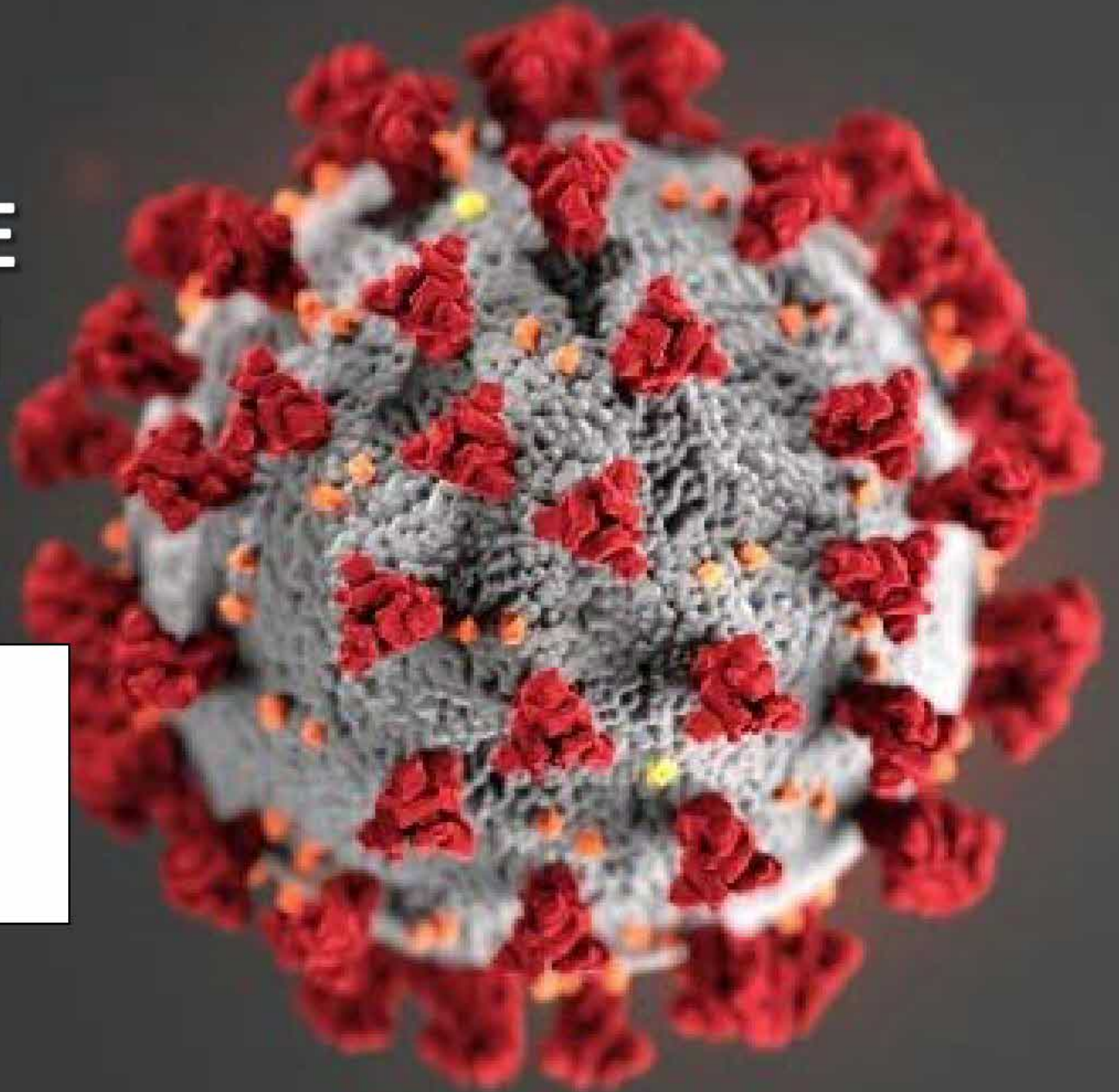


COVID-19 VACCINE ADMINISTRATION TRAINING

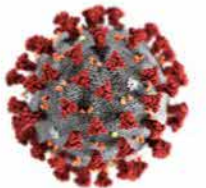
DECEMBER 3, 2020

(b)(6); (b)(7)(C)



Housekeeping

- Please utilize the Chat function to ask questions during and at the end of presentation
- Today's presentation is a continuation of COVID-19 Vaccination training and will be specific to the Pfizer COVID-19 vaccine
- Slides will be posted on the Sallyport COVID-19 Guidance page
- There will be additional presentations related to other vaccines, as it becomes available

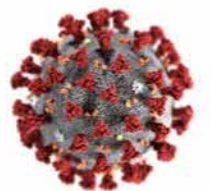


Objectives



At the end of this presentation, attendees will demonstrate knowledge of:

1. What documentation is needed regarding vaccine administration, including informed consent.
2. Preparing and administering the vaccine, and appropriately disposing of remaining supplies.
3. Timing of and scheduling options for the second vaccine dose.



Welcome and Introduction

CAPTAIN [REDACTED], MD, FACP

ACTING CHIEF, OFFICE OF QUALITY MANAGEMENT (OQM)

LCDR [REDACTED], DNP, FNP-C, WCC

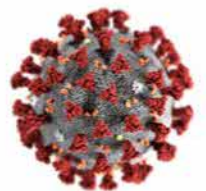
CHIEF NURSE

A solid red horizontal bar spanning the width of the slide at the bottom.

Employee Vaccine Prioritization

If vaccine supplies are low.....

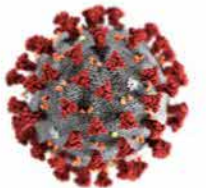
1. Healthcare providers
2. Staff with Temporary Job Modifications (TJMs)
3. Staff at Medical Referral Centers (MRCs)
4. Locations experiencing higher rates of COVID-19 transmission in the institution and/or community.



Inmate Vaccine Prioritization

At this time, COVID-19 vaccination for inmates in quarantine and isolation is not recommended

- **Priority 1: Inmates for COVID-19 vaccination (if vaccine supplies are low)**
 1. Inmates housed in nursing care units
 2. All inmates at Medical Referral Centers (MRCs)
 3. Inmates in Care Level 3 facilities
 4. Inmates in camps and open bay housing
- **Priority 2: All other inmates**



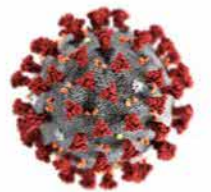
Engaging in Effective COVID-19 Vaccine Conversations

Plan



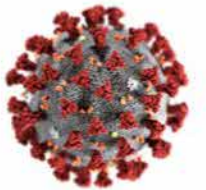
We cannot plan what vaccine administration will look like at your facility.

- VPOCs, VAMs, & leadership should run tabletop exercises
- Think of and plan for contingencies
- Plan your administration location logistics
- Consider optics of our vaccine allocation



Techniques for Vaccine Discussion

1. Start from a place of empathy and understanding
2. Assume patients will want to be vaccinated but may not have enough information to feel confident about their decision
3. Give your strong recommendation
4. Listen to and respond to patient questions
5. Wrapping up the conversation



Patients Will Have Easy Questions

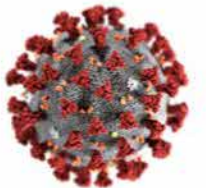
What side effects can I expect after vaccination?

