“Best Practice” Tools for Holding Safe Vaccination Clinics in Satellite, Temporary, or Off-site Locations: Checklist and Pledge

Current Issues in Immunization Netconference

May 2, 2017

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Immunization Services Division
Webinar Overview

1. Background
   — Unique challenges of vaccination clinics held in satellite, temporary, or off-site locations.

2. The Checklist
   — What is it, why was it created, and who should use it?
   — Description of each component of the checklist.
   — Situations when the vaccination clinic must stop.

3. The Pledge
   — What is it, why was it created, and who should sign it.

4. Case Scenario

5. Additional Resources and Wrap-Up
Background

- Satellite, temporary, and off-site vaccination clinics play an important role in improving vaccination coverage rates and vaccinating hard-to-reach populations.

- 17.6% of adults in the U.S. receive their influenza vaccination at their workplace¹.

- Temporary vaccination clinics can also be held at schools, community centers, churches, or other non-clinic settings.

Challenges of Vaccination Clinics in Temporary Settings

- Vaccination clinics held in these settings have unique challenges:
  - Training and oversight of HCP
  - Vaccine transport, storage and handling
  - Monitoring proper vaccine administration techniques
  - Managing documentation for large groups

- May lead to unsafe environments, vaccine temperature excursions, and vaccine administration errors.
Incident—New Jersey

- Sept 30, 2015: NJDOH was notified of infection control breach at a workplace-sponsored flu vaccination clinic:
  - A nurse used same syringe for >1 patient.

- Company A contracted with the nurse to provide flu vaccines at a workplace-sponsored flu vaccination clinic for Company B.

- Participant noticed the nurse reused a syringe and notified management at Company B. This was reported to NJDOH by Company A.

- NJDOH found other problems with the clinic.
  - Inadequate dosing
  - Inappropriate transport, storage and handling
Patients tested for HIV and hepatitis after nurse reuses syringe to administer flu shots

BY LAURIE HANNA / NEW YORK DAILY NEWS / Thursday, October 8, 2015, 5:45 AM
Coordinated Response

- Reported incident to NJ Board of Nursing.
  - Nurse gave up her license.

- Recommended testing for hepatitis B and C and HIV, receipt of hepatitis B vaccination, and revaccination with flu vaccine at local health department or urgent care center for clinic participants.

- 47 of 67 clinic participants were tested and vaccinated. Others chose to go to their personal health care provider for testing.
Notes from the Field: Injection Safety and Vaccine Administration Errors at an Employee Influenza Vaccination Clinic — New Jersey, 2015

Weekly

December 18, 2015 / 64(49);1363-4

Laura Taylor, PhD\(^1\); Rebecca Greeley, MPH\(^1\); Jill Dinitz-Sklar, MPH\(^1\); Nicole Mazur, MPH\(^1\); Jill Swanson, MPH\(^2\); JoEllen Wolicki, BSN\(^3\); Joseph Perz, DrPH\(^4\); Christina Tan, MD\(^1\); Barbara Montana, MD\(^1\)

On September 30, 2015, the New Jersey Department of Health (NJDOH) was notified by an out-of-state health services company that an experienced nurse had reused syringes for multiple persons earlier that day. This occurred at an employee influenza vaccination clinic on the premises of a New Jersey business that had contracted with the health services company to provide influenza vaccinations to its employees. The employees were to receive vaccine from manufacturer-prefilled, single-dose syringes. However, the nurse contracted by the health services company brought three multiple-dose vials of vaccine that were intended for another event. The nurse reported using two syringes she found among her supplies to administer vaccine to 67 employees of the New Jersey business. She reported wiping the syringes with alcohol and using a new needle for each of the 67 persons. One of the vaccine recipients witnessed and questioned the syringe reuse, and brought it to the attention of managers at the business who, in turn, reported the practice to the health services company contracted to provide the influenza vaccinations.
Incident Outcome

- NJDOH held a final testing and hepatitis B vaccination clinic for those who were impacted.

- No illnesses reported related to this incident.

- Need to increase training and oversight of employees, with more attention to proper procedures for transfer and storage of the vaccine and proper vaccine administration.
Other Reported Incidents

- Collier County, FL (2009): 77 students given wrong flu shot.  
  [Link](http://www.nbc-2.com/story/11477899/dozens-of-students-given-wrong-flu-shot)

- Montgomery County, TX (2015): $70,000 worth of revaccinations required after vaccines were stored at the wrong temperature.  

- Wellesley, MA (2010): School staff given insulin in flu vaccine error. Some staffers had to be hospitalized, but all recovered.  
  [Link](http://www.boston.com/news/education/k_12/articles/2010/01/19/wellesley_school_staff_given_insulin_in_flu_vaccine_error/)
Rationale for Creating the Checklist and Pledge

- No “gold standard” for organizations that run these clinics.

- In an effort to standardize the process of holding clinics in these non-traditional settings, National Adult and Influenza Immunization Summit (NAIIS)* Influenza Working Group developed:

  - A checklist of best practices for vaccination clinics held at satellite, temporary, or off-site locations.

  - A pledge for organizations implementing vaccination clinics held at satellite, temporary, or off-site locations affirming they will adhere to best practices.

*The NAIIS Influenza Working Group consists of public health experts, medical center occupational health directors, industry, and vaccine contractors
The Checklist
Purpose and Function of the Checklist of Best Practices

- Comprehensive, step-by-step guide for clinic coordinators/supervisors overseeing vaccination clinics
  - The designated clinic coordinator/supervisor should sign and date checklist each time a clinic is held, which should be kept on file.

