Community Vaccination Clinics

Toolkit

Community Vaccination Clinics

TOOLKIT

Part 1: CLINIC DOCUMENTS

Part 2: CLINIC GUIDANCE

**Please note that these are *suggested* templates. Consult your legal authority for required documentation.

Part 3: MODEL EMERGENCY PLANS

Part 4: VACCINE STORAGE and HANDLING

Part 5: COMMUNICATION

Community Vaccination Clinics

TOOLKIT

Part 1: CLINIC DOCUMENTS

1.1 Checklist of Best Practices for Vaccination Clinics
https://www.izsummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf

1.2 Live Intranasal Influenza Vaccine Information Sheet
https://www.cdc.gov/vaccines/hcp/vis/vis-statements/flulive.pdf

1.3 Inactivated Injectable Influenza Vaccine Information Sheet
https://www.cdc.gov/vaccines/hcp/vis/vis-statements/flu.pdf

1.4 Vaccine Information Sheet for All Other Vaccines
https://www.cdc.gov/vaccines/hcp/vis/current-vis.html

1.5 Screening Checklist for Contraindications- Children and Teens
https://www.immunize.org/catg.d/p4060.pdf

1.6 Screening Checklist for Contraindications- Adults
https://www.immunize.org/catg.d/p4065.pdf

1.7 After the Shot Parent Information Sheet
https://www.immunize.org/catg.d/p4015.pdf

Community Vaccination Clinics

TOOLKIT

Part 2: CLINIC GUIDANCE

Checklist of Best Practices for Vaccination Clinics

We have included a link to the following checklist that is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. It should be used in any non-traditional vaccination clinic setting, including but not limited to: workplaces, community centers, schools, makeshift clinics in remote areas, and even medical facilities when vaccination occurs in the public areas or classrooms. Temporary clinics also include mass vaccination events, and vaccination clinics held during pandemic preparedness exercises. This checklist outlines CDC guidelines and best practices that are essential for patient safety and vaccine effectiveness. A clinic coordinator/supervisor at the site should complete, sign, and date this checklist EACH TIME a vaccination clinic is held. To meet accountability and quality assurance standards, all signed checklists should be kept on file by the company that provided clinic staffing. This checklist should be used in conjunction with CDC's Vaccine Storage and Handling Toolkit.

https://www.izsummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Scheduling and Protocol for Curbside Visits, Including Vaccines

The following guidance was shared with the Maine Immunization Program by two of our local provider offices. Use this template as a guide to set up curbside visits and adjust to meet your facilities needs.

For scheduling:

At the request of parent/guardian (hereafter referred to as parent), car visits may be scheduled for vaccines only.

If the child is 26 months of age or younger, they are strongly encouraged to schedule a complete in office well visit. If the parent remains uncomfortable with coming in to the office despite reviewing our safety procedures, they can be scheduled as an office visit with their Primary Care Provider and clinical staff coming to the vehicle. Contact clinical staff for scheduling a car well visit.

Template for Protocol Procedures:

1. **Determine if curbside visit is appropriate.**
    a. Determine Curbside vs Inside:
        Challenges to consider when planning
            i. Weather
            ii. Not much space in vehicles even with door open
            iii. Increased risk of needle stick
            iv. Animals in vehicle
            v. Other kids in the vehicle
    b. Well Child Check (to complete exam and vaccines) or acute visit

2. **If appropriate, document visit type, noting "Curbside" in visit notes.**
    a. Instruct family to call when they arrive. Do not come in. Wait in car.

3. **Supplies:**
    a. PPE: Gloves, Surgical mask, gowns
    b. Hand sanitizer
    c. Alcohol swabs
    d. Otoscope/ophthalmoscope/stethoscope
    e. Chucks to place child on parent's lap
    f. Vaccine curbside cart (see 6A)
    g. Clipboard with paper/pen
    h. Other possible items:
        i. Strep swab (Airborne precautions)
        ii. Glucometer
        iii. Phone to take pictures

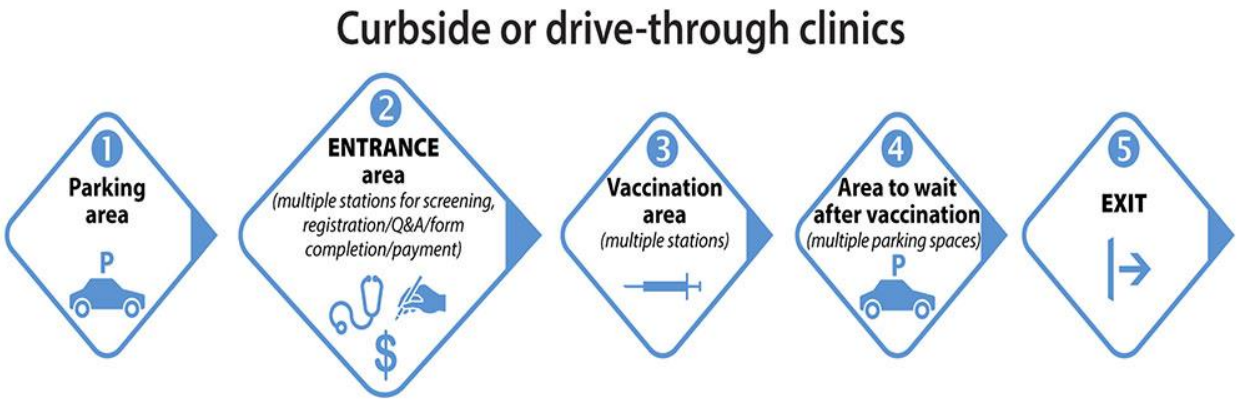
4. **Curbside Visit**
    a. Family calls the front desk upon arrival to alert MA/provider
    b. All family members must put on a surgical mask, if not already wearing one
    c. Turn off car
    d. Give mask to any one in car over two years of age
    e. Approach driver's side vehicle
    f. Ask Covid screening questions for all in car
    g. Examine patient in passenger seat or on parent's lap
        1. On parent's lap: put down chucks pad on parent's lap
        2. In truck/SUV: consider going to the back with a chucks to lay child down on

5. **Limitations**
    a. Weather issues
        a. Bring umbrella
        b. Consider moving the clinic inside if too cold/raining too hard

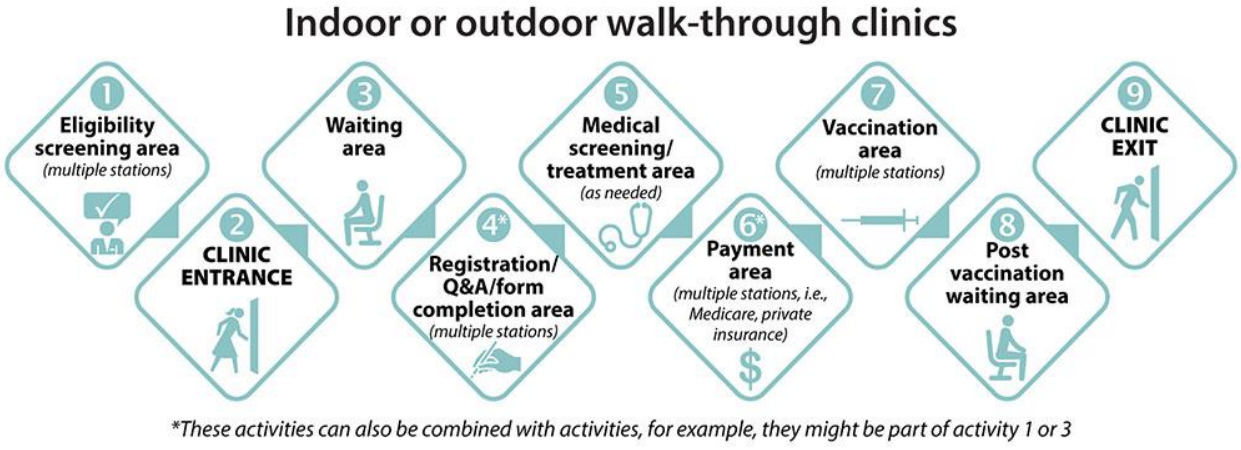
6. **Vaccines**
    a. Curbside cart
        i. PPE: gloves, surgical mask, gowns
        ii. Sharps container
        iii. Alcohol swabs
        iv. Gauze
        v. Bandaids
        vi. VIS forms (not on cart)
        vii. Lancets/supplies for hgb/lead
        viii. Drawn up vaccines
        ix. EpiPen
        x. Fluoride kit
    b. How to administer
        i. Hand sanitizer for adult holding child, chucks on parent's lap
        ii. Have parent/guardian hold infant/child
        iii. Ideally Parent/guardian to restrain child
        iv. Other provider/MA can restrain if needed
    c. Patient must wait in parking lot for 10 minutes if under 10 years old and 15 minutes if 10 years old and older
        1. Call main # _____ if any issues

7. **Documentation/Billing**
    a. Provider: document curbside exam is done. Mention any limitations.
    b. Vaccines: bill as nurse visit

Blueprint for conducting a curbside/drive-through clinic:



Blueprint for conducting a walk-through clinic:



Framework for Planning
Vaccine Clinics

These recommendations and guidelines were developed to assist with planning vaccination clinics.