PFIZER

- *Fatigue (3.8%)*
- *Headache (2%)*

MODERNA

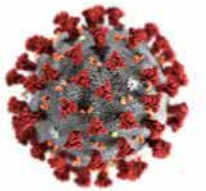
- *Fatigue (9.7%)*
- *Muscle aches (8.9%)*
- *Joint aches (5.2%)*
- *Headache (4.5%)*
- *Pain at the injection site (4.1%)*
- *Redness around the injection site (2%)*



Patients Will Have Hard Questions

Be prepared to answer questions patients may have regarding vaccine:

- *How do we really know if COVID-19 vaccines are safe?*
- *Is the vaccine that helpful?*
- *Will getting COVID-19 give you better immunity than the protection a vaccine can give.*
- *Can it actually make my illness worse if I do end up getting COVID-19?*
- *How do we know that these vaccines are safe when they are so new?*
- *Couldn't they cause problems that we don't know about yet?*
- *What about long-term problems?*

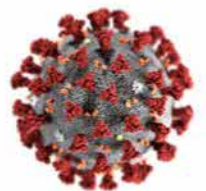


You Will Have Answers!

Educate yourself on the science behind the vaccine:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>

<https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>



COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals



» Communicating with Patients about Vaccines

Healthcare professionals play a key role in improving vaccine acceptance as they are in contact with patients throughout the office visit. By fostering a culture of immunization in the practice, both providers and patients can vaccinate with confidence.

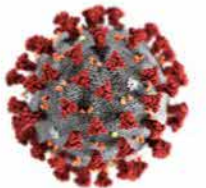
<u>How Nurses and Medical Assistants Can Foster a Culture of Immunization in the Practice video</u>	Research shows that healthcare professionals are patients' most trusted source of information when it comes to vaccines. By highlighting key points before, during, and after a patient's visit, this presentation will support vaccine conversations and reinforce best practices for improving vaccination coverage.
<u>"#HowIRecommend" vaccination video series</u>	These videos explain the importance of vaccination, how to effectively address questions from patients about vaccine safety and effectiveness, and how clinicians routinely recommend same-day vaccination for their patients.
<u>Provider Resources for COVID-19 Vaccine Conversations with Patients</u>	Information for healthcare providers on how to talk to patients about COVID-19 vaccines, including giving strong recommendations, setting expectations about vaccine availability, and preparing to answer likely patient questions.
<u>Epidemiology and Prevention of Vaccine-Preventable Diseases</u>	Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 3, discusses essential strategies healthcare professionals can use when talking to patients about vaccines (updated 2020).

» COVID-19 Vaccine Training and Clinical Materials

* From attachment "COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf"

How to Overcome Reluctance

- Acknowledge that there is often a lack of patient understanding. Studies show patients only remember 50% of what HCPs share.
- Understand that social issues may be influencing the decision.
- Realize that change is difficult, even if one's health is at stake.
- Utilize objective measures that help support your advocacy.



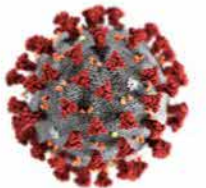
How to Overcome Reluctance

Don't:

- Engage in political discussion or speculation about government motives.
- Make staff or inmates feel they *must* take the vaccine. Vaccination is required for no one. Vaccine acceptance is a personal decision for each person. Our role is to help them make an educated decision.

Do:

- Be supportive, be positive, be prepared.
- Offer alternatives times for vaccination.



Vaccine Administration Documentation – VAMS: Employees

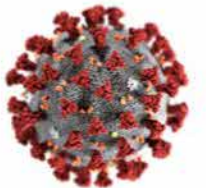
The Healthcare Provider Level

LCDR (b)(6); (b)(7)(C), MS, RHIA, CHDA
HEALTH INFORMATICS SPECIALIST

VAMS Overview

VAMS Terminology Review

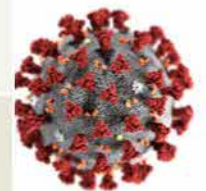
- Clinic = Institution Site
- Clinic Administrator = Primary or alternate administrator
- Clinic Inventory Manager = Manages the Vaccine Inventory
- Healthcare Professional = Vaccine Administrator (*clinical role)
- Recipient = Employee



VAMS Roles for Vaccine Administrators

Primary Role: Administer vaccine to recipients

Processes	Related Tasks
• Create and manage employee's record	• Enter and update demographics, date of birth, gender etc.
• Administer vaccine	• Access employee's record • Review employee's record • Add note to employee's record • Review previously added notes • Record decision to administer vaccine • Log vaccination • Log waste
• Find VAMS support or additional training resources when needed	• Search for your question in the FAQs on the Help page



Consent Forms

CAPT (b)(6); (b)(7)(C), RN, PHN, CIC, CCHP

NATIONAL OQM COORDINATOR, INFECTION PREVENTION & CONTROL

Employee Consent Form

- Employees have one consent form for both vaccine doses
- The consent form has been developed specifically for COVID-19 vaccines
- Consider mail merge to pre-print forms prior to clinics

I have been provided a copy of the COVID-19 Vaccine Emergency Use Authorization (EUA) fact sheet dated _____. I have had the opportunity to ask questions about the benefits and risks of vaccination.

☐ I consent to receive the COVID-19 vaccination.

Dose	Employee Signature	Witness Signature	Date
#1			Click or tap to enter a date.
#2			Click or tap to enter a date.

Health Questions Prior to COVID-19 Vaccination (Check yes or no)

Yes	No	Health Questions
<input type="checkbox"/>	<input type="checkbox"/>	Are you sick today?
<input type="checkbox"/>	<input type="checkbox"/>	Have you ever had serious reaction to an immunization?
<input type="checkbox"/>	<input type="checkbox"/>	Are you pregnant or is there a chance you could become pregnant during the next month?
<input type="checkbox"/>	<input type="checkbox"/>	Have you had any other vaccinations in the last 14 days?
<input type="checkbox"/>	<input type="checkbox"/>	Do you have a history of Guillain-Barré syndrome (progressive paralysis)?

☐ I decline to receive the COVID-19 vaccination.

Reasons for declining the COVID-19 vaccine:

- ☐ I have already been vaccinated by my private provider
☐ I plan to be vaccinated by my private provider
☐ Other: _____

Employee Signature	Witness Signature	Date
		Click or tap to enter a date.

COVID-19 Vaccine Information

Dose	Date	Manufacturer/ CVX Code	Lot Number	Expiration Date	Route	(R) Right deltoid (L) Left deltoid
#1	Click or tap to enter a date.	Select		Click or tap to enter a date.	IM	Select
Administered by: (name/title)		<input type="checkbox"/>		<input type="checkbox"/>		
		<input type="checkbox"/>		<input type="checkbox"/>		
#2	Click or tap to enter a date.	Select		Click or tap to enter a date.	IM	Select
Administered by: (name/title)		<input type="checkbox"/>		<input type="checkbox"/>		
		<input type="checkbox"/>		<input type="checkbox"/>		

(PRINT) Employee Name (Last, First)	DOB	Institution

Employee Consent Form

BP-PENDING
U.S. DEPARTMENT OF JUSTICE

COVID-19 VACCINE CONSENT – EMPLOYEES

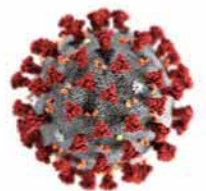
CDFRM NOV
FEDERAL BUREAU OF PRISONS

I have been provided a copy of the COVID-19 Vaccine Emergency Use Authorization (EUA) fact sheet dated _____. I have had the opportunity to ask questions about the benefits and risks of vaccination.

☐ I consent to receive the COVID-19 vaccination.

Dose	Employee Signature	Witness Signature	Date
#1			Click or tap to enter a date.
#2			Click or tap to enter a date.

