking a booster dose, escalate case to the appropriate supervising provider for your site.

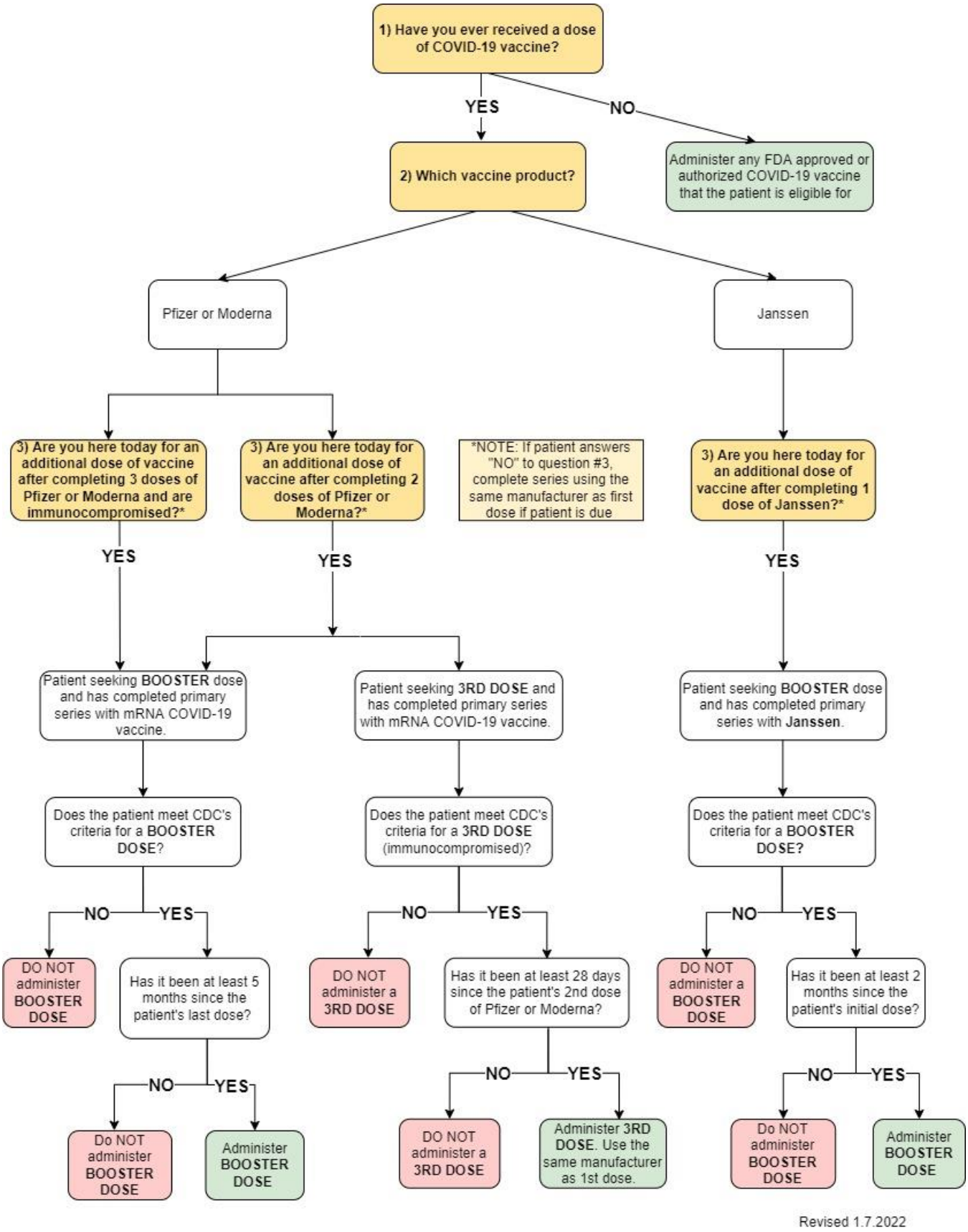
Patients seeking third vaccine dose

- If 12+ patient answers YES to Questions #1 and #3, AND selects Pfizer (12+ yo) or Moderna (18+ yo) in Question #2, AND meets CDC criteria (immunocompromised) for **third dose** of Pfizer (12+ yo) or Moderna (18+ yo) they may proceed with a third dose **at least 28 days** after their last mRNA COVID-19 vaccine dose. 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 5-11 yo patient answers YES to Question #1, Pfizer to Question #2 and YES to Question #3, AND meets CDC criteria for a **third dose**, they should proceed with an additional dose **at least 5 months** after their 2nd Pfizer vaccine dose.
- If patient was vaccinated with Janssen COVID-19 vaccine, they are considered fully vaccinated. The patient may be eligible for *booster* if 1st dose of Janssen was administered at least 2 months ago.

People who received COVID-19 vaccination outside the United States

- For patients that have completed their vaccination series with FDA-approved, FDA-authorized, or WHO-authorized vaccines, they should NOT complete another one here. Follows booster guidance above.
- For patients that have received the first dose of a WHO authorized vaccine series (e.g. first dose AstraZeneca), they should receive a single dose of the Pfizer COVID-19 vaccine at least 28 days since their first dose to complete their vaccination series, after which they are considered fully vaccinated.
- For patients who have received all or some vaccination with vaccines that are not approved or authorized by the FDA or WHO, they should be offered a complete series with an FDA-approved or FDA-authorized vaccine (preferably with an mRNA COVID-19 vaccine), at least 28 days after their last vaccine dose. Following completion of primary vaccination with an FDA-approved/authorized COVID-19 vaccine, these individuals are considered fully vaccinated and are not recommended to receive an additional or booster dose at this time.

- For patients that have only started an FDA-approved or FDA-authorized vaccine series (e.g. first dose of Pfizer), they should receive their second dose as per protocol.
- For patients who have completed all of the recommended doses of a WHO-authorized vaccine that is not FDA-authorized or FDA-approved **or** who completed a heterologous series composed of any combination of FDA-authorized/approved or WHO-authorized vaccines, they are eligible to receive:
    - An **additional dose** of the Pfizer ≥12 year old [30 ug] formulation at least 28 days after receiving the 2nd vaccine dose of their primary series if they are ≥12 years old and are moderately or severely immunocompromised and/or
    - A **single booster dose** of the Pfizer ≥12 year old [30 ug] formulation at least 5 months after completing their primary series if they are ≥12 years old (including moderately or severely immunocompromised people who received an additional primary dose).



Revised 1.7.2022

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 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 2: Triage of Persons Presenting for COVID-19 Vaccination

5. 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

6. 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

7. Have you received antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19 in the last 90 days?

DO NOT VACCINATE, advise patient to reschedule 90 days after therapy

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 (21 days after Pfizer dose and 28 days 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. *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

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 (21 days)
Pfizer	11 turning 12 between 1st and 2nd dose	Dose 1: Orange Dose 2: Purple	Dose 1: 10 ug (0.2 mL) Dose 2: 30 ug (0.3 mL)*	2 (21 days)
Pfizer	≥12	Purple	30 ug (0.3 mL)	2 (21 days)
Moderna	≥18	N/A	100 ug (0.5 mL)	2 (28 days)
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 (**purple**) 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).

