Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

Vaccine Administration, Vaccine Storage and Handling Best Practices

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National Adult Influenza Immunization Summit

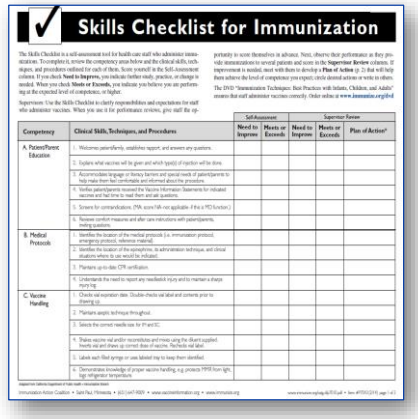
May 9, 2017

Disclosures

- **JoEllen Wolicki is a federal government employee with no financial interest in, or conflict with, the manufacturer of any product named in this presentation**
- **The speaker will not discuss the off-label use of any vaccines**
- **The speaker will not discuss a vaccine not currently licensed by the FDA**

Knowledgeable Staff is Critical!

- **All staff who will store, handle and administer vaccines should:**
  - Receive competency-based training
  - Have knowledge and skills validated
- **Integrate competency-based training into:**
  - New staff orientation
  - Annual education requirements
- **Ongoing education:**
  - Whenever vaccine administration recommendations are updated
  - When new vaccines are added to inventory
- **Don't forget to assess vaccine administration skills of temporary staff**

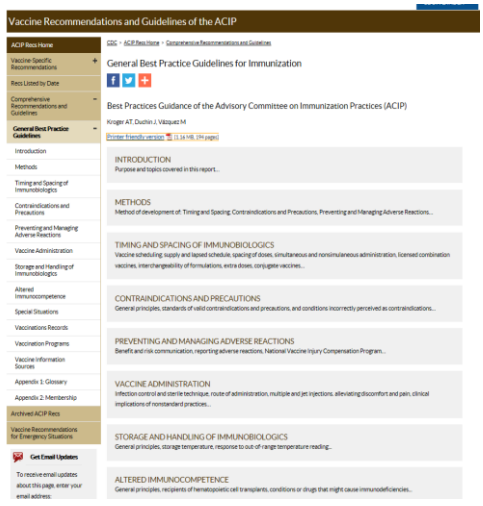


Skills Checklist for Immunization

Immunization Action Coalition: Skills Checklist for Immunization www.immunize.org/catg.d/p7010.pdf

Advisory Committee on Immunization Practices
General Best Practice Guidelines for Immunizations
Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)

- **Failure to adhere to recommendations for storage and handling of vaccines can reduce or destroy their potency, resulting in inadequate or no immune response in the recipient**
- **Recommendations for route, site, and dosage of vaccines are derived from data from clinical trials, practical experience, preventive health care visits, schedule, and theoretical considerations**



https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Preparing the Patient

- **Obtain complete immunization history at every health care visit:**
  - Accept only written, dated records (except self-reports of influenza and PPSV23)
  - Use recommended schedule to determine vaccines needed based on age, medical condition, and risk factors
- **Screen for contraindications and precautions prior to administering any vaccine**
- **Discuss vaccine benefits and risks and vaccine-preventable disease risks using VISs and other reliable resources**
- **Provide after-care instructions**

www.immunize.org/catg.d/p4060.pdf
www.immunize.org/catg.d/p4065.pdf
http://publichealth.lacounty.gov/ip/immunization/parents/comfort-bethereE.pdf

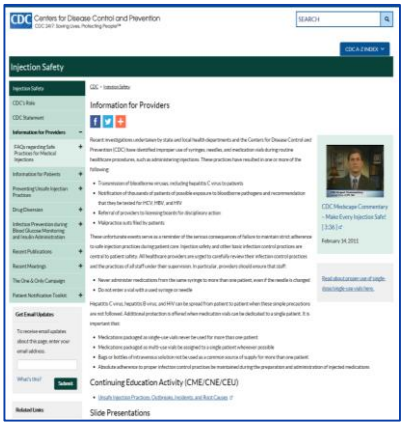
Infection Control

- **Perform hand hygiene:**
  - Before preparing and administering vaccines
  - Between patients
  - Anytime hands become soiled
- **Gloves are not required to be worn when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on hands:**
  - If gloves are worn, they should be changed between patients
  - Perform hand hygiene between patients even if wearing gloves
- **Maintain proper infection control practices while preparing and administering vaccines:**
  - Draw up and prepare vaccines in a clean medication preparation area
- **Equipment disposal:**
  - Puncture-proof biohazard container
  - Empty or expired vaccine vials are medical waste