- Print EUA fact sheet and record date it was issued
- Check vaccine consent box
- Employee signs for each vaccine dose when it is administered



Employee Consent Form

Health Questions Prior to COVID-19 Vaccination (*Check yes or no*)

Yes	No	Health Questions
<input type="checkbox"/>	<input type="checkbox"/>	Are you sick today?
<input type="checkbox"/>	<input type="checkbox"/>	Have you ever had serious reaction to an immunization?
<input type="checkbox"/>	<input type="checkbox"/>	Are you pregnant or is there a chance you could become pregnant during the next month?
<input type="checkbox"/>	<input type="checkbox"/>	Have you had any other vaccinations in the last 14 days?
<input type="checkbox"/>	<input type="checkbox"/>	Do you have a history of Guillain-Barré syndrome (progressive paralysis)?

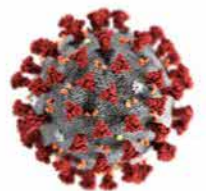
☐ **I decline to receive the COVID-19 vaccination.**

Reasons for declining the COVID-19 vaccine:

- ☐ I have already been vaccinated by my private provider
- ☐ I plan to be vaccinated by my private provider
- ☐ Other: _____

Employee Signature	Witness Signature	Date
		Click or tap to enter a date.

- Employee answers the health questions
- Vaccination declination box is separate from the consent box



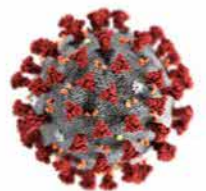
Employee Consent Form

COVID-19 Vaccine Information

Dose	Date	Manufacturer/ CVX Code	Lot Number	Expiration Date	Route	(R) Right deltoid (L) Left deltoid
#1	Click or tap to enter a date.	Select		Click or tap to enter a date.	IM	Select
Administered by: (name/title)		<input type="checkbox"/>		<input type="checkbox"/>		
		<input type="checkbox"/>		<input type="checkbox"/>		
#2	Click or tap to enter a date.	Select		Click or tap to enter a date.	IM	Select
Administered by: (name/title)		<input type="checkbox"/>		<input type="checkbox"/>		
		<input type="checkbox"/>		<input type="checkbox"/>		

(PRINT) Employee Name (Last, First)	Institution

- Fill in vaccine information
- PRINT employee name at bottom of page
- ✓ **Keep consent form for 2nd dose; file in employee health record after 2nd dose**



Inmate Consent Form

- Consent forms specific for COVID-19 vaccines
- Consider mail merge to pre-populate and print forms prior to clinic

I have been provided a copy of the COVID-19 Vaccine Emergency Use Authorization (EUA) fact sheet dated _____. I have had the opportunity to ask questions about the benefits and risks of vaccination.

☒ I consent to receive the COVID-19 vaccination.

Dose	Inmate Signature	Witness Signature	Date
#1			Click or tap to enter a date.

Health Questions Prior to COVID-19 Vaccination (Check yes or no)

Yes	No	Health Questions
<input type="checkbox"/>	<input type="checkbox"/>	Are you sick today?
<input type="checkbox"/>	<input type="checkbox"/>	Have you ever had serious reaction to an immunization?
<input type="checkbox"/>	<input type="checkbox"/>	Are you pregnant or is there a chance you could become pregnant during the next month?
<input type="checkbox"/>	<input type="checkbox"/>	Have you had any other vaccinations in the last 14 days?
<input type="checkbox"/>	<input type="checkbox"/>	Do you have a history of Guillain-Barré syndrome (progressive paralysis)?

☐ I decline to receive the COVID-19 vaccination.

Reasons for declining the COVID-19 vaccine:

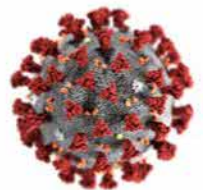
- ☐ I have already been vaccinated by my private provider
☐ I plan to be vaccinated by my private provider
☐ Other: _____

Inmate Signature	Witness Signature	Date
		Click or tap to enter a date.

COVID-19 Vaccine Information

Dose	Date	Manufacturer/ CVX Code	Lot Number	Expiration Date	Route	(R) Right deltoid (L) Left deltoid
#1	Click or tap to enter a date.	Select		Click or tap to enter a date.	IM	Select
Administered by: (name/title)		<input type="checkbox"/>		<input type="checkbox"/>		
		<input type="checkbox"/>		<input type="checkbox"/>		

(PRINT) Inmate Name (Last, First)	Register Number	
Institution	Unit	Work Assignment



Inmate Consent Form

BP-PENDING
U.S. DEPARTMENT OF JUSTICE

COVID-19 VACCINE CONSENT – INMATE

CDFRM NOV
FEDERAL BUREAU OF PRISONS

I have been provided a copy of the COVID-19 Vaccine Emergency Use Authorization (EUA) fact sheet dated _____. I have had the opportunity to ask questions about the benefits and risks of vaccination.

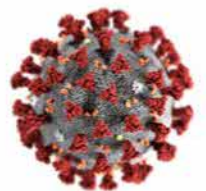
☐ I consent to receive the COVID-19 vaccination.

Dose	Inmate Signature	Witness Signature	Date
#1			Click or tap to enter a date.

☐ Health Questions Prior to COVID-19 Vaccination (Check yes or no)

Yes	No	Health Questions
<input type="checkbox"/>	<input type="checkbox"/>	Are you sick today?
<input type="checkbox"/>	<input type="checkbox"/>	Have you ever had serious reaction to an immunization?
<input type="checkbox"/>	<input type="checkbox"/>	Are you pregnant or is there a chance you could become pregnant during the next month?
<input type="checkbox"/>	<input type="checkbox"/>	Have you had any other vaccinations in the last 14 days?
<input type="checkbox"/>	<input type="checkbox"/>	Do you have a history of Guillain-Barré syndrome (progressive paralysis)?

- Print EUA fact sheet and record date it was issued
- Check consent box
- Inmate answers the health questions



Inmate Consent Form

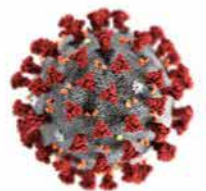
☐ I decline to receive the COVID-19 vaccination.

Reasons for declining the COVID-19 vaccine:

- ☐ I have already been vaccinated by my private provider
- ☐ I plan to be vaccinated by my private provider
- ☐ Other: _____

Inmate Signature	Witness Signature	Date
		Click or tap to enter a date.

- Check declination if inmate refuses vaccine
- Have inmate sign declination
- Add witness signature
- Enter data into BEMR



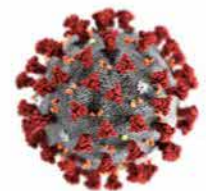
Inmate Consent Form

COVID-19 Vaccine Information

Dose	Date	Manufacturer/ CVX Code	Lot Number	Expiration Date	Route	(R) Right deltoid (L) Left deltoid
#1	Click or tap to enter a date.	Select		Click or tap to enter a date.	IM	Select
Administered by: (name/title)		<input type="checkbox"/>		<input type="checkbox"/>		
		<input type="checkbox"/>		<input type="checkbox"/>		

(PRINT) Inmate Name (Last, First)	Register Number	
Institution	Unit	Work Assignment

- Enter vaccine information
- Print or pre-populate vaccine administrators names
- PRINT inmate name at bottom of page



COVID-19 Vaccine Procedure Guidance



COVID-19 Vaccine Procedure Guidance – *Module 12*

MODULE 12. COVID-19 VACCINES

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from SARS-CoV-2 (the virus that causes COVID-19) by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC).

