

## Guidelines for Vaccination Clinic Operations

### Introduction

These guidelines were developed to facilitate the operation of vaccination clinics, such as annual flu clinics, school-based clinics, and vaccination clinics in response to small-scale emergencies. They do not address such issues as crowd control, security and clinic lay-out. For larger-scale clinics, please see

***Guidelines for Large-Scale Influenza Vaccination Clinic Planning*** at

[http://www.cdc.gov/flu/professionals/vaccination/vax\\_clinic.htm](http://www.cdc.gov/flu/professionals/vaccination/vax_clinic.htm), which includes these topics:

- [Leadership roles](#)
- [Human resource needs](#)
- [Vaccination clinic location](#)
- [Clinic lay-out and specifications](#)
- [Crowd management outside of the clinic](#)
- [Crowd management inside of the clinic](#)
- [Clinic security](#)
- [Clinic advertising](#)

### 1. Preparation Before the Clinic

- All personnel, including staff, contractors, and volunteers, who administer vaccines, must receive training and demonstrate competency in vaccine storage, handling, and administration, and management of adverse events. See Resources for Educating Staff at the end of this document.
- Validate staff knowledge and skills with the *Skill Checklist for Immunization* <http://www.immunize.org/catg.d/p7010.pdf>
- Use standing orders signed by an authorized prescriber for each vaccine type and for managing adverse events. Find standing orders for all routine vaccines and managing adverse events at <http://www.immunize.org/standing-orders/>.
- Ensure access to the Massachusetts Immunization Information System (MIIS). All immunizations administered in Massachusetts must be reported to the MIIS. More information can be found at <https://www.contactmiis.info/>
- Review and utilize, if applicable, *Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations* from the National Adult and Influenza Immunization Summit, which can be found at: <https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/>
- Before the beginning of the clinic, review the following with clinic staff:
  - Purpose of the clinic
  - Command or supervision structure
  - Vaccine(s) being administered
  - Indications, contraindications, and precautions
  - Correct dose and route of administration
  - Signed standing orders for vaccines to be administered and for management of managing adverse events

Massachusetts Department of Public Health  
Massachusetts Immunization Program

- All clinic screening and documentation forms
- Massachusetts Immunization Information System (MIIS) fact sheet  
<http://www.mass.gov/eohhs/docs/dph/cdc/immunization/miis-parents-patients.pdf>
- All clinic staff should also review relevant vaccine package inserts and Vaccine Information Statements (VISs) before the clinic begins.
  - Package inserts for all vaccines: <http://www.immunize.org/packageinserts/>
  - VISs: <http://www.immunize.org/vis/>
- Additional resource: *General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)*  
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

## 2. Vaccine Transport, Storage and Handling

- Ensure plans are in place for maintaining vaccine at appropriate temperatures while it is stored and throughout the clinic day.

Recommended Vaccine Storage Temperatures	
<b>Freezer</b>	
○	Between -58°F and +5°F (between -50°C and -15°C)
<b>Refrigerator</b>	
○	Between 36°F and 46°F (between 2°C and 8°C)
○	Average: 40°F (5°C)

- Ship vaccine directly to the clinic site, if possible.
- If it is necessary to transport vaccine:
  - Limit the amount of vaccine transported to only what will be needed that workday. Transport and workday should total not more than 8 hours.
  - Use a calibrated temperature monitoring device with continuous monitoring and recording capabilities during transport.
  - CDC recommends using a portable refrigerator/freezer unit for transport.
  - When packing vaccines for transport, use a barrier layer between cold packs and vaccines and place a calibrated temperature monitoring device next to the vaccines.
  - Place vaccines in an appropriate storage unit(s) at the recommended temperature range(s) immediately upon arrival at the alternate facility.
  - Read and record storage unit temperature at off-site/satellite facility a minimum of 2 times during the work day.

