Aseptic Technique and Related Skills for COVID 19 Vaccine Clinics

Elizabeth Dallman, PharmD, MS, BCSCP, BCPS

Pharmacy Compliance Coordinator

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Disclosures

Nothing to disclose

Learning Objectives

1. Identify the critical sites of a syringe and vial.
2. Show proper hand hygiene in the COVID 19 Vaccine Clinic.
3. Demonstrate how to draw up vaccine doses in the COVID 19 Vaccine Clinic.

Aseptic Technique

Aseptic Technique

Aseptic Technique is defined by USP as: “A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.”

In other words, **aseptic technique is not a singular technique but encompasses everything we do in the** [illegible] **co** [illegible] **are**

- Proper Hand Hygiene, Garbing, and Conduct.
- Maintaining a Proper Controlled Compounding Area
- Choice of Sterile Components and Equipment
- Maintaining Sterility of Components and Equipment

The Joint Commission. Preventing Central Line–Associated Bloodstream Infections: Useful Tools, An International Perspective. Nov 20, 2013.

Controlled Compounding Area: General Notes

1. Use of a Segregated Compounding Area or an ISO Classified Buffer Room & Ante room
2. Maintain integrity of controlled compounding areas (doors to the anteroom and buffer room are not open at the same time, minimize traffic, etc.)
3. Routine monitoring of controlled compounding areas.
4. Routine cleaning of controlled compounding areas.

The Joint Commission. Preventing Central Line–Associated Bloodstream Infections: Useful Tools, An International Perspective. Nov 20, 2013.

Controlled Compounding Areas: Application to COVID 19 Vaccine Clinics

Atypical compounding area…does not mirror a traditional sterile compounding segregated compounding area (SCA).

Location of a "Designated Vaccine Compounding Area"

- Separate room away from other activities
- Located away from potential airflow disruptions (e.g. doors/window/vents) or areas of potentially poor air quality (e.g. food prep areas/restrooms)

Unnecessary equipment/materials are kept away from the designated area **including food/drinks.**

Plastic backed preparation mats are used to ensure a clean environment for compounding. Per clinic standard work, these mats should be changed every 30 minutes.

Hand Hygiene and Garbing: General Notes

1. Use of Garb (+/-) PPE as described by policy
   - Reminder: no Cellphones
2. Minimum 30 Second Hand Hygiene during initial garbing.
3. Routine disinfection of hands during compounding (especially after touching non-sterile items).
4. Movement and talking in controlled compounding areas is minimized to only what is necessary AND is slow and purposeful.

The Joint Commission. Preventing Central Line–Associated Bloodstream Infections: Useful Tools, An International Perspective. Nov 20, 2013.

Hand Hygiene and Garbing: Application to COVID 19 Vaccine Clinics

The Designated Vaccine Compounding Area does mirror the traditional SCA…so it follows that hand hygiene does not either.

Hands should be sanitized with an alcohol-based hand sanitizer BEFORE donning gloves.

Garb requirements for vaccine compounding is a single pair of powder free gloves.

- Gloves should be changed every 30 minutes
- Gloves should be inspected regularly for tears/holes and immediately replaced if compromised

Gloves should be sanitized routinely with sterile isopropyl alcohol (sIPA). Per clinic standard work, this is recommended at minimum before staring manipulation with a new vaccine vial OR after accidently touching non-compounding related equipment (including exposed skin)

Components & Equipment: General Notes

1. Sterile components and materials are chosen as starting ingredients.
2. Components are stored in a way to maintain their sterility (packaging is intact, off the floor, etc.)
3. Only essential items are brought into the controlled compounding area (no corrogated cardboard).

The Joint Commission. Preventing Central Line–Associated Bloodstream Infections: Useful Tools, An International Perspective. Nov 20, 2013.

Components and Equipment: Application to COVID 19 Vaccine Clinics

All available COVID-19 vaccines are manufactured in sterile multidose vials.