This document provides general guidance to help ensure smooth operations at vaccine clinics and is broken into 4 phases, each with specific considerations:

1. Planning
2. Clinic Set-up
3. Clinic Operations
4. After-Clinic Activities

PHASE 1: Planning

- Identify leaders for overall vaccination delivery operations.
- Identify partners to fulfill mass immunization roles.
- Register your clinics.
- Develop a communication plan among all clinic partners.
- Develop clinic processes, including: location, size, # of stations, and staff required.
- Identify staff to fill the positions.
- Meet the language needs of the community using multi-lingual staff as appropriate.
- Prepare staff members regarding their roles and responsibilities during clinic operations.
- Cross-train staff members, if possible, to enable flexibility in meeting needs at various stations as demands fluctuate.
- If possible, provide additional staff to meet fluctuating clinic demands and schedule breaks for staff.
- Ensure the presence of an onsite emergency medical kit and supplies.
- Ensure that emergency procedures are in place to respond to urgent medical problems.

Vaccine Clinic Location

- If you plan to vaccinate a large number of patients at one time, consider holding the clinic in school gyms, auditoriums, or other large covered spaces that can accommodate a large number of patients and staff.
- If you plan to vaccinate smaller numbers of patients, carefully consider the building layout to ensure adequate clinic flow. Items such as adequate lighting and heating, functional and accessible restrooms, adequate space for all clinic functions such as screening, registration, vaccine storage, vaccination, and staff breaks are considered.

Clinic Notification & Patient Consent

- Ensure that adequate vaccine is available for the clinic.
- Providing consent forms and information packets to patients prior to the clinic date and sending reminders to return the consent forms. Reminders can include mailings, email, personal or automated phone calls, and text messages.
- Prior to vaccinating patients, staff should review the consent forms to verify that the patients have fully completed the forms.
- Provide Vaccine Information Sheet (VIS). A VIS is a document, produced by CDC, that informs vaccine recipients – or their parents or legal representatives – about the benefits and risks of a vaccine they are receiving. All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act (NCVIA- https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapXIX-part2-subpartc-sec300aa-26.pdf) to give the appropriate VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines. For up to date forms: https://www.cdc.gov/vaccines/hcp/vis/current-vis.html

PHASE 2: Clinic Set-up

Clinic Lay-out and Specifications

- You may want to adjust your clinic's lay-out based on items identified during the initial clinic planning phase.
- Use signs in multiple languages, as needed.
- Provide seating for patients and staff if possible.
- Provide a waiting area where patients can be observed after vaccination.
  See "Example of Influenza Vaccine Clinic Lay-Out" on next page.

Clinic Security/Safety

- Especially if your facility will be utilizing outside volunteers to help operate your clinic, consider using name tags or ID badges to ensure those inside the clinic are authorized to be there.
- Assure that vaccine is stored in a safe and secure location that can be locked and access can be restricted to medical personnel only.
- Recruit local volunteers as needed to assist with clinic flow.
- Depending on the time of the clinic you may want to coordinate and collaborate with local community resources.

PHASE 3: Clinic Operations

- Accommodations for patients with disabilities will need to be taken into account for access into the clinic.
- Direct arriving patients into clinic to expedite vaccine delivery.
- Ensure all patients receiving vaccine have completed all forms, including the consent form and health screen.
- Based on the results on the health screening process, determine the correct vaccine presentation (multi-dose, pre-filled, nasal mist, etc) for each patient and direct them to the correct vaccination station.
- In order to keep the flow moving, non-medical clinic staff can be utilized as supply runners to assist in the clinic supply management process.
- Maintain a steady flow of patients through the clinic so that vaccinators are never without a client at their stations; redirect patients to other stations if bottlenecks occur.

PHASE 4: After-Clinic Activities

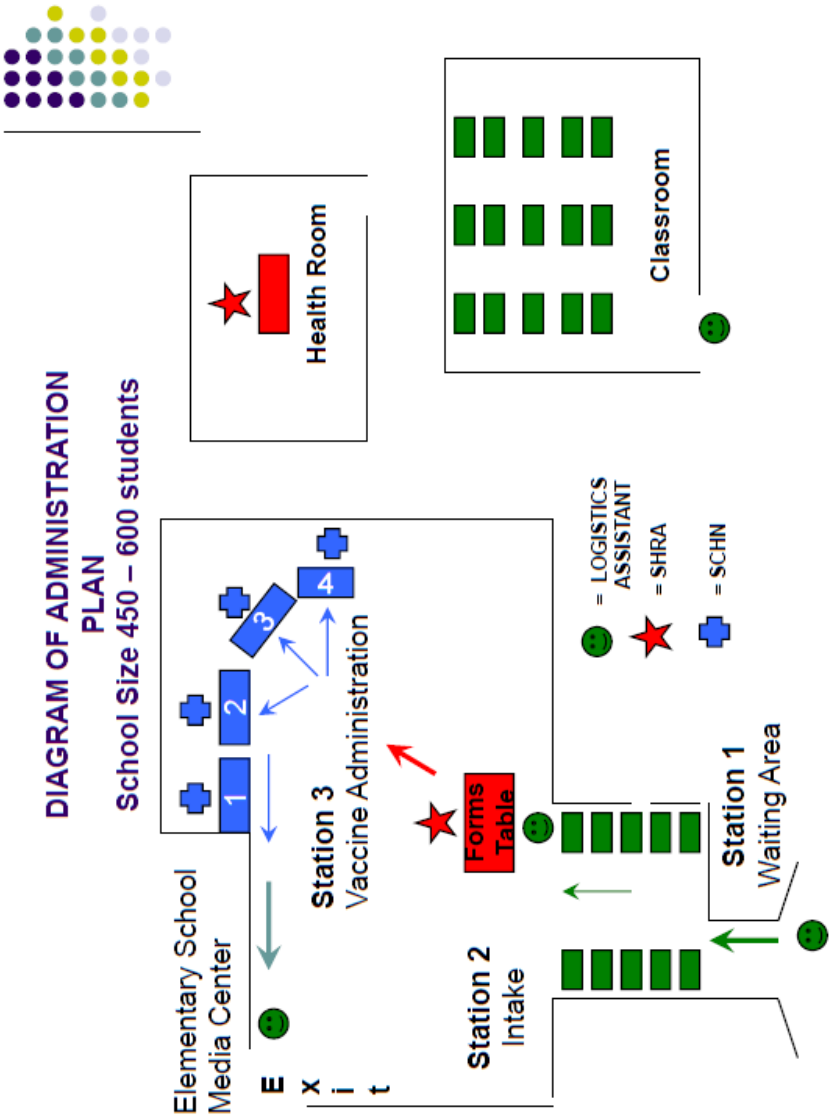
- After-clinic activities need to be part of the initial planning process.
- Step 1: Close the vaccine clinic
    - Clear all the patients for the vaccination area prior to closing
    - Post clear signage indicating that the site is closed
    - Assign staff for breakdown of site
    - Catalog and restock consumable supplies
    - Collect and dispose of trash
    - Bag and properly dispose of medical waste (sharps containers)
- Step 2: Clean-up
    - Follow your facility's policy regarding post-event clean-up
- Step 3: Report doses administered
    - Delays in doses administered reporting can have multiple effects;
        - Results in delayed billing and reimbursement for vaccine
        - Inability of the person's healthcare provider to view up-to-date vaccination history, which may lead to double vaccination of the patient.

COMMUNITY HEALTH PARTNER WORKING WITH A SCHOOL- TIMELINE

Stage of Development/ Timeframe	Task/Activity	Responsible Party
Prior to SLVC/July	Contact school to determine interest in SLVC. Review vaccine inventory from prior year clinic – estimate number of doses needed. Order 40% vaccine doses needed based on state-based estimates.	Partner Partner Partner
Prior to beginning of school/August	Print SLVC Toolkit, VIS, consent forms and state forms Organize paperwork to be sent home to parents. Send forms to language line service for translation.	School Nurse/Partner School Nurse School Nurse
Immediately following beginning of school/ September (Second or third week)	Notify parents of clinics to be held in October and to expect upcoming clinic schedule (do not include clinic notices with other school notifications). Receive and store vaccine in a refrigerator designated solely for vaccines. Notify school nurse when vaccine has been delivered. Determine clinic dates, times and schedule (youngest students first).	School Nurse/Partner Partner Partner School Nurse/Partner
Prior to Clinic (one week)/ September or early October	Advertise School Clinic dates in school social media, newsletters or local newspapers; update and refresh school website: clinic schedule, permission slip and immunization forms. Send additional notification one week prior to day of clinic. Confirm projected student/dose count needed with school nurse needed one week out.	School Nurse Partner Partner
Prior to Clinic (day before)/ September or early October	Call school nurse day before clinic for final count. Organize clinic supplies: EPI pens, Benadryl, standing order for vaccine administration, medical dosing sheet, pens, chucks pads, tissues, gloves, 2x2 gauze, band aids, hand sanitizers, alcohol pads, needles, syringes (if not prefilled) extra forms, rosters and VIS sheets, coolers, ice packs, vaccine – separated by lot number identification, thermometers. If possible, outreach to families who have not returned permission slips.	Partner Partner School Nurse

Day of Clinic/Flu Season	Set up clinic location at school: • Seating for waiting • 2 tables with chairs for registration & taking temperatures • Immunization stations equipped with waste basket, sharps container, hand sanitizer and tissues Attach lot number stickers to permission slips. Copy front and back of school employee insurance card. <u>Complete rosters required for billing</u>: patient name, date of birth, date of service, clinic site, vaccinator name, attach flu forms with roster. <u>Review/verify information on consent forms</u>: Student name, date of birth, contraindication sign off, type of vaccine (nasal or injection), vaccinator nurse sign off (initial/date injection given). <u>Vaccinate</u>: Seat student, roll up sleeve, clean injection area of the arm with alcohol, while drying verify student name and form information, give immunization. Place time sticker on student just prior to receiving snack and clearance – 15 minutes after immunization return to classroom.	School Nurse/Partner Partner School Nurse/Partner Partner Vaccinator School Nurse/Partner
Immediately following Clinic/October or November	Billing: Enter doses into ImmPact (within 5 days of administering vaccine) & EMR system and send copies of forms to relevant schools. Quality Assurance: Run reports on numbers of vaccines entered into Electronic Medical Record vs. ImmPact. Doses Redistributed: Contact the Maine Immunization Program regarding leftover vaccine so that it can be redistributed.	School Nurse/Partner Partner Partner

