#### Vaccine Management and Administration

Replaces:Vaccine Storage & Handling (11-12-14) & Boston EMS Vaccinator ProgramEffective:09-26-2022

#### PURPOSE

To support the health and wellness of personnel and members of the community, Boston EMS has instituted a vaccinator program, overseen by the department's Medical Director and Designated Infection Control Office (DICO) team. The program, as outlined in this policy, includes the safe receipt, handling, storage, and administration of vaccines. Currently, Boston EMS EMTs are authorized to administer both COVID-19 and Influenza vaccines. Personnel certified as paramedics have authorization to administer COVID-19, Influenza, and additional vaccines, as approved by the Department of Public Health and Boston EMS Medical Director. This document will be reviewed and updated annually, when vaccine management policies change, and when staff with designated vaccine management responsibilities change.

#### BACKGROUND

Both EMTs and Paramedics have state approval to administer COVID-19 and Influenza vaccines through the Massachusetts Department of Public Health's authorization granted by the Commissioner's Order, pursuant to the Department's Drug Control Program (DCP) regulations, 105 CMR 700.004(H). Boston EMS members with paramedic certification have additional authorization to administer certain vaccines through an approved Community EMS Program, as outlined in 105 CMR 173.000, and authorized by 105 CMR 700.003(A)(4) of the DCP regulations.

#### SECTION 1: ADMINISTRATIVE CONSIDERATIONS

- 1.1 Roles and Responsibilities: Medical Director and Vaccine Coordinator
- A. The Boston EMS Medical Director or their designee shall fulfill the role of Medical Director.
- B. Members of the Boston EMS Designated Infection Control Officer team will be identified as the Primary and back up Vaccine Coordinators. They are responsible for managing vaccine supply and records, as described in this plan. Both should be equally knowledgeable about vaccine management and the backup should be capable of fulfilling all vaccine storage and handling requirements when the primary Vaccine Coordinator is absent.
- C. The Boston EMS Medical Director or designee will serve as the Vaccine Clinic Medical Lead at all Boston EMS vaccination clinics to oversee vaccine management and administration, providing clinical advice and consultation as appropriate.

#### SECTION 2: VACCINE HANDLING

#### 2.1 Vaccine Storage & Handling

- A. Two refrigerators or more, designated for vaccine storage will be maintained at Boston EMS headquarters. One will be designated as the primary vaccine storage refrigerator and the second refrigerator will be designated for vaccine distribution.
- B. One freezer designated for vaccine storage will be maintained at the Boston EMS headquarters.
- C. Freezer and refrigerators will be housed in secure, access-restricted locations.
- D. Freezer and refrigerators will be used *solely* for the storage of vaccines. No other food, specimens or any other substance will be stored in the designated vaccine refrigerators.
- E. Refrigerated vaccines will be stored within the temperature range of 2° C to 8°
  C, or as otherwise specified by the vaccine manufacturer.
- F. Frozen vaccines will be stored within the temperature range of -15 C to -50 C, or as otherwise specified by the vaccine manufacturer.
- G. Diluent is not to be stored in the freezer. Diluent may be stored at refrigerated or room temperature, or as otherwise specified by the manufacturer.
- H. Nothing shall be stored on top of the freezer or refrigerators to avoid an object preventing the door from completely closing, other than designated paper temperature logs and digital thermometers.
- I. The vaccine stock will be rotated on a routine basis to ensure short-dated vaccine is used first.
- J. If state-supplied vaccine is acquired at any time, it will be clearly marked to differentiate it from other purchased vaccine.
- K. A digital data logger probe will be kept in each refrigerator/freezer and will be located in a central area of the refrigerator adjacent to the vaccine.
- L. All vaccines will be stored centrally in the refrigerator, and away from walls to allow for proper air circulation. There should be sufficient space between rows of vaccine boxes or bins and shelving units to allow proper air circulation. The refrigerators should not be overcrowded, especially during flu season.
- M. Materials to prepare a cooler will be stored near the vaccine, in case the need arises to transport vaccine during an emergency.
- N. A "DO NOT UNPLUG" sign will be posted next to the electrical outlet for all vaccine storage units and a "DO NOT DISCONNECT" sign will be posted next to the circuit for any vaccine storage units on the circuit breaker.
- O. All vaccine storage units will be plugged directly into a wall outlet. Never plug storage units into power strips, surge protectors or use extension cords. Never plug storage units into Ground Fault Circuit Interrupter outlets (GFC).

