

“Best Practice” Tools for Holding Safe Vaccination Clinics in Temporary Settings: NAIIS Influenza Working Group Update - Checklist and Pledge 101

NAICP Quarterly Call Webinar

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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

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.

1. <https://www.cdc.gov/flu/fluview/nifs-estimates-nov2016.htm>

Challenges of Vaccination Clinics in Temporary Settings

- Vaccination clinics held in these settings have unique challenges:
 - Training and oversight of HCP
 - Vaccine storage and handling
 - Proper vaccine administration
- 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

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Morbidity and Mortality Weekly Report (MMWR)

[MMWR](#)



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, PhD¹; Rebecca Greeley, MPH¹; Jill Dinitz-Sklar, MPH¹; Nicole Mazur, MPH¹; Jill Swanson, MPH²; JoEllen Wolicki, BSN³; Joseph Perz, DrPH⁴; Christina Tan, MD¹; Barbara Montana, MD¹

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.

Other Reported Incidents

- Collier County, FL (2009): 77 students given wrong flu shot.
<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.
<http://www.click2houston.com/news/local/montgomery-county/re-vaccinations-required-after-error-in-montgomery-county>
- Wellesley, MA (2010): School staff given insulin in flu vaccine error. Some staffers had to be hospitalized, but all recovered.
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





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

VACCINE ADMINISTRATION

| YES | NO | N.A. | |
|--------------------------|--|---|---|
| <input type="checkbox"/> | <input type="checkbox"/>  |  | Vaccine Information Statements (VISs) are being provided to every patient, parent, or guardian before vaccination (as required by federal law). |
| <input type="checkbox"/> | <input type="checkbox"/>  |  | All patients are being screened for contraindications and precautions for the specific vaccine(s) in use before receiving that vaccine(s). |




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: . 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.
4. 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, or concerns about other responses that you have marked as "NO" on rows that do not have the .
5. This checklist should be used in conjunction with CDC's Vaccine Storage and Handling Toolkit: <http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>. For information about specific vaccines, consult the vaccine manufacturer's package insert.
6. This checklist **applies ONLY to vaccines stored at REFRIGERATED temperatures**.
7. 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.)
8. Attach the staff sign-in sheet (with shift times and date) to the checklist (or checklists if more than one clinic 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): _____
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” Section of the Checklist

BEFORE THE CLINIC (Please complete each item before the clinic starts.)

VACCINE SHIPMENT

| YES | NO | N.A. | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Vaccine was shipped directly to the facility/clinic site, where adequate storage is available. <i>(Direct shipment is preferred for cold chain integrity.)</i> |



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

| YES | NO | N.A. | |
|--------------------------|--|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/>  | <input type="checkbox"/> | 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). <u>Coolers available at general merchandise stores or coolers used to transport food are NOT ACCEPTABLE.</u> See CDC's <i>Vaccine Storage and Handling Toolkit</i> for information on qualified containers and pack-outs: http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf . |
| <input type="checkbox"/> | <input type="checkbox"/>  | <input type="checkbox"/> | The person transporting the vaccines confirmed that manufacturer instructions for packing configuration and proper conditioning of coolants were followed. <i>(Your qualified container and pack-out should include packing instructions. If not, contact the company for instructions on proper packing procedures.)</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The person transporting the vaccines confirmed that all vaccines were transported in the passenger compartment of the vehicle (NOT in the vehicle trunk). |
| <input type="checkbox"/> | <input type="checkbox"/>  | <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The amount of vaccine transported was limited to the amount needed for the workday. |

“AFTER the Clinic” Section

AFTER THE CLINIC (Please complete each item after the clinic was conducted.)

POST-CLINIC ACTIONS

| YES | NO | N.A. | |
|--------------------------|---|--------------------------|---|
| <input type="checkbox"/> | <input checked="" type="checkbox"/>  | <input type="checkbox"/> | Temperature of remaining vaccine was checked and recorded at the end of clinic. If not still at manufacturer-recommended temperature (<i>i.e.</i> , 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Any remaining vaccine in provider predrawn syringes, opened multidose vials, or activated manufacturer-filled syringes (MFSs) was properly discarded. <i>An MFS is activated when the sterile seal is broken (i.e., cap removed from needle or needle added to the 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.</i> |
| <input type="checkbox"/> | <input checked="" type="checkbox"/>  | <input type="checkbox"/> | Viable, unused vaccine was placed back in proper storage equipment that maintains the manufacturer-recommended temperature range at the end of the clinic day, and was not stored in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances. (This includes vaccine transported for a multi-day clinic to a remote location where adequate storage at the site is not available.) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Any needlestick injuries were recorded in a sharps injury log and reported to all appropriate entities (e.g., local health department and your organization). |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Any vaccine administration errors were reported to all appropriate entities. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | All biohazardous material was disposed of properly. |

Additional Information and Resources

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>

Vaccine administration: www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html

Injection safety: www.cdc.gov/injectionsafety/providers.html

Vaccine Information Statements: www.cdc.gov/vaccines/hcp/vis/

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

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

The Immunization Action Coalition and the Alliance for Immunization in Michigan have patient education materials available:

Screening tools: <http://www.immunize.org/handouts/screening-vaccines.asp>

Vaccination after-care:

Children: <http://www.immunize.org/catg.d/p4015.pdf>

Adults: <http://www.aimtoolkit.org/docs/vax.pdf>

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

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

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

Manufacturers' product information and package inserts with specific, detailed storage and handling protocols for individual vaccines: 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

- **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 NAHS Clinic Pledge Coordinator:**
 - vaxclinicpledge@izsummitpartners.org

Benefits of Signing the Pledge



National
Adult and
Influenza
Immunization
Summit

HOME

WORKGROUPS

ANNUAL SUMMIT

SUMMIT AWARDS

ADULT STANDARDS

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

Pledge Components

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.)

Where to Find These Documents

- **National Adult and Influenza Immunization Summit Influenza Work Group page:** <https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/>
 - Checklist:
 - https://www.izsummitpartners.org/content/uploads/2017/02/NAIS-Vaccination-Clinic-Checklist_v2.pdf
 - Pledge:
 - http://www.izsummitpartners.org/content/uploads/2016/08/NEW-Pledge-for-organizations-providing-vaccination-clinics_8-24-2016-FINAL-1.pdf
- **The links can also be accessed from CDC's website:**
 - <http://www.cdc.gov/flu/business/>
 - <http://www.cdc.gov/flu/toolkit/long-term-care/resources.htm>

Frequently Asked Questions

- Resource page was created to address commonly asked questions:

<https://www.izsummitpartners.org/content/uploads/2017/02/FAQs-for-NAIS-checklist-for-vax-clinics.pdf>

Questions on the FAQ include:

- 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?

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
- **Work in Progress: link pending!**

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
- IWG Members listed on the NAIS webpage
 - <https://www.izsummitpartners.org/nais-workgroups/influenza-workgroup/members/>