- This sterility is guaranteed until an end-user first punctures the vial septum.

Vials (Drug & Diluent) AND compounding materials (syringes, needles, alcohol wipes, etc.) are:

- Stored OFF the floor
- Kept intact in their original packaging until their time of use (e.g. syringes are not removed from their sterile wrapper).
- Reviewed for any quality issues BEFORE use (e.g. drug appearance is as expected, syringe needles are not bent).

Maintaining Sterility: General Notes

1. Minimizing non-sterile to sterile contact.
2. Components are wiped off with appropriate disinfectants prior to entry into controlled compounding areas.
3. Only essential items (no paper) are brought into the hood to reduce clutter and maintain first air as described below
4. Observance of First Air (as applicable) - technique is dependent upon the type of primary engineering control (hood) being used.

The Joint Commission. Preventing Central Line–Associated Bloodstream Infections: Useful Tools, An International Perspective. Nov 20, 2013.

Maintaining Sterility: Application to COVID 19 Vaccine Clinics

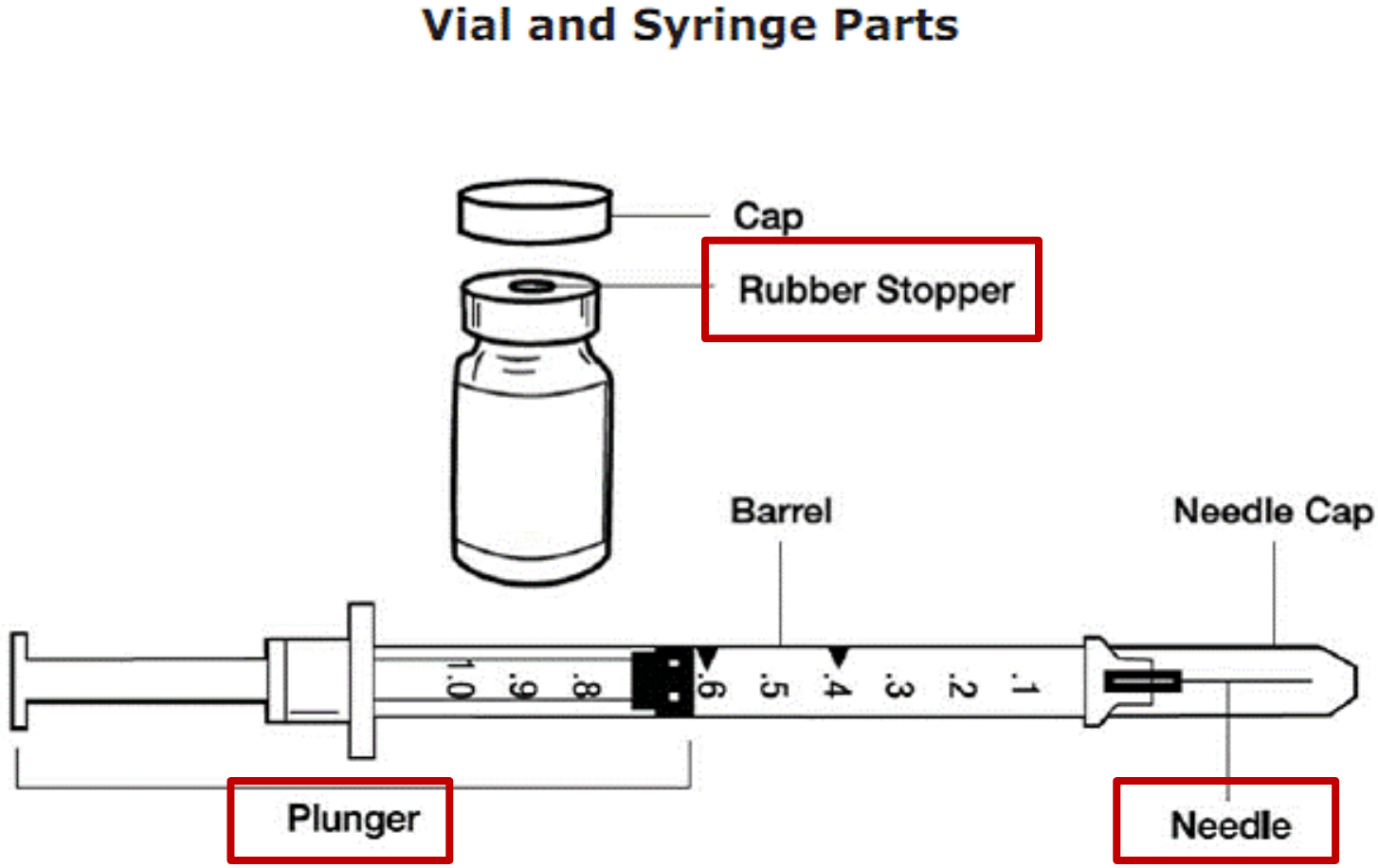
Again, noting the unique designated vaccine compounding area…items do NOT need wiped down with a disinfecting agent prior to placement on your workstation. You will not be working within a hood for preparation of vaccines.

