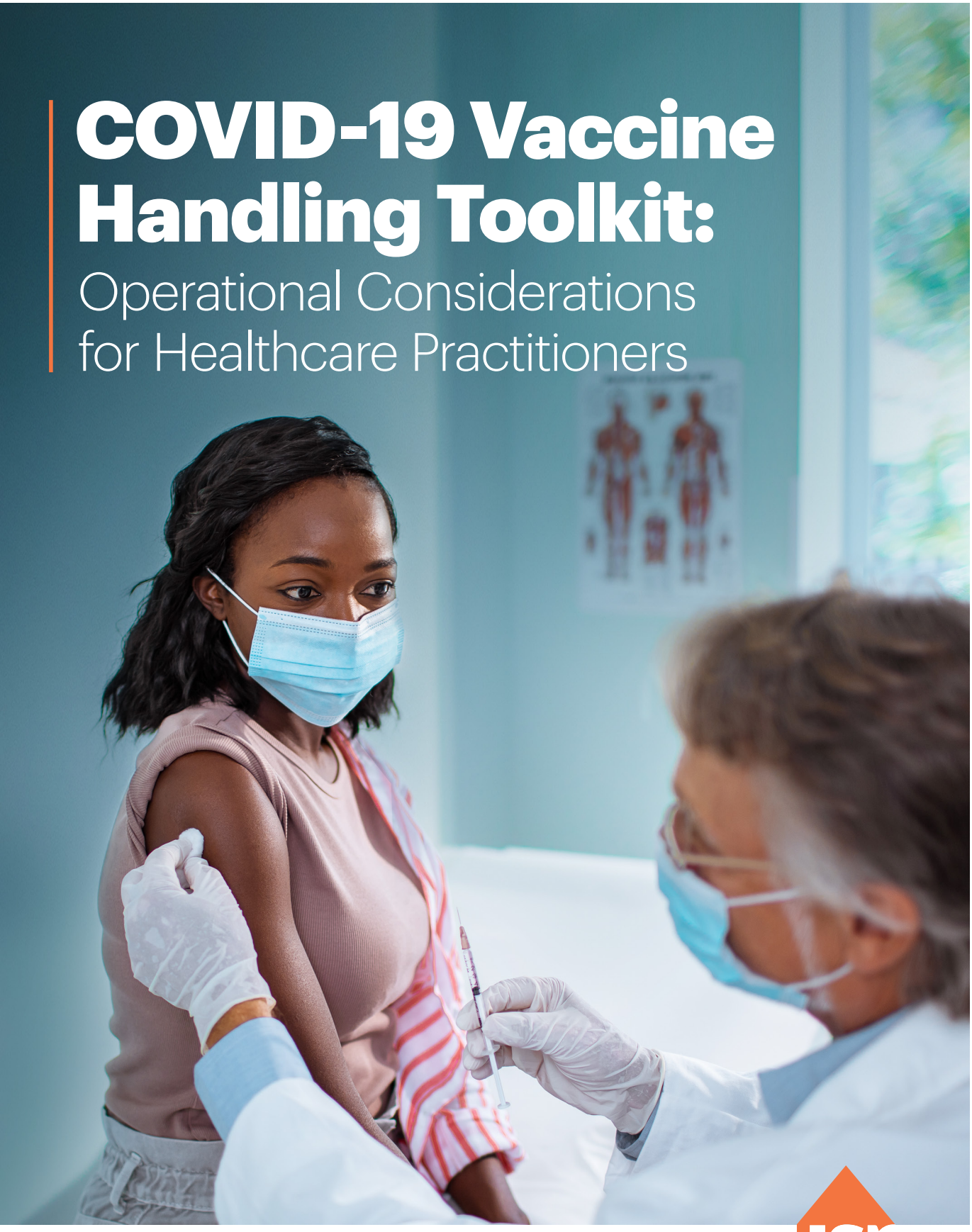
COVID-19 Vaccine Handling Toolkit:

Operational Considerations for Healthcare Practitioners



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We encourage you to sign up for updates at www.usp.org/covid-vaccine-handling. This toolkit will be updated **as additional vaccines are authorized** and other information becomes available.