- Checklist is divided into before, during, and after clinic sections and covers:
  - Vaccine Shipment
  - Vaccine Transport
  - Vaccine Storage and Handling
  - Clinic Preparation and Supplies
  - Vaccine Administration
  - Documentation
Importance of the “Stop Sign” Symbol

- Critical steps for patient safety and vaccine effectiveness are identified with a stop sign icon.
- If any of these stop sign items are checked as “NO,” users are directed to STOP the clinic and follow their organization’s protocols and/or contact the state or local health department before proceeding.

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<th>VACCINE ADMINISTRATION</th>
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<td>YES NO N.A.</td>
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<td>Vaccine Information Statements (VISs) are being provided to every patient, parent, or guardian before vaccination (as required by federal law).</td>
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<tr>
<td>□ □ STOP</td>
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<tr>
<td>All patients are being screened for contraindications and precautions for the specific vaccine(s) in use before receiving that vaccine(s).</td>
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Title Page of Checklist

Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

OVERVIEW OF THIS DOCUMENT
This checklist 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. 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.

INSTRUCTIONS
1. A staff member who will be at the vaccination clinic should be designated as the clinic coordinator/supervisor. (This individual will be responsible for completing the steps below and will be referred to as “you” in these instructions.)
2. Review this checklist during the planning stage of the vaccination clinic—well in advance of the date(s) when the clinic will be held. This checklist includes sections to be completed before, during, and after the clinic.
3. Critical guidelines for patient safety and vaccine effectiveness are identified by the stop sign icon.
4. If you check “NO” in ONE OR MORE answer boxes that contain a stop sign icon, DO NOT move forward with the clinic. Follow your organization’s protocols and/or contact your state or local health department for guidance BEFORE proceeding with the clinic. Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.
5. Contact your organization and/or health department if you have any concerns about whether vaccine was transported, stored, handled, or administered correctly, concerns about whether patients’ personal information was protected appropriately, concerns about other responses that you have marked as “NO” on rows that do not have the stop sign icon.
6. This checklist should be used in conjunction with CDC’s Vaccine Storage and Handling Toolkit: [http://www.cdc.gov/vaccines/hcp/admin/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage-handling-toolkit.pdf). For information about specific vaccines, consult the vaccine manufacturer’s package insert.
7. This checklist applies ONLY TO vaccines stored at REFRIGERATED temperatures.
8. Sign and date the checklist upon completion of the clinic or completion of your shift (whichever comes first). If more than one clinic coordinator/supervisor is responsible for different aspects of the clinic, you should complete only the section(s) for which you were responsible.
9. Attach the staff sign-in sheet (with shift times and date) to the checklist (or checklists if more than one clinic coordinator/supervisor is overseeing different shifts), and submit the checklist(s) to your organization to be kept on file for accountability.

Name and credentials of clinic coordinator/supervisor: ________________________________

Name of facility where clinic was held: ____________________________________________

Address where clinic was held (street, city, state): _________________________________

Time and date of vaccination clinic shift (the portion you oversaw): __________________

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Signature of clinic coordinator/supervisor: ________________________________
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Address where clinic was held (street, city, state):

Time and date of vaccination clinic shift (the portion you oversaw):

Time (AM/PM) Date (MM/DD/YYYY)

Time and date when form was completed:

Time (AM/PM) Date (MM/DD/YYYY)

Signature of clinic coordinator/supervisor:
### BEFORE THE CLINIC (Please complete each item before the clinic starts.)

#### VACCINE SHIPMENT

<table>
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#### VACCINE TRANSPORT (If it was not possible to ship vaccines directly to the facility/clinic site)

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- Vaccines were transported using a portable vaccine refrigerator or qualified container and pack-out designed to transport vaccines within the temperature range recommended by the manufacturer (i.e., between 2-8°C for vaccines requiring refrigeration and -15°C for vaccines requiring deep freezing).
- Coolers available at general merchandise stores or coolers used to transport food are NOT ACCEPTABLE. See CDC’s Vaccine Storage and Handling Toolkit for information on qualified containers and pack-out: [http://www.cdc.gov/vaccines/hcp/admin/transport/toolkit/storage-handling-toolkit.html](http://www.cdc.gov/vaccines/hcp/admin/transport/toolkit/storage-handling-toolkit.html)
- The person transporting the vaccines confirmed that manufacturer instructions for packing configuration and proper conditioning of coolers were followed. (Your qualified container and pack-out should include packing instructions. If not, contact the company for instructions on proper packing procedures.)
- The person transporting the vaccines confirmed that all vaccines were transported in the passenger compartment of the vehicle (NOT in the vehicle trunk).
- A digital data logger with a buffered probe and a current and valid certificate of calibration testing was placed directly with the vaccines and used to monitor vaccine temperature during transport.
- The amount of vaccine transported was limited to the amount needed for the worksite.