Massachusetts Department of Public Health  
Massachusetts Immunization Program

- CDC does not recommend keeping vaccines in a transport container unless it is a portable refrigerator or freezer unit. If vaccines must be kept in transport containers during an off-site clinic:
  - Keep container(s) closed as much as possible.
  - Place calibrated temperature monitoring device(s) (preferably with a buffered probe) as close as possible to vaccines.
  - Read and document the temperature(s) inside the container(s) at least hourly.
  - Remove only the amount of vaccine needed at one time (no more than 1 multidose vial or 10 doses) for preparation and administration by each vaccinator.
- Transporting diluents:
  - Transport diluents with the corresponding vaccines at the storage temperatures specified in the package insert.
  - In advance, refrigerate diluents stored at room temperature before transporting in the same container as refrigerated vaccines so that they will not increase temperature in the container.
  - NEVER freeze diluents, even in transport.
- Transporting varicella-containing vaccines:
  - Frozen varicella-containing vaccines should never be transported except in an emergency, with the goal of minimizing the time these vaccines are not stored between -50°C and -15°C.
  - If it is absolutely necessary to transport varicella-containing vaccines:
    - Use a portable freezer that maintains the temperature between -58°F and +5°F (-50°C and -15°C).
    - Do NOT use dry ice to transport varicella-containing vaccines.
    - Varicella-containing vaccines that have not been reconstituted may be transported at refrigerated temperatures between 36°F and 46°F (2°C and 8°C), for up to 72 continuous hours prior to reconstitution. You MUST contact the vaccine manufacturer for guidance upon arrival at the off-site facility.
- Follow vaccine storage and handling guidelines in the MDPH *Guidelines for Compliance with Federal and State Vaccine Administration Requirement*, Section B: Vaccine Management <http://www.mass.gov/eohhs/docs/dph/cdc/immunization/guidelines-vaccine-compliance.pdf>
- Additional information can be found at <http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>

### 3. Vaccine Administration

- **Patient screening for vaccine history, contraindications and precautions**
  - Assess patient's vaccine history. Only accept a patient's verbal report as proof of vaccination for influenza vaccine and PPSV23. However, when evaluating pneumococcal vaccination in history in those 65 years of age and older, try to determine whether PCV13 or

Massachusetts Department of Public Health  
Massachusetts Immunization Program

PPSV23 was given and at what age. This will assist with deciding which type vaccine (PCV13 or PPCV23) may be due next.

- Use current immunization schedules to determine which vaccines the patient needs, based on age and medical conditions.
- Screen for contraindications and precautions using a standardized screening tool.
  - See *Guide to Contraindications and Precautions to Commonly Used Vaccines* <http://www.immunize.org/catg.d/p3072a.pdf>
  - Vaccination Screening Questionnaires are available at <http://www.immunize.org/clinic/screening-contraindications.asp>
  - Physical examination and vital signs are not necessary before or after administration of vaccines, unless specifically indicated.
- Consult with the medical director on site about potential vaccinees with a contraindication or precaution.
- Refer anyone for whom vaccine is deferred because of a contraindication or precaution to their primary care provider for evaluation and confirmation of the contraindication or precaution.
- **Patient Education**
  - Provide the patient with a Vaccine Information Statement (VIS) every time a dose of vaccine is administered. VISs in English and other languages are available at <http://www.immunize.org/vis/>
  - Allow time for questions and after-care instructions before administering vaccines. See *After the Shots* at <http://immunize.org/catg.d/p4015.pdf>
  - Provide patient with the MIIS fact sheet <http://www.mass.gov/eohhs/docs/dph/cdc/immunization/miis-parents-patients.pdf>

***Remember! A strong provider recommendation and offer of vaccine is the strongest determinant of whether or not a patient accepts vaccination.***

- **Patient Care During Vaccine Administration**
  - Prepare patients for vaccination considering their age and stage of development.
  - When determining patient positioning and restraint, consider the patient's comfort, safety, age, activity level, and the site of administration.
  - Encourage parent/guardian to hold child in sitting position.
  - Always have older children and adults sitting or lying down for vaccination.
  - Use evidence based strategies to ease injection pain. See *Procedural Pain Management in Epidemiology and Prevention of Vaccine-Preventable Diseases*, pp. 84-87. <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-admin.pdf>

Massachusetts Department of Public Health  
Massachusetts Immunization Program

- Observe patients for 15 minutes after vaccination. This can be done in a separate waiting area to keep the flow moving. Also see Preventing and Managing Adverse Events on p. 8.
- **Infection Control**
  - Perform hand hygiene before vaccine preparation, between patients, and any time hands become soiled.
  - Use a waterless alcohol-based hand rub. If hands are visibly dirty or contaminated with body fluids, wash with soap and water.
  - OSHA does not require wearing gloves when administering vaccines, unless the vaccinator is likely to come into contact with body fluids, or has open lesions on the hands.
  - If wearing gloves, change them and perform hand hygiene between each patient.
  - Place used syringe and needle devices in biohazard containers immediately after use. Biohazard containers must be closable, puncture-resistant, leak-proof, and labeled.
  - Never recap, cut, or detach needles from syringes before disposal.