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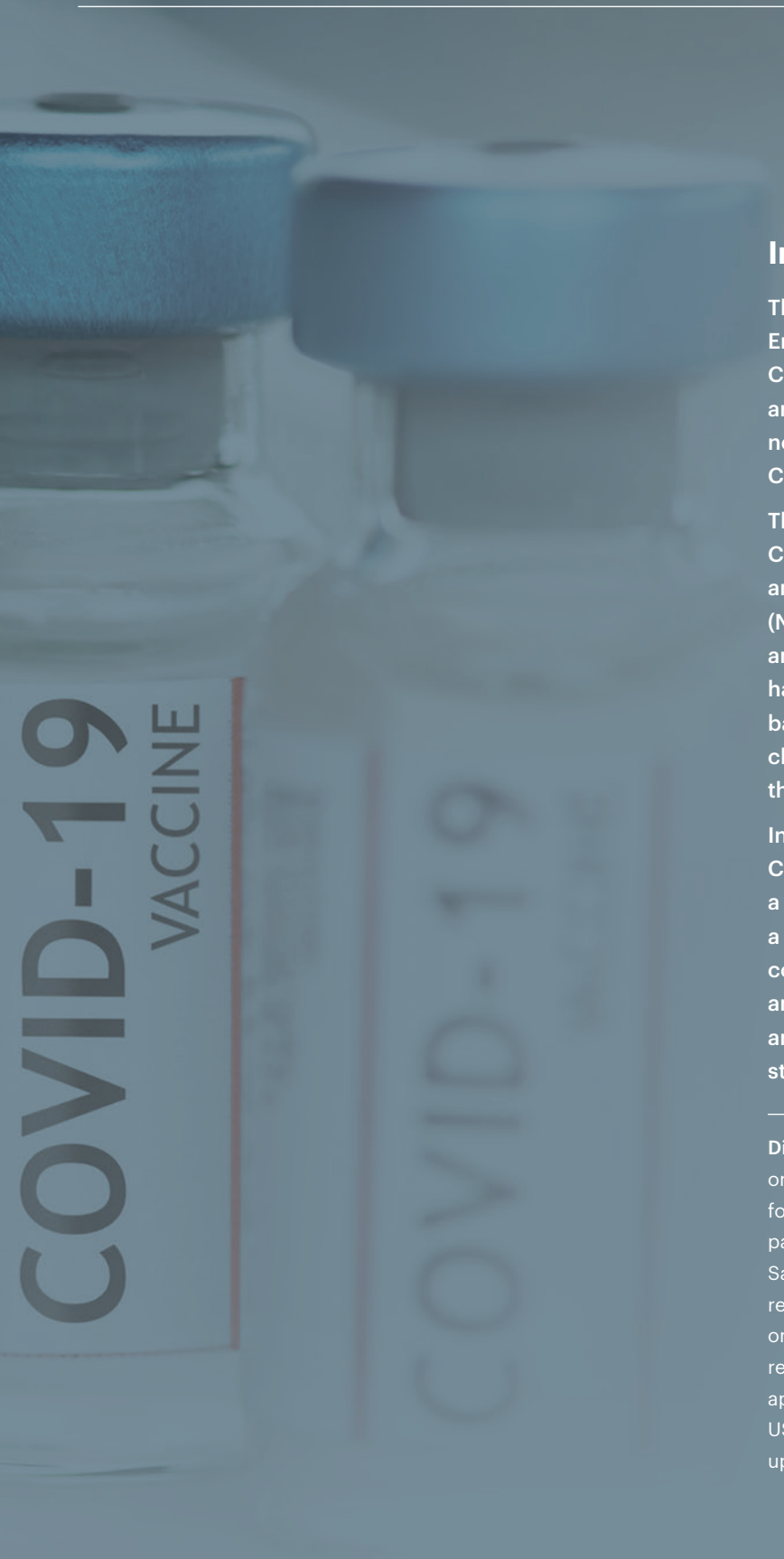


Introduction

The Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUAs) for two new COVID-19 vaccines in the United States. These are both mRNA-based vaccines. However, there is no available data on the interchangeability of the COVID-19 vaccines.[1]

The USP Healthcare Safety and Quality Expert Committee (HSQ EC) with experts from the Package and Distribution (PD EC), Nomenclature and Labeling (NL EC), Health Information and Technology (HIT EC) and Compounding (CMP EC) Expert Committees have developed the following operational strategies based on stakeholder input and in anticipation of challenges that may arise during the preparation of these COVID-19 vaccines.

In light of the public health emergency posed by COVID-19, this document was developed without a public comment period. This document is not a USP compendial standard; rather, it reflects considerations developed by the USP HSQ EC and other EC members, based on their scientific and professional expertise, and with input from stakeholders and regulatory agencies.

Disclaimer: This document is for informational purposes only and is intended to address operational considerations for COVID-19 vaccine preparation during the COVID-19 pandemic. This does not reflect the USP Healthcare Safety and Quality Expert Committee's opinions on future revisions to official text of the *USP–NF*. Parties relying on the information in this document bear independent responsibility for awareness of, and compliance with, any applicable federal, state, or local laws and requirements. USP is actively monitoring the evolving situation and will update this document accordingly.

1 Preparation

Operational Considerations for COVID-19 Vaccine Preparation During the Pandemic (January 26, 2021)

Background

Preparing a conventionally manufactured COVID-19 vaccine, such as a vaccine that has received an EUA from the FDA, should be performed in accordance with the directions in the manufacturer's labeling.[2,3] This section focuses on considerations for preparation of COVID-19 vaccines for administration and can be used to supplement a manufacturer's labeling, but not replace them. In addition, this information should not replace a facility's policies and procedures.

Environmental Considerations for Vaccine Preparation

Achieving and maintaining sterility and overall freedom from contamination of the vaccines is dependent on the environmental conditions under which the preparation process is performed. The following considerations should be made when selecting an environment for preparation of vaccines:

