FAQ for Optimizing COVID-19 Vaccine Preparation and Safety

This document is for informational purposes only and is intended to address best practices for optimizing syringe, needle, and related preparation considerations for COVID-19 vaccines. 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.

Use of Low Dead-Volume (LDV) Syringes and/or Needles in COVID-19 Vaccine Preparation[1,2]

The Pfizer-BioNTech COVID-19 vaccine multidose vials are intended to yield 6 doses (0.3 mL) of vaccine per vial.[3] Practice settings have reported that ancillary kits shipped for the purposes of vaccine administration and dilution by the Centers for Disease Control and Prevention (CDC) often contain a combination of LDV and non-LDV (standard) syringe or needle combinations. Given the availability of these ancillary supplies, we aim to provide best practices to maximize vaccine volume in the preparation stage of the Pfizer-BioNTech COVID-19 vaccine and also for the Moderna COVID-19 vaccine.

Dead volume (commonly referred to as dead space) is the volume of medical product remaining in the needle and the hub of a syringe after an injection. Low Dead-Volume Syringe and needle combinations are those that have 0.035 mL or less of dead volume. Practice settings have reported success using a combination of at least 3 LDV syringes (creating dead volume of 0.105 mL or less) and 3 non-LDV syringes for vaccine withdrawal. The Frequently Asked Questions below are intended to address common questions related to dead volume and optimizing number of doses per vial while ensuring quality, safety, and efficiency across practice settings.

What is the composition of the CDC ancillary kits as far as syringes for preparation and administration?

As of February 2021, the CDC is shipping ancillary kits with approximately an 80% composition of LDV syringes and 20% composition of non-LDV syringes for Pfizer-BioNTech products. Not all of the LDV syringes being shipped are 1 mL VanishPoint® syringes as there are multiple syringe/needle products that are LDV. Please see **Appendix I** for example shipments of adult ancillary kits for the Pfizer-BioNTech COVID-19 Vaccine.

The kits provide 1 mL, 3 mL, or 5 mL syringes and needles that range from 22 to 25 gauge and needles that are 1 to 1.5 inches in length. Administration should be performed using the 1 mL syringes whenever possible. The 3 mL and 5 mL syringes should be used for diluting the Pfizer-BioNTech COVID-19 vaccine only. Smaller-gauge needles (i.e., larger thickness) or blunt-tip needles should also be used for diluting vaccine. Blunt-tip needles should not be used for vaccine administration.

The ancillary kits arrive with 1.5-inch needles for the purpose of dose administration for patients who meet age and weight requirements per the CDC.[4]

Is a cleanroom or ISO Class 5 air environment required for vaccine preparation?

A cleanroom or hood with an ISO class 5 air environment is **not** required for dilution or preparing vaccine doses. The Emergency Use Authorization (EUA) Fact Sheets for both the Pfizer-BioNTech and Moderna vaccines allow 6 hours at room temperature once vials have been punctured, regardless of dilution or preparation environment. Both Pfizer and Moderna have data on file supporting stability of their respective vaccines in polycarbonate and polypropylene syringes for up to 6 hours as discussed in the USP COVID-19 Vaccine Handling Toolkit, which provides additional detail on this BUD.[5]

In-depth answer: *Under the current USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations (2008), the beyond-use date applied to unpreserved vials punctured in worse than ISO 5 air is one hour. However, the USP Compounding Expert Committee in 2020 released a resource titled Operational Considerations for Sterile Compounding During COVID-19 Pandemic that addresses preparation of a conventionally manufactured COVID-19 vaccine and recommends following the directions in the EUA Fact Sheets. Neither the Pfizer-BioNTech nor the Moderna vaccine EUA Fact Sheets specify air quality when assigning 6 hours to a punctured vial, therefore this BUD can be applied regardless of the environment.*

The selection of needles and syringes in the preparation and dose withdrawal are critical practice considerations to maximize the number of doses per vial. What are the recommended needle or syringe types for preparation and administration of COVID-19 Vaccines?