→ ACIP Guidance for COVID-19 vaccine(s) is available at: XXXXXXXX

→ The Emergency Use Authorization (EUA) fact sheet for the PFIZER VACCINE NAME COVID-19 vaccine is available at: XXXXXXXXXXXXXXXX

→ The BOP COVID-19 Immunization Plan, which is based on the CDC document entitled “COVID-19 Vaccine Implementation Plans for Federal Agencies Receiving Vaccine” and was developed in collaboration with the CDC, is available at: XXXXXXXXXXXXXXXX

COVID-19 Vaccine Abbreviations:
BNT162 (PFIZER VACCINE NAME)

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty and upon successful completion of the skills checklist and signature sheet for COVID-19 vaccines (see Appendix 1. *Skills Checklist for Pfizer COVID-19 Vaccine Administration* and Appendix 2. *COVID-19 Vaccine Procedure Module Signature Sheet*), may vaccinate adults who meet the indications below for the COVID-19 vaccine. The ACIP recommends COVID-19 vaccination for everyone X of age and older, if they have no contraindications.

In the BOP, priority of vaccine administration will be directed by the Health Services Division of the Central Office and through the local Clinical Director or designee based on COVID-19 risk and vaccine availability. It will align with the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) recommendations for priority populations.

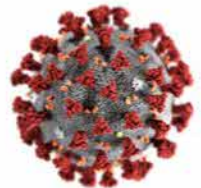
→ This module will be **updated** as new information becomes available (e.g., when new vaccine products become available and are used by the BOP and when vaccination indications change).

→ Vaccine supply availability is expected to change as the BOP's COVID-19 immunization program progresses; therefore, planning should be targeted and flexible. Since vaccine supply initially will be limited, allocation of vaccine doses has been prioritized by the BOP into three priority levels (see below). However, vaccine supply is projected to increase over time thus allowing for the expansion of vaccination efforts. It is important to note that recommendations concerning BOP's priority levels and associated population groups may change based not only on vaccine availability but also on the availability of different COVID-19 vaccines, changing COVID-19 disease epidemiology, and local community factors.

1. Two doses of COVID-19 vaccine are indicated for all adults 16 to 85 years of age or older. Vaccine should be administered according to the three priority levels determined by the BOP.

- All persons preparing and administering vaccine should be familiar with the COVID-19 vaccine module.

- Education:
 - ✓ *Skills Sheet – Appendix 1*
 - ✓ *Signature Sheet – Appendix 2*



APPENDIX 1. SKILLS CHECKLIST FOR PFIZER COVID-19 VACCINE ADMINISTRATION

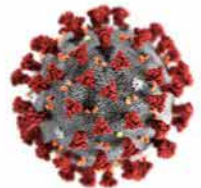
SKILLS CHECKLIST FOR PFIZER COVID-19 VACCINE ADMINISTRATION					
FACILITY:				EMPLOYEE:	
Self-Assessment		Supervisor/Preceptor Review		SKILLS	
Needs to Improve	Meets or Exceeds	Needs to Improve	Meets or Exceeds		
PATIENT EDUCATION					
				Welcomes patient; verifies identification. Accommodates language/literacy barriers and special needs.	
				Explains what vaccine will be given.	
				Provides Emergency Use Authorization (EUA) fact sheet for all vaccine doses. Answers questions.	
				Reviews potential side effects, comfort measures, and after care instructions.	
SCREENING/PREPAREDNESS					
				Screens patient for vaccine eligibility (based on EUA), history of adverse reactions, allergies, contraindications, and precautions.	
				Verbalizes signs and symptoms of potential medical emergency or anaphylaxis.	
				Able to initiate CPR and maintain airway, if necessary. Locates Epinephrine.	
				Can state procedure for responding to and reporting needle stick injuries.	
VACCINE HANDLING AND PREPARATION, PFIZER VACCINE NAME					
				Remove vaccine from refrigerator and allow to come to room temperature (< 30 minutes).	
				Invert vial gently 10 times to mix. <i>DO NOT SHAKE.</i>	
				Obtain sterile 0.9% Sodium Chloride Injection, USP.	
				Cleanse the vaccine and sodium chloride vial stoppers with an alcohol swab.	
				<i>Add only 1.8 ml of sodium chloride into the vaccine vial using a 3 or 5 ml syringe with a 21 or narrower gauge needle. *Only reconstitute vaccine that will be used within 6 hours.</i>	
				<i>Prior to withdrawing the syringe from the vaccine vial, equalize pressure by withdrawing 1.8 ml of air into the empty diluent syringe.</i>	
				Discard the remaining 0.9% sodium chloride solution regardless of fluid remaining. Do not reuse.	
				Gently invert the vial containing the vaccine and diluent 10 times to mix. <i>DO NOT SHAKE.</i>	
				Label the vial and record the date and time of dilution on the label.	
				The vaccine vial now contains 5 (five) separate 0.3 ml vaccine doses, each with 30 mcg of vaccine product in a labeled, multi-dose vial.	
				Store the diluted, labeled, and ready to use multi-dose vaccine vial at refrigerated or room temperatures between 2°C to 25°C (35°F to 77.0°F) for up to 6 hours.	
ADMINISTERING VACCINES					
				Washes or disinfects hands before and in-between patient encounters. If gloves are worn, they are changed and hand hygiene performed between patients.	
				Demonstrates knowledge of the appropriate route and dose for each vaccine.	
				Positions patient for vaccination and preps injection site with alcohol wipe, allowing it to dry.	
				Injects vaccine and applies gauze/bandage, if needed, with gentle pressure to injection site.	
				Disposes of needle and syringe in sharps container.	
				Vaccine doses not used after 5 days must be maintained in a separate area and labeled "DO NOT USE" until further instruction is available.	
DOCUMENTATION					

COVID-19 Vaccine Procedure Guidance – *Module 12*

APPENDIX 2. COVID-19 VACCINE PROCEDURE MODULE SIGNATURE SHEET BOP HEALTH SERVICES UNIT

Institution:		
Authorization is given for the checked (✓) categories of healthcare providers to use the checked (✓) vaccine procedure module (below) for administration of COVID-19 vaccines without individual patient medication orders. Healthcare providers who are authorized to administer vaccines using this Vaccine Procedure Module should have demonstrated vaccine administration skills. File a copy of this Signature Sheet in each authorized healthcare provider's credential file.		
<input type="checkbox"/>	Registered Nurses	
<input type="checkbox"/>	Advanced Practice Providers	
<input type="checkbox"/>	Licensed Practical Nurses	
<input type="checkbox"/>	Pharmacists	
<input type="checkbox"/>	Dentists	
<input type="checkbox"/>	Other:	
The following new vaccine procedure module and specific vaccine brands are approved for use in this facility, if the specific vaccine brand(s) is checked (✓) below:		
<input type="checkbox"/>	12. COVID-19 vaccine	
<input type="checkbox"/>	A. Pfizer COVID-19 vaccine	
Signatures:		
IP&C Coordinator (Last, First) – PRINT	Signature	Date
Health Services Administrator (Last, First) – PRINT	Signature	Date
Clinical Director (Last, First) – PRINT	Signature	Date
Healthcare Provider (Last, First) – PRINT	Signature	Date

The signature sheet when signed by the Clinical Director allows administration of COVID-19 vaccines without an individual medication order or standing order.