- A dedicated area or room should be utilized for vaccine preparation.
  - The dedicated area or room should be a clean, uncluttered, functionally separate workspace.
  - The dedicated area or room should be away from windows, doors, air vents, etc. to minimize airflow disruptions.
  - Items that are not necessary for vaccine preparation should be removed from the vaccine preparation area (i.e., food, drinks, and other materials).
  - If not possible, alcohol-based hand sanitizer (see USP Hand Sanitizer Toolkit,[4] WHO guidance[5]) should be available. For alcohol-based hand sanitizers, the Centers for Disease Control & Prevention (CDC) recommends a concentration of 60% to 95% ethanol or isopropanol (i.e., isopropyl[6]) alcohol.[7]
  - Whenever possible, the area dedicated for vaccine preparation should not be located in or close to where environmental control challenges could negatively affect the air quality (e.g., restrooms, warehouses, or food preparation areas).
- Equipment to include in the dedicated area or room may comprise of sharps container, alcohol swabs, sink and/or hand sanitizer, and materials for personnel hygiene and garbing.
- When manufacturer labeling permits, COVID-19 vaccines can be prepared in ambient air without using a Primary Engineering Control (PEC) device (i.e., prepared outside of an ISO Class 5 air environment). A PEC is defined as a device or zone that provides an ISO Class 5 air environment which minimizes the risk of microbial contamination.
- Understanding that the vaccine preparation will take place across a variety of practice settings, it is important to adhere to aseptic technique to ensure the quality and safety of the preparation of these vaccine products.
  - Clean and disinfect the surface where the vaccine preparation will take place using a solution of at least 70% isopropyl alcohol or optionally utilize clean preparation mats per your institution's policy and procedures.

Personnel Hygiene and Garbing

Healthcare workers who supervise the preparation of the vaccines should ensure that personnel are adequately skilled, educated, and trained to correctly perform preparation of the COVID-19 vaccines. Before beginning preparation of COVID-19 vaccines, personnel should consider the following aspects of hygiene and garbing:

- Personnel should remove hand, wrist, and other exposed jewelry that could interfere with the effectiveness of garbing or otherwise increase the risk of contamination of the vaccines.
- Fingernails should be clean and neatly trimmed to minimize particle shedding and avoid glove punctures.
- Personnel should perform hand hygiene by washing hands with soap and water for at least 30 seconds or by using hand sanitizer rubbed between hands and fingers and allowed to dry.
- Personnel should don powder-free gloves before preparing vaccines for administration. Powder-free gloves should be inspected regularly for holes, punctures, or tears and must be replaced immediately if such defects are detected.
- Personnel should don and replace garb (e.g., masks, freshly laundered lab coat, powder-free gloves, clean scrubs) immediately if it becomes visibly soiled or if its integrity is compromised.

Basic Aseptic Considerations for Vaccine Preparation

Aseptic technique is a set of processes used to keep objects and areas free of microorganisms and thereby minimize infection risk to patients. Aseptic technique should be utilized to prepare vaccines for administration in order to prevent the vaccines from being contaminated with microorganisms from the environment or from the persons preparing them. Manufacturer supplied information on the steps for thawing, storage temperatures, and preparation of the available COVID-19 vaccines are provided on the Pfizer-BioNTech and Moderna COVID-19 resource webpages.[2,3] Aseptic technique considerations for vaccine preparation should include the following:

- Follow facility and regulatory requirements related to competency, training, or certification of vaccine preparation and administration, as appropriate
- Inspect vials for cracks or leaks prior to proceeding further.
- Disinfect entry points on the diluent and vaccine vials (e.g., vial stoppers) by wiping the vials with single-use alcohol swabs. Allow the alcohol to dry before piercing stoppers with sterile needles.
- During preparation of the vaccine, personnel should avoid touching critical parts of the components being used for preparation of the vaccines (e.g., needles, disinfected vial stoppers) in order to minimize microbial contamination.
- Place all used syringes, needles, and vials into puncture-proof containers (e.g., sharps container) and dispose the containers according to regulatory requirements.

Withdrawing Doses

Manufacturer supplied information on the steps for preparation of the available COVID-19 vaccines is provided on the Pfizer-BioNTech and Moderna COVID-19 Vaccine resource webpages.[2,3] Additional considerations, including how to ensure complete doses are withdrawn and safe practices, include the following:

- If applicable, ensure needle and syringe are tightly luer-locked together.
- Consider using the smallest syringe appropriate for the dose to improve dose accuracy. For example, a 0.3 mL or 0.5 mL dose should be drawn up using a 1 mL syringe.
- The same needle should be used for withdrawal and administration. This eliminates the need to change needles and therefore reduces the risk of touch contamination to the vaccine and potential loss of volume.
- Exercise care to avoid contaminating or bending the needle if being used for both withdrawal and administration.
- Refrain from using transfer devices, mini spikes, or one needle to prepare multiple syringes due to potential loss of medicine in dead space.
- Refrain from using dispensing pins or needleless devices due to risk of vaccine loss or incompatibility with materials. These devices have not been tested and may result in damage to the stopper and loss of integrity of the vial.
- Utilize safe practices when recapping the needle after withdrawing and before administration.
- In the case of excess air bubbles in the syringe, small bubbles can be ignored. Personnel should avoid tapping the syringe due to theoretical risk of inactivating the vaccine or degraded quality.

