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 **Dayton MMRS GMVEMSC**

**EMS Agency COVID-19 Mobile Vaccination Teams (MVTs)**

**in Montgomery County**

Overview

This document provides a safe and effective process for COVID-19 Vaccination Programs by EMS Agencies in Montgomery County. It incorporates recommendations from the CDC and local health departments. EMS agencies providing vaccines will be referred to as Mobile Vaccination Team(s) (MVTs), whether providing vaccines at a fixed location (e.g., a station, church, or other public facility) or at different sites (e.g., homes of homebound individuals).

Depending on the vaccine used, be sure to follow the brand-specific EUA for Providers, and provide patients with the brand-specific EUA for Recipients and Caregivers.

EMS agencies providing an MVT may do so at their stations, at other locations (e.g., a city hall), or as mobile teams visiting locations such as residences, shelters, etc.

Public Health – Dayton & Montgomery County (PHDMC) Responsibilities including Documentation

* “PHDA Vax” (a PHDMC database) will be used to track vaccinations and upload data to the state.
* Will transport thawed vaccine (punctured or unpunctured vials or filled syringes as appropriate) to and from the pre-arranged time and location with an employee or contract employee. Said employee need not be medically trained since EMS personnel will administer the vaccines.
* Will transport the vaccine in an appropriate container.
* If vaccinating at multiple locations (e.g., homebound persons), PHDMC employee will accompany EMS to each location.
* Will follow storage and handling best practices to include maintaining vaccine cold-chain custody.
* In addition to vaccine, PHDMC will provide needed supplies that are part of the vaccine packs to include needles, syringes, gloves, sharps containers, copies of EUA Fact Sheets, V-safe Information Sheets, and CDC COVID-19 Vaccination Record Cards, etc.
* Will record time of first puncture of vials and ensure vaccine is not administered beyond permitted timeframe. Vials may not be placed back in refrigeration after vaccine is brought to room temperature)
* Will record time and min/max temperatures:
	+ At the start of transport
	+ Whenever the transport container is opened
	+ When transport concludes
* Will provide the “EUA Fact Sheet for Recipients and Caregivers” to each person or caregiver prior to giving the vaccine, including any needed multi-lingual materials.
* Will document or assist EMS with completing vaccination documentation in a system that submits data to the Ohio Impact Statewide Immunization Information System (ImpactSIIS)
* Both EMS and PHDMC will ensure that vaccine given matches the Lot Number and brand in the PHDA system for that patient.
* Both EMS and PHDMC are responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS): vaccine administration errors whether or not associated with an adverse event, serious adverse events (irrespective of attribution to vaccination), cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death.
	+ Submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>
* Provide a CDC COVID-19 Vaccination Record Card to the recipient or their caregiver with the name (brand) of the vaccine and date of administration to document vaccination.
* Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe.

EMS Agency Responsibilities

* EMS will coordinate with PHDMC for a time to give vaccines, and provide PHDMC with the approximate number of vaccine doses and the brand needed, by contacting Tracy Clare at tclare@phdmc.org or 937-225-5713.
* EMS will notify PHDMC as much in advance as possible.  Earlier notice assists the health department and increases the likelihood that vaccine and PHDMC employees will be available at the times needed.
* EMS will, as feasible, encourage people to complete vaccine registration in advance at <https://bit.ly/PHDMC-POD-signup> or with the QR code to the right.
* When moving from site to site (e.g., residences of homebound individuals) EMS agencies should advise the patients that EMS will arrive within a two-hour window, so that the patients know to be available.
* Complete any other documentation required by the EMS agency or PHDMC
* Each paramedic or AEMT who will perform injections of a COVID vaccine will need to create a digital signature in PHDA. For EMS who have not already established their digital signature, this takes only a couple of minutes, and will be done at the time PHDMC arrives on site. This may be done over the phone as well. EMS personnel who have vaccinated at PHDMC PODs will already have a digital signature in the system.

Training

* All participating EMS personnel must have completed the vaccination training at [www.gmvemsc.org](http://www.gmvemsc.org) and any other training required by PHDMC
* All participating EMS personnel must have thoroughly reviewed the Just in Time Standing Order (JITSO) and the EUA for Providers for the brand(s) of vaccine to be administered.
* Only personnel who have completed the above training and review, who are certified at the Advanced EMT or Paramedic level, and who are current on GMVEMSC Standing Orders may administer vaccine.
* EMTs or EMRs may assist with documentation and patient monitoring.
* Summary of clinical considerations of three vaccine brands: <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>

Operations

The JITSO for the vaccine provided to the EMS Agency is incorporated as a component of this plan. All aspects of the JITSO must be followed, as well as the items below:

* Use only on age group specified for the brand of vaccine
* Vaccinate all eligible unvaccinated persons at a location as long as vaccine is available. For example, if vaccinating a homebound individual, offer vaccine to friends, relatives, caregivers, maintenance personnel, etc.
* Have appropriate medical treatment to manage immediate allergic reactions available in the event an acute adverse or anaphylactic reaction occurs
* Coordinate with PHDMC regarding any “left over usable vaccine”
* Discard vaccine if not used within allotted times according to PHDMC procedures.
* Follow all Warnings and Precautions in the EUA.