Maintaining the Vaccine Cold Chain

Vaccine Storage Options at Facility



Source: Centers for Disease Control and Prevention



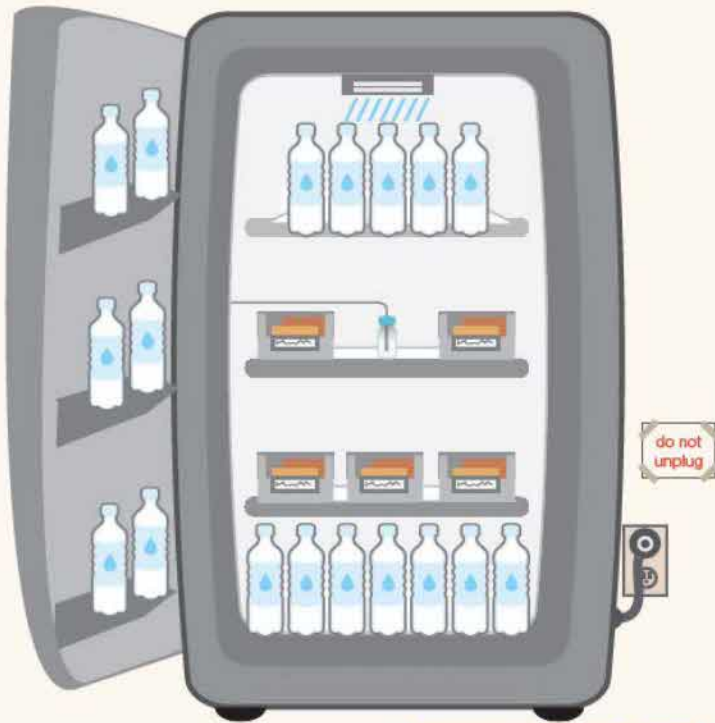
**DO NOT UNPLUG
REFRIGERATOR**

**¡No desconecte
el refrigerador o congelador!**

**EXPENSIVE VACCINE IN STORAGE!
¡AVISO! CONTIENE VACUNAS CARAS.**

In the event of a problem, immediately contact
Si hay un problema, comuníquese inmediatamente con

How to Store Vaccines



Digital
Data
loggers



Source: National Institute of Standards and Technology (NIST)

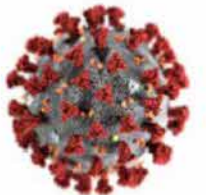


Source: Centers for Disease Control and Prevention

Cold Shippers

- Will be sent to sites this week, includes: foam box within cardboard box, ice packs, cardboard payload boxes, temp data loggers, instructions on packing box and for using data logger
- Freeze ice packs several days in advance
- Start data logger per instruction sheet and include with vaccine
- VPOC responsible to ensure temp logs from all time vaccine in cold shippers kept on file, same as vaccine refrigerators

COMING TO ALL INSTITUTIONS THIS WEEK



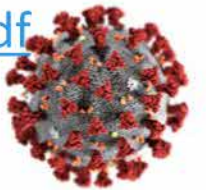
[illegible]

COVID-19 Vaccine Temperature Excursion

Definition: Any *temperature reading that is outside the recommended range for vaccine storage* as defined by the manufacturer's package insert or EUA fact sheet.

- Identify temperature excursions quickly and take immediate action to correct them.
- For COVID-19 vaccines, contact the vaccine manufacturer if you experience temperature excursions.

Refer to: <https://www.cdc.gov/vaccines/hcp/admin/downloads/vacc-admin-storage-guide.pdf>



Handling a Temperature Excursion

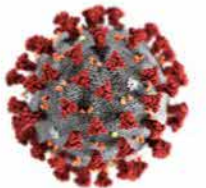
HANDLING A TEMPERATURE EXCURSION IN YOUR VACCINE STORAGE UNIT			
Any temperature reading outside the ranges recommended in the manufacturers' package inserts is considered a TEMPERATURE EXCURSION. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.			
NOTIFY!	DOCUMENT!	CONTACT!	CORRECT!
<p>Immediately notify the Primary or Alternate Vaccine Coordinator or report the problem to a supervisor.</p> <ul style="list-style-type: none"> To notify other staff, label the affected vaccines, "DO NOT USE," and place them in a separate container, apart from the other vaccines in the storage unit. Keep affected vaccines refrigerated or frozen, as appropriate. Do NOT discard these vaccines. Await instructions from the manufacturer. 	<p>Document details of the temperature excursion:</p> <ul style="list-style-type: none"> Date and time Storage unit temperature (including minimum/maximum temperatures at the time of the event, if available) Room temperature, if available Name of the person completing the report General description of what happened If using a digital data logger (DDL), determine the length of time vaccine may have been affected. Inventory of affected vaccines List of items in the unit other than vaccines (including water bottles) Any problems with the 	<p>Contact your facility's immunization program and/or the vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).</p> <p>Be prepared to provide documentation and DDL data so they can offer you the best guidance.</p> <p>Manufacturer contact numbers:</p> <ol style="list-style-type: none"> Merck 1-800-672-6372 Sanofi Pasteur 1-800-822-2463 GlaxoSmithKline 1-888-825-5249 Pfizer 1-800-438-1985 Seqirus 1-855- 358-8966 	<p>If the temperature alarm goes off repeatedly, do NOT disconnect the alarm until you have determined and addressed the cause.</p> <p>Check the basics, including:</p> <ul style="list-style-type: none"> Power supply Unit door(s) Thermostat settings <p>If the excursion is the result of a temperature fluctuation, refer to the CDC's <i>Vaccine Storage and Handling Toolkit</i> for detailed guidance on adjusting the storage unit temperature to the appropriate range:</p> <p>https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html</p> <ul style="list-style-type: none"> If you believe the storage unit has failed, implement your

Attachment 3: Immunization Guidance



Vaccine Storage - Pfizer

- **UNDILUTED**, vaccine can be stored at refrigerated temperatures (2-8°C or 36-46°F):
 - ✓ for 5 days in refrigerator, *with temp monitoring*
- Once **DILUTED**, vaccine must be used **within 6 hours**.

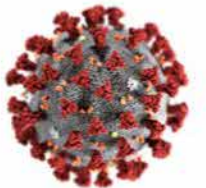


Expiration Dates

Always check the expiration date of the vaccine and diluent, if applicable, before preparing vaccine.

For COVID-19 vaccine:

- The expiration date on the vial is a placeholder.
- The actual expiration date will be listed in the product insert.
- Expiration dates may be extended as more stability data become available.

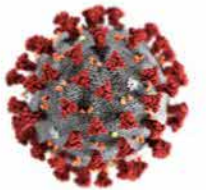


Vaccine Preparation

Vaccine Preparation

Whether performing clinic vaccination or mass vaccination:

- *Prepare vaccine in a clean, designated area away from where the patient is being vaccinated and away from any potentially contaminated items*
- CDC recommends – *To draw up vaccine at time of administration*

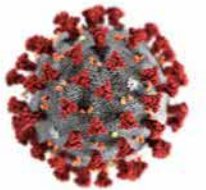


Vaccine Preparation - Pfizer



The vaccine will come in a 2 ml glass preservative free multi-dose vial

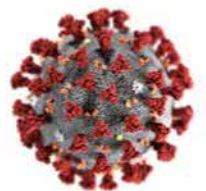
- The vial contains 0.45 ml liquid vaccine product
- The vaccine requires reconstitution with 1.8 ml of diluent prior to use



Vaccine Preparation Steps - Pfizer

1. Remove thawed vaccine vial from the refrigerator and allow it to come to room temperature.

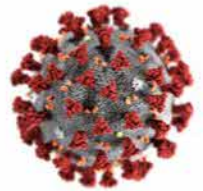
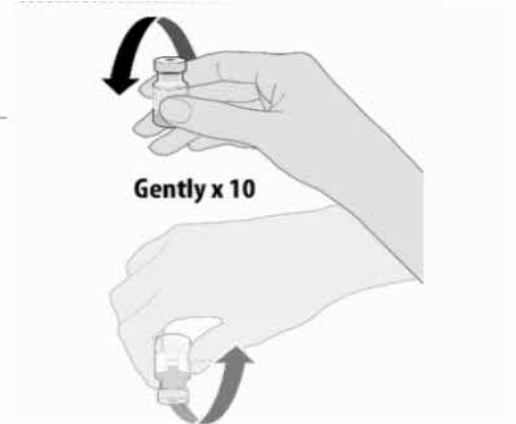
- This will take less than 30 minutes
- Undiluted vaccine should not be out of refrigeration for more than 2 hours