Pfizer-BioNTech COVID-19 Vaccine Considerations

- Manufacturer supplied information on the steps for dilution is available on the Pfizer-BioNTech COVID-19 Vaccine resources webpage.[2]
- Regardless of diluent vial size, only a single needle entry can be used to withdraw a single 1.8 mL volume of preservative-free 0.9% sodium chloride diluent to prepare one vial of the Pfizer-BioNTech COVID-19 Vaccine. Any excess diluent must be discarded.
- It has been shown that the Pfizer-BioNTech COVID-19 Vaccine vials can produce more than 5 doses per a single vial.
- The manufacturer recommends preferentially using a low dead-volume *syringe or needle* to maximize the number of doses per vial.[2] A low dead-volume *syringe* is designed to limit dead space that exists between the syringe hub and needle. A low dead-volume *needle* is designed with less space between the needle and the plunger.
- The manufacturer provides that for dose preparation, a 21-gauge or narrower needle helps prevent leaking from the stopper when doses are withdrawn.
- Maximize doses withdrawn from vials (6 or 7 doses from the Pfizer-BioNTech COVID-19 vaccine vial or 11 doses from the Moderna COVID-19 vaccine vial) by utilizing low dead-volume syringes/needles, whenever possible. A low dead-volume syringe is designed to limit dead space that exists between the syringe hub and needle. A low dead-volume needle is designed with less space between the needle and the plunger.
- To ensure practice settings who may not have adequate quantities of low dead-volume syringes to more consistently achieve the maximum doses withdrawn, a combination of low dead-volume syringes and non-low dead-volume syringes could also maximize doses withdrawn (e.g., 3 low dead-volume syringes and 3 non-low dead-volume syringes). Inserting the needle in various locations of the vial septum can reduce leaking of vaccine and maximize doses withdrawn.
- Carefully consider the number of pre-drawn syringes to prepare to minimize vaccine waste.

The following steps can help maximize the number of Pfizer-BioNTech COVID-19 Vaccine doses per vial:

To reconstitute the Pfizer-BioNTech COVID-19 Vaccine:

1. Inject 1.8mL of sodium chloride, preservative free, diluent into the vaccine vial.
2. Draw out 2.1mL of air before removing the needle from the vial.

When drawing up each dose of the Pfizer COVID-19 vaccine:

1. Inject 0.2mL of air into the vial of reconstituted vaccine.
2. Draw up 0.3mL of vaccine into the administration syringe. Do not change needle unless patient meets weight requirements.
3. Rotate where you insert the needle in various locations of the vial septum for each withdrawal to reduce leaking of vaccine

Moderna COVID-19 Vaccine Considerations

- Some practice settings have reported being able to withdraw more than 10 doses of a single vaccine vial. The FDA has issued guidance allowing this usage.[1]
- The manufacturer provides that for dose preparation, a 20-22-gauge needle is recommended and for administration a 22-25-gauge needle. A single 22-gauge needle can be used to both draw up and administer the vaccine.

Beyond-Use Dating Considerations for Pre-drawn Syringes

We recognize that practice settings may benefit from certain operational efficiencies that support a separation of the vaccine preparation steps from vaccine administration to the patient. For example, this may be when a practice setting prepares and pre-draws vaccine into syringe in one area and then transports the pre-drawn syringes to a different site for administration. Use pre-drawn syringes with earliest discard time first to avoid waste. If pre-drawn syringes are used, consider the following manufacturer released information supporting stability data of vaccine pre-drawn into syringes:

Pfizer-BioNTech COVID-19 Vaccine

- Pfizer has conducted physical and chemical stability studies which have shown that the vaccine maintains all its measured quality attributes when diluted vaccine is stored in polycarbonate and polypropylene syringes with stainless steel needles for 6 hours at 2°C to 25°C (35.6°F to 77°F) after the source vial is diluted.
- Microbiological risk was assessed through a microbiological challenge study which showed that microbiological growth has a greater potential to occur after 6 hours. The hold time of 6 hours, from the time the source vial is diluted, is not specifically tied to a preparation environment and can be applied to doses prepared outside of ISO Class 5 environment (PEC).
- Keep out of direct sunlight.

Moderna COVID-19 Vaccine

- According to the Chemistry, Manufacturing and Control (CMC) department at Moderna, pre-drawn syringes 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 6 hours of the first time the source vial is punctured.
- Per the manufacturer, common disposable syringes made of polypropylene or polycarbonate are suitable for use.
- Keep out of direct sunlight.

Labeling Considerations

When the COVID-19 Vaccines are not being prepared for immediate administration, appropriate labeling considerations should be undertaken. If the vaccines are sent outside the facility in which they were prepared for administration, a designated person must ensure that contact information of the preparation facility is conveyed and available at the site where they will be administered. Labels should be adhered to the container(s) (e.g., light protected zip-lock bag in which pre-drawn syringes are stored and transported). Pre-drawn syringes prepared for administration must be labeled with legible identifying information to prevent errors during storage, dispensing, transport, and use.

Personnel should consider adding the following labeling components to the containers in which the pre-drawn vaccine syringes are stored as well as the pre-drawn vaccine syringe.

Container labeling components:

- Facility name and phone number
- Quantity of syringes
- Name and amount of vaccine
- The exact beyond-use date and time (e.g., 6 hours for pre-drawn syringes for both Pfizer-BioNTech and Moderna COVID-19 Vaccines from when the vaccine is diluted or the first dose is withdrawn from vial, respectively)[2,3]
- Lot number
- Initials of preparer

Examples of pre-drawn syringe storage container labels

Pfizer-BioNTech COVID-19 Vaccine (30 mcg / 0.3 mL) IM suspension
Facility name and phone number:
Quantity of syringes:
Date & Time to discard (6 hours after dilution):
Lot #:
Initials of preparer:

Moderna COVID-19 Vaccine (100 mcg / 0.5 mL) IM suspension
Facility name and phone number:
Quantity of syringes:
Date & Time to discard (6 hours after puncture):
Lot #:
Initials of preparer:

Pre-drawn syringe labeling components

- Name and amount of vaccine
- The exact beyond-use date and time (e.g., 6 hours for pre-drawn syringes for both Pfizer-BioNTech and Moderna COVID-19 Vaccines from when the vaccine is diluted or the first dose is withdrawn from vial, respectively)[2,3]
- Lot number
- Initials of preparer

Examples of pre-drawn syringe labels

Pfizer-BioNTech COVID-19 Vaccine (30 mcg / 0.3 mL) IM suspension
Date & Time to discard (6 hours after dilution):
Lot #:
Initials of preparer:

Moderna COVID-19 Vaccine (100 mcg / 0.5 mL) IM suspension
Date & Time to discard (6 hours after puncture):
Lot #:
Initials of preparer:

References

1 https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/moderna-covid-19-vaccine-frequently-asked-questions
2 https://www.cvdvaccine-us.com/resources
3 https://www.modernatx.com/covid19vaccine-eua/providers/
4 https://www.usp.org/covid-19/hand-sanitizer-information
5 https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf
6 https://www.cdc.gov/niosh/npg/npgd0359.html
7 https://www.cdc.gov/coronavirus/2019-ncov/hcp/hand-hygiene.html

2 Storage and Transportation

Operational Considerations for Storage, Handling, and Transporting of COVID-19 Vaccines During Pandemic (January 26, 2021)

Background

Proper storage, handling, and transportation of COVID-19 vaccines are critical activities in their integrated supply chain. Failure to store and handle vaccines properly can potentially reduce potency, leading to inadequate immune response in patients and poor protection against COVID-19. Proper storage, handling, and transportation of the COVID-19 vaccines begins with an effective cold chain process, which is temperature-controlled, using related equipment and procedures. It begins with cold storage at the manufacturing facility and extends to the proper receiving, storage, and handling of the vaccine at the provider facility, and in some situations, transporting off-site or to satellite facilities.

Manufacturer-supplied information for storing and handling the two new COVID-19 vaccines in the United States is provided on the Pfizer-BioNTech and Moderna COVID-19 resource webpages.[1,2] This document focuses on considerations for storing, handling, and transporting vaccines and can be used to supplement a manufacturer's labeling, but not replace them. In addition, this document should not replace a facility's policies and procedures.

Quality Management System (QMS)

Developing and maintaining clearly written, detailed, and up-to-date receiving, storage, handling, and transporting standard operating procedures (SOPs) are essential. This occurs within the framework of a robust QMS, which is a set of policies, processes, and procedures required to execute core activities. Due to the risk associated with vaccine transport caused by improper packing or storage unit failure, it is necessary to include detailed packing and transport protocols in the organization's storage and handling SOPs (including those that address inclement weather, natural disasters, and traffic disruptions). The QMS, along with related SOPs, helps ensure proper procedures are followed and problems (e.g., damaged packages or vials) are identified, reported, and corrected. SOPs should also provide direction for handling emergencies, such as equipment malfunctions, power failures, or natural disasters. All staff members who come in contact with the vaccines, or who administer the vaccines should be trained on all relevant practices and procedures. The objective of the training should be to reduce the gap between existing staff competencies and those required to perform the job (see USP General Chapter <1079> *Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products)*.

Receiving Vaccine

When vaccines arrive at the facility, they should be transferred as quickly as possible to a designated storage area and stored at the recommended temperature. Receiving areas should protect the product from inclement weather during unloading, and the receiving area should limit access to authorized persons only. Deliveries should be examined at receipt in order to check that shipping containers are not damaged, and that the shipment corresponds to the order. Check the temperature monitoring device, if applicable, for any indication of temperature

excursion(s) during transit. Each organization should have a receiving procedure that determines the appropriate checks for this operation. A checklist can be used as a reminder of what to inspect and what to record (see USP General Chapter <1079> *Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products)*.

Vaccine Storage

Storage units are required to maintain the product temperature between the limits defined on the product label (see USP General Chapter <695> *Packaging and Storage Requirements*). Detailed information on vaccine storage and temperature monitoring equipment is included in section 3 of the CDC Vaccine Storage and Handling Toolkit.[3] Manufacturer-supplied information for storing the two new authorized COVID-19 vaccines in the United States is provided on the Pfizer-BioNTech and Moderna COVID-19 resource webpages.[1,2]

According to the CDC Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum section, it is essential to utilize continuous temperature monitoring systems to ensure the vaccines are stored within the correct temperature range and a digital data logger (DDL) with an external display is preferred. A DDL is an electronic device that records data digitally over time or in relation to location either with a built-in or external instrument or sensor. Although automated systems monitor temperature continuously, manual checks must be performed as appropriate to ensure functionality and when the vaccine is removed from storage. Temperature monitoring devices should be calibrated (NIST traceable[3]) against nationally accepted standards to ensure accuracy of readings (see USP General Chapter <1118> *Monitoring Devices—Time, Temperature, and Humidity*). Calibration testing should be done every one to two years or according to the manufacturer's suggested timeline. Alarm systems may be part of the temperature monitoring system.

Pharmaceutical-grade refrigerators and freezers are preferred because they are designed specifically for storing biopharmaceuticals, including vaccines. Per CDC guidance, "household-grade units can be an acceptable alternative for refrigeration in some situations. However, the freezer compartment of household-grade units is not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If your facility provides frozen vaccine, a separate freezer unit is necessary."[3] Under no circumstance should a vaccine be stored in a dormitory-style refrigerator/freezer unit. Food and drinks and/or biological specimens should not be stored in the same unit as the vaccine.