Additional and Booster Doses of COVID-19 Vaccine:

1. *Additional dose* is defined as an additional dose of vaccine administered when the immune response following a primary vaccine series is likely to be insufficient.
2. *Booster dose* is defined as an additional dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time.
    a. *Heterologous booster dose (mix-and-match booster)* is a subsequent dose of vaccine that is a different product from the primary series
    b. *Homologous booster dose* is a subsequent dose of vaccine that is the same product as the primary series

Table 1: Additional vs Booster Dose for patients who were vaccinated with a currently FDA-approved/authorized COVID-19 Vaccine

	Additional Dose	Booster Dose
Indication	For moderate to severely immune compromised patients following completion of a 2-dose mRNA vaccine series.	For select populations with concern for waning immunity.
Rationale	Insufficient immune response to 2-dose series	Waning immunity over time
Injection Dose (Volume)	Pfizer: • **5-11 year old:** 10 ug (0.2 mL, orange cap formulation) • **12+ year old:** 30 ug (0.3 mL, purple or gray cap formulation) Moderna: 100 ug (0.5 mL) – Full dose Janssen: N/A	Pfizer: 30 ug (0.3 mL) Moderna: 50 ug (0.25 mL) – Half dose Janssen: 5×10^{10} viral particles (0.5 mL) Booster dose and volume are the *same* regardless of whether dose is homologous or heterologous.
Dosing Interval	Pfizer and Moderna: At **least 28 days (4-day grace period)** after completion of the initial 2-dose mRNA COVID-19 vaccine series If the additional dose of mRNA COVID-19 vaccine is given <24 days after 2nd dose, the additional dose **should** be repeated.	Pfizer and Moderna: **At least 5 months (4-day grace period)** after completion of the initial 2-dose Pfizer-BioNTech or Moderna primary series Janssen: **At least 2 months or 8 weeks (4-day grace period)** after their Janssen initial dose If the booster dose is given earlier than the 4-day grace period (i.e., more than 4 days before 5 months after 2nd mRNA primary vaccine dose or 4 days before 2 months after Janssen primary dose), the booster dose does **not need** to be repeated.
Eligibility	Pfizer: Age **5 years and older** with moderate to severe immune compromise Moderna: Age **18 years and older** with moderate to severe immune compromise Janssen: Not Authorized for Additional Dose at this time. However, patient may be eligible for *booster dose* if 1st dose of Janssen was administered at least 2 months ago.	Pfizer: Patients that **should** get a booster dose • 12-17 years old even if they were age 11 or younger at time of the primary series (can only get Pfizer as a booster dose) • 18 years and older (can get any of the COVID-19 vaccines authorized in U.S) Moderna and Janssen: Patients that **should** get a booster dose • 18 years and older (can get any of the COVID-19 vaccines authorized in U.S)
Pfizer Initial Series (2 doses)	Additional Dose Options: 1. **Age 5-11 years old:** Pfizer 5-11 Year Old Dose (orange cap formulation) at 28 days or more	Booster Option in 12-17 years old: 1. Pfizer Full Dose at 5 months or more Booster Options (Default listed 1st) in 18+: 1. Pfizer Full Dose at 5 months or more

	2. **Age 12 years and older:** Pfizer Full Dose at 28 days or more	2. Moderna Half Dose at 5 months or more 3. Janssen Full Dose at 5 months or more
Moderna Initial Series (2 doses)	Additional Dose Options: 1. Moderna Full Dose at 28 days or more	Booster Options (Default listed 1st) in 18+: 1. Moderna Half Dose at 5 months or more 2. Pfizer Full Dose at 5 months or more 3. Janssen Full Dose at 5 months or more
Janssen Initial Series (1 dose)	Although there is currently no authorization for Additional Dose, the patient may be eligible for a *booster dose*: 1. Pfizer Full Dose at 2 months 2. Moderna Half Dose at 2 months 3. Janssen Full Dose at 2 months	Booster Options (Default listed 1st) in 18+: 1. Pfizer Full Dose at 2 months or more 2. Moderna Half Dose at 2 months or more 3. Janssen Full Dose at 2 months or more
Inadvertent mixing of Pfizer and Moderna during initial series	Additional Dose Options: 1. Pfizer Full Dose or Moderna Full Dose at 28 days or more	Booster Options in 18+: 1. Pfizer Full Dose, Moderna Half Dose, *or* Janssen Full Dose at 5 months (mRNA vaccine is preferred over Janssen vaccine)
Pfizer or Moderna followed by Janssen due to reaction to Pfizer or Moderna	Additional Dose Options: 1. Janssen Full Dose at 2 months	Booster Options in 18+: 1. Janssen Full Dose at 2 months (unless reaction was determined not to be specific to shared mRNA formulation)
Note	The additional mRNA COVID-19 vaccine dose should be the **same vaccine product** as the initial 2-dose mRNA COVID-19 primary vaccine series. However, if the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. Moderately to severely immunocompromised children aged 5-11 years who received a 2-dose Pfizer primary series should receive an additional 10 ug dose of Pfizer (orange cap formulation) at least 28 days after completion of the primary series. Moderately to severely immunocompromised people aged ≥18 years who received a 2-dose mRNA primary series and an additional mRNA additional dose (3 total mRNA vaccine doses) **should receive** a single COVID-19 **booster** dose (Pfizer,	A mRNA vaccine is **preferred** over the Janssen COVID-19 vaccine as a booster dose, even for those who received Janssen for their primary series. Any of the mRNA COVID-19 vaccines can be used as booster, regardless of the vaccine product used for primary vaccination. When a heterologous booster dose is administered, the eligible population and interval are those of the vaccine used for primary vaccination. Boosters for Moderna and Janssen recipients are limited to ages ≥18. Boosters for Pfizer recipients are limited to ages ≥12. Individuals **12-17 years of age** who completed a primary series with Pfizer vaccine may **only** receive Pfizer as a booster dose. Default options will be available at all sites. Options 2 and 3 are based on availability upon request (can refer to a mass site if needed which will have all 3 options available).

	Moderna, or Janssen) at **least 5 months** after completing their third mRNA vaccine dose. Moderately to severely immunocompromised people aged 12 to 17 who received the Pfizer COVID-19 primary series and additional dose of Pfizer (3 total Pfizer vaccine doses) **should receive** a single Pfizer booster dose at **least 5 months** after completing their third Pfizer dose.	
Definitions	Immunosuppression (from medical condition or treatment): • 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 or hematopoietic stem cell transplant (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 • 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	

Contraindications: Patient Exclusion Criteria
A summary of the contraindications and precautions to COVID-19 vaccine is described in **Table 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.
CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines:

1. Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
2. Immediate allergic reaction to any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.
    a. An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four (4) hours following administration.

See **Table 3** for the list of ingredients in COVID-19 Vaccines. 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.

In patients who develop post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of mRNA Covid-19 vaccines. Refer to Appendix D in https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html for a summary of signs and symptoms associated with the different types of post-vaccination reactions. Providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Precautions
History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies) as a precaution but **not** a contraindication to vaccination. People with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in who it is unknown which component elicited the immediate allergic reaction, have a precaution to vaccination.

1. People with a contraindication to one type of COVID-19 vaccine have a precaution to the other type (e.g., mRNA, viral vector, etc.). Since the potential for cross-reactive hypersensitivity between the compounds in mRNA and Janssen COVID-19 vaccine exists, consultation with an allergist-immunologist should be considered to determine the safety of vaccination.
    a. People with a contraindication to mRNA COVID-19 vaccines (including known PEG allergy) may consider Janssen COVID-19 vaccination.

i. People who have received on mRNA COVID-19 vaccine 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.

b. People with a contraindication to Janssen COVID-19 vaccine (including known polysorbate allergy) may consider mRNA COVID-19 vaccination.
   i. Polysorbate allergy is a precaution and no longer a contraindication to mRNA COVID-19 vaccination.