General Best Practice Guidelines for Immunizations www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Safe Injection Practices

- **To ensure vaccination is as safe and effective as possible, incorporate:**
  - Professional standards for medication administration
  - Manufacturer's vaccine-specific guidelines
  - Evidence-based safe medication administration practices, including proper injection practices
- **Prepare and administer vaccines using aseptic technique:**
  - Use a new needle and syringe for every injection
  - Disinfect the medication vial by rubbing the diaphragm with a sterile alcohol wipe



CDC Injection Safety website

CDC Injection Safety www.cdc.gov/injectionsafety/

Vaccine Preparation Best Practices

- **Use only the manufacturer-supplied diluent to reconstitute a vaccine**
- **Inspect vaccine and diluent vials for damage or contamination**
- **Check the expiration dates for the vaccine and diluent.**
  - Also, check the expiration date injection equipment on the alcohol prep wipe, syringe, needle, if present.

Provider Predrawn Syringes

- **Predrawing vaccine is not recommended:**
  - Increases risk for administration errors
  - May lead to vaccine waste
  - Can cause growth of microorganisms in vaccines that do not contain a preservative
  - Administration syringes are not designed for storage
- **Consider using manufacturer-filled syringes for large immunization events because they are designed for both storage and administration**

Provider Predrawn Syringes

- **At clinic site, no more than 1 multidose vial or 10 doses should be drawn up at one time by each vaccinator**
- **If more than one vaccine type is being administered, set up separate administration stations for each vaccine type to prevent medication errors**
- **Patient flow should be monitored to avoid drawing up unnecessary doses**
- **Discard any remaining vaccine in syringes predrawn by providers at end of workday**

Single-dose Vials

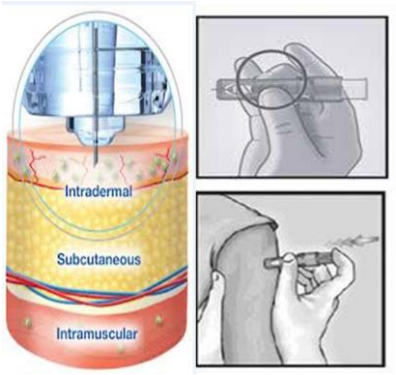
- **Use a single-dose vial for 1 patient ONLY**
  - Discard any leftover vaccine
  - Do NOT administer it to another patient
- **Open a single-dose vial only when ready to use**
- **Once protective cap is removed, vaccine must be used**
  - Discard unused vaccine at end of workday if not used

Manufacturer-filled Syringes

- **Once a manufacturer-filled syringe is activated, vaccine should be used or discarded at end of workday**
- **Activated is when the:**
  - Syringe cap is removed or
  - Needle attached

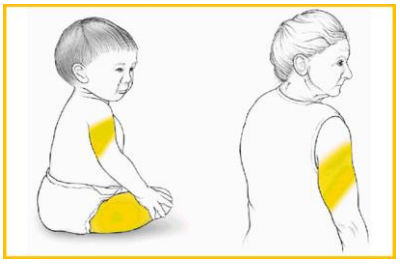
Administration Route and Site

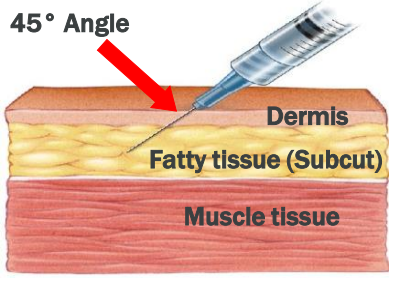
- **Route: Intradermal injection (ID)**
  - Vaccine: Fluzone ID
- **Needle gauge and length:**
  - 30-gauge, microneedle
- **Site:**
  - Deltoid region of upper arm
- **Technique:**
  - Hold the syringe between the thumb and the middle finger and using a short quick motion, insert the needle perpendicular to the skin



Administration Route and Site

- **Route: Subcutaneous injection (Subcut)**
  - Vaccines: MMR, VAR, VZV, IPV*, PPSV23*
  - Needle gauge and length:
    - 23- to 25-gauge needle, 5/8-inch
  - Site:
    - Thigh for infants younger than 12 months of age
    - Upper outer triceps of arm for children older than 12 months and adults (can be used for infants if necessary)
  - Technique:
    - To avoid reaching the muscle, pinch up the fatty tissue, insert the needle at a 45° angle, and inject the vaccine into the tissue