Standard operating procedures (SOPs) should be in place to ensure power supply or alternative options when power outage occurs. Routine maintenance should be conducted to ensure proper function of the refrigeration unit and, depending on the time of year (e.g., summer, winter), the thermostats may need to be reset depending on room temperature.

Typically, a refrigeration unit specification would be set to 5°C (41°F) with an allowable range of ± 3°C (37.4°F) to store products labeled 2°C to 8°C (36°F to 46°F). Freezer temperatures may vary and typically range from –25°C to –10°C (–13°F to 14°F). **Most standard freezer units do not meet ultra-cold freezer requirements for storing vaccines between –60°C and –80°C (–76°F and –112°F).**

If ultra-low freezer temperatures are required and the manufacturer provides or specifies the use of dry ice (e.g., Pfizer-BioNTech COVID-19 Vaccine), additional handling precautions should be taken, such as the following:

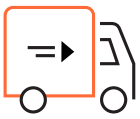
- Store thermal shippers containing dry ice, as well as dry ice replenishment containers, in a well-ventilated area. Because frozen carbon dioxide changes phase (i.e., melts) into a gaseous state, elevated levels of carbon dioxide can be dangerous to personnel operating within a poorly ventilated area, which may lead to asphyxiation.
- Because the thermal expansion of dry ice changes phases from frozen to gaseous, it should never be stored in a tightly sealed device.
- Wear impermeable loose-fitting gloves (e.g., leather, lined oven mitts, etc.) to protect from contact freezing (similar to a burn). Gloves must be insulated to protect from general freezing temperatures (dry ice is –78.5°C or –109.3°F).
- Wear goggles or a face shield to protect your eyes.

Temperature Excursions

Inclement weather, natural disasters, and traffic disruption can cause receiving delays and potential temperature excursions. A temperature excursion is any temperature reading outside of the recommended range for vaccine storage as defined in the manufacturer's package insert. Temperature excursions or inappropriate storage conditions require immediate action. Each excursion should be documented including the magnitude of the temperature excursion, and the total amount of time that temperatures were out of range. For refrigerated vaccines, mean kinetic temperature may be calculated (see USP General Chapter <1079.2> *Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and*

Transportation of Drug Products). To determine the impact of an excursion, and whether the vaccines are still viable, contact the manufacturer for guidance on whether the affected vaccines should be discarded or can be utilized. While this determination is being made, the vaccines should be maintained at the appropriate temperature and clearly labeled "DO NOT USE pending guidance by the manufacturer." See example label below. Place them in a separate container apart from other vaccines and do not discard these vaccines. The ability of the manufacturer to determine the excursion impact will depend on the information provided. Therefore, it is critical to detail information about the excursion such as excursion time, product response like bubbling, etc. Each excursion event is unique and a manufacturer's recommendation for a specific excursion event should not be applied to future events that appear to be similar.

DO NOT USE pending guidance by the manufacturer.



Vaccine Transport (Off-site or Satellite Facilities)

Vaccine transport off-site or to satellite facilities involves the process of transporting vaccines over short distances and time frames in accordance with practice setting SOPs. When vaccine transport is necessary, transport the vaccines using a portable refrigerator and/or freezer unit with a temperature monitoring device. If a portable refrigerator and/or freezer unit is not available, qualified containers and packouts with a temperature monitoring device can be used. A container or packout is 'qualified' through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time and are available through packaging suppliers. When transporting the vaccine, the temperature should be validated whenever the storage container is opened. The manufacturer-supplied packaging can be used in accordance with the directions in the manufacturer's labeling.

The total time for transport should be minimized to reduce potential risk for a temperature excursion due to a storage unit or thermal packaging system failure. Sufficient transport supplies (e.g., materials and equipment) are needed. These can include portable refrigerator/freezer units, qualified containers, coolant materials, insulating materials, and the required temperature monitoring devices.

Vaccines must be secured from theft and tampering, as other medications, when not under supervision of healthcare personnel. Strategies to ensure secure transport can include the use of 'tamper proof' or 'tamper evident' measures (e.g., locks, tape) on these containers as appropriate per the health professional's judgment.

Transport of frozen solid vaccine vials

Pfizer-BioNTech COVID-19 Vaccine[1]

- Use a continuous temperature monitoring device to ensure consistent temperature monitoring during transport.
- Frozen Pfizer-BioNTech COVID-19 Vaccine is maintained at a temperature of −80ºC to v60ºC (–112ºF to –76ºF)
- Per manufacturer labeling, the only allowable containers for frozen transfer are: 1) portable ultra-cold freezers; or 2) original thermal shipper containers, if following re-icing guidelines.
  - Pfizer provides detailed instructions for *Dry Ice Replenishment* when stored in the original thermal shipper (including information on dry ice replenishment, pellet size, and pack-out instructions for re-icing thermal packaging).[4]
  - Appropriate measures should be taken to ensure the vaccine is cushioned and protected from agitation during transport.
- If the storage condition is changed to an unmonitored temperature container, this is when the allowable storage time for non-frozen condition begins (120 hours at refrigeration temperatures).
- When the vaccine's storage condition is changed, it is critical to utilize appropriate labeling to indicate the beyond-use date, per the manufacturer. The CDC offers manufacturer-specific vaccine labels for beyond-use date tracking.[5]