- P. All primary vaccine storage units will be plugged into circuits that are connected to the backup generator such that in the event of a power failure, their power will be maintained by the generator.
- Q. The Boston EMS Facilities Director will be made aware of the presence of vaccine storage refrigerator/freezers
- 2.2 Temperature Monitoring
  - A. All monitoring and temperature documentation will be performed using a digital data logger only. The digital data logger will have a calibrated glycol-encased probe and be certified by an appropriate agency, such as the National Institute of Standards and Technology.
  - B. When vaccine is being stored in the freezer or refrigerator, minimum and maximum temperatures will be checked and recorded each workday.
  - C. If a reading is missed, leave a blank entry in the log.
- 2.3 Vaccine Receiving
  - A. Staff receiving shipments will notify the Primary Vaccine Coordinator or backup as soon as a vaccine shipment arrives.
  - B. All shipping containers must be opened immediately upon arrival.
  - C. The recipient will check the cold chain monitors to make sure the temperature stayed within appropriate range during transport.
  - D. If there are any concerns or inaccuracies with the vaccine order or cold chain monitors, the Vaccine Manager or designee will contact the MDPH Vaccine Management Unit at (617) 983-6828 for guidance if the vaccine is from MDPH. Otherwise, the Vaccine Manager will contact suggested vaccine guidance contact for the product.
  - E. For those shipments sent from McKesson, the transit temperature monitors must be checked. If temperature monitors indicate a possible temperature variation, the Primary Vaccine Coordinator will contact McKesson Specialty at (877) 822-7746 by the end of the day.
  - F. For direct ship vaccines from Merck, the shipment date located on the packing list must be checked, as must the shipper insert, supplied in the box. If date received is greater than the shipper insert indicates, contact Merck Order Management Center before the end of the day of receipt at 800-637-8579.
  - G. Upon arrival, receivers must count vaccines in shipment and compare with packing list and original order to ensure the order and delivery is correct. They must also check to ensure that expiration dates and lot numbers match and that diluent is accounted for.
  - H. Immediately after inventory is complete, vaccine must be placed in the designated vaccine refrigerator or freezer, according to vaccine manufacturer guidelines.

- I. If there are any concerns or inaccuracies with the vaccine order, the Medical Director/Primary Vaccine Coordinator must be notified immediately.
- 2.3 Vaccine Transportation Procedures
  - A. The Medical Director or Vaccine Coordinator must approve the transportation of any vaccine outside of the storage and distribution refrigerators at Boston EMS headquarters.
  - B. When being transported, vaccines must be contained in appropriate packing containers and materials (e.g., frozen and refrigerated gel packs, bubble wrap) or 'packout' container to avoid breakage or deviations from acceptable temperatures. The department also has VariCoolers specific for vaccine transport and can be utilized.
  - C. If not utilizing VariCooler, refrigerated gel packs must be placed in the container used to transport refrigerated vaccines. Separate the vaccine from the cold packs with cardboard and /or bubble wrap.
  - D. A temperature colormetric monitor or digital data logger will be used in transport. Place the glycol bottle in each packing container near the vaccine to monitor the temperatures. Ensure that the cord of the glycol container is attached to the digital data logger.
  - E. Record the time and temperature when vaccine was removed from the storage units and placed in the containers at the beginning and end of the transport
- 2.4 State Provided Vaccine Ordering and Inventory Control In general, Boston EMS will not be the primary recipient of State provided vaccine. The below is to address the atypical situation when that might occur. If Boston EMS receives vaccine via BPHC, the department will follow directions from the BPHC Infectious Disease Bureau.
  - A. For state-provided vaccines, all orders will be placed through the MIIS Vaccine Management Module. When utilizing the module, the person placing the order must upload the most recent temperature logs for all vaccine storage units within one day of submitting order.
  - B. The Vaccine Coordinator or his/her designee will be responsible for reporting temperature log information into MIIS.
  - C. Complete a physical inventory of all vaccines in the refrigerator(s) and freezer(s), checking expiration dates at least monthly and before placing an order.
  - D. The MDPH Vaccine Management Unit must be contacted to update any changes in shipping address. Changes to shipping hours or shipping contact can be updated directly into the MIIS. Vaccines will be delivered directly to the provider's office based on shipping information in the MIIS.