Blueprint for conducting a SLVC clinc:



COMMUNITY HEALTH PARTNER WORKING WITH A SCHOOL-RESOURCES

Community Health Agency wanting to know how to hold a School/Mass Immunization Clinic. For help, suggest they contact:

- Marissa Lyshon, Maine General, 861-5282
  Marissa.Lyshon@MaineGeneral.org
- Cathy Bean, Northern Light Home Care & Hospice, 400-8725
  beanc@northernlight.org
- Rebecca Rosen, CHANS Home Health & Hospice, 721-1257,
  rrosen@midcoasthealth.com

You can also reference the SLVC section of the Maine Department of Education Website at: http://www.maine.gov/doe/schools/safeschools/healthed/nurseresources/manual/immunization

The website offers significant information pertaining to SLVC including:

- A complete copy of the *School-Located Vaccine Clinics for Influenza SLVC Toolkit.*
- Individual sections of the *Toolkit* available for printing
- *Health Screen & Permission Form*
- *Vaccine Information Statements* links to the CDC.
- Frequently asked questions.
- New information.

Insert your
School Identifier Here

Model Plan for

Standing Order for School-Located Vaccine Clinics

The following order provides direction to be followed at mass immunization clinics designated as School-Located Vaccine Clinics (SLVCs).

1. The school staff may work in coordination with other entities to order vaccine, manage inventory and/or administer vaccine at the school immunization clinics.

2. The school staff will use the Vaccine Health Screen and Permission Form (found in SLVC Toolkit) provided by the Maine Immunization Program to obtain relevant health history for the purpose of determining possible contraindications to receiving vaccine.

3. Vaccine clinic staff will screen for moderate or severe illness (including fever > 100) in clients. Persons who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If the client is ill, they should be directed to another SLVC for vaccination or to their healthcare provider. Persons with mild illness can usually get the vaccine.

4. An emergency plan must be in place in the event of anaphylaxis or symptoms of immediate hypersensitivity following administration of the vaccine. (See Part 3 of this Toolkit).

Prior to the clinic, clinic staff shall be familiar with the emergency procedures for anaphylaxis and the administration of Epinephrine and Benadryl.

Note: An Emergency Kit containing the following items must be at the clinic site:

- Aqueous epinephrine 1:1000 dilution, in ampules, vials of solution or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If epinephrine autoinjectors are to be stocked, both junior dose (0.15 mg) and adult dose (0.30 mg) should be available.
- Diphenhydramine (Benadryl) injectable (50mg/mL solution) and oral (12.5 mg/5 mL suspension) and 25 or 50 mg capsules or tablets.
- Syringes: 1-3 cc, 22-25g 1", 1 ½", and 2" needles for epinephrine and diphenhydramine (Benadryl).
- Pediatric and adult airways (small, medium, and large).
- Alcohol swabs
- Blood Pressure cuffs (child, adult & extra-large) and stethoscope
- Pediatric and adult size pocket masks with one-way valve
- Tongue depressors
- Flashlight with extra batteries (for examination of mouth and throat).
- Wrist watch

- Tourniquet
- Cell phone or access to an on-site phone

Ref: Epidemiology and Prevention of Vaccine-Preventable Diseases, 12th Edition; U.S. DHHS, CDC; May 2012, Appendix D-19

5. There must be a second responsible person present at each clinic site while vaccine is being administered in order to activate the Emergency Medical Services if necessary. The second person may be from a program other than the school.

6. There shall be no pre-filling of syringes at clinics if using multi-dose vials. All doses of vaccine and emergency medication shall be drawn up at the time of administration.

7. During the clinic, if the vaccine is stored in a transport container/cooler, the insulating barrier must be left in place between the vaccine and the refrigerated/frozen packs, and cold chain must be maintained.

8. During the clinic, cooler temperatures will be checked at least hourly to ensure that the cold chain is not broken. If the temperature range is out of the acceptable CDC ranges for storage of vaccine (36° to 46°F) the following action must be taken immediately:

    a. Label the vaccine that it has been stored out of temperature range.
    b. Notify the vaccine provider.
    c. Notify the manufacturer of the product for instructions in handling the vaccine (see contact numbers below).
    d. Notify the Maine Immunization Program (287-3746) if vaccine comes from the Maine Immunization Program.

9. The clinic health care staff shall verify that the Vaccine Health Screening and Permission Form is complete and shall be used for the purpose of determining possible contraindications to receiving the vaccine.

- Recommended best practice is to, keep a copy of the Vaccine Health Screening and Permission Form according to the school health record retention schedule.

10. Persons with a negative health history (no contraindications) or who have written permission from their primary health care provider may receive the vaccine.

11. Clinic health care staff shall have their own sharps container at their station. During use, sharps containers shall be:

    a. Easily accessible to personnel and located at the area where sharps are used or can be found.
    b. Maintained upright throughout use.
    c. Replaced when ⅔ full.
    d. Accounted for at all times.

The clinic health care staff shall notify the client that they are expected to remain at the clinic site for 15 minutes after receiving the vaccine for the purpose of observing for a reaction to the vaccine.

If an adverse reaction should occur, the clinical health care staff shall refer to "Medical Management of Vaccine Reactions in Children and Teens" available at www.immunize.org/catg.d/p3082a.pdf and the Model Emergency Plans provided in Part 3 of the Toolkit.

State Supplied Vaccine Manufacturer Contact Information for SLVCs:

Contact Information: Selected Vaccine Manufacturers & Distributors Manufacturer/Website	**Phone Number:**	**Products:**
Centers for Disease Control & Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.htm.	404-639-3670	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline www.gskvaccines.com	866-475-8222	Infanrix, Kinrix, Pediarix, Havrix, Engerix-B, Twinrix, Hiberix, Cervarix, Fluarix, FluLaval, Rotarix, Boostrix
Massachusetts Biological Labs https://www.amscomedical.com/brand/listing/massachusetts-biologic-labs/68	617-474-3000	IGIM, Td, TT
MedImmune, Inc. www.medimmune.com	877-633-4411	FluMist
Merck & Co., Inc. www.merckvaccines.com	800-637-2590	PedvaxHIB, Comvax, Vaqta, Recombivax-HB, Gardasil, M-M-R II, ProQuad, Afluria, Pneumovax 23, RotaTeq, Varivax, Zostavax, Td
Biotest Pharmaceuticals https://www.biotest.com/de/en/index.cfm	800-458-4244	HBIG
Novartis Vaccines https://www.novartis.com/	877-683-4732	Fluvirin, Agriflu, Menveo, RabAvert (distributer for Ixiaro)
Pfizer (Wyeth Vaccines) www.pfizerpro.com/	800-438-1985	Prevnar 13
Sanofi Pasteur www.vaccineshoppe.com	800-822-2463	Daptacel, Tripedia, Pentacel, ActHIB, Fluzone, Menomune, Menactra, IPOL, Imovax, Decavac, Tenivac, Adacel, Typhim Vi, YF-Vax
Talecris Biotherapeutics https://www.grifols.com/en/home#	800-520-2807	HBIG, IGIM, RIG, TIG

Maine Immunization Program: (207)287-3746 or 800-867-4775

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School Physician – Print Name

School Physician Signature

Date

COMMUNITY HEALTH PARTNER

MEMORANDUM OF AGREEMENT (MOA)
FOR CONDUCTING SCHOOL LOCATED *VACCINE CLINICS (SLVC) BETWEEN* _____SCHOOL UNIT _____ AND _____*name of partner here*____ FOR IMMUNIZATION OF SCHOOL CHILDREN AGAINST SEASONAL INFLUENZA (or other vaccine preventable diseases) IN THE SCHOOL SETTING

The above RSU and the above medical provider/partner agree to cooperate in setting up school clinics to vaccinate school children against seasonal influenza during the school year. This MOA is executed to ensure that all activities of SLVC are managed by an agreed upon responsible party. This agreement shall remain in effect from the date of execution through ___*date agreement ends here*____.

1. Contact information:
    A. School system:
    B. Partner:

2. Clinic Site Information:
    A. _____School *Date*

    B. _____School *Date*

    C. _____School *Date*

    D. _____School *Date*

*School system*___ will follow all procedures outlined in the SLVC Toolkit published by the Maine Center for Disease Control (MCDC) and Maine Department of Education.

___*Partne*r___ will send 1 or more medical providers in good standing to administer vaccine at the SLVC sites listed above.

(List all agreed upon responsibilities of the school and the partner in this section.)

The undersigned agree to administer seasonal influenza vaccine in accordance with Federal CDC guidelines. This agreement is between the school system and the healthcare provider/partner.

_____ _____

Signature of Partner Representative Date

_____ _____

School Superintendent Date

Model Plan: Reporting Adverse Events Following Vaccination

Staff should report any vaccine adverse events occurring in the clinic setting to the Vaccine Adverse Event Reporting System (VAERS).

Background

VAERS, administered by the Food and Drug Administration (FDA) and Centers for Disease Control Prevention (CDC), is a safety surveillance program that collects information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the US.