#### VACCINE STORAGE AND HANDLING (upon arrival at facility/clinic)

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- If vaccines were shipped, the shipment arrived within the appropriate time frame (according to manufacturer or distributor guidelines) and in good condition.
- If the vaccine shipment contained a cold chain monitor (CCM), it was checked upon arrival at the facility/clinic, and there was no indication of a temperature excursion during transit. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer). Note: CCMs are for one-time use and should be thrown away after being checked.
- Upon arrival at the facility/clinic (either by shipment or transport), vaccines were immediately unpacked and placed in proper storage equipment (i.e., a portable vaccine refrigerator or qualified container and pack-out specifically designed and tested to maintain the manufacturer-recommended temperature range). Follow the guidelines for unpacking and storing vaccines specified in CDC’s Vaccine Storage and Handling Toolkit: [http://www.cdc.gov/vaccines/hcp/admin/transport/toolkit/storage-handling-toolkit.html](http://www.cdc.gov/vaccines/hcp/admin/transport/toolkit/storage-handling-toolkit.html)
- Upon arrival at the facility/clinic, vaccines were still within the manufacturer-recommended temperature range (i.e., between 2-8°C for vaccines requiring refrigeration and -15°C for vaccines requiring deep freezing).
- Upon arrival at the facility/clinic, vaccines remained protected from light (per manufacturer’s package insert) until ready for use at the vaccination clinic.
- Upon arrival at the facility/clinic, expiration dates of vaccines and any medical equipment (syringes, needles, alcohol wipes) being used were checked, and they had not expired.

#### CLINIC PREPARATION AND SUPPLIES

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- A contingency plan is in place case vaccines need to be replaced.
- An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of the clinic.

If you check “NO” in ONE OR MORE answer boxes that contain a ☑️, DO NOT move forward with the clinic. Follow your organization’s protocols and/or contact your state or local health department for guidance before proceeding with the clinic. Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.
### BEFORE THE CLINIC (Please complete each item before the clinic starts.)

#### VACCINE SHIPMENT

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- [ ] Vaccine was shipped directly to the facility/clinic site, where adequate storage is available. *(Direct shipment is preferred for cold chain integrity.)*

#### VACCINE TRANSPORT (if it was not possible to ship vaccines directly to the facility/clinic site)

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- [ ] Vaccines were transported using a portable vaccine refrigerator or qualified container and pack-out designed to transport vaccines within the temperature range recommended by the manufacturers (i.e., between 2-8° Celsius or 36-46° Fahrenheit for all refrigerated vaccines). Coolers available at general merchandise stores or coolers used to transport food are NOT ACCEPTABLE. See CDC’s Vaccine Storage and Handling Toolkit for information on qualified containers and pack-outs: [http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf).

- [ ] The person transporting the vaccines confirmed that manufacturer instructions for packing configuration and proper conditioning of coolants were followed. *(Your qualified container and pack-out should include packing instructions. If not, contact the company for instructions on proper packing procedures.)*

- [ ] The person transporting the vaccines confirmed that all vaccines were transported in a manner not compatible with the vehicle (NOT in the vehicle trunk).

- [ ] A digital data logger with a buffered probe and a current and valid Certificate of Calibration was directly with the vaccines and used to monitor vaccine temperature during transport.

- [ ] The amount of vaccine transported was limited to the amount needed for the workday.

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**VACCINE DEPLOYMENT AND MANAGEMENT** *(Complete as of Facility/Date)*

- [ ]

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**VACCINE DELIVERY AND MANAGEMENT** *(Complete as of Facility/Date)*

- [ ]
**VACCINE STORAGE AND HANDLING (upon arrival at facility/clinic)**

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- **STOP** If vaccines were shipped, the shipment arrived within the appropriate time frame (according to manufacturer or distributor guidelines) and in good condition.
- **STOP** If the vaccine shipment contained a cold chain monitor (CCM), it was checked upon arrival at the facility/clinic, and there was no indication of a temperature excursion during transit. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer). *Note: CCMs are for one-time use and should be thrown away after being checked.*
- **STOP** Upon arrival at the facility/clinic (either by shipment or transport), vaccines were immediately unpacked and placed in proper storage equipment (i.e., a portable vaccine refrigerator or qualified container and pack-out specifically designed and tested to maintain the manufacturer-recommended temperature range). Follow the guidance for unpacking and storing vaccines specified in CDC’s Vaccine Storage and Handling Toolkit: [http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf).
- **STOP** Upon arrival at the facility/clinic, vaccines were still within the manufacturer-recommended temperature range (i.e., between 2-8°C Celsius or 36-46°F Fahrenheit for ALL refrigerated vaccines).
- **STOP** Upon arrival at the facility/clinic, vaccines remained protected from light (per manufacturer’s package insert) until ready for use at the vaccination clinic.
- **STOP** Upon arrival at the facility/clinic, expiration dates of vaccines and any medical equipment (alcohol wipes) being used were checked, and they had not expired.
### “BEFORE the Clinic” Section of the Checklist

#### CLINIC PREPARATION AND SUPPLIES

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- A contingency plan is in place if vaccines need to be replaced.
- An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of the clinic.
- All vaccination providers at the site are certified in cardiopulmonary resuscitation (CPR), are familiar with the signs and symptoms of anaphylaxis, know their role in the event of an emergency, and know the location of epinephrine and are trained in its indications and use.
- There is a designated area at the site for management of patients with urgent medical problems (e.g., fainting).
- Adequate infection control supplies, including hand hygiene supplies, adhesive bandage strips, individually packaged sterile alcohol wipes, a sufficient number of sterile needles and syringes, and biohazard sharps container(s) are provided.
- Needles in a variety of lengths are available to optimize injection based on the prescribed route/technique and patient size.
- Reasonable accommodations (e.g., privacy screens) are available for patient privacy during vaccination.
- Staff members administering vaccines have reviewed vaccine manufacturer instructions for administration before the vaccination clinic.
- If using a standing order protocol, the protocol is current and available at the clinic/facility site.
- A sufficient number of screening forms are available at the clinic/facility site.
- A sufficient number of Vaccine Information Statements (VISs) are available at the clinic/facility site.
- A designated clean area for vaccine preparation has been identified.
- A qualified individual has been designated to oversee infection control and comply with the standards of practice required by the Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC).
### DURING THE CLINIC
(Please complete each item while the clinic is occurring and review at the end of your shift.)