- 2.5 Privately Ordered Vaccine and Inventory Control
  - A. Non-state provided vaccines will be ordered at the discretion of the Medical Director and Vaccine Coordinator in conjunction with Boston EMS department leadership on an as-needed basis.
- 2.6 Temperature Out of Range
  - A. Upon discovery of an out-of-range temperature, the exposed vaccine must be maintained at proper temperature and marked 'Do Not Use'.
  - B. Any out-of-range temperature must be reported immediately to the Medical Director or Primary Vaccine Coordinator and the vaccine coordinator who will determine whether that vaccine may be used.
  - C. Any vaccine left out of a storage unit must be marked 'Do Not Use,' and returned to the refrigerator; subsequently the Medical Director or Primary Vaccine Coordinator or Primary Vaccine Coordinator should be notified.
  - D. Any vaccine determined to be damaged should be removed from the refrigerator and the Medical Director or Primary Vaccine Coordinator should be notified.
  - E. In the event of a temperature excursion, the Primary Vaccine Coordinator will be contacted. The Primary Vaccine Coordinator will immediately contact MDPH Vaccine Management Unit at 617-983-6828 as well as the vaccine manufacturer to determine if any vaccines have been damaged, the digital data logger data will be downloaded.
- 2.7 Power Failure/Refrigerator or Freezer Failure
  - A. A "Do Not Unplug" sign is posted next to the refrigerator power outlet. In the event of an extended building power failure or refrigerator failure, the Primary Vaccine Coordinate must be notified immediately. Vaccines will be packed in designated cooler (VariCooler) or 'packout' and transported to Materials Management or another available refrigerator, including the digital data logger

#### 2.8 Documentation

- A. Materials Management will also keep packing slips received in shipments from all manufacturers.
- B. Temperature logs will be maintained for a minimum of 3 years.
- C. The appropriate Vaccine Information Statement (VIS) will be offered to every patient with each dose of vaccine administered.
- D. The Medical Director will subscribe to the CDC's e-mail update for VIS at: www.cdc.gov/vaccines/hcp/vis/index.html.
- E. The Medical Director or his/her designee will report all relevant required information to MIIS as required by Massachusetts state regulation as indicated for any state supplied vaccine.

## 2.9 Compliance

A. The Primary Vaccine Coordinator and the Backup Vaccine Coordinator will participate in a vaccine related educational activity each year. Certificates of completion must be kept on file.

# 3. EDUCATION

- 3.1 Initial education protocols
  - A. All Boston EMS personnel wishing to serve as vaccinators will be required to complete online training and in-person practical skills training by the Medical Director or his/her designee, which will cover vaccine administration rationale, operating procedures, clinical techniques, contraindications, and documentation requirements.

# 3.2 Testing

- A. Testing will be provided as part of the online training and graded with 70% pass rate.
- 3.3 Refresher Training
  - A. All vaccinator candidates will be required to undergo an annual refresher training for the vaccination program. Prior to vaccinating that year.
- 3.4 Maintenance of list of qualified vaccinators
  - A. The vaccine coordinator and his/her designees will maintain a list of all vaccinators with up-to-date qualifications. This list will be updated annually.