- Each report provides valuable information that is added to the VAERS database that supplies the information needed for evaluation of vaccine safety.
- Anyone can file a VAERS report; including health care providers, vaccine recipients and parents or guardians.
- Vaccine recipients and parents/guardians should consult their health care provider if they suspect an adverse event associated with the vaccine.
- FDA and CDC do not provide individual medical treatment, advice or diagnosis.

What can be reported to VAERS?

- Report any clinically significant medical event that occurs after vaccination, even if you are not sure whether the vaccine caused the adverse event.
- The National Childhood Vaccine Injury Act requires health care providers to report any adverse event listed by the vaccine manufacturer as a contraindication to receive additional doses of the vaccine and any adverse event listed in the "VAERS Table of Reportable Events Following Vaccination" that occurs within the specified time period after vaccination. For influenza this includes events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert).

How to report to VAERS:

- **Anyone may report** but preferably Clinic Vaccinator or Clinic Authority should complete the VAERS report if the event occurs in the clinic setting.
- Download the VAERS Form (located at https://vaers.hhs.gov/uploadFile/index.jsp)
- Request a VAERS Form by sending email to info@vaers.org, by calling (800)822-7967, or by faxing a request to (877)721-0366.
- Before you begin review the Instructions for Completing the VAERS Paper Form.

- 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 pre-paid postage stamp is included on the back of the form.
- Federal CDC will send you a confirmation after the report is received.

Clinic Guidance During Covid

Guidance has been developed for the administration of vaccines at pharmacies, temporary, off-site, or satellite clinics, and large-scale influenza clinics. Other approaches to vaccination during the COVID-19 pandemic may include drive-through immunization services at fixed sites, curbside clinics, mobile outreach units, or home visits.

The general principles outlined for healthcare facilities should also be applied to alternative vaccination sites, with additional precautions for physical distancing that are particularly relevant for large-scale clinics, such as:

•Providing specific appointment times or other strategies to manage patient flow and avoid crowding.

•Ensuring sufficient staff and resources to help move patients through the clinic flow as quickly as possible.

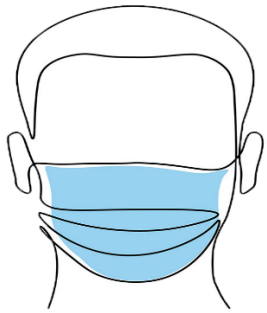
•Limiting the overall number of attendees at any given time, particularly for populations at increased risk for severe illness from COVID-19.

•Setting up a unidirectional site flow with signs, ropes, or other measures to direct site traffic and ensure physical distancing between patients.

•When feasible, arranging a separate vaccination area or separate hours for persons at increased risk for severe illness from COVID-19, such as older adults and persons with underlying medical conditions.

•Selecting a space large enough to ensure a minimum distance of 6 feet between patients in line or in waiting areas for vaccination, between vaccination stations, and in postvaccination monitoring areas (the Advisory Committee on Immunization Practices recommends that providers consider observing patients for 15 minutes after vaccination to decrease the risk for injury should they faint).

Vaccination Clinic Location and Layout



Satellite, temporary, or off-site locations must consider federal, state, and local guidance when establishing measures to protect clinic staff and clients from the virus that causes COVID-19. Regardless of the site type (i.e., walk-through, curbside, drive-through, or mobile clinic), temporary locations must have sufficient capability to accommodate physical distancing, inventory management, and appropriate personal protective equipment (PPE) for staff and face coverings for patients.

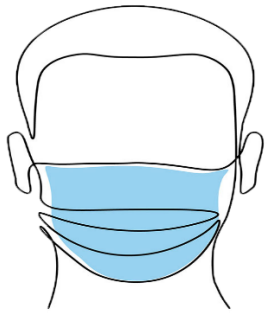
Clinic locations and processes that were successful in previous years might not be appropriate during the COVID-19 pandemic because of the need for enhanced safety precautions. Even if the same space is used, it will likely need to be set up and function differently because of COVID-19 requirements.

Consider conducting appointment-only temporary clinics held in schools, churches, and pharmacies. Smaller clinics can be laid out more efficiently and serve fewer people to help reduce exposure risk for staff and patients. Large-scale clinics, particularly those held indoors, may not be feasible during the COVID-19 pandemic because they might be difficult to implement under federal, state, and local guidance for physical distancing. Curbside and drive-through clinics may provide the best option for staff and patient safety during the COVID-19 pandemic.

For walk-through clinics, it's important to establish line queues that maintain separation between individuals or to ask individuals to wait in their vehicles or another location until called. Clinic flow should be one way. individual sites will have benefits and limitations and that site assessments will be required prior to use.

Consider using online or phone options for scheduling appointments and completing paperwork, when possible. Such processes should include registration, obtaining insurance information, and billing (if needed), screening for contraindications and precautions, and texting or emailing vaccine information statements (VISs) or emergency use authorization (EUA) forms.

Supplies and Materials

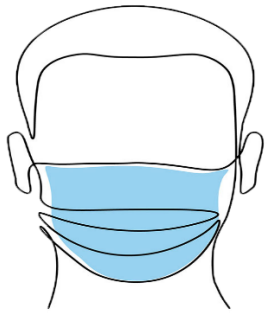


During the COVID-19 pandemic, protection must be available for staff and patients. Supplies required during the COVID-19 pandemic include:

- Alcohol-based hand sanitizer with at least 60% alcohol and hand soap
- Cleaning supplies for more frequent cleanings, using EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2external icon
- Cloth face coverings for patients who arrive without one
- Personal protective equipment (PPE) for staff, including face masks, gloves, and eye protection, based on current guidance for the safe delivery of vaccination services. (see page 26 of toolkit.)
- Thermometers for checking patients' temperatures before they enter the clinic, if required
- Tissues

Note that quantities may be more than was needed prior to the pandemic.

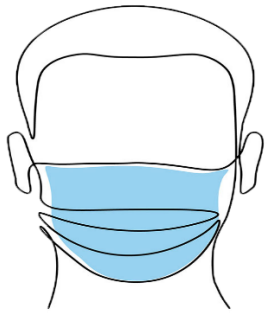
Training



Staff training is critical. Ensure all staff is trained to answer common questions about the vaccine.

During the COVID-19 pandemic, all staff should be on when to use PPE, what PPE is necessary, how to properly don (put on) and off (take off) PPE, and how to properly dispose of PPE.

General Operations



During the clinic, ensure physical distancing and enhanced infection control measures are in place and implemented. Measures include:

- Cleanse and disinfect vaccination stations between each patient.
- Ensure all patients and accompanying attendants wear a cloth face covering or face mask that covers the nose and mouth. If a patient or attendant is not wearing a cloth face covering, ensure face coverings or face masks are available. (Note: Face coverings should not be placed on a child under 2 years of age, anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.)
- Ensure staff is wearing appropriate PPE.
- Ensure supplies such as tissues, hand sanitizer, and wastebaskets are readily accessible throughout the clinic.
- If gloves are worn by those administering vaccine, they should be changed, and hand hygiene should be performed between patients.
- Make sure there are signs, barriers, and floor markers throughout the clinic to instruct patients to maintain a 6-foot distance from others and promote use of hand hygiene, respiratory hygiene, and cough etiquette.

Provide extra cleaning and sanitizing support. Frequently clean and disinfect all patient service counters and patient contact areas, including frequently touched objects and surfaces such as workstations, keyboards, telephones, and doorknobs.

For additional information regarding clinic planning, pre-clinic activities, during the clinic, and post-clinic activities, reference the following link:

https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html

[1]CDC.Updated National Center for Immunization and Respiratory Diseases for the Interim Guidance for Immunization Services During COVID-19 Pandemic. 2020.

General Practices for the Safe Delivery of Vaccination Services

The potential for asymptomatic transmission of the virus that causes COVID-19 underscores the importance of applying infection prevention practices to encounters with all patients, including physical distancing, respiratory and hand hygiene, surface decontamination, and source control while in a healthcare facility. Immunization providers should refer to the guidance developed to prevent the spread of COVID-19 in healthcare settings.

To help ensure the safe delivery of care during vaccination visits, providers should:

- Minimize chances for exposures, including:
    - Screen for symptoms of COVID-19 and contact with persons with possible COVID-19 prior to and upon arrival at the facility and isolate symptomatic patients as soon as possible.
    - Limit and monitor points of entry to the facility and install barriers, such as clear plastic sneeze guards, to limit physical contact with patients at triage.
    - Implement policies for the use of a cloth face covering in persons over the age of 2 years (if tolerated).
    - Ensure adherence to respiratory hygiene, cough etiquette, and hand hygiene.
- Ensure all staff adhere to the following infection prevention and control procedures:
- Follow Standard Precautions, which includes guidance for hand hygiene and cleaning the environment between patients.
- Wear a medical facemask at all times.
- Use eye protection based on level of community transmission:
- Moderate to substantial: Healthcare providers should wear eye protection given the increased likelihood of encountering asymptomatic COVID-19 patients.
- Minimal to none: Universal eye protection is considered optional, unless otherwise indicated as a part of Standard Precautions.
- Additional considerations for vaccine administration:
- Intranasal or oral vaccines:
    - Healthcare providers should wear gloves when administering intranasal or oral vaccines because of the increased likelihood of coming into contact with a patient's mucous

membranes and body fluids. Gloves should be changed between patients in addition to performing hand hygiene.
    - Administration of these vaccines is not considered an aerosol-generating procedure and thus, the use of an N95 or higher-level respirator is not recommended.
- Intramuscular or subcutaneous vaccines:
    - If gloves are worn during vaccine administration, they should be changed between patients in addition to performing hand hygiene.
- Ensure physical distancing by implementing strategies, such as:
    - Separating sick from well patients by scheduling these visits during different times of the day (e.g., well visits in the morning and sick visits in the afternoon), placing patients with sick visits in different areas of the facility, or scheduling patients with sick visits in a different location from well visits (when available).
    - Reduce crowding in waiting areas by asking patients to remain outside (e.g., stay in their vehicles, if applicable) until they are called into the facility for their appointment.
    - Ensure that physical distancing measures, with separation of at least 6 feet between patients and visitors, are maintained during all aspects of the visit, including check-in, checkout, screening procedures, and postvaccination monitoring using strategies such as physical barriers, signs, ropes, and floor markings.
    - Utilize electronic communications as much as possible (e.g., filling out needed paperwork online in advance) to minimize time in the office as well as reuse of materials (e.g., clipboards, pens).