Moderna COVID-19 Vaccine[2]

- Use a continuous temperature monitoring device to ensure consistent temperature monitoring during transport.
- Frozen Moderna COVID-19 Vaccine is maintained at a temperature of –25ºC to –15ºC (–13ºF to 5ºF).
- Transporting Moderna COVID-19 Vaccine in frozen state is preferred.
- A portable freezer can be utilized to transport frozen vaccine product.
  - Appropriate measures should be taken to ensure the vaccine is cushioned and protected from agitation.
- Per manufacturer labeling, dry ice should not be used in transferring vaccine product.
- If the storage condition is changed to an unmonitored temperature container, this is when allowable storage time for non-frozen condition starts (e.g., 30 days in refrigerated temperatures).
- When the vaccine's storage condition is changed, it is critical to utilize appropriate labeling to indicate beyond-use date, per the manufacturer. The CDC offers manufacturer-specific vaccine labels for beyond-use date tracking.[5]

Transport of thawed, multidose vaccine vials

Pfizer-BioNTech COVID-19 Vaccine[1]

- Use a continuous temperature monitoring device to ensure consistent temperature monitoring during transport.
- Undiluted vials can be maintained at refrigeration temperatures at 2ºC to 8ºC (35ºF to 46ºF) for 120 hours.
- Undiluted vials can be maintained at room temperature for up to 25ºC (77ºF) for 30 minutes.
- Diluted vials can be maintained at room temperature for up to 25ºC (77ºF) for 6 hours and must be discarded after 6 hours.
- A portable refrigerator unit can be utilized to transport thawed vaccine product.
  - Appropriate measures should be taken to ensure the vaccine is cushioned and protected from agitation.
- Expanded polystyrene foam containers can be used for maintaining cold chain/temperature consistency across transport to administration site.
  - In addition, to protect from damage during transport, a hard-plastic container should be considered to carry the expanded polystyrene foam container (NOTE: a hard-sided plastic container alone may not be sufficient to maintain temperature control).
- If a cooling agent is used, a thick barrier (at least 1 inch) of bubble wrap or corrugated cardboard may be utilized as a barrier between the transport container cooling agent and the container with pre-drawn syringes. This is to prevent direct contact between pre-drawn syringes and the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.[6]
- When the product is thawed, do not refreeze.
- When the vaccine's storage condition is changed, it is critical to utilize appropriate labeling to indicate beyond-use date, per the manufacturer. The CDC offers manufacturer-specific vaccine labels for beyond-use date tracking.[5]

Moderna COVID-19 Vaccine[2]

- Use a continuous temperature monitoring device to ensure consistent temperature monitoring during transport.
- Vials can be maintained at refrigeration temperatures between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.
- A portable refrigerator unit can be utilized to transport thawed vaccine product.
  - Appropriate measures should be taken to ensure the vaccine is cushioned and protected from agitation during transport.
- Expanded polystyrene foam containers can be used for maintaining cold chain/temperature consistency across transport to administration site.
  - In addition, to protect from damage during transport, a hard-plastic container should be considered to carry the expanded polystyrene foam container (NOTE: a hard-sided plastic container alone may not be sufficient to maintain temperature control).
- If a cooling agent is used, a thick barrier (at least 1 inch) of bubble wrap or corrugated cardboard may be utilized as a barrier between the transport container cooling agent and the container with pre-drawn syringes. This is to prevent direct contact between pre-drawn syringes and the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.[6]
- When the product is thawed, do not refreeze.
- When the vaccine's storage condition is changed, it is critical to utilize appropriate labeling to indicate beyond-use date, per the manufacturer. The CDC offers manufacturer-specific vaccine labels for beyond-use date tracking.[5]

Transfer of pre-drawn syringes

The following operational considerations are offered for both Pfizer-BioNTech and Moderna COVID-19 Vaccines according to the temperatures defined below for pre-drawn syringe stability provided by the manufacturer:

- Use a continuous temperature monitoring device to ensure consistent temperature monitoring during transport.
- Portable refrigerated units may be used to transport the vaccine.
  - Appropriate measures should be taken to ensure the vaccine is cushioned and protected from agitation.
- Expanded polystyrene foam containers can be used for maintaining cold chain/temperature consistency across transport to administration site.
  - In addition, to protect from damage during transport, a hard-plastic container should be considered to carry the expanded polystyrene foam container (NOTE: a hard-sided plastic container alone may not be sufficient to maintain temperature control).
- If a cooling agent is used, a thick barrier (at least 1 inch) of bubble wrap or corrugated cardboard may be utilized as a barrier between the transport container cooling agent and the container with pre-drawn syringes. This is to prevent direct contact between pre-drawn syringes and the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.[6]

Pfizer-BioNTech COVID-19 Vaccine

- Pfizer has conducted physical and chemical stability studies which have shown that the vaccine maintains all its measured quality attributes when the diluted vaccine is stored in polycarbonate and polypropylene syringes with stainless steel needles for 6 hours at 2°C to 25°C (35.6°F to 77°F) after the source vial is diluted.

Moderna COVID-19 Vaccine

- According to the Chemistry, Manufacturing and Control (CMC) department at Moderna, pre-drawn syringes 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 6 hours of the first time the source vial is punctured.