**VACCINE STORAGE AND HANDLING (at facility/clinic)**

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Vaccines are being kept in proper storage equipment that maintains the manufacturer-recommended temperature range (i.e., a portable vaccine refrigerator or qualified container and pack-out specifically designed and tested to maintain correct temperatures when opened and closed during the clinic).

Vaccine temperature is being monitored during the clinic using a digital temperature data logger with a buffered probe (placed directly with vaccines) and a current and valid Certificate of Calibration Testing. Follow the temperature monitoring guidance specified in CDC’s Vaccine Storage and Handling Toolkit: [http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf).

If vaccines are being stored in a storage unit at the site, vaccine temperature data are being reviewed and documented a minimum of 2 times during each clinic workday (preferably at the beginning and middle of an 8-hour shift) to ensure they remain at correct temperatures (i.e., between 2-8° Celsius or 36-46° Fahrenheit for ALL refrigerated vaccines). If you are a VFC provider, check with your state immunization program for specific requirements for vaccine temperature monitoring during mass vaccination clinics.

If vaccines cannot be stored in a storage unit at the site, they are being kept in the portable vaccine refrigerator or qualified pack-out with a temperature monitoring device (with a probe in a thermal buffer) placed as closely as possible to the vaccines, and temperatures are being read and recorded at least once an hour. The container is being kept closed as much as possible.

Vaccines are being protected from light during the vaccination clinic per the manufacturer.
## VACCINE PREPARATION

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Expiration dates of vaccines (and diluents, if applicable) are being checked again during preparation, and only vaccines that have not expired are being administered.

Vaccines are prepared in a clean, designated medication area, away from any potentially contaminated items.

If using reconstituted vaccines, they are being prepared according to the manufacturer’s guidelines.

Vaccines are being prepared at the time of administration.

If vaccines are predrawn from a multidose vial, only the contents of 1 multidose vial (a maximum of 10 doses per vial), are being drawn up at one time by each staff member administering vaccines.

If using single-dose or multidose vials, syringes are being labeled with the name of the vaccine and dose.

Once drawn up, vaccines are being kept in the recommended temperature range. *(Questions about specific time limits for being out of the recommended temperature range should be referred to the manufacturer.)*
**“DURING the Clinic” Section of the Checklist**

### VACCINE ADMINISTRATION

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- **Vaccine Information Statements (VISs)** are being provided to every patient, parent, or guardian before vaccination (as required by federal law).
- All patients are being screened for contraindications and precautions for the specific vaccine(s) in use before receiving that vaccine(s).
- Staff is using proper hygiene techniques to clean hands before vaccine administration, between patients, and anytime hands become soiled.
- If gloves are being worn by staff administering vaccines, they are being changed and hands are being cleaned using proper hygiene techniques between each patient.
- Staff is triple-checking labels, contents, and expiration dates or beyond use dates (as noted in the manufacturer’s package insert, if applicable) before drawing up and administering vaccine.
- Vaccines are normal in appearance (i.e., not discolored, without precipitate, and easily resuspended when shaken).
- If injectable vaccine being administered, a new needle and new syringe are being used for each injection. Needles and syringes should never be used to administer vaccine to more than one person.
- Each staff member is administering only the vaccines they have prepared.
- If more than one vaccine type is being administered, separate preparation stations are set up for each vaccine type to prevent medication errors.
- Single-dose vials or manufacturer-filled syringes are being used for only one patient.
- Vaccines are being administered using aseptic technique and following safe injection practices.
- Seats are provided so staff and patients are at the same level for optimal positioning of anatomic site and injection angle to ensure correct vaccine administration.
- Staff is identifying injection site correctly. (For intramuscular route: deltoid muscle of arm [preferred] or vastus lateralis muscle of anterolateral thigh for adults, adolescents, and children aged ≥3 years; vastus lateralis muscle of anterolateral thigh for infants aged ≤12 months. For subcutaneous route: thigh for infants aged <12 months; upper outer triceps of arm for children aged 1 year and adults [can be used for infants if necessary].)
- Staff is inserting needles quickly at the appropriate angle: 90° for intramuscular injections (e.g., injectable influenza vaccines) or 45° for subcutaneous injections (e.g., measles, mumps, rubella vaccine).
- Staff is administering vaccines to the correct patient (e.g., if a parent/guardian and child or two siblings are at the vaccination station at the same time, patient’s name and date of birth are verified prior to vaccination).
- Staff is administering vaccines using the correct route per manufacturer instructions.
- Staff is administering the correct dosage (volume) of vaccine.
- Staff has checked age indications for the vaccines and is administering vaccines to the correct age groups.
- For vaccines requiring more than 1 dose, staff is administering the current dose at the correct interval, if applicable. Follow the recommended guidelines in Table 1 of the General Recommendations on Immunization: [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm).