[1]CDC.Updated National Center for Immunization and Respiratory Diseases for the Interim Guidance for Immunization Services During COVID-19 Pandemic. 2020.

Community Vaccination Clinics
TOOLKIT

Part 3: MODEL EMERGENCY PLANS

Model Plan:
Emergency Plan for Anaphylaxis

I. Purpose:

To define allergic hypersensitivity to drugs administered by parenteral route as well as the emergency management that is to be provided by the vaccine provider.

II. Policy:

- A plan for contacting emergency medical services that are available in the area shall be established prior to starting any clinic.
- The plan shall include local emergency telephone numbers.
- Recipients of medication, vaccine, or biologicals administered by parenteral route shall be requested to remain on site for a minimum of 15 minutes for sign of hypersensitivity or anaphylactic reaction. Symptoms of anaphylaxis usually begin within 15 minutes after administration of the drug, and intervention should be implemented immediately. A vaccine provider shall remain on site for 15 minutes after each drug is administered.
- Individuals with symptoms categorized as mild may only require close monitoring on site with notice to their health care provider. Individuals with symptoms that progress shall require intervention including the administration of epinephrine. (See Toolkit, Model Plan: Administration of Epinephrine and Benadryl.

Model Plan:
Administration of Epinephrine and Benadryl

NOTE:

The signs and symptoms of anaphylactic shock are: hypotension, respiratory distress such as laryngeal edema, dyspnea, wheezing, a sense of retrosternal pressure or tightness, rapid and/or irregular pulse, urticarial, loss of consciousness, agitation, faintness, burning and/or itching eyes, tearing, congestion and itching nose, rhinitis, nausea, vomiting, abdominal pain, diarrhea, flushed skin, general itching, non-pruritic swelling of extremities as well as the face and perioral or periorbital regions, and/or a sense of uneasiness.

- After an injection of medication and/or vaccine it is determined that the individual has symptoms categorized as mild, the client may only require close monitoring on site with notice to their health care provider.

- Using clinical judgment, when the individual's symptoms progress to those of anaphylactic shock, vaccine providers shall initiate the emergency procedure for the administration of Epinephrine and Benadryl.

Special Instructions:

1. Equipment needed includes:
    - Ampules of Epinephrine (adrenaline) 1:1000 (or epinephrine auto-injectors)
    - 1 vial of Benadryl (diphenhydramine) 50mg/ml
    - 4 TB syringes
    - (2) 3cc syringes (w/needle-22-25ga, 1-1.5" length)
    - Alcohol Swabs
    - Blood Pressure cuff and stethoscope
    - CPR mask

2. All vaccine providers are required to be trained in Health Care Provider cardiopulmonary resuscitation (CPR).

3. In the event of a medical emergency during a clinic session, vaccine providers shall activate emergency medical services and notify the responsible health care provider and/or call an ambulance or other local emergency medical services.

4. Vaccine provider staff shall initiate CPR if the situation warrants it, unless there is a "Do Not Resuscitate" order in place.

In an emergency:

1. Call for assistance
2. Notify local emergency medical services
3. Establish and maintain an airway

To administer Epinephrine and Benadryl, follow the steps below:

1. Administer Epinephrine (per dosage chart/guidelines)

A. Using tuberculin (1cc)-syringe draw up only the amount of Epinephrine needed, based on the weight of the child or the dosage amount for an adult, or use epinephrine autoinjector.

B. Administer the Epinephrine subcutaneously. NOTE: DO NOT GIVE if symptoms of angina are present.

Epinephrine Dosage Guidelines:*

Epinephrine (Adrenaline Chloride) 1:1000

0.1cc for children < 20 lbs. (0-12 months of age)

0.2cc for children 20 – 45 lbs. (1-4 years old)

0.3cc for children > 45 lbs. (> 4 years of age)

0.3cc for adults

C. Guidelines for Epinephrine autoinjectors, see dosage and images below.

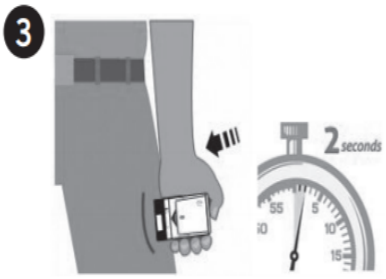
Epinephrine Autoinjector Dosage Guidelines:*

0.15 mg (junior dose) indicated for child under 66 pounds

0.3 mg (adult dose) indicated for over 66 pounds.

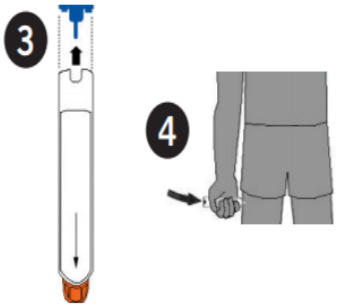
HOW TO USE AUVI-Q® (EPINEPRHINE INJECTION, USP), KALEO

1. Remove Auvi-Q from the outer case.
2. Pull off red safety guard.
3. Place black end of Auvi-Q against the middle of the outer thigh.
4. Press firmly until you hear a click and hiss sound, and hold in place for 2 seconds.
5. Call 911 and get emergency medical help right away.



HOW TO USE EPIPEN® AND EPIPEN JR® (EPINEPHRINE) AUTO-INJECTOR AND EPINEPHRINE INJECTION (AUTHORIZED GENERIC OF EPIPEN®), USP AUTO-INJECTOR, MYLAN AUTO-INJECTOR, MYLAN

1. Remove the EpiPen® or EpiPen Jr® Auto-Injector from the clear carrier tube.
2. Grasp the auto-injector in your fist with the orange tip (needle end) pointing downward.
3. With your other hand, remove the blue safety release by pulling straight up.
4. Swing and push the auto-injector firmly into the middle of the outer thigh until it 'clicks'.
5. Hold firmly in place for 3 seconds (count slowly 1, 2, 3).
6. Remove and massage the injection area for 10 seconds.
7. Call 911 and get emergency medical help right away.



HOW TO USE IMPAX EPINEPHRINE INJECTION (AUTHORIZED GENERIC OF ADRENACLICK®), USP AUTO-INJECTOR, IMPAX LABORATORIES

1. Remove epinephrine auto-injector from its protective carrying case.
2. Pull off both blue end caps: you will now see a red tip.
3. Grasp the auto-injector in your fist with the red tip pointing downward.
4. Put the red tip against the middle of the outer thigh at a 90-degree angle, perpendicular to the thigh.
5. Press down hard and hold firmly against the thigh for approximately 10 seconds.
6. Remove and massage the area for 10 seconds.
7. Call 911 and get emergency medical help right away.

ADMINISTRATION AND SAFETY INFORMATION FOR ALL AUTO-INJECTORS:

1. Do not put your thumb, fingers or hand over the tip of the auto-injector or inject into any body part other than mid-outer thigh. In case of accidental injection, go immediately to the nearest emergency room.
2. If administering to a young child, hold their leg firmly in place before and during injection to prevent injuries.
3. Epinephrine can be injected through clothing if needed.
4. Call 911 immediately after injection.

2. Administer Benadryl (per dosage chart/guidelines)

Administer the Benadryl deep I.M. in a large muscle.

Benadryl Dosage Guidelines
****Adult:** Benadryl 50mg. Deep I.M. in large muscle
*****Pediatric Patients other than premature infants or Neonates:** Benadryl 1mg/kg Deep I.M. in large muscle

3. Observe the clinical condition of the individual including the apical pulse rate and rhythm, respiratory rate, blood pressure, and level of consciousness.

    A. Monitor the blood pressure and pulse every 2-5 minutes until stable. Also note a change in any of the symptoms or the development of new symptoms.

    B. If symptoms persist, give a second dose of Epinephrine in 15 minutes, using a second ampule of Epinephrine.
    Do not repeat more than one time.

    C. If the individual exhibits signs of shock treat him/her by having him/her lie in a supine position with legs elevated and keeping the person(s) warm with blankets, if necessary.

    D. Reassure the individual and the family (if present).

    E. If CPR becomes necessary, institute as per current CPR protocols. The responder must be certified to conduct CPR.

*American Academy of Pediatrics, Abbott Laboratories, American Hospital Formulary Service, Mosby's Nursing Drug Reference
**Nursing 2006 Handbook, 26th edition. New York: Lippincott Williams & Wilkins.
***Nelson's Textbook of Pediatrics, 15th edition. Philadelphia: Saunders

Model Plan: Evaluation and Follow-up Of an Exposure to Blood and Other Potentially Infectious Material

Special Instructions:

1. Any Vaccinator who sustains a needle stick injury or other parenteral or mucosal exposure to blood or other potentially infectious material (OPIM) shall immediately wash the affected area with soap and water. If washing facilities are not available, the Vaccinator shall use the alcohol based hand gel and paper towels. Mucous membranes should be flushed with water.[1]

2. The Vaccinator shall proceed to the closest Urgent Care/Emergency Department for post exposure evaluation and treatment if indicated. NOTE: Postexposure prophylaxis should be initiated as soon as possible, preferably within hours rather than days of exposure.[2]
    i. The Vaccinator who has sustained the exposure with blood or OPIM may enlist the assistance of personnel at the clinic site if needed.