2. 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)
   e. One appropriately counseled, these individuals may receive the vaccine and will need to be observed for 30 minutes post vaccination.

Table 2: 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†∞ • Known (diagnosed) allergy to a component of a COVID-19 vaccine†	**Among people without a contraindication, a history of:** • Any immediate allergic reaction* to other vaccines or injectable therapies‡ • Non-severe, immediate (onset <4 hours) allergic reaction∞ after a previous dose of COVID-19 vaccine# Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#	**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†	**Actions:** • Risk assessment • Consider referral to allergist-immunologist • 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

† See Table 3 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).

∞ 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.

** 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.*

‡ 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.

 # 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.

Table 3: Ingredients included in COVID-19 vaccines

Description	Pfizer-BioNTech (mRNA) for 5-11 YO	Pfizer-BioNTech (mRNA) for ≥12 YO	Moderna (mRNA)	Janssen (viral vector)
Active Ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive Ingredient	2 [(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl) bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Tromethamine	Sodium chloride	Tromethamine	Sodium chloride
	Tromethamine hydrochloride	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Sucrose	Potassium chloride	Acetic acid	
		Dibasic sodium phosphate dihydrate	Sodium acetate	
		Sucrose	Sucrose	

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

1. **History of Myocarditis or Pericarditis**: There are limited data on the safety and efficacy of COVID-19 vaccines in patients with a history of myocarditis or pericarditis.
    a. People with a history of myocarditis or pericarditis **prior** to COVID-19 vaccination may receive any currently FDA-authorized or FDA-approved COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., no evidence of heart inflammation or sequelae as determined by the person's clinical team and special testing to assess cardiac recovery).
    b. People who develop myocarditis or pericarditis **after receipt** of first dose of an mRNA COVID-19 vaccine but before receipt of second dose should not receive subsequent dose of any COVID-19 vaccine. Administration of a subsequent dose of the COVID-19 vaccine may be considered in certain circumstances including: personal risk of severe acute COVID-19, level of COVID-19 community transmission and personal risk of infection, timing of immunomodulatory therapies.
    c. People who *choose* to receive the second dose of mRNA COVID-19 vaccine should wait at least until their episode of myocarditis or pericarditis has completely resolved (i.e., no evidence of heart inflammation or sequelae as determined by the person's clinical team and special testing to assess cardiac recovery).

2. **Immunocompromised persons** (including persons living with HIV, other immunocompromising conditions, or who take immunosuppressive medications or therapies): The current FDA-authorized and FDA-approved COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised individuals.

    Recent studies have found evidence of reduced immune response to a 2-dose primary mRNA COVID-19 vaccine series in some groups of immunocompromised people, who also may have a higher rate of breakthrough COVID-19 infections compared to the general population. Small studies have shown that an additional mRNA COVID-19 vaccine dose may enhance antibody response in this population. The potential to increase response combined with an acceptable safety profile supports the use of a third mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series in **moderately and severely immunocompromised** people with the following conditions and treatments but are not limited to:

    a. Active treatment for solid tumor and hematologic malignancies
    b. Receipt of solid-organ transplant and taking immunosuppressive therapy
    c. Receipt of CAR-T cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
    d. Moderate or severe primary or acquired immunodeficiency (e.g., advanced or untreated HIV infection, DiGeorge syndrome, or Wiskott-Aldrich syndrome)
    e. Active treatment with high-dose corticosteroids (i.e., $\geq$ 20mg prednisone or equivalent per day, alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis blockers, and other biologic agents that are immunosuppressive or immunomodulatory.)

The additional dose of an mRNA COVID-19 vaccine should be administered at **least 28 days** after completion of the initial 2-dose mRNA COVID-19 vaccines series, based on expert opinion. The patient's clinical team should determine the degree of immune compromise and the appropriate timing of vaccination. 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.

The additional mRNA COVID-19 vaccine dose should be the **same vaccine product** as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine may be administered. Currently there is insufficient data to support the use of an additional mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccine series in immunocompromised people.

Whenever possible, mRNA COVID-19 vaccine doses (both primary series and additional dose) should be completed at least two weeks before starting or resuming immunosuppressive therapies.

The utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care has not been established and is **not recommended at this time**.

Immunocompromised persons (including people who receive a third dose of mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series) should be counseled about the potential for reduced immune response to the vaccine and the need to continue to follow all current prevention measures (i.e., wear a mask, stay 6 feet apart from others they don't live with, avoid crowds and poorly ventilated indoor spaces) to protect themselves against COVID-19.

3. **Individuals with Autoimmune Conditions:** Individuals with autoimmune conditions were eligible for enrollment into the clinical trials. Imbalances in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders were not observed in those receiving COVID-19 vaccines compared to placebo.

   Individuals with autoimmune conditions may receive any FDA-authorized or FDA-approved COVID-19 vaccine.

4. **History of Guillain-Barré syndrome (GBS):** Reports of adverse events following use of the Janssen COVID-19 vaccine under EUA suggest an increased risk of GBS during the 42 days following vaccination. Currently, there has been no increased risk of GBS identified with mRNA vaccines. ACIP's general best practice guidelines for immunization do not include history of GBS as a contraindication or precaution to vaccination.

   Individuals with a history of GBS can receive any currently FDA-authorized or FDA-approved COVID-19 vaccine. However, given the possible association of increased risk of GBS and the Janssen COVID-19 vaccine, the availability of mRNA COVID-19 vaccine should be discussed between the patient and their clinical team.

   There is no data on the safety of administering a booster dose of either Janssen vaccine or an mRNA vaccine to people who had GBS following the first dose of Janssen vaccine. People who had GBS after Janssen vaccine may receive an mRNA COVID-19 vaccine booster at least 2 months after the Janssen dose. However, Janssen vaccine may still be used as a booster, particularly if the GBS was outside of

the 42 days after vaccination or was assessed as related to a non-vaccine factor. Prior to booster vaccination, a conversation the patient and their clinical team may assist with decisions about administration of a COVID-19 booster vaccine and timing of the booster vaccination.

Any occurrence of GBS following COVID-19 vaccination should be reported to the VAERS.

5. **History of Bell's palsy:** Although cases of Bell's palsy have been reported during the COVID-19 vaccine clinical trials following vaccination of participants, the FDA has not concluded that these cases were causally related to vaccination. Unless otherwise contraindicated, individuals with a history of Bell's palsy may receive any currently FDA-authorized or FDA-approved COVID-19 vaccine. Any occurrence of Bell's palsy following COVID-19 vaccination should be reported to the VAERS.

6. **History of dermal filler use:** Infrequently, persons who have received dermal fillers may develop swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine. No similar occurrences were observed in the Janssen COVID-19 vaccine clinical trials. The swelling appears to be temporary and can resolve with medical treatment, including corticosteroid therapy. Any currently FDA-authorized or FDA-approved COVID-19 vaccine may be administered to persons who have received injectable dermal fillers who have no contraindications or precautions to vaccination. However, these persons should be advised to contact their healthcare provider for evaluation if they develop swelling at or near the site of dermal filler following vaccination.