**Additional Points:**

- Multidose vials are being used only for the number of doses approved by the manufacturer.
- Vaccines are never being transferred from one syringe to another.
- Used needles and syringes are being immediately placed in a sharps container following administration. (Needles should NOT be recappped.)
- Any persons with a needlestick injury, a vaccine administration error, or an urgent medical problem are being evaluated immediately and referred for additional medical care if needed.
- Patients are being encouraged to stay at the clinic for 15 minutes after vaccination to be monitored for adverse events.
### “DURING the Clinic” Section of the Checklist

#### VACCINE DOCUMENTATION

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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Each vaccination is being fully documented with name of person vaccinated; vaccination type, lot number, manufacturer; patient receipt of Vaccine Information Statement (VIS), including edition date and date VIS was provided; injection site; vaccination route; dosage; and name, title, and office/company address of person who administered the vaccine.

Patients are receiving documentation for their personal records and to share with their medical providers.
### POST-CLINIC ACTIONS

**YES** | **NO** | **N.A.**
---|---|---

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<td><strong>STOP</strong></td>
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**Temperature of remaining vaccine was checked and recorded at the end of clinic.** If not still at manufacturer-recommended temperature (i.e., between 2-8° Celsius or 36-46° Fahrenheit for ALL refrigerated vaccines), follow your organization’s protocols and/or contact your state or local health department for guidance.

**Any remaining vaccine in provider predrawn syringes, opened multidose vials, or activated manufacturer-filled syringes (MFSs) was properly discarded.** An MFS is activated when the sterile seal is broken (i.e., cap removed from needle or needle added to syringe). If absolutely necessary, a partially used multidose vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained, the vaccine is normal in appearance, and the maximum number of doses per vial indicated by the manufacturer has not already been withdrawn, or the beyond use date indicated by the manufacturer has not been met. However, a partially used vial cannot be transferred from one provider to another or across state lines, or returned to the supplier for credit.

**Viable, unused vaccine was placed back in proper storage equipment that maintained recommended temperature range at the end of the clinic day, and was not stored in a style combined refrigerator/freezer unit under any circumstances.** (This includes sending the day’s clinic to a remote location where adequate storage at the site is not available.)

**Any needlestick injuries were recorded in a sharps injury log and reported to all applicable health department and your organization.**

**Any vaccine administration errors were reported to all appropriate entities.**

**All biohazardous material was disposed of properly.**
### POST-CLINIC DOCUMENTATION

<table>
<thead>
<tr>
<th>YES</th>
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<tr>
<td>Vaccinations were recorded in the jurisdiction’s immunization information system (IIS) or vaccine registry, where available.</td>
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<tr>
<td>If not submitted to an IIS or vaccine registry, vaccination information was sent to primary health care providers as directed by an established procedure based on state or jurisdiction regulations.</td>
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<tr>
<td>Any adverse events were reported to the Vaccine Adverse Event Reporting System (VAERS): <a href="https://vaers.hhs.gov/index">https://vaers.hhs.gov/index</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**STOP**

All patient medical information was placed in secured storage locations for privacy protection.

The staff sign-in sheet was attached to this document (with shift times, clinic location, and date).
Additional Information and Resources

If you are concerned that CDC guidelines were not followed during your vaccination clinic held at a satellite, temporary, or off-site location, contact your organization and/or state or local health department for further guidance.

CDC's guidelines for vaccine storage, handling, administration, and safety were updated in 2016:
- Vaccine storage and handling: [http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)
- Vaccine administration: [www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html](http://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html)
- Injection safety: [www.cdc.gov/injectionsafety/providers.html](http://www.cdc.gov/injectionsafety/providers.html)
- Vaccine Information Statements: [www.cdc.gov/vaccines/hcp/vis/](http://www.cdc.gov/vaccines/hcp/vis/)

The Immunization Action Coalition has a skills checklist for staff administering vaccines:

The Immunization Action Coalition and the Alliance for Immunization in Michigan have patient education materials available:
- Vaccination after-care:
  - Adults: [http://www.aimtoolkit.org/docs/vax.pdf](http://www.aimtoolkit.org/docs/vax.pdf)

The Immunization Action Coalition has information on the medical management of vaccine reactions:

Manufacturers’ product information and package inserts with specific, detailed storage and handling protocols for individual vaccines: [http://www.immunize.org/packageinserts/pi_influenza.asp](http://www.immunize.org/packageinserts/pi_influenza.asp)

Medical waste disposal is regulated by state environmental agencies. Contact your state immunization program or state environmental agency to ensure that your disposal procedures comply with state and federal regulations.
The Pledge
The Pledge

- Organizations pledge to adhere to CDC guidelines and best practices when implementing vaccination clinics.
  - Including adhering to the checklist

- Reviewed and signed annually by an organization executive.

- Completed pledges should be sent to NAIIS Clinic Pledge Coordinator:
  - vaxclinicpledge@izsummitpartners.org
Organizations Pledging Support to Adhere to CDC Guidelines and Best Practices When Implementing Vaccination Clinics at Satellite, Temporary, or Off-site Locations

Each organization listed below has formally pledged to follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation when implementing vaccination clinics at satellite, temporary, or off-site locations. These guidelines and best practices are essential for patient safety and vaccine effectiveness.

