

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.

More information can be found at

- CDC's Mass Vax Clinics, Planning <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/planning-activities.html>
- Immunize.org's Supplies You May Need at an Immunization Clinic <https://www.immunize.org/wp-content/uploads/catg.d/p3046.pdf>
- CDC's Considerations for Planning Vaccination Clinics <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/curbside-vaccination-clinics.html>
- CDC's Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/vaccination-clinic-supply-checklist.html>
- National Adult and Influenza Immunization Summit (NAIIS) Tools to Assist Satellite, Temporary, and Off-Site Vaccination Clinics <https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/>

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.mass.gov/massachusetts-immunization-information-system-miis>
- 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

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- Correct dose and route of administration
- Signed standing orders for vaccines to be administered and for management of managing adverse event
- 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)/EUA Fact Sheets before the clinic begins.
 - Package inserts for all vaccines: <http://www.immunize.org/packageinserts/>
 - VISs: <http://www.immunize.org/vis/>
 - EUAs: <https://www.immunize.org/official-guidance/fda/pkg-inserts/>
- 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

- Refer to the **MDPH Vaccine Transport SOP** for detailed information:
<https://www.mass.gov/doc/vaccine-transport-sop-2023-0/download>
 - Transport packing methods differ between 1) Emergency transport and 2) Planned transport such as for off-site clinics, satellite facilities, or re-location of stock. In either case, a portable refrigerator/freezer is always the preferred method.
 - Emergency transport requires either portable vaccine storage units (portable vaccine refrigerator/freezer), qualified containers and pack-outs, or the conditioned water bottle transport system.
 - For step-by-step guidance on packing a cooler for emergencies using the conditioned water bottle method, see [CDC's Packing for Emergency Transport](#).
 - Planned transport requires either portable refrigerators/freezers or qualified containers and pack-outs (e.g., Cool Cubes, TempArmour, etc.). The conditioned water bottle method should not be used for planned transport.
 - Anytime your practice is moving vaccines off-site, regardless the transport method unit you are using, the **vaccines must be monitored by an external digital data logger device**. Do not add vaccines until the external data logger device is reading in-range temperatures and **never** transport refrigerated vaccines on **frozen ice packs**.

Recommended Vaccine Storage Temperatures

Freezer

- Between -58°F and +5°F (between -50°C and -15°C)

Refrigerator

- Between 36°F and 46°F (between 2°C and 8°C)
- Average: 40°F (5°C)

- Also refer to
 - MDPH *Guidelines for Compliance with Federal and State Vaccine Administration Requirements*, <https://www.mass.gov/doc/guidelines-for-compliance-with-federal-vaccine-administration-requirements/download>
 - CDC Vaccine Storage and Handling Toolkit <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

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.
 - 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 Checklists 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.
 - 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.
 - Information and strategies on how to deal with anxiety related to vaccinations can be found at <https://www.immunize.org/clinical/topic/admin-vaccines/>
- **Patient Education**
 - Provide the patient with an appropriate Vaccine Information Statement (VIS) or Fact Sheet for Recipients and Caregivers every time a dose of vaccine is administered. VISs in English and other languages are available at <http://www.immunize.org/vis/> and EUAs are available at <https://www.immunize.org/official-guidance/fda/pkg-inserts/>
 - Allow time for questions and after-care instructions before administering vaccines. See *After the Shots* at <http://immunize.org/catg.d/p4015.pdf>

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

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- **Patient Care During Vaccine Administration**
 - Prepare patients for vaccination considering their age and stage of development.
 - When determining patient positioning, 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>
 - Observe patients for 15 minutes after vaccination. This can be done in a separate waiting area to keep the flow moving.
- **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 Exposures

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 evaluation and possible treatment at:**
 - Your occupational health setting;
 - Regular health care setting; or
 - Emergency department
- Post-exposure management should be started within 2 hours of exposure.
- See CDC emergency Needle Stick Information: <https://www.cdc.gov/niosh/topics/bbp/emergnedl.html>
- Questions about appropriate medical treatment for occupational exposures, 24-hour assistance is available from the clinicians' Post Exposure Prophylaxis Hotline (PEpline) at 1-888-448-4911. www.nccc.ucsf.edu.

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- **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 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.
 - Gently 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.
- 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.

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- CDC does not recommend providers 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 appropriately 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
- Provide patient with their own immunization record that includes vaccine(s) administered and date administered.
- 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)
 - Bronchospasms
 - Stridor (high-pitched breathing)
 - Hypoxia
 - Respiratory compromise:
 - Dyspnea (difficulty breathing)
 - Wheezing
 - Low blood pressure
 - Gastrointestinal tract involvement
 - Persistent crampy abdominal pain
 - Vomiting
- 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.
- Follow standing orders for Medical Management of Vaccine Reactions. Standing orders are available at <http://www.immunize.org/standing-orders>

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: H₁ 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>

6. Reporting Adverse events and Vaccine administration Errors

- Report adverse events to VAERS:
 - Online through a secure website <https://vaers.hhs.gov/index>
- Healthcare providers are required by law to report to the **Vaccine Adverse Events Reporting System (VAERS)** (<https://vaers.hhs.gov/>):
 - Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination ([https://vaers.hhs.gov/docs/VAERS Table of Reportable Events Following Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf)) that occurs within the specified time period after vaccinations
 - Any adverse event listed by the vaccine manufacturer as a contraindication to further doses.
- Healthcare providers are strongly **encouraged** to report to VAERS:
 - Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event.
 - Vaccine administration errors (e.g., wrong route, wrong dose, and wrong age)
- Online reporting is encouraged. Please [report](#) clinically important adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- All providers should report directly by going to the VAERS website (<https://vaers.hhs.gov/reportevent.html>), and either:
 - Fill out the online reporting tool; or
 - Complete a fillable VAERS PDF form and upload it onto the VAERS website.
- Accommodations will be made for persons unable to submit reports electronically. Additional assistance is available via email at info@vaers.org or by phone at 1-800-822-7967.

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