Vaccine Preparation Steps - Pfizer

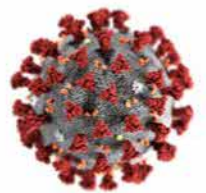
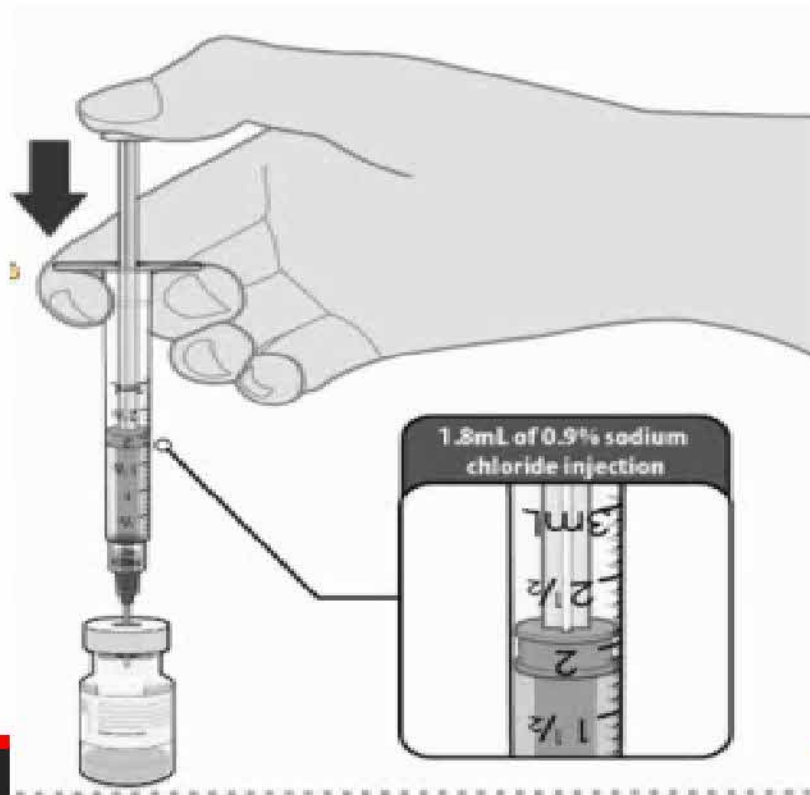
2. Prepare to add diluent to the vaccine:

- Invert the vaccine vial gently 10 times to mix. *DO NOT SHAKE.*
- Obtain sterile 0.9% sodium chloride injection, USP.
- Cleanse the vaccine and sodium chloride vial stoppers with an alcohol swab.



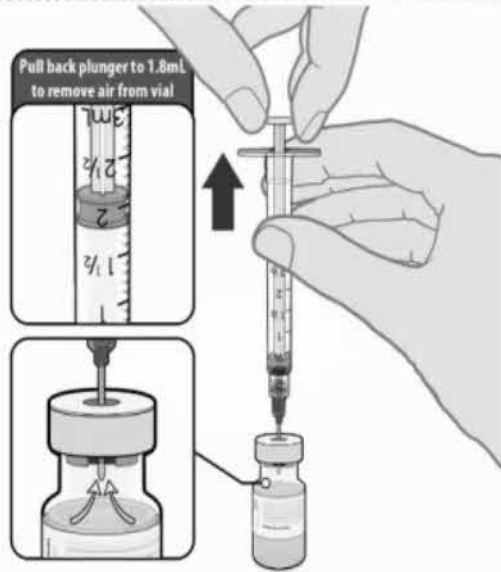
Vaccine Preparation Steps - Pfizer

3. ***Add only 1.8 ml of 0.9% sodium chloride into the vaccine vial*** using a 3 or 5 ml syringe with a 21 or narrower gauge needle.

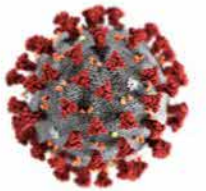


Vaccine Preparation Steps - Pfizer

4. Prior to withdrawing syringe from the vial, withdraw 1.8 ml of air into the empty diluent syringe.



- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe

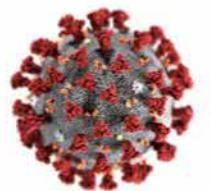
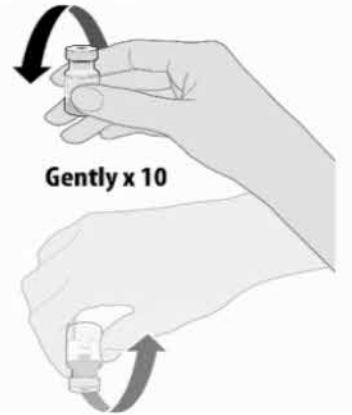


Vaccine Preparation Steps - Pfizer

5. Discard the remaining 0.9% sodium chloride solution regardless of the fluid remaining. *DO NOT REUSE.*

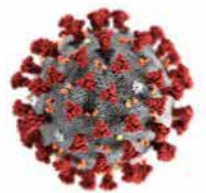
6. Gently invert the vial containing the vaccine and diluent 10 times to mix. *DO NOT SHAKE.*

7. *Label the diluted vaccine vial* and record the date and time of dilution on the label.



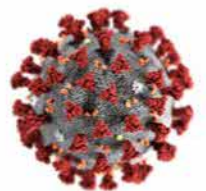
Diluted Vaccine Vial - Pfizer

- The **vaccine vial now contains 5 (five) separate 0.3 ml doses** of vaccine, each with 30 mcg of vaccine product.
- *Egg and cell free vaccine*
- Store the diluted, labeled multi-dose vaccine at refrigerated or room temperature between (2°-25°C, 35°-77°F), for up to 6 hours.



Vaccine Preparation - Moderna

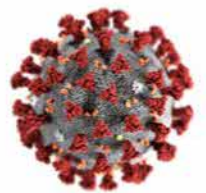
- Vaccine will arrive at institutions in a refrigerated state
- *No diluent is needed*
- Vaccine will be in a glass multi-dose vial, with **ten (10)** individual 0.5 ml, 100 mcg doses per vial
 - *Refrigerated vaccine must be used within 30 days*
- Room temperature vaccine must be discarded within six hours
- Vaccine is egg and cell free vaccine



Vaccine Preparation – Pfizer and Moderna

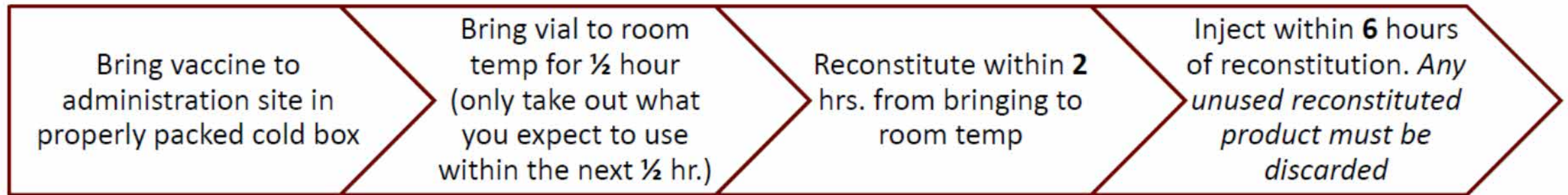
If vaccines must be predrawn:

- Draw up vaccine at the clinic or mass event site
- Each person administering vaccines should draw up no more than one multidose vial
 - Pfizer – one multidose vial = 5 doses
 - Moderna – one multidose vial = 10 doses
- Monitor patient flow to avoid drawing up unnecessary doses.