Supporting Organizations

- Name — www.domain.com
The Full Pledge

Pledge for Organizations Implementing Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations

Our organization pledges to adhere to the guidelines and best practices of the Centers for Disease Control and Prevention (CDC) when implementing vaccination clinics that are held at satellite, temporary, or off-site locations. (The Checklist of Best Practices is available online.) The pledge will be reviewed and signed annually by an employee in an executive-level position within our organization.

Completed pledges should be sent to the National Adult and Influenza Immunization Summit (NAIS) Clinic Pledge Coordinator. Pledging organizations are recognized on the NAIS Organizations Pledging Support page.

As an organization, we pledge to:

A. Follow best practices at each vaccination clinic, as outlined in the Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations.

B. Adhere to all manufacturer storage and handling guidelines during vaccine shipment or transport and administration, including using a portable refrigerator or qualified container and pack-out if transporting vaccine and performing recommended temperature monitoring.

C. Adhere to CDC vaccine administration and immunization schedule guidelines.

D. Establish a plan to replace mishandled, expired, or damaged vaccine and have a documented plan to complete the clinic.

E. Accommodate language or literacy barriers and special needs of patients/guardians to help make them feel comfortable and informed about the vaccination process.

F. Provide all patients with Vaccine Information Statements (VIS) prior to immunization, as required by federal law.

G. Designate a clean area for vaccine preparation and designate a qualified individual to oversee infection control.

H. Ensure the presence of an emergency medical kit with epinephrine at the site and a designated trained healthcare provider, certified in CPR, who can administer treatment for allergic reactions and address urgent medical problems.

I. Ensure all vaccinees are legally allowed to administer vaccines, per local jurisdiction law and/or policy.

J. Communicate immunization and emergency medical protocols to all staff administering vaccines.

K. Encourage all employees to be up to date on their vaccinations, including annual influenza vaccine.

L. Ensure staff who prepare and administer vaccines have been trained and have demonstrated competency in the following areas:

   1. Adhering to CDC guidelines for vaccine shipment or transport, storage and handling, preparation, administration, and documentation.

   2. Adhering to all standard precautions, which include proper hand hygiene and safe injection practices when preparing and administering vaccines, and knowing the location of and how to administer epinephrine in clinical situations in which its use would be indicated.

   3. Reporting any needlestick injury and maintaining a sharps injury log.

   4. Reporting adverse immunization events to the Vaccine Adverse Event Reporting System (VAERS).

   5. Retaining all patient medical information in an appropriate storage location.

   6. Disposing of all hazardous materials properly.

   7. Documenting all vaccinations per HIPAA and local jurisdiction laws and, whenever possible, entering vaccination records into a state immunization information system (vaccination registry).

Printed Name and Title of Organization Executive: ________________________________

Signature of Organization Executive: ____________________________________________

Date: ____________________ (This form is valid for one year from date signed.)

Version 1 (updated 9/1/2016)
Pledge Components

Pledge for Organizations Implementing Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations

Our organization pledges to adhere to the guidelines and best practices of the Centers for Disease Control and Prevention (CDC) when implementing vaccination clinics that are held at satellite, temporary, or off-site locations. (The Checklist of Best Practices is available online.) The pledge will be reviewed and signed annually by an employee in an executive-level position within our organization.

Completed pledges should be sent to the National Adult and Influenza Immunization Summit (NAIIS) Clinic Pledge Coordinator. Pledging organizations are recognized on the NAIIS Organizations Pledging Support page.

As an organization, we pledge to:

[List of pledge components]

[Signature page for organization representatives]
As an organization, we pledge to:

A. Follow best practices at each vaccination clinic, as outlined in the Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations.

B. Adhere to all manufacturer storage and handling guidelines during vaccine shipment or transport and administration, including using a portable refrigerator or qualified container and pack-out if transporting vaccine and performing recommended temperature monitoring.

C. Adhere to CDC vaccine administration and immunization schedule guidelines.

D. Establish a plan to replace mishandled, expired, or damaged vaccine and have a documented plan to complete the clinic.

E. Accommodate language or literacy barriers and special needs of patients/guardians to help make them feel comfortable and informed about the vaccination process.

F. Provide all patients with Vaccine Information Statements (VIS) prior to immunization, as required by federal law.
Pledge Components (Cont)

G. Designate a clean area for vaccine preparation and designate a qualified individual to oversee infection control.

H. Ensure the presence of an emergency medical kit with epinephrine at the site and a designated trained health care provider, certified in CPR, who can administer treatment for allergic reactions and address urgent medical problems.

I. Ensure all vaccinators are legally allowed to administer vaccines, per local jurisdiction laws and/or policies.

J. Communicate immunization and emergency medical protocols to all staff administering vaccines.

K. Encourage all employees to be up to date on their vaccinations, including annual influenza vaccine.
Pledge Components (Cont)

L. Ensure staff who prepare and administer vaccines have been trained and have demonstrated competency in the following areas:

1. Adhering to CDC guidelines for vaccine shipment or transport, storage and handling, preparation, administration, and documentation.

2. Adhering to standard precautions, which include proper hand hygiene and safe injection practices when preparing and administering vaccines, and knowing the location of and how to administer epinephrine and clinical situations in which its use would be indicated.