**Blood and Body Fluid Exposure Protocol**

If you are stuck by a needle or other sharp, or get blood or other potentially infectious materials in your eyes, nose, mouth, or on broken skin:

- Immediately flood the exposed area with water and clean any wound with soap and water or a skin disinfectant.
- Report incident immediately to the clinic manager.
- Notify clinician who signed the standing orders.
- Identify the source of exposure to facilitate testing to guide medical management.
- ***Seek immediate medical attention*** at:
  - Your occupational health setting;
  - Regular health care setting; or
  - Emergency department
- Post-exposure management should be started within 2 hours of exposure.

***For MDPH clinics:***

- Contact Dr. Susan Lett at (617) 983-6823 or (617) 777-9891.
- Notify the employee's supervisor, who must, within 24 hours:
  - Submit an Incident Report to the Worker's Compensation Claims Manager (Human Resources Administrator).
  - Initiate an accident investigation.

Massachusetts Department of Public Health  
Massachusetts Immunization Program

- **Vaccine Preparation**

- In provider offices, hospitals, or other health care settings:
  - Draw up vaccines in a designated clean medication area.
  - Do not keep or access multidose vials in immediate patient treatment areas.
- In off-site clinics, keep and draw up from multidose vials at a separate table from where vaccines are administered.
- Equipment selection:
  - Use a separate 1-mL or 3-mL sterile syringe for each injection.
  - OSHA requires using only safety-engineered injection devices
  - Check expiration date of needle and/or syringe, if there is one.
  - Select a separate sterile syringe and needle for each injection based on route and patient age and weight. See *Administering Vaccines: Dose, Route, Site, and Needle Size* for children at <http://www.immunize.org/catg.d/p3085.pdf> and for adults at <http://www.immunize.org/catg.d/p3084.pdf>
- Visually inspect the vaccine for discoloration, precipitation or if it cannot be re-suspended prior to administration. If problems are noted, the vaccine should not be administered.
- Vaccines requiring reconstitution:
  - Reconstitute vaccines according to manufacturer guidelines just before administration.
  - Use *ONLY* the manufacturer-supplied diluent for that vaccine.
  - Check the expiration dates on the vaccine AND diluent vials.
  - Use all of the diluent supplied for a single dose; then draw up all of the vaccine in the vial after it has been reconstituted, if it is a single-dose vial.
  - Agitate vial to thoroughly mix vaccine.
  - Discard all unused reconstituted vaccine at the end of the day, or sooner if indicated in the package insert. Note: Some reconstituted vaccines must be discarded if not used immediately. Check the package insert!
  - Also see *Vaccines with Diluents: How to use them* <http://www.immunize.org/catg.d/p3040.pdf>
- Check the package insert to determine if the vaccine has a “beyond use date” for the correct time (days or hours) the vaccine can be stored once the vial has been entered or reconstituted.
  - Calculate the beyond use date using the time interval in the package insert.
  - Label the vaccine with the correct beyond use date/time and your initials.
- Do not change the needle between drawing up and administering the vaccine, unless the needle is contaminated.
- Disinfect the rubber septum of the vaccine vial with alcohol prior to piercing.

Massachusetts Department of Public Health  
Massachusetts Immunization Program

- *Use a new needle and new syringe to withdraw each dose.*
- Prepare vaccines just prior to administration.  
Each vaccinator should prepare the vaccine they administer.
- CDC does not recommend provider pre-drawn syringes. Consider using manufacturer-filled syringes for large immunization events because they are designed for both storage and administration.
  - At clinic site, each vaccinator should draw up no more than one multidose vial or 10 doses at one time. Pre-drawing includes activating manufacturer-prefilled syringes by removing the needle guard or attaching a needle. If not immediately administered, label syringes.
  - If more than one vaccine type is being administered, set up separate administration stations for each vaccine type to prevent medication errors.
  - Monitor number of patients to avoid drawing up unnecessary doses.