Please see the Maximizing Doses of Pfizer-BioNTech COVID-19 Vaccine infographic for preparation and dose withdrawal strategies. Please refer to CDC resources that includes general injection safety.[7] Vaccine preparation training is also available on the CDC website to support COVID-19 Vaccine Administration Training, including critical practice techniques.[8]

Dilution of Pfizer-BioNTech COVID-19 Vaccine:

- The ancillary kits provide 1 mL, 3 mL, or 5 mL syringes and needles that range from 22 to 25 gauge and needles that are 1 to 1.5 inches in length.
- The 3 mL and 5 mL syringes should be used for diluting the Pfizer-BioNTech COVID-19 vaccine only. Smaller-gauge needles (i.e., larger thickness) or blunt-tip needles should also be used for diluting vaccine.
- Luer-lock needle or syringes should be tightened before beginning the dilution process to prevent any diluent loss due to loose needle or syringes.
- Syringe packages should be opened immediately prior to the beginning of the dilution process. ISMP has received reports during mass vaccinations where multiple packages of syringes were opened simultaneously and 1.8 mL of air drawn into syringe. Then the syringes were later used to inject 1.8 mL of air directly into the thawed concentrate injection, without first diluting the vaccine, resulting in improper vaccine dosing.

Dose withdrawal for Pfizer-BioNTech COVID-19 Vaccine Administration:

- Based on the current CDC ancillary kit composition, it is recommended to use 1 mL syringe for administration, prioritizing the smallest syringe possible (e.g., 1 mL) for Pfizer-BioNTech COVID-19 Vaccine Administration versus the 3 mL syringes for Moderna COVID-19 Vaccine Administration.
  - Use 1-inch needles, 22-gauge or narrower, (e.g., 25-gauge), to withdraw vaccine for administration.
  - Use 1 mL syringes with 0.01 mL markings for accurate dose withdrawal.
  - While graduations on the syringe barrels of 3 mL syringes may allow visual measurement of 0.3 mL, there is variation in the accuracy of small-volume measurements in these syringes.
  - Use the same needle for withdrawal and administration to prevent loss of vaccine unless the patient meets the age and weight requirement for a 1.5-inch needle per the CDC.[4]
  - A safety needle is required for vaccine administration in the United States per the Needlestick Safety and Prevention Act of 2000.[9]

Dose withdrawal for Moderna COVID-19 Vaccine Administration:

- Sites should use syringes provided through the ancillary kits. The smallest syringe possible (e.g., 1 mL) should be prioritized for Pfizer-BioNTech COVID-19 Vaccine Administration. If ancillary kits provided include enough 1 mL syringes for Moderna vaccine administration, they can be utilized. Otherwise, based on the current CDC ancillary kit composition, 3 mL syringes may be used for administration.
  - Use 1-inch needles, 22-gauge or narrower, (e.g., 25-gauge), to withdraw vaccine for administration.
  - Use the same needle for withdrawal and administration to prevent loss of vaccine unless the patient meets the age and weight requirement per the CDC.4
  - A safety needle is required for vaccine administration in the United States per the Needlestick Safety and Prevention Act of 2000.[9]

Why is the practice of using dispensing pins, vial adapters, or strategies where a needle is inserted into the vial septum for multiple medication withdraws (i.e., essentially a needle is used as a dispensing pin) strongly discouraged?

The CDC Medication Preparation Questions FAQs regarding Safe Practices for Medical Injections is a good resource for practitioners to review.[7]

> *"A needle should not be left inserted into a medication vial septum for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid."* Both the Pfizer-BioNTech and Moderna COVID-19 Vaccines are preservative free.

The use of vial adapters and dispensing pins cause concern for a variety of reasons:

- Syringes will be filled with exact dose (e.g., 0.3 mL for Pfizer-BioNTech COVID-19 Vaccine) and the syringes will be capped without considering that vaccinator will add a needle for intramuscular injection. Then, upon withdrawal of needle from patient, some fluid will remain in any dead space, having not reached muscle and thus not providing a full dose.
- Such devices can more easily cause the vial stopper to be pushed into the vial, contributes to greater vial leaking, and makes it very challenging to account for the dead space or vaccine loss discussed previously.