# 4.0 DEPLOYMENT

- 4.1 Scheduling vaccinators
  - A. All qualified Boston EMS personnel who have undergone the appropriate training, will be included on a list of vaccinators. Department personnel whose responsibilities include staffing overtime and details will keep this list.
- 4.2 Internal Vaccination Events
  - A. Boston EMS vaccinators may be deployed at the request of the Medical Director or Primary Vaccine Coordinator to support department vaccinations and PPD placement as appropriate for infectious disease control and prevention.
  - B. Internal vaccine events, whether administered at a single clinic site or in the field, will be held for all three shifts to ensure adequate coverage of all members requiring vaccination.

- C. Boston EMS will maintain internal records of all vaccine administered and PPD skin test placed. The Medical Director or his/her designee will be responsible for ensuring that follow-up care (PPD reading, vaccine series completion) occurs in a timely and confidential fashion.
- D. The vaccinator is responsible for communicating who had PPD testing and vaccination.
- E. Boston EMS members are also offered the option of obtaining vaccinations at their primary care provider, outside clinic or City of Boston Occupational Health designated provider.

## 4.3 External Vaccination Events

- A. At the discretion of the Medical Direction in conjunction with the Boston Public Health Commission and the Chief of Boston EMS, Boston EMS vaccinators may be deployed to external vaccination events or PPD placements outside of its membership for infectious disease control and prevention.
- B. Logistics for external events (vaccinations, administration supplies, tables, chairs etc.) may be coordinated by Boston EMS or be the responsibility of the external agency.
- C. Provision of vaccine product and reporting to MIIS for external events will be the responsibility of the entity leading event coordination, unless already determined to be completely by Boston EMS as part of preplanning.
- D. For vaccines requiring series or administration of any care requiring specific follow-up, such as a second vaccine in a series, it will be at the discretion of Boston EMS whether this will be offered.
- E. Anyone receiving a vaccination will be informed of any guidelines regarding follow-up.
- F. For any external vaccination event, Boston EMS will endeavor to offer materials in other languages and offer translation services, as resources and personnel allow.

#### 4.4 Vaccine Deployment

A. When the date and time of a vaccine event or detail has been confirmed, the Medical Director, Vaccine Coordinator or designee will move the appropriate number of vaccine doses from the vaccine storage freezer or refrigerator to the distribution refrigerator. He/she will provide the vaccinator(s) with the vaccine nearest to its expiration date and will note the lot number of the vaccines. The vaccinator(s) will check the Temperature Monitoring Device to ensure vaccine is within range and take the anticipated number of vaccine doses required for his/her vaccination detail or event. These vaccines should not be removed until just before leaving for the detail or event.

- B. At the end of the event or detail, the vaccinator(s) will return all unused vaccines to the distribution refrigerator and discard any vaccines that have surpassed their beyond use time, as determined by the vaccine manufacturer.
- C. The vaccine coordinator or designee will be responsible to move vaccine from the distribution refrigerator to the primary storage vaccine refrigerator.

## 5.0 VACCINE ADMINISTRATION

A. All vaccines will be given as per written Standing Orders provided to all Vaccinators (See Appendix B).

## 5.1 Vaccine Screening

Prior to vaccine administration, the vaccinator will:

- A. Explain what vaccine(s) will be given, and which type(s) of injection(s) will be done.
- B. Answer questions and accommodate language or literacy barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure
- C. Confirm written or oral patient consent for vaccine as appropriate
- D. Verify the patient received the Vaccine Information Statement (VIS) for indicated vaccine(s) and has had time to read them and ask questions.
- E. Screen for contraindications.
- F. Review comfort measures and aftercare instructions with patient
- G. Identify the location of the medical protocols (e.g., immunization protocol, emergency protocol, reference material)
- H. Identify the location of epinephrine, its administration technique, and clinical situations where its use would be indicated
- I. Understand the need to report any body fluid exposure
- J. Demonstrate knowledge of proper vaccine handling, e.g., maintains vaccine at recommended temperature and protects MMR from light.