3. Reporting any needlestick injury and maintaining a sharps injury log.

4. Reporting adverse immunization events to the Vaccine Adverse Event Reporting System (VAERS).

5. Returning all patient medical information to an appropriate storage location.

6. Disposing of all biohazardous materials properly.

7. Documenting all vaccinations per HIPAA and local jurisdiction laws and, whenever possible, entering vaccination records into a state immunization information system (vaccination registry).

Printed Name and Title of Organization Executive: _______________________________________

Signature of Organization Executive: _______________________________________

Date: ________________________ (This form is valid for one year from date signed.)
Who We Are

• Founded in 1994
• 260 travel medicine clinics in North America
  • Administer >600k vaccines annually
• National nurse network
  • Plus an additional 1,000+ surge nurses hired annually
• Leading provider of onsite workplace wellness services
  • Vaccinations provided in offices, hotel conference rooms, prisons, dairy farms, distribution centers, and on-board ships
• Disaster response services
Business Case and Challenges

• Passport Health’s mission is to protect people from disease, and safety is our top priority.

• Active industry participant on the NAIIS Influenza Working Group

• The Passport Health team saw the Checklist as a tool to aid nurses working off-site events
  • Nurses can get flustered when events are in non-standard locations or things do not unfold as expected.
  • Checklist similar to hand-washing signs in hospitals, the goal is to remind nurses of the critical components to ensuring a safe and effective vaccine event.
How We Approached the Checklist

• As the Checklist developed, length became a concern.
• Worked with the WG to discuss the challenge and understand reasoning behind each of the 75 line items.
• Developed an understanding that 100% compliance was the goal – not the expectation, at least early on.
• Limited implementation in 2016
• Initial Checklist compliance rate – 57%
  • Areas of non-compliance included:
    • Contingency plan in place should vaccines need to be replaced
    • Staff are triple-checking labels and expiration dates
    • A qualified individual has been designated to oversee infection control at the clinic
    • There is a designated area at the site for management of patients with urgent medical problems
Existing Systems Included
• Robust training for surge clinicians, including required modules on:
  • Vaccine education
  • Vaccine preparation and administration
  • Vaccine storage before, during, and after the event
  • Hazardous waste disposal
  • Safety procedures and emergency protocols
  • Records management
  • And many more
• Nurse hotline available 24/7 during flu season to address nurse questions

Checklist System Updates for Nurse Training Included
• Management of direct shipment of supplies to client
• Additional requirements when vaccine is transported by the nurse to the client
Year 1 Implementation – Vaccine Transport

- Significant investment in the development of self-contained coolers. Coolers ship in marked Wellness Kits designed to meet Checklist guidelines.
- Coolers manufactured by Thermosafe were tested to maintain cold chain for up to five days in 120 degree heat.
- Effort to educate business clients to encourage direct shipment of supplies.
Year 2 Implementation

• Utilize Checklist at select clinic locations
  • clinics > 2 hours in duration with > 50 participants
• 80% compliance goal
• Primary challenges remaining:
  • Cold Chain Monitors
  • Digital Temperature Data Loggers
  • Documentation of vaccine temperature during event
  • Onsite storage in a portable vaccine refrigerator with qualified pack-out and temperature monitoring device (with problem and thermal buffer)
  • If more than one vaccine type is being administered, separate preparation stations are set up for each vaccine type to prevent medication errors
  • Recording vaccine in the immunization information system or record sent to PCP
Additional Tools

- “Frequently Asked Questions” page
- 1-page resource that summarizes the checklist
Frequently Asked Questions about the National Adult and Influenza Immunization Summit “Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations” and Pledge for Implementing the Checklist

Last updated: March 31, 2017

The questions in this document relate to the checklist and pledge found here:

https://www.izsummitpartners.org/content/uploads/2017/02/NAILF-Vaccination-Clinic-Checklist_v2.pdf


Questions about the purpose of the checklist and pledge

1. What is the purpose of the checklist? It seems long and complicated.
   Recently, reports have been published of major errors occurring at vaccination clinics held at satellite, temporary, or off-site locations related to the safe transport, storage, and administration of vaccines. These reports are likely the tip of the iceberg. To prevent future errors at clinics in these settings, we developed this checklist as 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. This checklist outlines CDC guidelines and best practices that are essential for patient safety and vaccine effectiveness.

2. What is the pledge, who is it for, and why should we sign up to be a pledging organization?
   This pledge is for any organization that conducts satellite, temporary, or off-site vaccination clinics to sign annually affirming that they will adhere to best practices by using the “Checklist of Best Practices” at every vaccination clinic they hold in these settings. Organizations that sign the pledge will be recognized on the Summit website for their commitment to provide safe and effective vaccine clinics. This can be a great way to promote your organization as one that conducts vaccination clinics using the highest standards. Additionally, companies seeking to hire an organization to conduct a vaccination clinic can check to see if that organization has signed the pledge and is recognized on the Summit website.
Frequently Asked Questions

Examples of Questions on the FAQ:

- All of our staff have many years of experience and we do hundreds of vaccination clinics a year. Do we still need to use the checklist?

- We have many new staff all over the country. The checklist seems too cumbersome to use in our situation. Do we need to use it?