I am concerned about the needle being blunt after using the needle to withdraw the vaccine dose from the vial and then used for administration. **Is it okay for me to switch needles after withdrawing the vaccine dose into syringe?**

- Needle bluntness is not a cause for changing the needle following vaccine withdrawal due to significant risk of underdosing the patient due to volume of vaccine in needle upon dose withdrawal from vial.
- In a large health-system setting, out of more than 35,000 doses administered, only a single needle had blunting issues that required a root cause analysis. Learn more about preparing a root cause analysis here.[10]
  - It is critical to document and analyze any situation where needle bluntness or vaccine leaking due to device (e.g., syringe/needle not being tightly luer-locked causing leaking upon injection). This is to help identify any medical device failure and as part of the practice setting's continuous improvement planning.

I know that the Needlestick Safety and Prevention Act of 2000 requires that I use safety devices when administering vaccine. **What should I do if I cannot access safety needles for administration or the safer device that I choose is on back order?**[11]

"Safety equipment must be available at all times. If for some reason an engineering control is not available (due to supply shortages, back orders, shipping delays, etc.), this must be documented in your Exposure Control Plan.[12] *You would then be responsible for implementing the chosen control(s) as soon as it becomes available and adjusting your exposure control plan to illustrate such. In the meantime, work practice controls must be used and, if occupational exposure still remains, personal protective equipment must also be used."*

When is it appropriate for me to change needle after withdrawing the vaccine into syringe?

Vaccine preparation training is available on the CDC website to support COVID-19 Vaccine Administration Training, including critical practice techniques on inserting needle into vial, visuals, etc.[8]

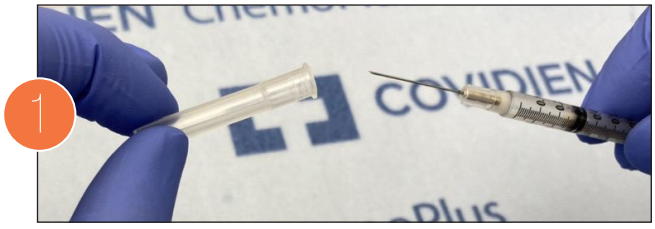
It is only recommended to change the needle after dose withdrawal in syringe in situations when the patient meets age and weight requirements per the CDC. In critical situations where the needle is obviously bent and would prevent appropriate IM administration, the needle should be replaced. After withdrawing the appropriate volume, remove the needle from the vial, pull back the plunger until there is some air in the syringe, remove the needle and insert a new needle, then slowly push the plunger back to fill up the dead space. This is not a step that should be taken in general to replace needles prior to vaccine administration. It is of critical importance for practice settings to primarily use the same needle for vaccine withdrawal and administration unless the patient meets the CDC age and weight requirements.[4]

I am aware that I can ignore certain air bubbles in a syringe. **What is an example of what I can ignore and what I should address, particularly for an intramuscular injection?**

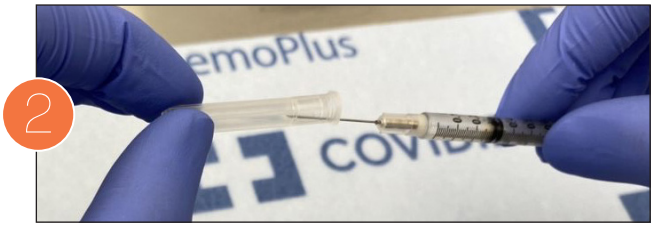
- Air bubbles in a syringe are typically problematic due to their impact on accuracy of vaccine dose (i.e., large air bubbles reduce the volume of vaccine in syringe, thus creating risk for underdosing).
- While small air bubbles can be ignored, large air bubbles can lead to underdosing and should be addressed. Minimize tapping of the syringe due to theoretical risk of inactivating the vaccine or degrading quality.
- **Figure 1** demonstrates examples of air bubbles that must be addressed (while needle is still in vial, to prevent vaccine loss and contamination) and smaller bubbles that can be ignored.

Figure 1: Example of small air bubbles (acceptable) and large air bubbles (must remove)

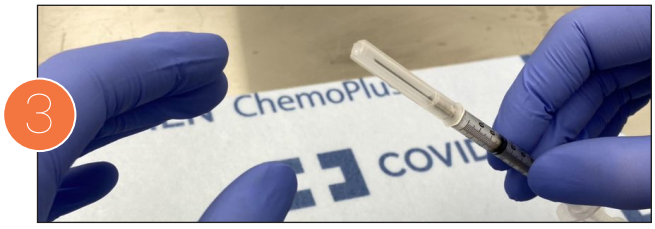
What is the best strategy for recapping needles after vaccine dose withdrawal?