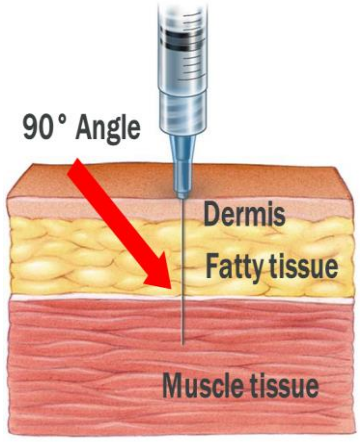




*IPV and PPSV23 may be administered by subcutaneous or intramuscular injection

Administration Route

- **Route: Intramuscular injection (IM)**
  - Vaccines: HepA, HepB, Hib, DTaP, DT, Flu, HPV, IPV*, MenACWY, MenB, PCV13, PPSV23*, Td, Tdap,
  - Needle gauge and length:
    - 23- to 25-gauge
    - Needle length varies based on age and muscle mass**
  - Technique:
    - Spread the skin of the site taut between the thumb and forefinger, isolating the muscle
    - Another technique, acceptable mostly for pediatric and geriatric patients, is to grasp the tissue and "bunch up" the muscle
    - Insert the needle fully into the muscle at a 90° angle and inject

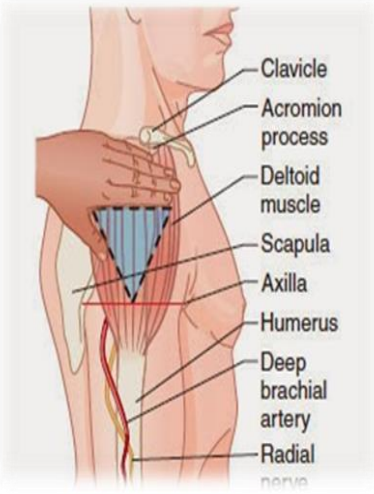


Aspiration is NOT recommended

*IPV and PPSV23 may be administered by subcutaneous or intramuscular injection
** Use professional judgement when choosing needle length

Intramuscular (IM) Injection Sites and Needle Lengths Adults 19 Years and Older

- **Sites:**
  - Deltoid muscle (upper arm) is preferred
  - Vastus lateralis muscle (anterolateral thigh) may be used
- **Needle length varies based on patient size and muscle mass**



Needle Size

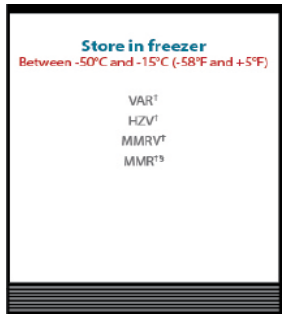
	Needle Size
Men and women, <60 kg (130 lbs)	1 inch (25 mm)
Men and women, 60-70 kg (130-152 lbs)	1 inch (25 mm)
Men, 70-118 kg (152-260 lbs) Women, 70-90 kg (152-200 lbs)	1-1.5 inches (25-38 mm)
Men, >118 kg (260 lbs) Women, >90 kg (200 lbs)	1.5 inches (38 mm)

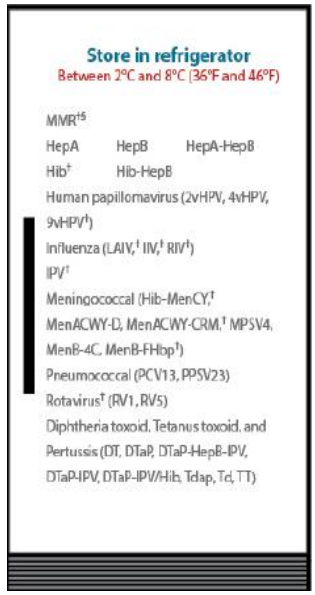
General Best Practice Guidelines for Immunization Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Vaccine Storage and Handling

Vaccine Storage Equipment

- **CDC recommends the following freezers and refrigerators:**
  - Purpose-built (stand-alone or combination)
  - Household stand-alone





Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

Vaccine Storage Equipment

- **If existing equipment is a household combination refrigerator/freezer, use only the refrigerator compartment for storing vaccines**