***At end of workday,  
discard any remaining vaccine in provider predrawn syringes.***

- **Vaccine Administration**

- Have supplies available, including hand hygiene supplies (e.g. bottles of alcohol-based hand rub), individually packaged sterile alcohol wipes, syringes, a supply of needles in varying lengths appropriate for the clinic population, bandages, and.
- Always have patients sitting or lying down during vaccine administration.
- Use an appropriate sized needle for each patient, depending on age, weight, and gender. See *Administering Vaccines: Dose, Route, Site, and Needle Size* at <http://www.immunize.org/catg.d/p3085.pdf>
- Use a new needle and new syringe for each patient. *Never use needles and syringes to administer vaccine to more than one patient.*
- Immediately place the needle and syringe in a sharps container following administration. *Do not recap the needle.*

**Rights of  
Vaccine Administration**

- ✓ Right patient
- ✓ Right vaccine and diluent
- ✓ Right time
  - Correct age
  - Minimum intervals
  - Expiration time/date
- ✓ Right dose
- ✓ Right route
  - Needle gauge and length
  - Technique
- ✓ Right site
- ✓ Right documentation

#### 4. Documentation

- Document vaccination in the patient's permanent record, including:
  - Type of vaccine
  - Date of administration
  - Vaccine manufacturer
  - Vaccine lot number
  - Expiration date
  - Dose, site, and route
  - Address of facility where the record will reside
  - Vaccine Information Statement (VIS)
    - Date printed on VIS
    - Date VIS given to patient
  - Name/title/initials of person administering the vaccine
- See MDPH *Vaccine Clinic Administration Record* at <http://www.mass.gov/eohhs/docs/dph/cdc/immunization/record-vaccine-admin.pdf>
- Provide patient with their own immunization record that includes vaccine(s) administered and date administered. In addition, you should also notify patient's provider about immunizations given.
- Enter vaccine information into the MIIS

#### 5. Preventing and Managing Adverse Events

- Screen patients for contraindications and precautions before vaccination every time.
- Always have patients sitting down when being vaccinated.
- Consider observing patients for 15 minutes after vaccination. This can be done in a separate waiting area to keep the flow moving.
- Observe for signs of anaphylaxis, which usually begin within minutes of vaccination. These signs and symptoms include:
  - Skin reactions:
    - Pruritus (itching)
    - Erythema (redness)
    - Urticaria (hives)
    - Angioedema (facial swelling)
  - Respiratory compromise:
    - Dyspnea (difficulty breathing)
    - Wheezing
    - Bronchospasms
    - Stridor (high-pitched breathing)
    - Hypoxia

Massachusetts Department of Public Health  
Massachusetts Immunization Program

- Low blood pressure
- Gastrointestinal tract involvement
  - Persistent crampy abdominal pain
  - Vomiting

**Medications and Supplies for Managing Vaccine Reactions**

**First-line medication**

- ✓ Epinephrine, aqueous 1:1000 dilution, in ampules, vials of, or prefilled syringes, including epinephrine auto-injectors (e.g., EpiPen and Epinephrine injection, USP auto-injector). If autoinjectors are stocked, have at least three available (both pediatric and adult formulations).

**Optional medication: H<sub>1</sub> antihistamines**

- ✓ Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution).
- ✓ Hydroxyzine (e.g., Atarax, Vistaril) oral (10 mg/5 mL or 25 mg/5 mL liquid, 25 mg capsules).

**Needed supplies for a community immunization clinic**

- ✓ Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") for epinephrine, diphenhydramine, or hydroxyzine. For ampules, use filtered needles.
- ✓ Alcohol wipes
- ✓ Tourniquet
- ✓ Airways (small, medium, and large)
- ✓ Child- and adult- size pocket masks with one-way valve
- ✓ Oxygen (if available)
- ✓ Stethoscope
- ✓ Sphygmomanometer with child-size, adult-size, extra-large cuffs
- ✓ Tongue depressors
- ✓ Flashlight with extra batteries (for examination of the mouth and throat)
- ✓ Wristwatch with a second hand or other timing device
- ✓ Cell phone or access to onsite phone

IAC. Medical Management of Vaccine Reactions in Children and Teens

<http://www.immunize.org/catg.d/p3082a.pdf>

IAC. Medical Management of Vaccine Reactions in Adult Patients

<http://www.immunize.org/catg.d/p3082.pdf>

- Have facilities, personnel, emergency medications and equipment available to treat immediate hypersensitivity reactions regardless of the clinic setting.
  - Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information on your agency's clinical incident form.