7. **History of COVID-19 infection:** Vaccination is recommended for everyone aged 5 years and older, regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection; this includes people with prolonged post-COVID-19 symptoms and applies to primary series, additional doses, and booster doses. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

8. **Pregnant or breastfeeding/lactating women:** COVID-19 vaccination is recommended for all individuals aged 12 years and older, including those who are pregnant, lactating, and those trying to get pregnant now or who might become pregnant in the future. Any of the currently FDA-authorized or FDA-approved COVID-19 vaccines can be given to people in these groups. However, women aged <50 years should be aware of the rare risk of thrombosis with thrombocytopenia (TTS) after receipt of Janssen COVID-19 vaccine and the availability of other COVID-19 vaccines (i.e., mRNA vaccines).

   Pregnant women with COVID-19 are at increased risk of severe illness and might be at increased risk of adverse pregnancy outcomes, such as preterm birth or preeclampsia. A growing body of evidence on the safety and efficacy of COVID-19 vaccine indicates that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. Although not required, a discussion between the patient and provider may assist with decisions about the use of COVID-19 vaccine. Pregnant people who receive a COVID-19 vaccine are encouraged to enroll in v-safe.

   The currently FDA-authorized and FDA-approved COVID-19 vaccines cannot cause SARS-CoV-2 infection in either the lactating person or the infant. Recent reports have even shown that antibodies developed from the mRNA COVID-19 vaccination were present in breastmilk samples. More data are needed to determine if these antibodies correlate to protection against COVID-19 for neonates and infants.

Post-vaccination side effects in pregnant people are similar to those among non-pregnant people. Acetaminophen may be offered for pregnant people experiencing a fever or other post vaccination symptoms.

Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended. Those who are trying to become pregnant do not need to avoid pregnancy after receipt of a COVID-19 vaccination. There is **no** evidence that any COVID-19 vaccine affects future fertility.

9. **Children and adolescents:** Currently, children and adolescents 5-17 years old are eligible to receive the 2 dose Pfizer COVID-19 primary series with appropriate assent. Moderately or severely immunocompromised people ages 5 years and older (Pfizer recipients) or people ages 18 years and older (Moderna recipients) should receive an additional dose of the mRNA COVID-19 vaccine administered for the primary series. Adolescents 12-17 years of age who received the Pfizer COVID-19 vaccine as their primary series may receive a single booster dose of the Pfizer vaccine 5 months following completion of the primary series, even if they were 11 years or younger at the time of the primary series.

   Children should receive the age-appropriate vaccine formulation regardless of their size and weight. If a child *turns* 12 years old between their 1st and 2nd dose:

   a) Per CDC, they should receive the age-appropriate 30 ug Pfizer ≥12 years (**purple**) formulation for their 2nd dose to complete their series
   b) Per FDA EUA, they may receive, for either dose, either: Pfizer 5-11 years (**orange**) formulation ***or*** the Pfizer ≥12 years (**purple**) formulation.

   If such dosing occurred, the child is considered fully vaccinated. No VAERS report is indicated.

Deferrals

1. **Individuals with current confirmed COVID-19 infection:** Vaccination should be deferred until recovery from acute illness (if person had symptoms) **and** criteria have been met to discontinue isolation. Current evidence about the optimal timing between SARS-CoV-2 infection and vaccination is insufficient to inform guidance.

2. **Individuals with known COVID-19 exposure:** COVID-19 vaccines are not currently recommended for management of outbreaks or for post-exposure prophylaxis. Persons in the community or outpatient setting with known COVID-19 exposure should not seek vaccination until quarantine period has ended to avoid exposing healthcare personnel (HCP) or other persons during vaccination visit. This recommendation also applies to people with a known COVID-19 exposure before receipt of the second mRNA vaccine dose. Residents of congregate healthcare settings (e.g., LTCF) may be vaccinated as administration of the vaccine likely would not result in additional exposures. Residents of other congregate settings (e.g., correctional facilities or homeless shelters) may be vaccinated in order to avoid delays and missed opportunities for vaccination.

   Residents of both healthcare and non-healthcare congregate settings with a COVID-19 exposure who are awaiting results of testing may be vaccinated if infection is not strongly suspected. Vaccination may be deferred pending outcome of testing results in persons with strong suspicion for COVID-19 infection.

   Prior to receiving vaccination, individuals will be screened onsite to assess for COVID-19 exposure (close contact of less than 6 feet for 15 minutes or more or live in the same household) with someone who has been in isolation for COVID-19 or had a positive COVID-19 test within the last 14 days. Patients screening positive should be referred for COVID testing. For healthcare workers who have

frequent close contact with COVID-positive persons at their place of employment, vaccination should be deferred if they have had a high-risk exposure within the last 14 days. A high-risk exposure is defined as close contact with a COVID-positive person and that involved a breach in personal protective equipment (PPE).

3. **History of Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A):** The mechanisms of MIS-C and MIS-A are not well understood but include a dysregulated immune response to SARS-CoV-2 infection. The risk of recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 among people with a history of MIS-C or MIS-A is unknown. It is also unknown if some people with a history of MIS-C or MIS-A may be at risk for an MIS-like illness following vaccination with the COVID-19 vaccine. Given the lack of data on safety of COVID-19 vaccines in people with a history of MIS-C or MIS-A, a conversation with a specialist is strongly encouraged to assist with decisions about the use of the COVID-19 vaccine. The benefits of a COVID-19 vaccine for children and adolescents may outweigh the theoretical risk for people who meet the following criteria:
    a. Clinical recovery has been achieved, including return to normal cardiac function;
    b. It has been ≥ 90 days since diagnosis of MIS-C;
    c. They are in an area of high or substantial community transmission of SARS-CoV-2 or otherwise have an increased risk for exposure and transmission; and
    d. Onset of MIS-C occurred before any COVID-19 vaccination

    COVID-19 vaccine may be considered for people with a history of MIS-C who do not meet all the above criteria or for people with a history of MIS-A. Additional factors when considering individual benefits and risk may include: an increased personal risk of severe COVID-19, and timing of immunomodulatory therapies. People diagnosed with MIS-C or MIS-A after a COVID-19 vaccine should be referred to a specialist in infectious disease, rheumatology, or cardiology. These individuals should be assessed for laboratory evidence of current or prior SARS-CoV-2 infection. In addition, all illnesses consistent with MIS-C or MIS-A occurring in persons who received any COVID-19 vaccine should be reported to VAERS.

4. **Individuals who previously received passive antibody therapy for COVID-19:** Currently, there are no data on the safety and efficacy of COVID-19 vaccination in individuals who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should **be deferred for at least 90 days**, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses. There is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.

5. **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

Special Considerations for use of Janssen COVID-19 vaccine in certain populations

1. **Women aged <50 years**: Women aged <50 years can receive any currently FDA-authorized or FDA-approved COVID-19 vaccine, but they should be aware of the increased risk for thrombosis with thrombocytopenia (TTS) after the receipt of the Janssen COVID-19 vaccine and the availability of other COVID-19 vaccine types (i.e., mRNA vaccine). The reporting rates to VAERS for TTS were 7 cases per million Janssen COVID-19 vaccine doses administered to women aged 18-49 years and 0.9 per million to women aged ≥50 years.

2. **People with a history of thrombosis or risk factors for thrombosis**: The etiology of TTS appears to be similar to another rare immune-mediated syndrome, heparin-induced thrombocytopenia (HIT). For unvaccinated people, until more information becomes available, people with a history of an immune-mediated syndrome with thrombosis and thrombocytopenia, such as HIT, should be offered another type of COVID-19 vaccine (i.e., mRNA vaccine) if it has been ≤90 days since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized or FDA-approved COVID-19 vaccine.