- Are we allowed to use coolers purchased at big box stores/retail stores for transporting vaccine?
TEN PRINCIPLES FOR HOLDING SAFE VACCINATION CLINICS
AT SATELLITE, TEMPORARY, OR OFF-SITE LOCATIONS

DURING ALL STAGES (PRE-CLINIC, DURING THE CLINIC, AND POST-CLINIC):
1. Keep vaccines at the correct temperature at all times using proper procedures for vaccine transport, handling and storage. Document temperature monitoring at appropriate intervals during all stages. For further guidance:
   http://www.cdc.gov/vaccines/vpd/vapri/toolkit/storage-handling-toolkit.pdf

PRE-CLINIC:
2. Have vaccine shipped directly to the site. If direct shipment is not possible, transport vaccine using correct storage and handling guidelines.
3. Train staff to perform CPR and treat medical emergencies, including anaphylaxis. Ensure supplies are on site, including an emergency medical kit and infection control supplies, as well as enough Vaccine Information Statements (VISs).

DURING THE CLINIC:
4. Always check for medical contraindications and allergies before vaccinating anyone. Provide VISs for all patients or guardians.
5. Only use vaccines that are not damaged, not expired, at the correct temperature, and prepared using aseptic technique.
6. Follow manufacturers’ instructions for injection dose, site, and route.
7. Follow manufacturers’ instructions and Advisory Committee on Immunization Practices guidelines for correct age and intervals (for vaccines that require more than one dose).
8. Follow safe injection practices, including using a new needle and syringe for every injection. Dispose of all sharps in a sharps container.
9. Document every vaccination and give patients a copy.

POST-CLINIC:
10. Keep patient information secure and private. Record vaccinations in the Immunization Information System (IIS), if available.

For further guidance, refer to the full checklist:

***This document is NOT intended to replace use of the checklist.
1- Page Summary Resource

- Summary document of the main points on the checklist
- Can be used by all staff (not just clinic coordinators/supervisors)
- Can be posted on the wall of the clinic as a quick reference guide
NEW! Pledge for Organizations Holding Clinics at Satellite, Temporary, or Off-site Locations
Be recognized along with other clinics pledging to follow CDC guidelines and best practices in these settings.
Access signature resources from the Summit: IVATS and Vaccine Pocket Guides. Find recommendations, materials, and staff tools on influenza and influenza vaccination, as well as a listing of helpful resources for providers of adult immunization.

- Adult Vaccination Resources
- Influenza Vaccination Resources
- Influenza Vaccine Availability Tracking System—IVATS
- Vaccine Pocket Guides

Tools for Off-Site Clinics
Tools to Assist Satellite, Temporary, and Off-Site Vaccination Clinics

Satellite, temporary, and off-site vaccination clinics play an important role in improving vaccination coverage rates and vaccinating hard-to-reach populations. However, vaccination clinics held in these settings also have unique challenges. In an effort to standardize the process of holding clinics in these non-traditional settings, we have developed a checklist of best practices and created a pledge for organizations that adhere to the checklist (see below).

Since this is the first year that the checklist has launched, we recognize that it might not be possible for organizations to complete every aspect of the checklist or to sign the pledge. However, it would be great practice for your organization to implement the components that you can on a pilot basis and work towards increasing the rows that you can complete so that, in future years, you are able to implement every item on the checklist.

For individuals who have used the checklist (either on a pilot basis or as part of your standard operating procedures), we ask that you complete a short survey so that we can improve the checklist. The survey should take less than 5 minutes to complete.

Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations

This checklist 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. This checklist outlines CDC guidelines and best practices that are essential for patient safety and vaccine effectiveness.
Where to Find These Documents

- Landing page for all 4 documents: [https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/](https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/)

- Checklist:
  - [https://www.izsummitpartners.org/content/uploads/2017/02/NAIIS-Vaccination-Clinic-Checklist_v2.pdf](https://www.izsummitpartners.org/content/uploads/2017/02/NAIIS-Vaccination-Clinic-Checklist_v2.pdf)

- Pledge:

- FAQs:

- 1-Page Resource
Discussion

- We are trying to distribute these documents widely. Please spread the word.

- Please provide us with feedback!
  - Send questions/comments on the checklist to: checklist@izsummitpartners.org
  - Organizations that want to take the pledge or that have questions/comments, send to: vaxclinicpledge@izsummitpartners.org
  - Survey for individuals who have used the checklist: https://www.surveymonkey.com/r/checklist2016
Thank You!

- **Contact Information:**
  - Amy Parker Fiebelkorn, CDC
    - dez8@cdc.gov
  - Amy Behrman, American College of Occupational and Environmental Medicine (ACOEM)
    - behrman@mail.med.upenn.edu
  - Kelly McKenna, EverThrive Illinois
    - kmckenna@everthriveil.org
Additional Resources

- CDC Vaccine Administration Recommendations and Guidelines
  - [www.cdc.gov/vaccines/hcp/admin/recs-guidelines.html](http://www.cdc.gov/vaccines/hcp/admin/recs-guidelines.html)

- CDC Vaccine Storage and Handling Toolkit
  - [www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-holding-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-holding-toolkit.pdf)

- Vaccine Information Statements
  - [www.cdc.gov/vaccines/hcp/vis/](http://www.cdc.gov/vaccines/hcp/vis/)
# Acknowledgments

Members of the NAIIS Influenza Working Group:

- Carolyn Bridges
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- LaDora Woods
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- Anna Fedorowicz
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- Sydney Devine
- Sunny Hynds
- Juley Jenkins
- Eric Sweeney
- Randall Linn
- Rick Murphy
- Terri Murphy
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- Cynthia Morgan
- Lynne Goulet
- Troy Knighton
- Dani Moula
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- Elizabeth Frenzel
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