2. The employer of the Vaccinator shall be notified as soon as possible, within 24 hours, of the exposure.

3. The Centers for Disease Control and Prevention (CDC) recommends that the post exposure evaluation and follow-up includes[1]:
    i. Documentation of the routes and circumstances of the exposure;
    ii. Identification and testing of the source individual, if possible, in accordance with state laws. If the source person is known, the source person may be asked to voluntarily submit to a blood test;
        a. Under certain circumstances, and in accord with M.R.S.A. 19203-C, a source that has refused to voluntarily submit to a blood test may be required by a court order to do so.
    iii. Testing of the exposed employee's blood for HBV, HVC and HIV.
        a. The HIV blood test may consist of specimens drawn at the time of exposure and at recommended intervals up to 6 months. Counseling occurs according the state law M.R.S.A. 19203-B, or when requested.

iv. Postexposure prophylaxis as ordered by the physician.
v. Postexposure counseling, as indicated for the employee.
    a. If the employee declines evaluation or treatment they shall sign a declination form that indicates that the employee has been counseled regarding the risks, treatment has offered and the employee refused the evaluation and treatment.

4. The clinic coordinator/school shall maintain strict confidentiality in accord with statutes, policies and procedures. The employer of the vaccine provider shall maintain accurate, confidential, separate records for each employee with an occupational exposure. Per OSHA requirements, these records shall be maintained consistent with the maintenance of OSHA records, for a period of 30 years after the termination of the employee.

[1]CDC.Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HVC, and HIV and Recommendations for Postexposure Prophylaxis.MMWR.2001.50(RR11);1-42

[2]CDC.Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV: Recommendations for Postexposure Prophylaxis. MMWR 2005;54(RR09);1-17

Model Plan: Prevention of Post-Immunization Syncope-Related Injuries

Syncope, also called fainting, is a temporary loss of consciousness resulting from decreased blood flow to the brain. Immunization providers should be aware of the potential for syncope associated with vaccination, particularly among adolescents. Syncope after vaccination itself is usually not a serious event, and patients generally recover within a few minutes. The main concern is injury, especially head injury. Vaccine clinic staff should take appropriate measures to prevent syncope and to readily respond to the patient who feels faint.

Steps to Prevent Syncope-Related Injuries

- Make sure the patient is either seated or lying down at the time of vaccination.
- Observe patients for 15 minutes after vaccination for signs and symptoms that commonly precede syncope, such as weakness, dizziness, light-headedness, nausea, sweatiness, coldness of the hands or feet, paleness or visual disturbances.
- If patient is experiencing possible signs or symptoms of fainting, take the following steps to prevent syncope and injury from falling:
    - Have the patient sit or lie down immediately.
    - Have the patient lie flat or sit with head between knees for several minutes.
    - Loosen any tight clothing and maintain an open airway.
    - Apply cool, damp cloths to the patient's face and neck.
    - Observe the patient until symptoms completely resolve.
- If patient falls but does not experience loss of consciousness:
    - Check the patient to determine if injury is present before attempting to move him/her.
    - Place the patient flat on back with feet elevated.
    - Observe the patient until symptoms completely resolve.
- If patient loses consciousness:
    - Check the patient to determine if injury is present before attempting to move him/her.
    - Place the patient flat on back with feet elevated.
    - Maintain an open airway.
    - Call 911 if the patient does not recover immediately.

References:

The Children's Hospital of Philadelphia. Vaccine Update for Healthcare Providers. Technically speaking: Guidance for preventing fainting and associated injuries after vaccination. Available at: http://www.chop.edu/professionals/vaccine-healthcare-providers/technically -speaking/. Accessed on 6/6/2012.

CDC. General Recommendations on Immunization: A Report of the Advisory Committee on Immunization Practices. MMWR 2011; 60(RR02):1-60.

CDC. Vaccine Safety: Fainting (Syncope) After Vaccination. Available at: http://www.cdc.gov/vaccinesafety/Concerns/syncope.html. Accessed on 6/4/2012.

Immunization Action Coalition. Medical Management of Vaccine Reactions in Children and Teens. Available at: http://www.immunize.org/catg.d/p3082a.pdf. Accessed on 6/4/2012.

Community Vaccination Clinics

TOOLKIT

Part 4: VACCINE STORAGE and HANDLING

Proper Maintenance and Storage of Vaccine by Clinic Coordinator

Special Instructions:

NOTE: The refrigerator must be designated for vaccines, medications and biologicals only. No food or beverage is allowed to be stored in them.

1. One vaccine coordinator and a backup person shall be assigned the responsibility for the proper storage and handling of vaccines.

2. Each location that stores vaccine shall have a working refrigerator and a certified calibrated digital data logger suitable for checking internal temperatures of the refrigerator. The refrigerator thermometer must be able to record temperatures at or above 36°F - 46°F (2-8°C).

3. Refrigerator temperature should be maintained between 36° and 46° F. The temperature of the refrigerator must be checked and documented each workday at the beginning of the day. The temperatures shall be recorded on the log sheets that are obtained from the Maine Immunization Program and placed on or near the refrigerator. Each log shall be maintained for three years and then destroyed.

4. Upon arrival of the vaccine, the designated vaccine coordinator or backup person shall immediately unpack the vaccines and place them in the refrigerator or freezer as appropriate. The vaccines shall be stored inside the refrigerator and never placed on the door shelves (there is too much temperature variation when the door is open). The vaccines shall be placed so that the cool air can circulate around the vaccines. The newest vaccine shall be placed behind any of the same type of vaccine that has an earlier expiration date.

5. The vaccines shall be written into the vaccine record book and added to the supply on hand so that the count in the record book matches the count in the refrigerator. Records shall be retained in the office for three years and then destroyed.

6. The vaccine coordinator shall rotate the vaccines monthly so that the ones with the earliest expiration dates are placed in the front of the refrigerator and used first.

7. Ice packs shall be placed inside the freezer to help maintain the temperature when the door is opened.

8. Bottles of cold water shall be placed to line the inside walls of the refrigerator and on the door shelves in order to maintain the internal temperature of the refrigerator when the door is opened.

9. The vaccine coordinator shall place a "Do Not Disconnect" sign on each refrigerator and circuit breaker. The electrical connection shall be protected from accidental disconnect by either a protected location or protective plug cover.

10. If the temperature of the refrigerator or freezer is measuring above or below the allowable temperatures listed above, the vaccine coordinator discovering a refrigerator or freezer out of temperature range shall:

    - Label the vaccine that it has been stored out of range and not to use the vaccine until given the permission to use from the manufacturer.
    - Notify the Manufacturer of the product for instructions in handling the vaccines (contact numbers below). Contact the Maine Immunization Program, if obtained from the Maine Immunization Program.

11. In the event of an extended power outage the vaccine coordinator shall follow the procedure for extended power outages.

12. For further instructions for storing frozen vaccine, please reference the link below, pages 33-35: https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/documents/MIP-Policies-and-Procedures.pdf

Contact Information: Selected Vaccine Manufacturers & Distributors Manufacturer/Website	**Phone Number:**	**Products:**
Centers for Disease Control & Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.htm.	404-639-3670	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline www.gskvaccines.com	866-475-8222	Infanrix, Kinrix, Pediarix, Havrix, Engerix-B, Twinrix,

		Hiberix, Cervarix, Fluarix, FluLaval, Rotarix, Boostrix
Massachusetts Biological Labs https://www.amscomedical.com/brand/listing/massachusetts-biologic-labs/68	617-474-3000	IGIM, Td, TT
MedImmune, Inc. www.medimmune.com	877-633-4411	FluMist
Merck & Co., Inc. www.merckvaccines.com	800-637-2590	PedvaxHIB, Comvax, Vaqta, Recombivax-HB, Gardasil, M-M-R II, ProQuad, Afluria, Pneumovax 23, RotaTeq, Varivax, Zostavax, Td
Biotest Pharmaceuticals https://www.biotest.com/de/en/index.cfm	800-458-4244	HBIG
Novartis Vaccines https://www.novartis.com/	877-683-4732	Fluvirin, Agriflu, Menveo, RabAvert (distributer for Ixiaro)
Pfizer (Wyeth Vaccines) www.pfizerpro.com/	800-438-1985	Prevnar 13
Sanofi Pasteur www.vaccineshoppe.com	800-822-2463	Daptacel, Tripedia, Pentacel, ActHIB, Fluzone, Menomune, Menactra, IPOL, Imovax, Decavac, Tenivac, Adacel, Typhim Vi, YF-Vax
Talecris Biotherapeutics https://www.grifols.com/en/home#	800-520-2807	HBIG, IGIM, RIG, TIG

Maine Immunization Program: (207)287-3746 or 800-867-4775

Vaccine Clinic Checklist for Safe Vaccine Handling and Storage

Here are the 17 most important things you should do to safeguard your vaccine supply.
Are you doing them all?
Note: Some of these are VFC requirements and would not apply unless enrolled in the program**