   There is no data on the safety of administering a booster dose of either the Janssen vaccine or an mRNA vaccine to people who had TTS following the first dose. Given the clinical severity of TTS, experts do not recommend administering a second dose of the Janssen vaccine to patients who had TTS after their first dose. The people may receive a dose of an mRNA COVID-19 vaccine as a booster at least 2 months following their dose of the Janssen vaccine and after their clinical condition has stabilized. Prior to booster vaccination, a discussion with a specialist or clinical team may assist with decisions about using an mRNA vaccine as a booster and the timing of the booster vaccination.

   People with risk factors for venous thromboembolism (VTE) (e.g., inherited or acquired thrombophilia including Factor V Leiden, antiphospholipid syndrome, etc.) or a history of other types of thromboses not associated with thrombocytopenia are unlikely to be at increased risk for TTS. Because the biologic mechanisms for VTE differ from the underlying immune-mediated mechanism for HIT, these individuals can receive any COVID-19 vaccine, including Janssen.

   Although thrombosis is increased during pregnancy and postpartum, and with certain hormonal contraceptives (e.g., combined oral contraceptives, patch, and ring), these factors do not make people more susceptible to TTS after receipt of Janssen COVID-19 vaccine. Hence, these individuals may also receive any COVID-19 vaccine, including Janssen.

3. **Use of aspirin or anticoagulants**: People who normally take aspirin or anticoagulants do not need to stop these medications prior to receipt of any FDA-authorized or FDA-approved COVID-19 vaccine. It is not recommended that people take aspirin or an anticoagulant before receiving any COVID-19 vaccine.

4. **History of GBS:** Please refer to the "History of Guillain-Barré syndrome (GBS)" section under Special Populations/Considerations.

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

1. People who were vaccinated outside the U.S. who have completed a COVID-19 vaccination series with a World Health Organization (WHO)-authorized or a currently FDA-approved or FDA-authorized COVID-19 vaccine **do not need** any additional doses with an FDA-approved or FDA-authorized vaccine.
   WHO-authorized COVID-19 vaccines*: Pfizer (BNT162b2, COMIRNATY), Moderna (mRNA-1273), Novavax (NVX-coV2373, Nuvaxovid), Janssen (Ad26.COV2.S), AstraZeneca (AZD1222 Vaxzevria), Serum Institute of India (CoviShield), Sinopharm (BBIBP-CorV, Vero Cell Inactivated), Sinovac (CoronaVac, Vero Cell Inactivated), Bharat Biotech (Covaxin, Vero Cell Inactivated)

2. People who completed a primary vaccine series outside the U.S. and received FDA-approved, FDA-authorized, or WHO authorized COVID-19 vaccines as a mixed dose regimen are considered fully vaccinated and do not need to restart a primary series.

3. People who received only the first dose of a WHO-authorized COVID-19 vaccine do not need to restart a primary vaccination series in the United States. They should receive a single dose of Pfizer COVID-19 vaccine at least 28 days since receipt of their first dose, after which they are considered fully vaccinated.

4. People who received some or all the recommended doses of a vaccine not authorized or approved by the WHO *or* the FDA should be offered re-vaccination with an FDA-authorized or FDA-approved COVID-19 vaccine series, preferably with an mRNA COVID-19 vaccine.

*Note: This is **NOT** an all-encompassing list. Please be sure to reference https://extranet.who.int/pqweb/vaccines/covid-19-vaccines for the most updated list of WHO-authorized COVID-19 vaccines.

Table 4: 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 1, 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 1, Attachment F**	Primary series: Complete series with 2nd dose as close to the recommended time as possible; 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 1, 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 1, Attachment F**
WHO-authorized (but not FDA-authorized/ approved):	Primary series: Completed; Do not re-vaccinate Additional Dose‡ : Moderately to severely immunocompromised patients aged ≥12	Primary series: People who received only the first dose of a WHO-authorized vaccine should receive a single dose of the Pfizer vaccine at least 28 days since receipt of their first dose.

AstraZeneca (AZD1222 Vaxzevria) **Serum Institute of India** (CoviShield) **Sinopharm** (BBIBP-CorV, Vero Cell Inactivated) **Sinovac** (CoronaVac, Vero Cell Inactivated) **Bharat Biotech** (Covaxin, Vero Cell Inactivated) **Novavax** (NVX-coV2373, Nuvaxovid)	years should receive an additional dose of Pfizer at least 28 days after completing primary series Booster Dose‡ : Patients aged ≥12 years (including moderately or severely immunocompromised who received additional dose) should receive a booster dose of Pfizer at least 5 months after completing primary series	Additional Dose: Moderately or severely immunocompromised people aged ≥12 years who received the Pfizer COVID-19 vaccine to complete the initial series should receive an additional dose of the Pfizer COVID-19 vaccine at least 28 days later Booster Dose: People aged ≥12 years (including moderately or severely immunocompromised people who received an additional dose) should receive a single Pfizer COVID-19 vaccine dose at least 5 months after completion of the primary series
Neither FDA nor WHO authorized	Primary series: Re-vaccinate with an FDA-approved or authorized vaccine series†, preferably with an mRNA COVID-19 vaccine Additional/Booster Dose: Not recommended at this time Exception: Patients who completed a Moderna for Children 6-17 Years Old 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 Additional/Booster Dose: Not recommended at this time

†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**

‡ 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 (i.e., AstraZeneca) **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)

Clinical trial participants who did not receive all of the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive FDA-approved or FDA-authorized COVID-19 vaccine series.

Clinical trial participants who are considered fully vaccinated as detailed above should receive an **additional dose** of the Pfizer COVID-19 vaccine at least 28 days after receiving the second vaccine dose of their primary series if they are ≥12 years and are moderately to severely immunocompromised. Fully vaccinated clinical trial participants ≥12 years (including moderately or severely immunocompromised people who received an additional dose) should receive a **booster dose** of the Pfizer COVID-19 vaccine .

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
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: **Respiratory:** sensation of throat closing or tightness, stridor (high-pitched sound while breathing), hoarseness, respiratory distress (such as shortness of breath or wheezing),	**Outpatient clinic sites:** ▪ Follow Ambulatory Services BRN 1, Anaphylaxis Standardized Procedure. **Community mass vaccination sites** (May be initiated by the RN):

Reaction	Symptoms	Management
	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).	▪ **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 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.

Reaction	Symptoms	Management
		○ All vital signs ○ Medications (time, dosage, response) ○ name of the medical personnel who administered the medication ○ 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	

Ma 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.)

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	• If received dose at age less than 5 years, do not give any additional dose at this time.* • If ages 5-11 years and: - Moderna was given as 1st dose, give a single dose of the age-appropriate Pfizer-vaccine at least 28 days after the Moderna COVID-19 Vaccine dose. - Janssen was administered, give a single dose of the age-appropriate Pfizer vaccine formulation at least 28 days after the Janssen vaccine • If age 12-17 years and: - Moderna administered as the first dose, administer the age-appropriate Pfizer vaccine formulation as the second dose at least 28 days after the Moderna vaccine dose. Should receive a booster dose at least 5 months later. - If Janssen was administered, consider administering a single dose of the age-appropriate Pfizer vaccine formulation at least 28 days after the Janssen vaccine. Should receive a booster dose at least 5 months later.
Formulation and Dosage	• If aged 5-11 years and Pfizer ≥12 years formulation (**purple or 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 (**purple or gray**) may be given 21 days after the dose given error.