# 5.2 Vaccine Preparation

The following guidelines will be followed by any member designated to support vaccine preparation.

- A. Vaccine preparation and administration will be considered an aseptic procedure. As per Boston SOP, aseptic procedures shall be used to prevent cross contamination. This includes wearing appropriate protective barriers to contamination such as gloves and masks, and avoiding touching the hair, glasses, clothing or any other "unclean" surface or object immediately before or during treatment of the patient.
- B. When removing vaccine from the refrigerator, the storage unit's temperature must be verified to make sure it is in proper range.

- C. Check vial expiration date. Double-check vial label and contents prior to drawing up.
- D. Prepare and draw up vaccines in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed.
- E. Select the correct needle size for IM and SQ based on patient age and/or weight, site, and recommended injection technique.
- F. Maintain aseptic technique throughout, including cleaning the rubber septum (stopper) of the vial prior to piercing it.
- G. According to manufacturer guidelines, gently rotate vaccine vial and/or reconstitutes and mix using the diluent supplied, if reconstitution is required. Invert vial and draw up correct dose of vaccine. Recheck vial label.
- H. Prepare a new sterile syringe and sterile needle for each injection. Check the expiration date on the equipment (syringes and needles) if present.

# 5.3 Administering Immunizations

The Boston EMS vaccinator will take the following steps to administer vaccine:

- A. Locate anatomic landmarks specific for injections.
- B. Confirm right patient, right vaccine or diluent, right time (includes administering at the correct age, the appropriate interval, and before vaccine or diluent expires), right dosage, right route, needle length, and technique and right site.
- C. Prep the site with an alcohol wipe, using a circular motion from the center to a 2" to 3" circle, and allow alcohol to dry.
- D. Control the limb with the non-dominant hand; hold the needle an inch from the skin and insert it quickly at the appropriate angle (90° for IM or 45° for SQ).
- E. Inject vaccine using steady pressure; withdraw needle at angle of insertion.
- F. Apply gentle pressure to injection site for several seconds
- G. Properly dispose of needle and syringe in "sharps" container.
- H. Properly dispose of vaccine vials.
- 5.4 Records Procedures
  - A. Vaccinators will fully document each vaccination in the appropriate vaccine documentation system or on designated paperwork as determined by the Primary Vaccine Coordinator, including patient's name, DOB, date, lot number, manufacturer, vaccine site, VIS date, name of vaccinator, and initials.
  - B. The Vaccine Coordinator or his/her designee will be responsible for ensuring that all required information regarding vaccines is reported to the Massachusetts Immunization Information System (MIIS) as mandated by the state.
- 5.5 Contraindications

- A. If there is any suspicion that a patient has a contraindication to the vaccine or other health condition creating extenuating circumstances (for example pregnancy, immunocompromised state, previous reaction to a vaccine, etc.) consultation with the Vaccine Clinic Medical Lead will be undertaken prior to administration of vaccine.
- B. The individual being vaccinated may elect or be advised to follow up with their primary care provider prior to vaccine administration.

#### 6.0 DISPOSAL MANAGEMENT

## 6.1 Sharps Management

- A. As per Boston EMS protocol.
- 6.2 Hazardous Waste Disposal
  - A. As per Boston EMS protocol.

## 7.0 ADVERSE EVENTS

- 7.1 Emergent Adverse Reactions
  - A. Any patient sustaining an apparent emergent, life-threatening adverse effect that occurs as a result of vaccine administration will be administered emergency care, as per Boston EMS protocols appropriate to the reaction, and will be transported to the nearest appropriate emergency facility.