- **Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/ freezer unit under any circumstances**

Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

Recommended Temperatures

- **Refrigerator:**
  - Between 2°C and 8°C (between 36°F and 46°F)
  - Average 40°F (5°C)
- **Freezer:**
  - Between -50°C and -15°C (between -58°F and +5°F)
- **Refer to manufacturers' package inserts:**
  - www.immunize.org/packageinserts/

Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

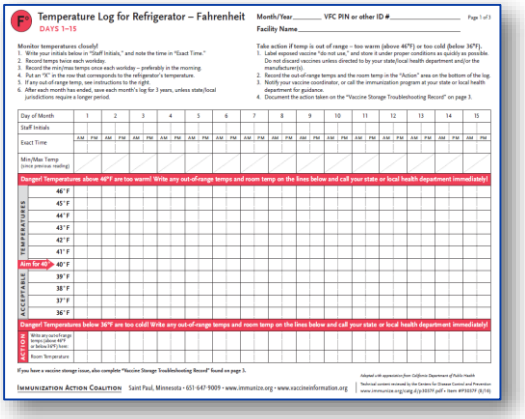
Vaccine Storage and Handling Best Practices Temperature Monitoring Equipment

- **CDC recommends digital data loggers (DDL) with continuous temperature monitoring and recording capabilities and a current and valid Certificate of Calibration Testing (Report of Calibration) with these features:**
  - Alarm for out-of-range temperatures
  - Temperature display of current, minimum, and maximum temperature can be easily read from outside the unit
  - Low-battery indicator
  - Accuracy of +/-0.5° C (+/-1° F)
  - Memory storage of at least 4,000 readings
  - Logging interval (or reading rate) that can be programed by the user to record at least every 30 minutes
  - A probe that best reflects the temperature of the vaccine, for example, a buffered probe

Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

Temperature Monitoring

- **CDC recommends:**
  - Review and record unit temperature at least 2 times each workday (morning and end of day)
  - Post log on or near by each storage unit
  - Download and review stored temperature log data at least 1 time each week
  - Keep logs and downloaded data at least 3 years or according to state record retention requirements



Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/
Sample log at: www.immunize.org/handouts/vaccine-storage-handling.asp

Expiration Dates

- **Monitoring expiration dates is a key component of managing your vaccine inventory**
- **Check expiration dates on vaccines and diluents at least once a week, and immediately remove any expired vaccines and diluents**
- **Interpreting expiration date**
  - When the expiration date has only a month and year, the product may be used up to and including the last day of that month
  - If a day is included with the month and year, the product may be used through the end of that day
- **Exceptions:**
  - Reconstitution with a beyond use date or time (BUD)
  - Multidose vial with BUD once opened
  - Manufacturer-shortened expiration date

Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

Multidose Vials and Expiration Dates

- **A multidose vial (MDV) that has been stored and handled properly may be used more than once**
- **Double-check the manufacturer's package insert (PI) for information on beyond-use date or dose limits (if applicable)**
  - IPV MDV may be used through the expiration date if stored and handled correctly and not contaminated
- **Some IIV products have a beyond-use-date and should be used within a certain number of days after being entered**
- **Fluzone IIV product PI indicates only 10 doses may be withdrawn from a MDV**
  - After the maximum number of doses has been withdrawn from the MDV, the vial should be discarded, even if the expiration date has not been reached or there is vaccine left in the vial

IAC Food and Drug Administration (FDA) Product Approval: Vaccine index http://www.immunize.org/fda/

Vaccine Transport Best Practices

- **CDC recommends that vaccine be delivered directly to an off-site/satellite facility**
- **If vaccine must be transported to the facility, DO:**
  - Limit the total transport PLUS workday time to no more than 8 hours
  - Transport in a portable refrigerator or qualified container/pack out with a calibrated continuous temperature monitoring device
  - Limit the amount of vaccine to the amount needed for that workday
  - Transport the vaccine container in the vehicle (not the trunk)

Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

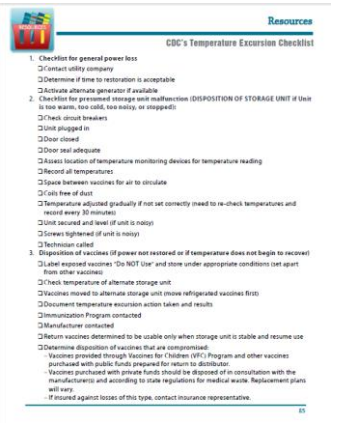
Transporting Vaccine: Temperature Monitoring Best Practices