Formulation and Dosage (continued)		• If the dose given in error is the 1st dose, administer the Pfizer ≥12 years formulation (**purple** **or** **gray**) dose 21 days after the last dose to complete the primary series.
	• If aged ≥18 and Pfizer 5-11 years formulation (**orange**) was administered, resulting in a lower than authorized dose.	• **Repeat dose immediately** with age appropriate dose and formulation.§ No minimum interval.
	• Higher-than-authorized dose volume administered of the **correct formulation**	• Do **not** repeat dose.† • Common errors include: - 0.5 mL 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 (**purple**) 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).
Administration	• Dose administered within 90 days of monoclonal antibodies or convalescent plasma for COVID-19 treatment	• Do **not** repeat COVID-19 vaccine dose. • No VAERS reporting required
	• Dose administered within 30 days of anti-SARS-CoV-2 monoclonal antibodies for post-exposure prophylaxis	• Do **not** repeat COVID-19 vaccine dose. • No VAERS reporting required
Intervals¶	• An mRNA primary series or additional primary dose administered prior to the recommended interval#	• Repeat dose after the invalid dose by at least the minimum interval.§ A second dose given earlier than the minimum interval allowed (i.e. sooner than the 4-day grace period) is considered invalid and should be repeated no sooner than either 21 days (Pfizer Vaccine formulation) or 28 days (Moderna COVID-19

		Vaccine) following the invalid second dose in order to complete the primary series.
	• Janssen COVID-19 Vaccine is fewer than 24 days from the mRNA COVID-19 vaccine dose	• Do not administer a second primary dose of the mRNA vaccine.
	• mRNA vaccine primary series or additional 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	• Do **not** repeat dose
Mixed series	• Incorrect mRNA COVID-19 vaccine administered for second dose in 2-dose primary series or as an additional primary dose.	• Do **not** repeat dose
Diluent (Pfizer only [purple cap and orange cap])	• Only diluent administered (i.e., sterile 0.9% sodium chloride)	• Administer the 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).
	• Incorrect diluent volume	• If dilution results in a higher-than-authorized dose, do **not** repeat dose and inform the recipient of the potential for local and systemic adverse events.[*†] - Pfizer ≥12 years formulation (**purple**): applies to doses administered with diluent volume less than 1.8 mL - Pfizer 5-11 years formulation (**orange**): applies to doses administered with diluent volume less than 1.3 mL • If dilution results in a lower-than-authorized dose, **repeat dose immediately** (no minimum interval). - Pfizer ≥12 years formulation (**purple**): applies to doses administered with diluent volume greater than 1.8 mL

		- Pfizer 5-11 years formulation (**orange**): applies to doses administered with diluent volume greater than 1.3 mL
	• 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 second dose, the decision to administer the subsequent dose may 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 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.

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

STORAGE, HANDLING, AND ADMINISTRATION OF COVID-19 VACCINES FOR MOBILE VACCINATION CLINICS AND HOME-BOUND PATIENTS PROTOCOL

PURPOSE: **To provide a standardized protocol for storing and handling of Moderna, Pfizer and Janssen COVID-19 vaccines at mobile vaccination clinics and for delivering vaccines to home-bound patients.**

GENERAL STORAGE AND HANDLING REQUIREMENTS

Moderna

	Temperature (ºC)	**Temperature (ºF)**	**Duration**
Storage before use: frozen	-50º to -15ºC	-58º to 5ºF	Up to manufacturer expiration date
Storage before use: refrigerated	2° to 8°C	36° to 46°F	Up to 30 days
Storage before use: room	8° to 25°C	46° to 77°F	Up to 24 hours
Thawing: refrigerated	2° to 8°C	36° to 46°F	5.5 mL: 2 hours 30 minutes 7.5 mL: 3 hours
Thawing: room	15° to 25°C	59° to 77°F	5.5 mL: 1 hour 7.5 mL: 1 hour 30 minutes
Storage after first vial puncture	2° to 25°C	36° to 77°F	12 hours

Pfizer

		Orange Cap (5-11 yo)	**Purple Cap (≥12 yo)**	**Gray Cap (≥12 yo)**
	Temperature ºC (ºF)	**Duration**	**Duration**	**Duration**
Storage before use: ULT freezer	-90 º to -60ºC (-130º to -76ºF)	Up to manufacturer expiration date	Up to manufacturer expiration date	Up to manufacturer expiration date
Storage before use: frozen	-25º to -15ºC (-13º to 5ºF)	N/A	Up to 2 weeks	N/A
Storage before use: refrigerated	2° to 8°C (36° to 46°F)	Up to 10 weeks	Up to 1 month	Up to 10 weeks
Storage before use: room	8° to 25°C (46° to 77°F)	Up to 12 hours	Up to 2 hours	Up to 12 hours
Thawing: refrigerated	2° to 8°C (36° to 46°F)	10 vials: 4 hours	25 vials: 2 hours 195 vials: 3 hours	10 vials: 6 hours
Thawing: room	15° to 25°C (59° to 77°F)	30 minutes	30 minutes	30 minutes
Storage after reconstitution	2° to 25°C (35° to 77°F)	12 hours	6 hours	N/A

Janssen

	Temperature (ºC)	**Temperature (ºF)**	**Duration**
Storage before use: refrigerated	2° to 8°C	36° to 46°F	Up to manufacturer expiration date
Storage before use: room	8° to 25°C	46° to 77°F	Up to 12 hours
Storage after first vial puncture: refrigerated	2° to 8°C	36° to 46°F	6 hours
Storage after first vial puncture: room	15° to 25°C	59° to 77°F	2 hours

Storage Prior to Use

Moderna

- The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light.
- Do not store on dry ice or below -50ºC (-58ºF).
- Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
- Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours.
- Do not freeze once thawed.

Pfizer

- Vaccine may be stored in an ultra-cold freezer between -90°C and -60°C (-130°F and -76°F) until the expiration date.
- Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to:
    - Purple Cap Formulation (≥12 yo): 1 month
    - Gray Cap Formulation (≥12 yo): 10 weeks
    - Orange Cap Formulation (5-11 yo): 10 weeks
- Vaccines that have thawed, but not been punctured can be kept at room temperature for
    - Purple Cap Formulation (≥12 yo): no more than 2 hours.
        - May return to fridge for up to 1 month if kept at room temperature for less than 2 hours.
        - Discard unmixed vaccine if kept at room temperature longer than 2 hours.
    - Gray Cap Formulation (≥12 yo): no more than 12 hours
        - Discard vaccine if kept at room temperature longer than 12 hours
    - Orange Cap Formulation (5-11 yo): no more than a cumulative of 12 hours
        - May return to the fridge for up to 10 weeks if kept at room temperature for less than 12 hours
        - If >12 hours, reference information on inadvertent storage excursions before discarding

Janssen

- Store unpunctured multi-dose vials at 2˚C to 8˚C and protect from light. Do not store frozen.
- Unpunctured vials may be stored between 8˚C to 25˚C for up to 12 hours.

Storage After First Puncture of the Vaccine Vial

Moderna

- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 12 hours. Do not refreeze.

Pfizer

- Once mixed, vaccine can be left at refrigerated or room temperature (2°C to 25°C [36°F to 77°F]) for:
    - Purple Cap Formulation: up to 6 hours
        - Discard any remaining vaccine after 6 hours.
        - Do not return to freezer storage.
    - Gray Cap Formulation: 12 hours
        - Discard any remaining vaccine after 12 hours
        - Do not return to freezer storage
    - Orange Cap Formulation: 12 hours
        - Do not return to freezer storage
        - If >12 hours, reference information on inadvertent storage excursions before discarding

Janssen

- The punctured vial should be held between 2˚C to 8˚C for up to 6 hours or at room temperature (max 25˚C) for up to 2 hours. Discard vial if doses are not used within these timeframes.