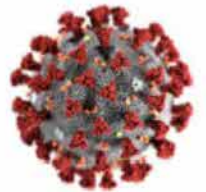


Vaccine Administration

Timeline for Administration of Pfizer COVID-19 Vaccine



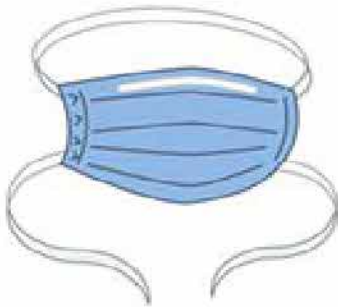
BOTTOM LINE: MAX 8 hrs. from removal from refrigeration to injection



Vaccine Administration

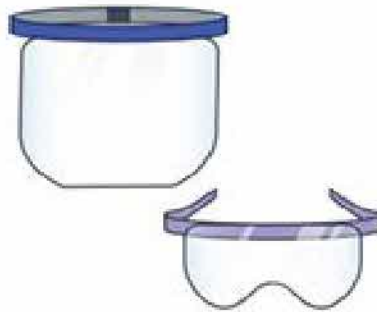
Personal Protective Equipment

- Ensure staff has proper PPE before administering vaccine



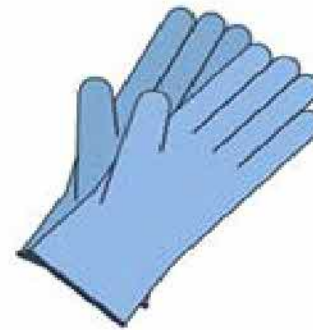
Face mask

- **Recommended:** All healthcare providers (N95 masks not recommended)



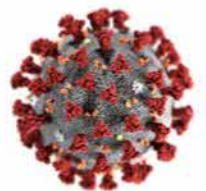
Eye protection

- **Recommended:** Areas of moderate/substantial community transmission
- **Optional:** Areas of minimal/no community transmission unless otherwise indicated as a part of standard precautions



Gloves

- **Recommended:** Intranasal or oral vaccines
- **Optional:** Intramuscular or subcutaneous vaccines



Administration of IM Vaccines

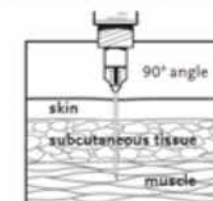
➤ Give vaccine intramuscularly (23-25g, 1-1½ inch needle) in the deltoid

✓ See Module 12: APPENDIX 5.

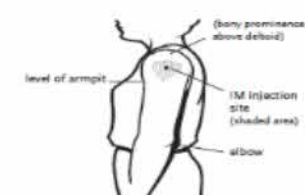
ADMINISTERING THE COVID-19 VACCINE: DOSE, ROUTE, SITE AND NEEDLE SIZE

ADMINISTERING THE VACCINE: DOSE, ROUTE, SITE, AND NEEDLE SIZE				
AGE XX AND OLDER – SEE PACKAGE INSERT FOR AGES XX AND YOUNGER				
VACCINE	DOSE >XX YRS	ROUTE	INJECTION SITE	KEY POINTS – SEE MODULES FOR COMPLETE INFORMATION
Pfizer (vaccine name) COVID-19 Vaccine	0.3 mL	IM	Deltoid	<ul style="list-style-type: none">Reconstitution required with 1.8 ml of 0.9% sodium chlorideEach reconstituted multi-dose vial contains five (5) separate doses of 0.3 ml vaccine dosesReconstituted vaccine will be used within six (6) hoursAfter six (6) hours label “DO NOT USE” and store in a place removed from vaccines “in use”
NEEDLE SIZE				
FOR INTRAMUSCULAR (IM) INJECTIONS				
Administer IM injections in the deltoid muscle, with a 23–25 gauge needle. Choose needle length based on person's age and body mass:				
<130 lbs. 5/8*–1" length needle				
Female 130–152 lbs. 1" length needle				
Female 153–200 lbs. 1-1½" length needle				
Female 200 + lbs. 1½" length needle				
Male 130–260 lbs. 1-1 ½" length needle				
Male 260+ lbs. 1½" length needle				
*A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, only if the skin over the deltoid is stretched taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.				

Intramuscular (IM) injection



Deltoid

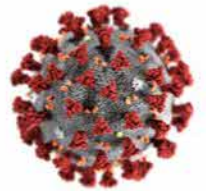


Ancillary Supply Kits

Ancillary Supply Kits



- Automatically ordered based on the number of vaccine orders
- Will arrive before or along with the vaccine
- Contain syringes, needles, diluent, alcohol pads, vaccination cards and limited PPE supplies
- PPE supplies are limited, plan ahead (i.e., face shields and gowns)
- **Gloves and sharps containers not supplied**



Ancillary Supply Kits

- Institutions will store ancillary supplies for COVID-19 vaccine administration separate from other similar supplies.

Pfizer Mega Kit





Adult Kit




Vaccine Documentation and Scheduling of 2nd Dose

Employee Documentation - VAMS

 **Welcome**
Vaccine Administration Management System

Jackie Reyes 


Select which portal you would like to access:



Jurisdiction Portal

- Register your jurisdiction
- Add organizations and clinics within your jurisdiction


[Access Portal](#)



Recipient Portal

- Register my patient information
- Schedule a COVID-19 vaccination appointment
- View my COVID-19 vaccination certificate


[Access Portal](#)



Organization & Employer Portal

- Register your organization's information
- Add employees or organization members for COVID-19 vaccination eligibility

[Access Portal](#)

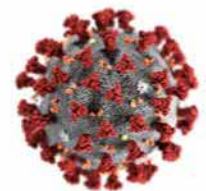


Clinic Portal

- Register your clinic information
- Manage vaccination appointments
- Log vaccinations

[Access Portal](#)

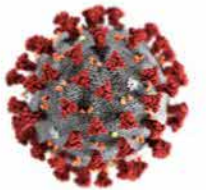
The clinic portal will be used to enter Employee vaccine information



Employee Documentation

Tracking employee vaccination at institutions:

- HR roster of employees
- May vary by institution
 - Example: Flu vaccine clinics or Annual training
- VAMS training video's and user guide is being prepared at this time
- VAMS access coming soon!



VAMS Resources

- ❖ VAMS Power Points – available under COVID-19 Vaccine Guidance section of the [COVID-19 Sallyport Page](#)
- ❖ VAMS Helpdesk: VAMSHelp@cdc.gov
- ❖ VAMS Help Line: 1-833-957-1100 (8am-8pm EST, Monday-Friday)
- ❖ Health Informatics Team: BOP-HSD-HealthInformatics@bop.gov

Inmate Documentation - BEMR

Administered: ☒ Now ☐ History of ☐ History Unknown, Not Administered

Immunization: COVID-19 Pfizer-BioNTech Vaccine

Drug: PFIZER-BIONTECH COVID-19 VACCINE- rn:

Drug Mfg:

Dose Number:

1

Location: Left Deltoid

Lot Number: XXXXXX-YZ

Dosage: 0.3 mL

Route: IM

**ENTER
VACCINE
DOSE #**

Inmate Documentation - BEMR

Message from webpage



Do you want to schedule next dose?