Vaccine Administration

* Ensure that each patient receives the EUA Fact Sheet prior to vaccinating
* Review the Pre-vaccination Checklist for COVID-19 Vaccines (using the most current version of the form, and appropriate language) **and check for contraindications in each individual.**
	+ Contraindications: Do not administer the vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine (see Full EUA Prescribing Information), or to individuals with other contraindications.
* Offer the patient the opportunity to ask any questions both before and after vaccination.
* Both EMS and PHDMC will ensure that vaccine given matches the Lot Number and brand in the PHDA system for that patient.
* Use aseptic technique and carefully select correct injection site
* **Use proper landmarks and technique to identify the deltoid injection site.** Aspiration is not recommended when administering vaccines
* Use proper needle length for age and size of patient
* Monitor COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the CDC guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).
	+ 30 minutes:
		- People with a history of an immediate allergic reaction of any severity to another vaccine or injectable therapy.
		- People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine should be observed for 30 minutes following Janssen vaccination).
		- People with a history of anaphylaxis due to any cause.
	+ 15 minutes: All other persons
* Consider performing a home safety inspection (smoke detectors, CO detectors, fall risks, etc.) during the 15- or 30-minute waiting period.
* Provide a CDC COVID-19 Vaccination Record Card to the recipient or their caregiver with the name (brand) of the vaccine, Lot Number, and date of administration to document vaccination.
* If administering the first dose of a vaccine which requires two doses, explain that to the patient, and provide the patient with information on how to schedule the second dose.
* Provide the V-safe Information Sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.
* Complete any other documentation required by the EMS agency or PHDMC.

Suggested Equipment Inventory for MVT

* Portable Radio
* 2 – Alcohol-Based Hand Cleaners (15 oz.)
* Sharps Containers
* Surgical Masks or N95 Respirators
* Oxygen and administration equipment
* GMVEMSC Drug Box, preferably ALS for Benadryl, etc., but at least a BLS Drug Bag for Epi-Pens
* Monitor/Defibrillator or AED
* First In Bag
* IV supplies recommended, but not required

Approved:

William R. Marriott, MD

Dayton MMRS/ Health Department \_\_\_\_\_\_\_ \_\_ (agency)

GMVEMSC Medical Director Medical Director

Medical Director

Date: Date: Date:

Appendix A: Janssen Johnson & Johnson COVID-19 Vaccine for MVTs

The Janssen vaccine may be preferred for use by EMS MVTs, since it does not require EMS to make additional trips for second doses, and temperature monitoring requirements are less stringent.

**Storage Prior to First Puncture of the Vaccine Vial**

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 36°F to 46°F and protect from light. Do not store frozen.

Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 47°F to 77°F for up to 12 hours.

**Storage After First Puncture of the Vaccine Vial**

After the first dose has been withdrawn, hold the vial between 36° to 46°F for up to 6 hours or at room temperature (maximally 77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

* The Janssen COVID-19 Vaccine does not contain a preservative. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. After the first dose has been withdrawn, hold the vial between 36° to 46°F for up to 6 hours or at room temperature (maximally 77°F for up to 2 hours. Discard if vaccine is not used within these times.

**Administration**

* The Janssen COVID-19 Vaccine is administered intramuscularly as a single dose (0.5 mL).
* Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by **swirling gently** in an upright position for 10 seconds. **Do not shake.**
* Each dose is 0.5 mL. Each vial contains five doses. **Do not pool excess vaccine from multiple vials, and do not withdraw more than five doses. Either would be considered a medication error.**
* **Contraindications: Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine (see JITSO and Full EUA Prescribing Information).**
* Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. During the visual inspection,
	+ visually inspect the vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exists, do not administer the vaccine.
	+ verify the final dosing volume of 0.5 mL.
	+ confirm there are no particulates and that no discoloration is observed.
	+ do not administer if vaccine is discolored or contains particulate matter.
* Use aseptic technique and carefully select correct injection site
* Administer the Janssen COVID-19 Vaccine intramuscularly in the deltoid muscle

Appendix B: Pfizer COVID-19 Vaccine for MVTs

* Thaw and then store undiluted vials in the refrigerator (35ºF to 46ºF) for up to 31 days
* Thawed at room temperature for immediate use, thaw undiluted vials at room temperature (up to 77ºF) for 30 minutes.
* Thawed vials can be handled in room light conditions.
* Vials must reach room temperature before dilution.
* **Undiluted vials may be stored at room temperature for no more than 2 hours.**

**Transportation of Thawed Vials**

* Available data support transportation of one or more thawed vials at 35°F to 46°F for up to 12 hours. Any hours used for transport at 35°F to 46°F count against the 120-hour limit for storage at 35°F to 46°F.

**Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.**

* Undiluted vials may be stored at room temperature for no more than 2 hours.
* After dilution, store vials between 35°F to 77°F and use within 6 hours from the time of dilution.
* After dilution, store vials between 35°F to 77°F and use within 6 hours from the time of dilution.
* During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
* Any vaccine remaining in vials must be discarded after 6 hours.
* Do not refreeze.
* Vials must reach room temperature before dilution.
* **Before dilution** invert vaccine vial ***gently*** 10 times.
* ***Do not shake.***
* Inspect the liquid in the vial prior to dilution. The liquid is a white to off- white suspension
* Do not use if liquid is discolored or contains particulate matter.
* Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (provided) to form the Pfizer-BioNTech COVID-19 Vaccine. **ONLY** use 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. **Do not add more than 1.8 mL of diluent.**
* Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
* Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
* Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
* ***Gently invert*** the vial containing the Pfizer-BioNTech COVID-19 Vaccine and diluent 10 times to mix.
* ***Do not shake.***
* Inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
* After dilution, one vial contains 6 doses of 0.3 mL.
* Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.
* Discard any unused vaccine 6 hours after dilution.

**PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE**

* Use a new, sterile needle and syringe for each injection. Use low dead-volume syringes/ needles to extract 6 doses from a single vial. If sufficient low-dead volume syringes are not available, withdraw vaccine using a combination of low dead-volume syringes and non-low dead-volume syringes per vial (e.g., 4 low dead-volume syringes and 2 non-low dead-volume syringes).
* Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.3 mL of mixed vaccine into the syringe.
* Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.3 mL. If the amount of vaccine remaining in the vial cannot provide a full 0.3 mL dose, discard the vial and contents.
* Do NOT combine vaccine from multiple vials to obtain a dose.
* Remove any significant air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle\* to withdraw and administer the vaccine. Ensure the prepared syringe is not cold to the touch.
* If the number of doses does not match what is expected, be sure to document that so that PHDMC can account for it. For example, if only five doses are able to be drawn from a vial of Pfizer instead of six, make note of that, and make PHDMC aware.
* **Do not pool excess vaccine from multiple vials.**
* **Contraindications: Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine (see GMVEMSC JITSO and Full EUA Prescribing Information).**

Appendix C: Moderna COVID-19 Vaccine for MVTs

* **After thawing, do not refreeze.**
* **Swirl vial gently after thawing and between each withdrawal. Do not shake. Do not dilute the vaccine.**
* The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
* The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
	+ A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
	+ A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
* Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial.
* Irrespective of the type of syringe and needle:
	+ Each dose must contain 0.5 mL of vaccine.
	+ If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents.
	+ Do not pool excess vaccine from multiple vials.
	+ Pierce the stopper at a different site each time, or use a single needle to fill syringes.
* After the first dose has been withdrawn, the vial should be held between 36° to 77°F.
* Record the date and time of first use on the Moderna COVID-19 Vaccine vial label.
* **Discard vial after 12 hours. Do not refreeze.**

**Administration**

* Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates.
* During the visual inspection,
	+ verify the final dosing volume of 0.5 mL.
	+ confirm there are no other particulates and that no discoloration is observed.
	+ do not administer if vaccine is discolored or contains other particulate matter.
* Administer the Moderna COVID-19 Vaccine intramuscularly.
* **CONTRAINDICATION: Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine (see Full EUA Prescribing Information).**
* Vials may be stored refrigerated between 36° to 46°F for up to 30 days prior to first use. Do not refreeze.
* **Vials may be stored between 46° to 77°F for a total of 24 hours.** After the first dose has been withdrawn, the vial should be held between 36° to 77°F.
* **Vials should be discarded 12 hours after the first puncture.**
* Thawed vials can be handled in room light conditions.
* Do not refreeze once thawed.

**Transportation of Thawed Vials at 35°F to 46°F**

* If transport at -58° to 5°F is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 35° to 46°F when shipped using shipping containers which have been qualified to maintain 35° to 46°F and under routine road and air transport conditions with shaking and vibration minimized.
* Once thawed and transported at 35° to 46°F, vials should not be refrozen and should be stored at 35° to 46°F until use within 12 hours.

Appendix D: Acronyms

CDC Centers for Disease Control and Prevention

EMS Emergency Medical Services

EMT Emergency Medical Technician

EUA Emergency Use Authorization

GDAFDMAA Greater Dayton Area Fire Departments’ Mutual Aid Agreement

GMVEMSC Greater Miami Valley EMS Council

JITSO Just in Time Standing Orders

LHD Local Health Department

MMRS Dayton Metropolitan Medical Response System

MVT Mobile Vaccination Team(s)

ODH Ohio Department of Health

PHDMC Public Health-Dayton and Montgomery County

PPE Personal Protective Equipment

RPAB Regional Physicians Advisory Board

SOP Standard Operating Procedures