Vial septums should be wiped with a sterile alcohol swap before EACH entry. A NEW swab should be used for every use (i.e. for every vial and between syringes).

Avoid touching **critical sites** on the vial or the syringe.

- If critical sites are compromised, re-disinfect the vial septum OR discard the needle as applicable.
- Syringes should be methodically removed from sterile packaging using the manufacturer indicated “peel” side instead of punctured through packaging.

Syringe/Vial Anatomy and Critical Sites



Including both the Hub and Shaft

https://globalrph.com/rx-list/relistor-drug/

Accurate Measurement

How to Accurately Measure in a Syringe

Used to Measure Liquids/Volume
(Choose the smallest syringe that will contain the desired volume for measurement). The least measurable quantity a syringe can measure is 20% of its capacity.

- Puncture the needle into the vial septum and INVERT. Ensure the tip is fully submerged in the liquid.
- Slowly PULL BACK THE PLUNGER to the desired volume.
- READ the final volume by aligning the **widest portion of the plunger** (i.e. NOT the domed tip) with the desired graduation mark.
- Remove syringe from the vial

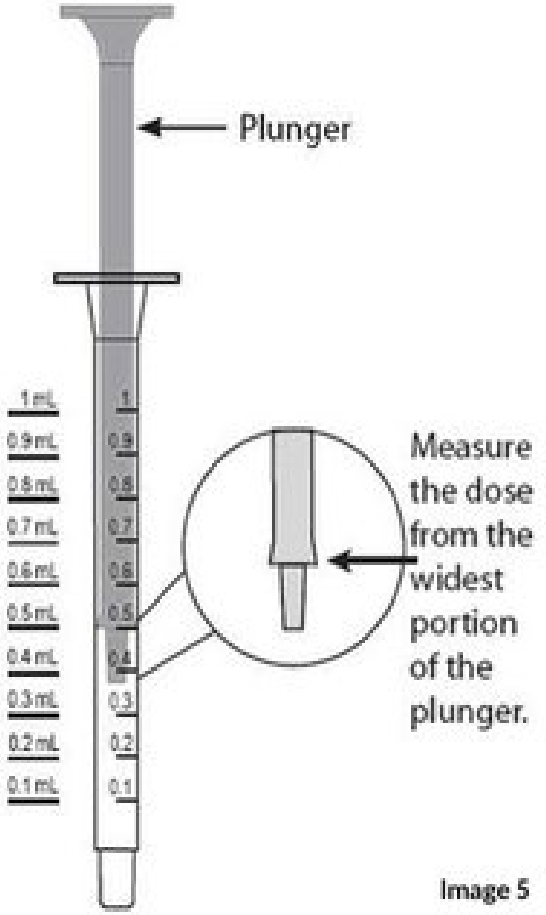


Image 5

https://withdrawal.theinnercompass.org/taper/using-syringes

How to Accurately Measure in a Syringe: Application to COVID 19 Vaccine Clinics

Vaccine Clinics Stock 2 Syringe Sizes:

- 1 mL Syringes for **vaccine doses** (accurately measure to 0.05 mL for volumes > 0.2 mL)
- 3 mL Syringes for **drawing up diluent** (accurately measure to 0.05 mL for volumes > 0.6 mL)

Preparation of COVID 19 Vaccines

Pfizer	Moderna	Johnson and Johnson
• Must be inverted 10x BEFORE reconstitution • Reconstitute with 1.8 mL NS • Release pressure by drawing out 2.1 mL air • Invert vial 10 x to gently mix • Draw up 0.3 mL for each dose	• No reconstitution or dilution required • Gently swirl vial in upright position before withdrawing dose • Draw up 0.5 mL for each dose	• No reconstitution or dilution required • Gently swirl vial in upright position before withdrawing dose • Draw up 0.5 mL for each dose

Labeling, Beyond Use Dating, Storage

Definitions

Expiration Date: An **expiration** date reflects the stability of the product as prepared by the manufacturer

Beyond Use Date: The beyond-use date (**BUD**) is the last date that a product can be safely used after it has been altered for patient use. BUDs for sterile compounding are based on:

1) POTENTIAL FOR MICROBIAL GROWTH
2) PACKAGING
3) STORAGE CONDITIONS (e.g. temperature, and exposure to light).

USP Chapter 797. 2008.

Labeling, BUDs and Storage: Application to COVID 19 Vaccine Clinics

All vials AND pre-drawn syringe doses should be labeled before leaving the compounder's hands. Labels should include:

- Vaccine Name
- Manufacturer LOT and Expiration
- Assigned BUD

OhioHealth vaccines are drawn up and assigned BUDs according to the manufacturer Emergency Use Authorization (EUA)

- Guidance from the Ohio Board of Pharmacy and United States Pharmacopeia state that sterility for pre-drawn COVID 19 vaccines is NOT dependent on use of ISO classified air.
- Use of manufacturer recommend BUDs requires compliance with manufacturer storage requirements.

Storage and BUD of COVID 19 Vaccines

	Pfizer	Moderna	Johnson & Johnson
Manufacturer BASELINE Storage	**"DEEP FREEZER" Storage** -80 to -60 C. May be removed to routine "FREEZER" Storage -25 to -15 C for up to 2 wks	**"FREEZER" Storage** - 25 to -15 C	"**FRIDGE" Storage** 2 to 8 C for 90 days
REMOVAL From Baseline Storage	"FRIDGE" Storage 2 to 8 C for 5 Days OR "ROOM TEMP" Storage < 25 C for 2 hours.	"FRIDGE" Storage 2 to 8 C for 30 Days	N/A
Vial BUD After Dilution	6 Hours room temperature from time of initial puncture	N/A	N/A
Syringe BUD For Drawn Up Dose	6 Hours room Temperature OR Fridge Storage from time of initial puncture	6 Hours room Temperature OR Fridge Storage from time of initial puncture	2 Hours room Temperature OR 6 Hours Fridge Storage from time of initial puncture

Next Steps

- Post-Test

- The final step to completion of this module is to get signed off in the clinic on the following:
  - Proper hand hygiene in the vaccine clinic
  - Drawing up vaccine doses in the vaccine clinic

- Clinic Lead will sign you off
- Form must be emailed/scanned to Laura Duvall, Pharmacy Learning Coordinator, within 1 week of beginning work onsite in the clinic
- CE for the course will be released within 30 days of receipt of the form
- No CE will be awarded if the form is not received within 30 days

Questions?

Elizabeth.Dallman@OhioHealth.com
Laura.Duvall@OhioHealth.com