OK

Cancel

Inmate

(b)(6); (b)(7)(C)

Details

Activity: COVID-19 Pfizer-BioNTech

Sched. Provider: Nurse 01

Priority: Normal

Frequency: One Time

Scheduled Date: 12/24/2020

End Date:

☐ M ☐ T ☐ W ☐ T ☐ F ☐ S ☐ S

Time(s): 0800

Status: Not Started

Actual Provider:

Completed Date:

Time

Comments: Dose two of Pfizer COVID-19 vaccine due.

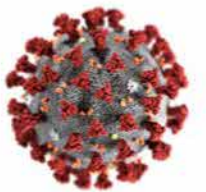
Pfizer COVID-19 Vaccine

- **Two dose vaccine 21 days apart**
- When administering first dose, plan and communicate regarding 2nd dose

✓ Example:

Dose one clinic on December 15th – 18th

Dose two clinic on January 5th – 8th



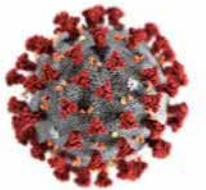
Moderna COVID-19 Vaccine

- **Two dose vaccine 28 days apart**
- When administering first dose plan and communicate regarding 2nd dose

✓ Example:

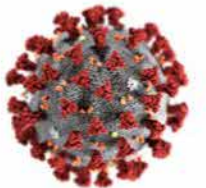
Dose one clinics on December 22nd – 25th

Dose two clinics on January 19th – 22nd



Inmate Medical Hold for Second Dose of Vaccine?

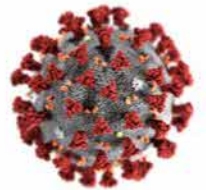
- The use of medical hold is approved for inmates at time of first vaccine – it cannot assure all inmates will stay in place
- Inmates being released:
 - *Consider print out of immunization flow sheet*
 - *Inmate vaccine cards that come with kits*
- Inmates being transferred – Information must be in BEMR exit summary COVID screening

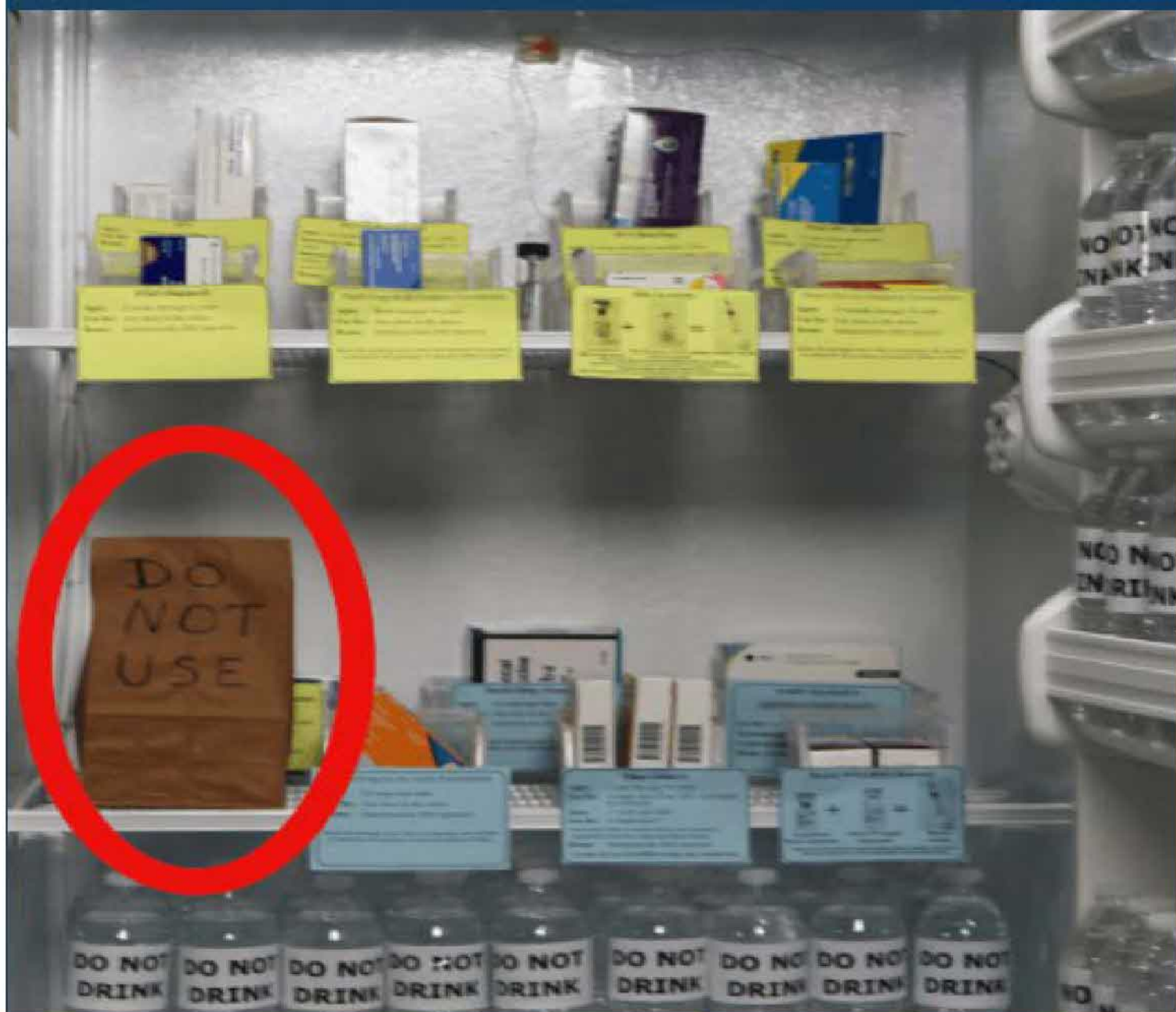


Vaccine Disposal

Vaccine Disposal

- Syringes and needles used for vaccination should be placed in biohazard hard lockable containers and bagged in biohazard bags just as any other vaccine.
- Store vaccine vials that are contaminated, expired or unused until further guidance is issued.
 - Label the vaccine vial “**DO NOT USE**” and store in a separate designated area, away from any vaccine that is in use.





Source: Centers for Disease Control and Prevention

Contacts

COVID-19–COVID19Questions@bop.gov

VPOCS –COVID19Questions@bop.gov

(b)(6); (b)(7)(C)

VAMS –BOP-HSD-Healthinformatics@bop.gov

(b)(6); (b)(7)(C)

Chief of HIM

(b)(6); (b)(7)(C)

HIM Informaticist

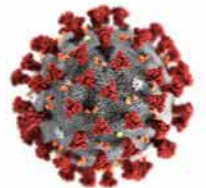
Administration Questions:

(b)(6); (b)(7)(C)

Chief Nurse

(b)(6); (b)(7)(C)

Central Office Infection Prevention and Control

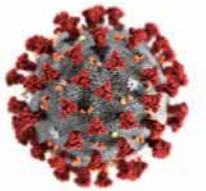


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- ❖ Health Informatics Team: BOP-HSD-HealthInformatics@bop.gov

Questions And Answers?

More to come.....



References

- [COVID-19 Clinical Training and Resources for Health Care Professionals posted to Sallyport](#)
- CDC Frequently asked questions for COVID-19 Vaccines: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>
- CDC Healthcare provider communication on COVID-19 vaccine: <https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>
- CDC Vaccine Toolkit: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>
- CDC At a Glance Vaccine Administration Storage Guide: <https://www.cdc.gov/vaccines/hcp/admin/downloads/vacc-admin-storage-guide.pdf>
- [Moderna's COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study](#)
- [Moderna Clinical Study Protocol 20 Aug 2020](#)
- [Pfizer/BioNTECH Vaccine Phase 3 Study](#)