1 **Hold needle cap between fingers towards the closed end.**



2 **Gently insert needle bevel into cap opening.**



3 **Release needle cap and allow to slide down needle.**

4 **Click needle cap into place.**

NOTE: Take care to not bend the needle during the recapping process.

Figure 2: Recapping needles safely after preparation. Do not recap needles after administration.

Appendix I

Pfizer-BioNTech COVID-19 Vaccine Ancillary Kit example

Figure 3: Adult ancillary kit example #1 for Pfizer-BioNTech COVID-19 Vaccine.

Photo courtesy of Avera Health, Sioux Falls, South Dakota

Figure 4: Adult ancillary kit example #2 for Pfizer-BioNTech COVID-19 Vaccine.

Photo courtesy of Avera Health, Sioux Falls, South Dakota

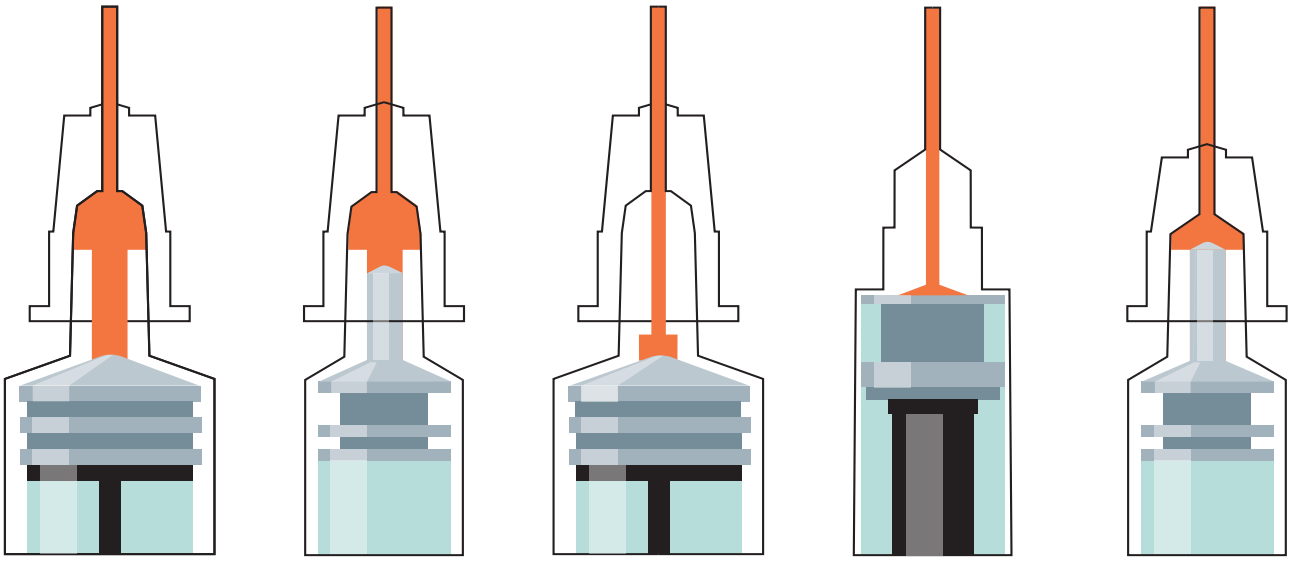
Appendix II

Examples of potential needle and syringe types and combinations that consistently yield 6 doses of the Pfizer-BioNTech COVID-19 Vaccine

What does Low Dead Volume look like?

