CORONAVIRUS DISEASE 2019 (COVID-19)

TH COVID 19 Vaccine Clinics: Pharmacy Best Practices



Audience: COVID-19 Vaccine Task Force

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What's Changed: On 01/19/2021, the USP clarified that Pfizer and Moderna COVID-19 vaccines, when prepared outside of an IV Room / Clean Room environment – for example in a clinic – when using proper aseptic technique, may extend the Beyond Use Dating (BUD) from 1 hour to a full 6 hours. <u>See this USP information.</u>

Purpose

To establish the best practices related to Pharmacy's support for both large COVID-19 vaccination clinics (high throughput) and smaller scale clinics (ie: ambulatory office practice clinics, etc). This document builds upon the current TH COVID19 Vaccine Storage and Handling SOP found in the vaccine guidebook. The term "pharmacy colleagues" is used throughout to represent pharmacists, pharmacy technicians, pharmacy interns, pharmacy students and any other pharmacy colleagues that the Director of Pharmacy at the Health Ministry deems appropriate for the given task based on licensure, registration, competency and other state and or local rules / directives.

Procedures

- 1. Large Scale COVID-19 Vaccination Clinics
 - a. Pharmacy colleagues should be present and participate in all large-scale vaccination clinics for the purposes of oversight and accountability for the security, storage and safe handling of the vaccine throughout the clinic.
 - b. Pharmacy colleagues should be utilized to transport vaccine to the clinic and to ensure the proper count of vaccine at the beginning of the clinic as well as to validate the proper temperature was maintained during transport as well as during the clinic and complete the necessary documentation.
 - c. Pharmacy colleagues should be utilized to dilute the Pfizer vaccine as noted in the EUA documents. Note: Moderna vaccine does NOT require dilution.

- d. Pharmacy colleagues should ensure adequate thawing times of frozen vaccine prior to administration.
- e. To ensure high-volume throughput, pharmacy colleagues may be utilized to pre-draw / pre-fill syringes of vaccine in a "just in time" manner to support the multiple vaccinators within the clinic. This will also require the labeling of each syringe with the name of the vaccine, lot number, expiration date and beyond use time of 6 hours following being drawn up date (BUD) for the vaccine. The use of preprinted labels is encouraged. Note: USP as of 1/19/2021 has clarified the BUD for both the Pfizer and Moderna vaccines prepared with proper aseptic technique outside of an IV clean room are allowed a 6-hour BUD. Due to the short 6-hour BUD, careful planning will be necessary as to NOT "over prepare" doses.
- f. As the end of the clinic approaches, pharmacy colleagues should be mindful of prepared vaccine supply. This may include coordinating with the vaccinators to minimize wasting doses and employing "standby" lists to ensure all prepared vaccine is utilized and NOT wasted.
- g. At the end of the clinic, pharmacy colleagues should be responsible for the accounting and documentation of the vaccine vials / doses that have been used, wasted or are being returned to the pharmacy.
- Pharmacy colleagues should be responsible for the transportation of all unused vaccine to the pharmacy and for transfer of supply to the pharmacy and note any possible BUD for any remaining vaccine – such that the pharmacy will have adequate information for redispensing if necessary.
- 2. Smaller Scale Vaccine Clinics
 - a. Pharmacy colleagues will likely not be able to participate in person during all smaller scale vaccine clinics. However, they should have oversight and should educate and train the vaccine clinic providers / vaccinators as to the following:
 - i. Storage and handling of COVID-19 vaccines
 - ii. Dilution of Pfizer vaccine
 - iii. Dosage of the Pfizer vaccine (0.3 ml) and of the Moderna vaccine (0.5 ml).
 - iv. Thawing process and times from freezer if necessary as well as the BUD dating once at refrigerator temperatures as well as room temperature (see table below)
 - v. Documentation of all doses being administered and wasted
 - b. Pharmacy colleagues will serve as a reference to the smaller scale vaccine clinics. Their contact number for emergency questions should be posted and available for all clinic staff to ask questions and express concerns.
 - c. Pharmacy colleagues should consider periodic auditing/ observation of the clinic colleagues to ensure that the above is done properly
 - d. The pharmacy colleagues should work in coordination with clinic staff regarding the transport / transfer of vaccine to and from these clinics.
- 3. Anaphylaxis Kit Support and Vaccine Side Effect Management Kit Support in Vaccination Clinics
 - a. Pharmacy colleagues will supply the clinics with a minimum of three anaphylaxis kits and side effect management kits / vaccine clinic.
 - b. Each anaphylaxis kit will contain epinephrine either as an autoinjector preferred (ie: EPIpen) or a "kit" with epinephrine injections and the supplies needed to administer up to two IM injections. (see the appendix for examples of epinephrine injection kit contents and dosing card).



- c. Each vaccine side effect management kit will contain medications as noted in the vaccine side effect management guidance document.
- d. Pharmacy and the vaccine clinic leader will coordinate the process by which, when used, a replacement anaphylaxis kit and vaccine side effect management kit will be promptly resupplied.

Vaccine & Manufacturer	Distribution	Ultra-cold Freezer (-80 to -60°C)	Freezer (-20°C)	Refrigerator (2-8°C)	Room Temperature (20- 25°C)
Pfizer & BioNTech	-60 to -80°C; Direct from Pfizer	6 months in ultra- low temperature freezer; 30 days in dry ice thermal shipper	N/A	5 days	6 hours after dilution
Moderna	-20°C; McKesson Wholesaler	N/A	6 months	30 days	12 hours total; 6 hours after vial puncture