___ 1. We have a vaccine coordinator or a designated person in charge of the handling and storage of our vaccines.
___ 2. We have a back-up person in charge of the storage and handling of our vaccines.
____3. A vaccine inventory log is maintained that documents:
- _____ Vaccine name and number of doses received
- _____ Date the vaccine was received
- _____ Arrival condition of vaccine
- _____ Vaccine manufacturer and lot number
- _____ Vaccine expiration date

____ 4. Our refrigerator for vaccines is either household-style or commercial-style, NOT dormitory-style. The freezer compartment has a separate exterior door. Alternatively, we use two storage units: a free-standing refrigerator and a separate, free-standing freezer.
____ 5. We do NOT store any food or drink in the refrigerator.
____ 6. We unpack vaccine immediately upon arrival and place it in the refrigerator.
____ 7. We store vaccines in the middle of the refrigerator, and NOT in the door.
____ 8. We check vaccine expiration dates before use.
____ 9. We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
____10. We always keep a certified calibrated thermometer in the refrigerator that can record temperatures at 36-46°F.
____11. The temperature in the refrigerator is maintained at 36–46ºF.
____12. We use bottles of cold water to line the inside walls of the refrigerator to help maintain cold temperatures.
____13. We post a temperature log on the refrigerator door on which we record the refrigerator minimum and maximum temperature once a day—first thing in the morning and we know whom to call if the temperature goes out of range.
____14. We understand that these temperature logs must be submitted to the Maine CDC Immunization Program at least monthly with copies maintained for three years. **
____15. We have a “Do Not Unplug” sign next to the refrigerator’s electrical outlet.
____16. In the event of a refrigerator failure, we take the following steps:
- _____ We call the manufacturer immediately.
- _____ We notify the Maine CDC Immunization Program. **
- _____ We label the vaccine stating that it has been stored out of range and not to use the vaccine until given the guidance to use from the manufacturer. (this vaccine should be kept in a cold storage unit)

____17. We keep important phone numbers posted where they are easily accessible including:

Contact Information: Selected Vaccine Manufacturers & Distributors Manufacturer/Website	**Phone Number:**	**Products:**
Centers for Disease Control & Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.htm.	404-639-3670	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline www.gskvaccines.com	866-475-8222	Infanrix, Kinrix, Pediarix, Havrix, Engerix-B, Twinrix, Hiberix, Cervarix, Fluarix, FluLaval, Rotarix, Boostrix
Massachusetts Biological Labs https://www.amscomedical.com/brand/listing/massachusetts-biologic-labs/68	617-474-3000	IGIM, Td, TT
MedImmune, Inc. www.medimmune.com	877-633-4411	FluMist
Merck & Co., Inc. www.merckvaccines.com	800-637-2590	PedvaxHIB, Comvax, Vaqta, Recombivax-HB, Gardasil, M-M-R II, ProQuad, Afluria, Pneumovax 23, RotaTeq, Varivax, Zostavax, Td
Biotest Pharmaceuticals https://www.biotest.com/de/en/index.cfm	800-458-4244	HBIG
Novartis Vaccines https://www.novartis.com/	877-683-4732	Fluvirin, Agriflu, Menveo, RabAvert (distributer for Ixiaro)
Pfizer (Wyeth Vaccines) www.pfizerpro.com/	800-438-1985	Prevnar 13
Sanofi Pasteur www.vaccineshoppe.com	800-822-2463	Daptacel, Tripedia, Pentacel, ActHIB, Fluzone, Menomune, Menactra, IPOL, Imovax, Decavac, Tenivac, Adacel, Typhim Vi, YF-Vax
Talecris Biotherapeutics https://www.grifols.com/en/home#	800-520-2807	HBIG, IGIM, RIG, TIG

Transportation of Vaccine

Rationale:

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that the potency is protected by maintaining the cold chain at all times. It is essential that refrigerated vaccine shall be maintained at 36 - 46 degrees Fahrenheit during transportation.

Instructions for all transported vaccine:

1. The vaccine provider shall pack the vaccine in the appropriately sized cooler the day of the clinic according to quantity guidelines outlined below. The vaccine should remain in their original boxes when transported to the home or clinic site.
2. The vaccine provider shall attach a label to the outside of the container to clearly identify the contents as fragile vaccines.
3. A calibrated data logger with a buffered probe shall be fixed to the outside of the cooler by velcro and used for all temperature readings.
4. The vaccine provider shall record the time and temperature inside the cooler on the *Vaccine Transport Temperature Log*.
5. The vaccine provider shall check the temperature at least hourly to ensure that the cold chain is not broken. Record the time and temperature on the *Vaccine Transport Temperature Log.* Do not open the cooler for hourly temperature readings. Retain these records for three years and then destroy.
6. If the temperature of the cooler falls outside of the recommended guidelines the vaccine provider shall take the following actions:

    - Label the Vaccine that it has been stored out of range
    - Notify the manufacturer of the product for instructions in handling the vaccine (Manufacturer's contact numbers are listed below)
    - If the vaccine was obtained from the Maine Immunization Program notify the Maine Immunization Program at 287-3746

Contact Information: Selected Vaccine Manufacturers & Distributors Manufacturer/Website	Phone Number:	Products:
Centers for Disease Control & Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.htm.	404-639-3670	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline www.gskvaccines.com	866-475-8222	Infanrix, Kinrix, Pediarix, Havrix, Engerix-B, Twinrix, Hiberix, Cervarix, Fluarix, FluLaval, Rotarix, Boostrix
Massachusetts Biological Labs https://www.amscomedical.com/brand/listing/massachusetts-biologic-labs/68	617-474-3000	IGIM, Td, TT
MedImmune, Inc. www.medimmune.com	877-633-4411	FluMist
Merck & Co., Inc. www.merckvaccines.com	800-637-2590	PedvaxHIB, Comvax, Vaqta, Recombivax-HB, Gardasil, M-M-R II, ProQuad, Afluria, Pneumovax 23, RotaTeq, Varivax, Zostavax, Td
Biotest Pharmaceuticals https://www.biotest.com/de/en/index.cfm	800-458-4244	HBIG
Novartis Vaccines https://www.novartis.com/	877-683-4732	Fluvirin, Agriflu, Menveo, RabAvert (distributer for Ixiaro)
Pfizer (Wyeth Vaccines) www.pfizerpro.com/	800-438-1985	Prevnar 13
Sanofi Pasteur www.vaccineshoppe.com	800-822-2463	Daptacel, Tripedia, Pentacel, ActHIB, Fluzone, Menomune, Menactra, IPOL, Imovax, Decavac, Tenivac, Adacel, Typhim Vi, YF-Vax
Talecris Biotherapeutics https://www.grifols.com/en/home#	800-520-2807	HBIG, IGIM, RIG, TIG

Special Instructions for Refrigerated Vaccine Transport:

MIP recommends transporting refrigerated vaccines with a portable refrigeration unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls, a Styrofoam vaccine shipping container, or other qualified container may be used as long as it maintains the recommended temperature range (36°F to 46°F [2°C to 8°C]).

• Using a hard-sided cooler, Styrofoam vaccine shipping container, or other qualified container requires the following:

o Coolers should be large enough to hold the supply of refrigerated vaccines.

o Label the container with the facility name, "Fragile Vaccines – Do NOT Freeze", and the date and time the vaccines was removed from the permanent storage unit.

NOTE: Do not use soft-sided collapsible coolers for transporting vaccine.

• Conditioned frozen water bottles are recommended for keeping vaccines cold.
o Use 16.9 oz. bottles for medium/large coolers and 8 oz. bottles for small coolers
o Before use, condition the frozen water bottles. This is done by placing them in a sink filled with several inches of cool or lukewarm water until there is a layer of water forming near the inner surface of the bottle. The bottle is properly conditioned when the ice block spins freely within the bottle when rotated.

NOTE: Do not reuse coolant packs from original vaccine shipping containers.

• Insulating material – two each of the following layers is needed:

o Corrugated cardboard – two pieces cut to fit the internal dimensions of the coolers(s) and placed between the insulating cushioning material and the conditioned water bottles.

o Insulating cushioning material such as bubble wrap, packing foam, or Styrofoam for a layer at least 2-inches thick above and below the vaccines. Ensure this layer covers the cardboard completely.

NOTE: Do not use packing peanuts or other loose material that may shift during transport.

• A data logger with a buffered probe must be used as a temperature monitoring device.

o Prepare the probe by pre-chilling it in the refrigerator for at least 5 hours prior to transport.

o Ensure the data logger has a current and valid certificate of calibration testing.

o Ensure the data logger certificate is documented to be accurate within +/- 1°F (+/- 0.5°C).

o The data logger currently stored in the refrigerator can be used for transport, as long as there is a device in place to measure the temperature for any remaining vaccines.

MIP recommends the following packing assembly for refrigerated vaccines:

• Line the bottom of the cooler with a single layer of conditioned water bottles.
• Place a sheet of corrugated cardboard over the water bottles. • Place at least a 2-inch layer of insulating material (i.e., bubble-wrap, packing foam, or Styrofoam) over the cardboard.

• Stack boxes of vaccines on top of the insulating material.

• When cooler is halfway full, place the data logger buffered probe in the center of the vaccines, but keep the display outside the cooler.

• Cover vaccines with another 2-inch layer of insulating material.

• Add the second layer of corrugated cardboard.

• Fill the remaining space in the cooler with conditioned water bottles.

• Close the lid of the cooler securely and attach the data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport.

• Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines were removed.

• If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.

• As soon as the destination site is reached, check and record the vaccine temperature.

As long as the vaccine temperature is 36°F to 46°F (2°C to 8°C), place the vaccine in the refrigerator.