# 7.2 Non-Emergent Adverse Reactions

- A. Any non-emergency adverse reaction, in which patient declines immediate medical care, will be reported to the Medical Director and the Vaccine Coordinator within 8 hours of the incident. Any delayed report of an adverse reaction (i.e. an adverse reaction that does not occur in the immediate vicinity of the vaccine administration) that is reported to a Vaccinator or other Boston EMS employee will be reported to the Medical Director or designee within 8 hours of the incident being reported.
- B. Any vaccination mistake, including but not limited to wrong dose, wrong vaccine, or wrong route, will be reported to the Medical Director and Vaccine Coordinator immediately.
- C. The Medical Director will be responsible for reporting any adverse reaction or vaccination mistake to the appropriate governing entities, such as the Vaccine Adverse Event Reporting System (VAERS).
- 7.3 Body Fluid Exposure
  - A. Any accidental body fluid exposure (unprotected exposure) sustained by a vaccinator will require the initiation of the same protocols instituted for all Boston EMS unprotected exposures as per existing department policies.

#### SECTION 8.0 STANDING ORDERS

8.1 A standing order for each vaccine type being administered will be signed by the Medical Director of Boston EMS or Boston Public Health Commission. A copy of the standing order will be kept at the vaccine clinic area, and all current and historical copies will be stored in a secure OneDrive folder labeled 'BEMS Vaccine Standing Orders'.

#### SECTION 9.0 OTHER PERSONNEL AS VACCINATORS

9.1 Boston EMS may also include qualified non-EMT or non-paramedic vaccinators at vaccine events. These may be Boston EMS-employed or contracted staff or volunteers. Non-EMT or non-paramedic vaccinators will receive appropriate training on vaccine management, storage and handing, and administration but are not required to complete written or practical exams. They will report to the Medical Director or designee.

Appendix A: Assessment Materials- Skills Checklist

A Skills Checklist such as the example below, or similar, will be utilized for the practical portion of the Vaccinator Program training.

Vaccinator Program Skills Sheet Evaluator: Initial next to each skill demonstrated by examinee



# PATIENT EDUCATION

SKILL	Initial
Explain which vaccines will be given	
Answer questions, accommodate language or literacy barriers/special needs	
Verify patient received Vaccine Information Statements (VIS)	
Screen for contraindications	
Review comfort measures	

# MEDICAL PROTOCOLS

Medical Protocols

SKILL	Initial
Identifies the location of standing orders, emergency protocols, reference materials	
Identifies location of epinephrine, its administration technique, and indications	
Understands the need to report any needle stick injury or body fluid exposure	
Demonstrates knowledge of proper vaccine handling (temperature, light exposure)	



Vaccine Preparation

# VACCINE PREPARATION

SKILL	Initial
Performs hand hygiene prior to preparing vaccine	
When removing vaccine from refrigerator, confirms proper storage temperature	
Checks vial expiration date and confirms contents	
Selects correct needle for IM and Sub-cut based on patient age/weight, and site	
Maintains aseptic technique throughout including cleaning rubber stopped	
Shakes vaccine vial and reconstitutes uses supplied diluent	
Inverts vial and draws up correct dose of vaccine	
Prepares new sterile syringe and needle for each injection	

# Vaccine administration

	SKILL	Initial
Vaccine Administration	Performs hand hygiene prior to vaccine administration	
	Confirm right patient, right vaccine, right route, right dose, right time	
	Positions patient and identifies injection site	
	Prepare site with alcohol	
	Hold needle at appropriate angle (90° for IM, $45^{\circ}$ for subcutaneous)	
	Injects Vaccine with Steady Pressure	
	Applies pressure to injection site then covers site	
	Properly dispose of vaccine vials and sharps	

# **Procedure Record**

	SKILL	Initial
d	Documents vaccine: name, date, lot number, manufacturer, VIS date, initials	
	Reports any adverse effects or mistakes to the appropriate authority	

# Procedure Recor