LDV syringe and needle features compared (the figures below represent dead volume in syringes)

Dead space comparision



Standard syringe with standard needle

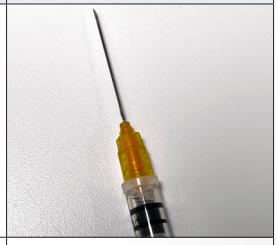
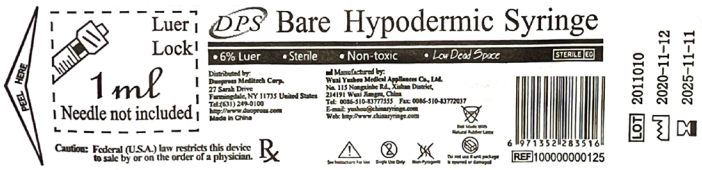
Low dead space with standard needle

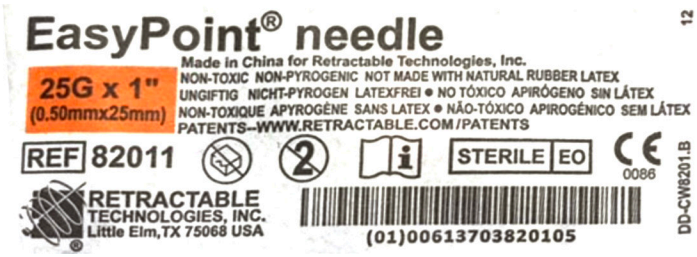
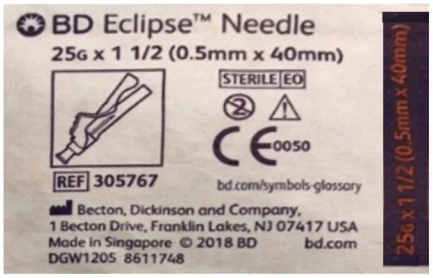
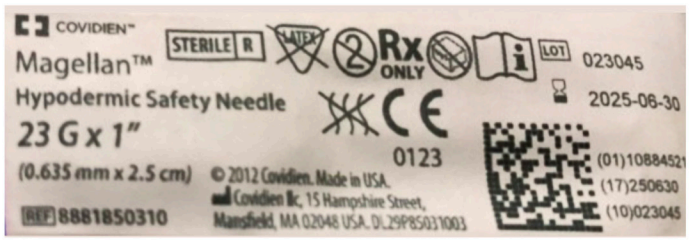
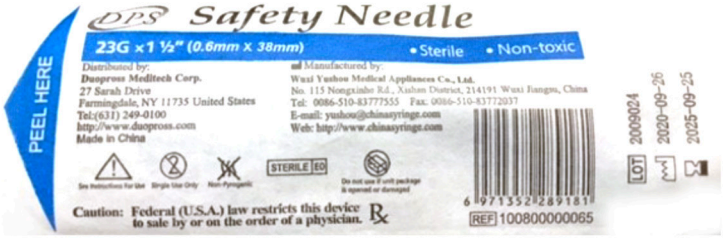
Standard syringe with low dead space needle

Low dead space syringe with fixed needle

HSW low dead space syringe with TSK low dead space needle

What are the types of syringe/needle combinations that maximize the doses withdrawn of both the Pfizer-BioNTech and Moderna COVID-19 Vaccines?

Combination Syringe and Needles (preferred)		
	Image of syringe/needle packaging	**Enhanced image of dead space**
HAIOU 1 mL Needle Retractable Safety Syringe		
VANISHPOINT 1 mL syringe with retractable safety needle		
ULTICARE 1 mL Tuberculin Safety Syringe		
Syringes (will need to attach compatible needles)		
DPS Bare 1 mL Hypodermic Syringe		
TKMD 1 mL Disposable Syringe		
MONOJECT 1 mL Tuberculin syringe		Not available

Needles (will need to attach compatible syringes) – possible for 6th dose		
	Image of syringe/needle packaging	**Notes**
EASYPOINT needle (25 gauge, 1”)		Must attach with LDV syringe (examples on page 7)
BD Eclipse Needle (25 gauge, 1.5“)		Must attach with LDV syringe (recommended only if patient meets CDC age and weight requirement)[4]
MAGELLAN Hypodermic safetyneedle (23 gauge, 1”)		Must attach with LDV syringe (examples on page 7)
DPS Safety Needle (25 gauge, 1.5”)		Must attach with LDV syringe (recommended only if patient meets CDC age and weight requirement)[4]
Safety Needle (23 gauge, 1.5”)		Must attach with LDV syringe (recommended only if patient meets CDC age and weight requirement)[4]

References

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