If the vaccine is below 36°F (below 2°C) or above 46°F (above 8°C), label the vaccine as “Do Not Use”, place in the refrigerator, and immediately contact the vaccine manufacturer to determine viability.

NOTE: Always keep vaccine properly stored until otherwise instructed by the vaccine manufacturer or MIP.

Special Instructions for Frozen Vaccine Transport:

Varicella and MMRV vaccines are fragile and must be kept frozen. MIP and the vaccine manufacturer do not recommend transporting varicella or MMRV. If these vaccines must be relocated in an emergency, the following steps must be taken:

• Portable Freezer – MIP recommends transport with a portable freezer unit that maintains the temperature between -58°F to +5°F (-50°C to -15°C). Portable freezers may be available for rent. Label the portable freezer with the facility name and “Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit.

• Temperature Monitoring Device – Use a certified and calibrated data logger with a current and valid certificate of calibration testing. Prepare the data logger by placing it in a freezer unit at least 2 hours before packing the vaccine.

• Cooler – If a portable freezer is unavailable, a hard-sided insulated cooler with at least 2-inch walls, a Styrofoam vaccine shipping container, or other qualified container may be used if temperatures between -58°F to +5°F (-50°C to -15°C) can be maintained. Label the container with the facility name and

“Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit.

• Use frozen water bottles in the cooler. Dry ice is not allowed to be used for transporting vaccines, even for temporary storage or emergency transport. Dry ice may allow the vaccine to be exposed to temperatures colder than -58°F (-50°C).

• Line the bottom of the cooler with a single layer of frozen water bottles.

• Place at least a 2-inch layer of insulating material (i.e., bubble-wrap, packing foam, or Styrofoam) over the frozen water bottles.

• Stack boxes of vaccines and diluents on top of the insulating material.

• When cooler is halfway full, place the data logger buffered probe in the center of the vaccines, but keep the display outside the cooler.

• Cover vaccines with another 2-inch layer of insulating material.

• Fill the remaining space in the cooler with frozen water bottles.

• Close the lid of the cooler securely and attach the data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport.

• Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines were removed.

• If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.

• As soon as the destination site is reached, check and record the vaccine temperature.

• Place the vaccines in a freezer that maintains a temperature range between -58°F to +5°F (-50°C to -15°C).

• Document the time and temperature the vaccine was removed from the transport container and placed in the alternate storage unit.

• Immediately contact the vaccine manufacturer for viability data and guidance when frozen vaccine has been exposed to a temperature above +5°F (-15°C). Do not discard the vaccine without contacting the manufacturer. Viability determination will be made on a case-by-case basis.

Instructions for Using Cool Cubes

VeriCooler Cool Cube 03

Phase Change Material (PCM): A non-toxic biodegradable temperature regulating substance inside the panels in the VeriCooler.
Ultra-low freezer – A freezer that maintains temperatures at lower than -25°C/-13°F.
Cool Cube Color Cards – Laminated cards that can be placed in the plastic on the outside of the cube. Use the "SERIES 4" card to indicate a refrigerated VeriCooler and use the "SERIES 20M" card to indicate a frozen VeriCooler.

	Refrigerator VeriCooler	Freezer VeriCooler
PCM Panel Prep	1. **Place 6 blue-tabbed PCM panels in a freezer until PCM is solid** (i.e. 2 hours at -15°C/+5°F). Shake to verify PCM is frozen. 2. **Transfer PCM panels into refrigerator at least 3 hours before use**. Panels may be stored in refrigerator until assembly or until PCM melts. *NOTE: If panels are used directly out of freezer, they may initially be below 0°C/32°F. 3. **Before assembly, shake panels to verify PCM is solid**. If liquid can be heard, panels may be used but hold times will decrease.	1. **Place 6 black-tabbed PCM panels in an ultra-low freezer until PCM is solid** (i.e. 24 hours at -25°C/-13°F). 2. **Before assembly, shake to verify PCM is solid.** If liquid can be heard, panels may still be used but hold times will decrease.
Acceptable VFC Temperature Range	36°F - 46°F OR 2.2°C – 7.8°C	-58°F - +5°F OR -50°C - -15°C
PCM Panel Assembly	Assemble 6 PCM panels into VeriCooler – one on the bottom, 4 on the sides, and one on the top. A calibrated data logger should ALWAYS be used.	
Care & Cleaning	Avoid puncture of the PCM panels. Cleaning using warm water & soap. Sanitization may be performed with a mixture of isopropyl alcohol and water (70/30 mix) or other salt-based disinfectants. Do not use: autoclave, solvents such as acetone, abrasive cleaners, or expose to extreme heat (above 75°C/167°F).	

Pack-Out Space & Weight	One VeriCooler Cool Cube 03 has a 3 liter capacity and weighs ~11 pounds with 6 PCM panels. Pack-out space measures 5.75” x 5.75” x 5.75”. Cube measures 11” x 11” x 11”.

VFC 5000-TP Data Logger

Software Download - http://www.vfcdataloggers.com/software-downloads/ (“VFC5000TP Software”)
Control Solutions - www.vfcdataloggers.com , 1-503-410-5996

Steps to Use VFC 5000-TP Data Logger:

1. Install software & USB driver
    a. Download software using “Software Download” link above.

2. Install battery (if not already installed)
    a. Use a small, pointed object to press on the metal button on the middle, back side of the data logger.
    b. Remove bottom half of data logger.
    c. Insert battery into data logger.
    d. Reattach bottom half of data logger, two halves should click into place when secure.

3. Configure data logger for use
    a. Plug data logger into USB port on computer.
    b. Double click on the EasyLog USB icon on desktop to open software. There are three options:
    c. Green Arrow icon (Set-up and start data logger)
        i. Click on green arrow icon.
        ii. Name your data logger, select a temperature scale & select a sample rate (i.e. how frequently the logger reads) according to VFC Requirements. Click “Next”.
        iii. Choose how often you want the display to stay on and select what the logger should do when it is full. Click “Next”.
        iv. Set “High Alarm” and “Low Alarm” according to VFC Requirements. Check the “Hold” button so the data logger alarm still says on even if the temperature returns to a non-alarm status. Click “Next”.
        v. Select when the data logger should begin recording. Click “Finish”, remove from USB drive – display should flash “PS” for “Push Start”. Plug probe into logger, then press button to begin logging.

4. Download data
    a. Unplug probe from data logger and plug data logger into USB port on computer.
    b. Click Red Arrow icon (Stop the USB data logger and download data).
        i. At next screen, select “OK”.
        ii. Name data file and save to a drive or computer (it’s important to name your file with a name that makes sense. A simple date of 07152019 may not make sense when looking at the graph at a later date).
        iii. EasyLog graph with data will appear
            1. “Data View” – Chart of every data point the logger recorded.

2. “Graph View” – Graph of every data point the logger recorded (move mouse over red data line to find a specific data/time).
3. “Statistics” – View the minimum and maximum temperatures during the logging session.

c. Data logger will be in “Stopped” mode until it is configured again (see Step 3).

5. Troubleshooting
    a. See back page of “Quick Start Guide” located in plastic pocket of VeriCooler.

Mobile Clinic Temperature Log and Best Practices

- Per US CDC recommendations, vaccine should not be stored in a mobile pack-out cooler for longer than 8 hours, including travel time.
    - Example: If travel time in a mobile pack-out cooler is 1 hour each way, the clinic should only last for 6 hours.
- Temperatures should be recorded at least hourly on the temperature log provided. Be sure to note the following:
    - Indicate if the log is for a refrigerator, or freezer
    - Indicate whether the temperature is measured in °F or °C
    - If there is more than one cooler being used, make sure to label each cooler with a unique name and document the name of the unit on the temperature log.
    - Document any temperature excursions and if so, ensure the manufacturers were contacted and document the guidance provided by manufacturer
    - Initials of the person taking the reading
    - Be sure to document the temperature at pickup and drop off of vaccine

Best Practices

Keep cooler closed AT ALL TIMES except when removing vaccine.

Keep cooler away from: heat sources, windows, doors, vents or anywhere temperature could be compromised.

Mobile Clinic Temperature Log

Circle One: **Refrigerator** **Freezer**

Time	Temperature Reading (°F or °C)	Initials
AM PM	Temperature at Pick Up	
AM PM		
AM PM		
AM PM		
AM PM		
AM PM		
AM PM		
AM PM		
AM PM	Temperature at Drop Off	

Actions Taken:

Community Vaccination Clinics

TOOLKIT

Part 5: COMMUNICATION

5.1 Clinic Resources

Clinic Resources

ImmPact, Questions pertaining to clinic registration and entering doses, call ImmPact Help desk 1-800-906-8754

Schools, for overall questions related to school and/or school health. Emily Poland, School Nurse Consultant, Maine Department of Education, 592-0387, Emily.Poland@maine.gov.

Maine Immunization Program, for questions pertaining to ordering and storing vaccine call the Maine Immunization Program: 1-800-867-4775.

MIP Vaccine Educators by County:

Clara Alvarez	IQIP Coordinator / Public Health Educator for **Aroostook, Lincoln, Oxford, Sagadahoc** and **Washington** counties	Clara.Alvarez@maine.gov
Caitlin Anton	Public Health Educator/Adolescent Coordinator for **Hancock, Knox, Penobscot** and **Waldo** counties	Caitlin.Anton@maine.gov
Moria Pratt	Project Coordinator/Vaccine Educator for **Androscoggin, Franklin, Kennebec, Piscataquis** and **Somerset** counties	Moria.Pratt@maine.gov
Amanda Luciano	Project Coordinator/Vaccine Educator for **Cumberland** and **York** counties	Amanda.Luciano@maine.gov