Massachusetts Department of Public Health  
Massachusetts Immunization Program

- Follow standing orders for Medical Management of Vaccine Reactions. These standing orders are available at <http://www.immunize.org/standing-orders> and <http://www.mass.gov/eohhs/docs/dph/cdc/immunization/mso-emergency-treatment.pdf>

## 6. Reporting Adverse events and Vaccine administration Errors

- The National Childhood Vaccine Injury Act (NCVIA) requires healthcare providers to report:
  - Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine; or
  - Any adverse event listed in the *VAERS Table of Reportable Events Following Vaccination* (<http://wonder.cdc.gov/wonder/help/vaers/reportable.htm>) that occurs within the specified time period after vaccination.
  - Consider reporting any adverse events even if you are unsure whether a vaccine caused them.
  - Vaccine administration errors (wrong dose, wrong route, wrong site as describe below) should also be reported to VAERS, and MUST be reported if they resulted in an adverse event. Please see below for guidance about reporting vaccine administration errors to the Institute for Safe Medication Practices (ISMP).

- Report adverse events to VAERS in one of three ways:

- Online through a secure website <https://vaers.hhs.gov/index>
- If you are unable to report online, you can fax a completed VAERS form\* to 877-721-0366.
- Mail a completed VAERS form\* to:

VAERS  
P.O. Box 1100  
Rockville, MD 20849-1100

\*A VAERS form can be downloaded from <https://vaers.hhs.gov/index>, or can be requested by telephone at 800-822-7967, or by fax to 877-721-0366.

- In Massachusetts, board of health clinics and clinics run by visiting nurse associations (VNAs) for boards of health should forward their VAERS forms to:

MDPH Immunization Program  
State Laboratory Institute  
305 South Street  
Jamaica Plain, MA 02130  
617-983-6800

- Report medication errors, including near-errors or hazardous conditions, administering the wrong drug, strength, or dose of medications; confusion over look-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications to:
  - The Institute for Safe Medication Practices (ISMP) at <http://www.ismp.org>; and
  - VAERS at <https://vaers.hhs.gov/index>

## Clinic Resources for Educating Clinic Staff

**General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP).** <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

**Administering Vaccines: Dose, route, site, and needle size**

<http://www.immunize.org/catg.d/p3085.pdf>

One-page reference table

**Administering Vaccines to Adults: Dose, route, site, and needle size**

<http://www.immunize.org/catg.d/p3084.pdf>

One-page reference table

**How to administer intramuscular and subcutaneous vaccine injections**

<http://www.immunize.org/catg.d/p2020.pdf>

Two-sided information sheet with illustrations

**How to administer intramuscular and subcutaneous vaccine injections to adults**

<http://www.immunize.org/catg.d/p2020a.pdf>

One-page information sheet with illustrations

**How to administer intradermal, intranasal, and oral vaccinations**

<http://www.immunize.org/catg.d/p2021.pdf>

This piece shows how to administer intradermal, intranasal, and oral vaccinations

**Vaccines with Diluents: How to use them**

<http://www.immunize.org/catg.d/p3040.pdf>

One-page information sheet outlining correct diluents for vaccines that need reconstitution

**Medical management of vaccine reactions in adult patients**

<http://www.immunize.org/catg.d/p3082.pdf>

Table describes procedures to follow if various reactions occur in adult patients, includes supply list

**Medical management of vaccine reactions in children and teens**

<http://www.immunize.org/catg.d/p3082a.pdf>

Table describes procedures to follow if various reactions occur in children and teens

**Skills Checklist for Immunization**

<http://www.immunize.org/catg.d/p7010.pdf>

Use the Skills Checklist to clarify responsibilities and expectations for staff who administer vaccines