References

1 https://www.cvdvaccine-us.com/resources

2 https://www.modernatx.com/covid19vaccine-eua/providers/

3 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

4 https://www.cvdvaccine-us.com/product-storage-and-dry-ice

5 https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf

6 https://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf

3 Waste Minimization and Ancillary Supply Disposal

Operational Considerations for Waste Minimization and Ancillary Supply Disposal for COVID-19 Vaccines (January 26, 2021)

Background and Introduction

The variety of COVID-19 vaccines in the manufacturing pipeline will continue to pose challenges for the safe and proper minimization of waste of unused vaccine and safe disposal of ancillary supplies (e.g., dry ice, syringes, needles). Disposal of unused vaccine or ancillary supply waste from a COVID-19 vaccine that has been authorized by local regulators should be performed in accordance with the directions in the manufacturer's labeling.[1,2] USP supports the Occupational Safety and Health Administration (OSHA) and other regulators setting and enforcing standards to ensure safe and healthful working conditions during the COVID-19 pandemic. This document focuses on considerations for disposal of unused or ancillary supply waste of COVID-19 vaccines and can be used to supplement a manufacturer's labeling, but not replace them. In addition, this document should not replace a facility's policies and procedures.

COVID-19 Vaccine Waste Minimization

Given the critical shortage of COVID-19 vaccines worldwide and their state-based allocation in the United States, sites should accordingly plan and build standard operating considerations (SOPs) to minimize loss of doses following local regulatory guidance. The following considerations should be made to minimize or control vaccine waste:

- A site should have plans in place to minimize vaccine waste of usable vaccine (e.g., waiting list for vaccines, plans to distribute vaccines if individuals do not show up for appointments, agreements with pharmacies and other local centers for vaccine transport, etc.).
- Ensure cold chain is properly maintained with proper storage conditions and continuous temperature monitoring to prevent the need to discard any product due to temperature excursions.
- Ensure vaccine preparers are properly trained and demonstrate competency for proper aseptic technique to minimize the risk of contaminating the product.
- Maximize doses withdrawn from vials (6 or 7 doses from the Pfizer-BioNTech COVID-19 Vaccine vial or 11 doses from the Moderna COVID-19 Vaccine vial) by utilizing low dead-volume syringes/needles, whenever possible. A low dead-volume syringe is designed to limit dead space that exists between the syringe hub and needle. A low dead-volume needle is designed with less space between the needle and the plunger.
- To ensure practice settings who may not have adequate quantities of low dead-volume syringes to more consistently achieve the maximum doses withdrawn, a combination of low dead-volume syringes and non-low dead-volume syringes could also maximize doses withdrawn (e.g., 3 low dead-volume syringes and 3 non-low dead-volume syringes).
  - Inserting the needle in various locations of the vial septum can reduce leaking of vaccine and maximize doses withdrawn (i.e., rotate the needle around the vial septum on each vaccine withdrawal).
- Carefully consider the number of pre-drawn syringes to prepare to minimize vaccine waste.
- Use pre-drawn syringes with earliest discard time first to avoid waste.

Considerations for the Disposal of Vaccines and Ancillary Supplies

The authorized COVID-19 Vaccines, the Pfizer-BioNTech and Moderna COVID-19 Vaccines, do not meet criteria for hazardous waste and their disposal should follow policies for disposal of medical waste. Medical waste is healthcare waste that may be contaminated by blood, body fluids, or other potentially infectious materials.[3] Medical waste disposal requirements are set by regulatory agencies. Thus, follow regulatory or facility policies for appropriate disposal. Empty vaccine vials are usually not considered hazardous or medical waste and do not require disposal in a biomedical waste container.[4]

Needles must be discarded in biohazard containers that are closable, puncture-resistant, leakproof on sides and bottom, labeled, and color-coded (e.g., sharps container). This is important to prevent an accidental needlestick which can lead to transmission of infection. Then, dispose of the biohazard containers according to facility and regulatory requirements.

Items to be discarded immediately after use or when the vaccine exceeds beyond-use-date and time may include:

- Empty vials
- Vials with unused vaccine
- Vials with unused diluent
- Pre-drawn syringes and needles
- Used syringes and needles (e.g., post patient injection, used in dilution process, etc.)

Considerations for the Disposal of Dry Ice Product

(applicable for Pfizer-BioNTech COVID-19 Vaccine storage)

Centers for Disease Control and Prevention (CDC) guidance on the storage and safe disposal of dry ice is available at the healthcare practitioner portal of the CDC, which can be accessed here,[5] or as posted by the manufacturer (e.g., Pfizer-BioNTech Dry Ice Disposal Guidance).[6] Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, causing asphyxiation. Exposed skin should be protected from contact with dry ice. Considerations include the following:

- Once dry ice is no longer needed (vaccine has been removed), open the container and leave it at room temperature in a well-ventilated area. It will readily sublime from a solid to a gas.
- DO NOT leave dry ice in an unsecured area.
- DO NOT place in a drain or flush in the toilet.
- DO NOT dispose in the trash.
- DO NOT place in a closed area, such as an airtight container or walk-in cooler.

References

1 https://www.cvdvaccine-us.com/resources

2 https://www.modernatx.com/covid19vaccine-eua/providers/

3 https://www.epa.gov/rcra/medical-waste

4 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

5 Disposal CDC Guidance. https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/dry-ice-safety-hcp.pdf

6 Pfizer-BioNTech Dry Ice Disposal Guidance. https://www.cvdvaccine-us.com/images/pdf/Shipping_and_Handling_Guidelines.pdf