Dose Preparation

Moderna

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes (5.5 mL vial) or 3 hours (7.5 mL vial). After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour (5.5 mL vial) or 1 hour and 30 minutes (7.5 mL vial).
- Swirl vial gently after thawing and between each withdrawal. Do not shake or dilute.
- The vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates.
  After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

Pfizer

- Thaw vials:
    - Purple Cap Formulation:
        - In fridge (2°C to 8°C) for 2 hours (25 vials) or 3 hours (195 vials)
        - Or at room temperature (15° to 25°C): 30 minutes
        - Vials thawed at room temperature must be diluted within 2 hours
    - Gray Cap Formulation:
        - In fridge (2°C to 8°C) for 6 hours (10 vials)

        - Or at room temperature (15° to 25°C): 30 minutes
        - Vials may be stored at 8°C to 25°C for 12 hours prior to first puncture
    - Orange Cap Formulation:
        - In fridge (2°C to 8°C) for 4 hours (10 vials)
        - Or at room temperature (15° to 25°C): 30 minutes
        - Vials may be stored at 8°C to 25°C for 12 hours prior to dilution
- Prepare Doses:
    - Purple Cap and Orange Cap Formulation:
        - Before dilution, invert vial gently 10 times, DO NOT SHAKE
        - Inspect liquid in vial prior to dilution to ensure:
            - Suspension should be white to off-white
            - Do not use if liquid is discolored or if other particles are observed
        - Once reconstituted, use all doses:
            - Purple Cap Formulation: within 6 hours or discard
            - Orange Cap Formulation: within 12 hours. If >12 hours, reference information on inadvertent storage excursions before discarding
    - Gray Cap Formulation:
        - Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
        - Before use, mix by inverting vial gently 10 times, DO NOT SHAKE.
        - Inspect vial after mixing to ensure:
            - Suspension should be white to off-white with no visible particles
            - Do not use if liquid is discolored or if particles are observed
        - After first puncture, use all doses within 12 hours or discard.

Janssen

- With the vial upright, gently swirl the vaccine for 10 seconds. DO NOT SHAKE. Gently swirl the vaccine before withdrawing subsequent doses.
- Examine the vaccine. It should be colorless to slightly yellow, clear to very opalescent suspension. Do not use if liquid contains particulate matter or is discolored.
- After the vial was first punctured, the vaccine should be kept between 2°C to 8°C (36°F to 46°F) for up to 6 hours or at room temperature (up to 25°C or 77°F) for 2 hours. Discard any unused vaccine if not used within these timeframes.

VACCINE COOLER STORAGE AND HANDLING

Pharmacy Duties:

1. The evening before clinic, move a predetermined number of vials from the freezer to the refrigerator to thaw for use during the next day's clinic.
    a. Moderna: All newly thawed vials must be labeled with a Beyond Use Date label 30 days from the current date/time.
    b. Pfizer (Purple Cap): All newly thawed vials must be labeled with a Beyond Use Date label 1 month from the current date/time.
    c. Janssen: N/A
2. The morning of clinic, remove thawed vials from the refrigerator. Use vials with an earlier Beyond Use Date first. Record this initial quantity.

3. Carefully and securely place the vials in the vaccine cooler, along with a digital data logger with a buffered probe to monitor vaccine temperature.
4. Prepare Hourly Temperature Log with number of doses and lot#.
5. Prepare appropriate number of normal saline vials for reconstitution of Pfizer vaccine.
6. Prepare emergency kit including at least 3 doses of epinephrine.
7. Place the vaccine cooler in the passenger seat of the vehicle, not in the trunk or back seat. Ensure that the vials will not be shaken or damaged during transport to clinic site.

Mobile Vaccination Clinic Lead Duties:

8. Upon arrival at the clinic site, check the temperature monitor to ensure the vaccines are still within the recommended temperature range.
    a. Remove a predetermined number of vials from the cooler, draw doses into syringes, and let stand at room temperature for at least 15 minutes to have on-hand for administration.
    b. Keep remaining vials in the cooler until needed for administration.
9. Use COVID-19 Vaccination Clinic - Vaccine Usage Work Sheet to track doses drawn and manage vaccine inventory to prevent wastage of vaccines.
10. Monitor vaccine usage every hour to determine whether an additional vial(s) must be removed from the cooler to draw additional doses.
11. Monitor and document cooler temperature every hour on Hourly Vaccine Temperature Log.
12. If cooler temperature goes out of range and notification was by audible alarm from DDL, take corrective action:
    a. If cooler is open, close the cooler and wait for the temperature to go back to range.
    b. If temperature is above 46°F but less than 77°F, write Beyond Use Date on unpunctured vial to be 24 hours from time of temperature change if the Moderna vaccine was affected, 2 hours if the Pfizer vaccine was affected, or 12 hours from time of temperature excursion if the Janssen vaccine was affected. Fill out Report Temperature Excursion Worksheet. Call Expo Clinic phone 669-297-2565 to notify.
    c. If temperature is below 2°C, quarantine vaccines and place “Do not use vaccines” sign on the cooler. Fill out Report Temperature Excursion Worksheet. Call Expo Clinic phone 669-297-2565 to notify pharmacist immediately to seek further guidance.
13. If cooler temperature goes out of range for a period of time and there was no audible alarm alert from DDL:
    a. Place “Do not use vaccines” sign on the cooler.
    b. Determine if there has been a temperature excursion.
    c. Fill out Report Temperature Excursion Worksheet.
    d. Call Expo Clinic phone 669-297-2565 to notify pharmacist immediately to seek further guidance.
14. At the end of clinic:
    a. Make every attempt to not waste unused doses by creating a waitlist to vaccinate leftover doses at the end of clinic.
    b. Gather used vials and reconcile with number of immunizations administered to determine vaccine usage and wastage. Document on COVID-19 Vaccination Clinic - Vaccine Usage Work Sheet
    c. If there are any remaining unopened vaccine vials in the cooler:
        i. Check and record temperature of remaining vaccine in the cooler.

ii. After leaving vaccination site and returning to storage location, move any unopened vials from the cooler to the storage refrigerator. Do not refreeze thawed vaccine.

HOMEBOUND VACCINATION PROCEDURE

15. Pre-vaccination planning:
    a. Estimate number of doses needed as accurately as possible. Plan to use all doses in a vial in advance to avoid waste.
        i. Moderna:
            1. 5.5 mL Vial: maximum 11 doses (primary series) or maximum 20 doses (booster)
            2. 7.5 mL Vial: maximum 15 doses (primary series) or maximum 20 doses (booster)
        ii. Pfizer: 6 doses per vial
        iii. Janssen: 5 doses per vial
    b. Contact recipients or caregivers in advance
        i. Determine who in the household will be vaccinated and what series (first, second, additional, or booster dose) and type (Pfizer, Moderna, or Janssen) is needed
        ii. If recipient or caregiver has email access, email the Screening and Consent form in advance of the visit so that it can be completed prior to team's arrival.
        iii. Conduct COVID-19 symptom screening of all household members within 24 hours of planned home visit.
        iv. Provide vaccine information in a variety of accessible formats (e.g., American Sign Language, multiple languages, braille, large font, low literacy, materials with pictures or visual cues)
    c. Map out travel plans ahead of time to ensure vaccine is used in appropriate time frames and to avoid vaccine wastage.
        i. Moderna: After the first dose has been drawn from the vial, the vial should be held between 2° to 25°C (36° to 77°F) for no more than 12 hours
        ii. Pfizer: Once reconstituted, all doses must be used within 6 hours (at room temperature or refrigerated)
        iii. Janssen: After first puncture, vaccine should be kept between 2°C to 8°C (36°F to 46°F) for up to 6 hours or at room temperature (up to 25°C or 77°F) for 2 hours
        iv. Include consideration of vaccine preparation time, administration time, and post-vaccination observation time (~45 minutes)
        v. Consider using a timer/alarm to monitor elapsed time since vial puncture.
        vi. If nearing the 6 hour expiration mark and there are unused doses remaining in the vial:
            1. Plan to give leftover doses to caregivers or other persons in the home to avoid waste.
            2. Coordinate transfer of leftover doses to nearest County or Mobile Clinic.
    d. Monitor and record temperature of vaccine from time vaccine is taken out of the facility, during transportation, and up to the time the vaccine is administered on the Vaccine Temperature Log

16. Storage and handling during transportation
    a. Follow transport guidance for specific vaccine product
    b. Transport vaccine using a portable vaccine refrigerator or qualified packout

i. A qualified packout includes a container and supplies specifically designed for use when packing vaccines for transport
ii. Avoid using commercially available soft-sided food or beverage coolers

c. A digital data logger placed near the vaccine or continuous temperature monitoring device should be used to monitor the temperature of the vaccine during transport
d. Document min/max temperatures when transportation begins, when the container is opened, and upon return to facility on the Vaccine Temperature Log
e. A punctured vial may be transferred from one home to another as long as the healthcare provider is the same and the cold chain is maintained.
f. Transport guidance
    i. Transport vaccines in the passenger compartment (not in the trunk or bed of a trunk)
    ii. Move containers to a vehicle already at a comfortable temperature
    iii. Keep containers out of direct sunlight
    iv. Secure loose vials to prevent them from shifting during transport
    v. Never leave container unattended in the vehicle
g. CDC recommends transporting vaccine in vials. However, if vaccine must be transported in a **pre-drawn syringe**:
    i. Pfizer vaccine (**purple cap**) when diluted maintains all of its stability in a polycarbonate and polypropylene syringes with stainless steel needles for 6 hours at 2°C to 25°C (35.6°F to 77°F)
    ii. Pfizer vaccine (**orange cap**) when diluted maintains all of its stability in polycarbonate or polypropylene syringes for a cumulative time up to 24 hours post-dilution with no more than 12 hours at room temperature (up to 30° C [86°F]) and the remainder in the refrigerator (2°C to 8°C (36°F to 46°F)). Microbiological risk must be considered if >12 hours.
    iii. Pfizer vaccine (**gray cap**) maintains all of its measured quality attributes when the vaccine is stored in polycarbonate or polypropylene syringes for a cumulative time up to 24 hours post-puncture with no more than 12 hours at room temperature (up to 30° C [86°F]) and the remainder in the refrigerator (2°C to 8°C (36°F to 46°F)). Microbiological risk must be considered.
    iv. Pre-drawn syringes of the Moderna vaccine can be either stored in the refrigerator at 2°C to 8°C (36°F to 46°F) or at ambient room temperature at 15°C to 25°C (59°F to 77°F) provided they are administered within 12 hours of the first time the source vial is punctured
    v. Syringe must have appropriate labelling components. Pre-drawn syringes of the Janssen vaccine can be either stored in the refrigerator at 2°C to 8°C (36°F to 46°F) for 6 hours or at ambient room temperature at 15°C to 25°C (59°F to 77°F) for 2 hours prior to administration.
        1. Name and amount of vaccine
        2. The exact beyond-use date and time (e.g., 6 hours)
        3. Lot number
        4. Initials of preparer
    vi. Use a continuous temperature monitoring device to ensure consistent temperature monitoring during transport
h. For homebound delivery, vaccine should preferentially be drawn up into a syringe after arrival on site and before entry into the house. The prepared syringe should be placed into a

Ziploc bag and then placed into a transport container that prevents sunlight exposure during transport from vehicle to house.

17. Vaccine Administration
    a. Wherever possible the vaccine recipient should be asked to come to the doorway or outside to receive vaccination. All vaccinators and any individuals who must enter the house should wear a surgical mask or N95, eye protection (face shield or eye goggles), and gloves (if in direct contact with client).
    b. Verify recipient identity by asking for name and date of birth. If second dose, re-verify first dose vaccine manufacturer.
    c. Screen each individual for contraindications and precautions.
    d. Provide each recipient a copy of the EUA fact sheet.
    e. Ask the persons if they have any questions or concerns. Obtain consent.
    f. Prepare and administer vaccine using aseptic technique.
    g. Vaccinators must document vaccine administration to the California Immunization Registry (CAIR2) within 24 hours of administration
    h. CDC recommends that persons who receive the vaccine should be observed for the following time periods:
        i. 30 minutes: Persons with a history of an immediate allergic reaction (within 4 hours) of any severity to a vaccine or injectable therapy, and persons with a history of anaphylaxis due to any cause.)
        ii. 15 minutes: all other persons
    i. Wherever possible the vaccine recipient should be asked to remain at the doorway or outside for monitoring during the observation period. If this is not possible then the vaccinator must be prepared to enter the house for the duration of the observation period. Adverse events must be reported to the Vaccine Adverse Event Reporting System (VAERS)
        i. Complete COVID-19 Vaccine Adverse Event Recording Sheet and submit to Pharmacy at the end of the day
    j. Medical waste should be collected in a portable sharps container. Non-medical waste can be left with the recipient to dispose of via normal household waste disposal.

Resources

1. Vaccine Management. EZIZ website. https://eziz.org/covid/vaccine-management/.
2. Vaccine Administration. EZIZ website. https://eziz.org/covid/vaccine-administration/.
3. Moderna Vaccine Fact Sheet for Healthcare Providers. FDA website. https://www.fda.gov/media/144637/download.
4. Moderna COVID-19 Vaccine: Vaccine Preparation and Administration Summary. CDC website. https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/prep-and-admin-summary.pdf.
5. Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary. CDC website. https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf
6. Janssen COVID-19 Vaccine (Johnson & Johnson). CDC website. https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html
7. Guidance for planning vaccination clinics held at satellite, temporary, or off-site locations. CDC website. https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html.
8. Vaccinating homebound persons with COVID-19 vaccine. CDC website. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/homebound-persons.html

9. USP COVID 19 Vaccine Handling Toolkit. USP website. https://www.usp.org/covid-19/vaccine-handling-toolkit
10. Pfizer-BioNTech COVID-19 Vaccine- (10 mcg/dose for 5 Through 11 Years)- Storage of the Vaccine Outside Recommendations in the EUA Prescribing Information (ORANGE CAP). Pfizer Medical Information website. https://www.pfizermedicalinformation.com/en-us/document/a0r68000000YvahAAC
11. Pfizer-BioNTech COVID-19 Vaccine- (30 mcg/dose for 12 Years and Older)- Storage of the Vaccine Outside Recommendations in the EUA Prescribing Information (GRAY CAP). Pfizer Medical Information website. https://www.pfizermedicalinformation.com/en-us/document/a0r68000000bLZ8AAM
12. Pfizer-BioNTech COVID-19 Vaccine- (30 mcg/dose for 12 Years and Older)- Storage of the Vaccine Outside Recommendations in the EUA Prescribing Information (GRAY CAP). Pfizer Medical Information website. https://www.pfizermedicalinformation.com/en-us/document/a0r68000000bL

ATTACHMENT J

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