- **Record temperature inside the packed container, along with date, time, and your initials:**
  - At the beginning of transport
  - Upon arrival at facility
  - When any remaining vaccines are returned to primary storage facility
- **Upon arrival at facility, immediately transfer vaccines to a refrigerator that maintains recommended temperature range and record the temperature, time, and initials**
  - Record the temperature at least twice during workday
- **If the vaccine is must be kept in a portable storage unit monitor the temperature hourly**

Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

Temperature Excursions

- **If stored vaccines have been exposed to temperatures outside recommended ranges**
  - Store the vaccines properly
  - Separate from other vaccine supplies
  - Mark “Do NOT Use”
  - Contact immunization program, vaccine manufacturer(s), or both for guidance


Resources

CDC's Temperature Excursion Checklist

1. Checklist for general power loss
   - ☐Contact utility company
   - ☐Determine if time to restoration is acceptable
   - ☐Activate alternate generator if available
2. Checklist for presumed storage unit malfunction (DISPOSITION OF STORAGE UNIT if Unit is too warm, too cold, too noisy, or stopped):
   - ☐Check circuit breakers
   - ☐Unit plugged in
   - ☐Door closed
   - ☐Door seal adequate
   - ☐Assess location of temperature monitoring devices for temperature reading
   - ☐Record all temperatures
   - ☐Space between vaccines for air to circulate
   - ☐Coils free of dust
   - ☐Temperature adjusted gradually if not set correctly (need to re-check temperatures and record every 30 minutes)
   - ☐Unit secured and level (if unit is noisy)
   - ☐Screws tightened (if unit is noisy)
   - ☐Technician called
3. Disposition of vaccines (if power not restored or if temperature does not begin to recover)
   - ☐Label exposed vaccines "Do NOT Use" and store under appropriate conditions (set apart from other vaccines)
   - ☐Check temperature of alternate storage unit
   - ☐Vaccines moved to alternate storage unit (move refrigerated vaccines first)
   - ☐Document temperature excursion action taken and results
   - ☐Immunization Program contacted
   - ☐Manufacturer contacted
   - ☐Return vaccines determined to be usable only when storage unit is stable and resume use
   - ☐Determine disposition of vaccines that are compromised:
     - Vaccines provided through Vaccines for Children (VFC) Program and other vaccines purchased with public funds prepared for return to distributor.
     - Vaccines purchased with private funds should be disposed of in consultation with the manufacturer(s) and according to state regulations for medical waste. Replacement plans will vary.
     - If insured against losses of this type, contact insurance representative.

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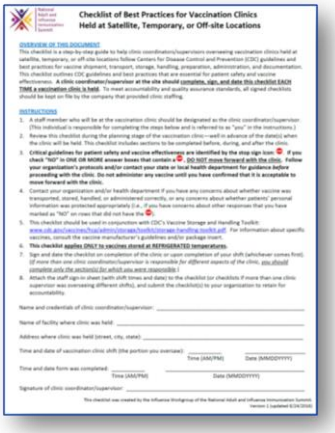
Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

Vaccination Clinics
How to Comply with Best Practices

- **Clinic supervisors should:**
  - Review the skills checklist of all staff administering vaccines
  - Provide comprehensive, competency-based training to address gaps in skills
  - Put accountability checks in place to ensure policies and procedures are followed

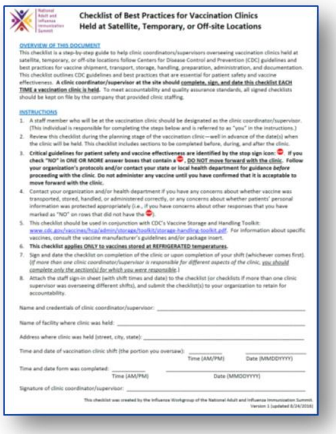

Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations

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

NAIIS: Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations
www.izsummitpartners.org/content/uploads/2016/08/NAIIS-Vaccination-Clinic-Checklist_8-24-2016-FINAL.pdf

Vaccination Clinics
How to Comply with Best Practices

- **Human resources personnel should:**
  - Assess the contractor or hiring agency's training policies and procedures for vaccine storage, handling, and administration.
  - Ensure the contractor or agency can demonstrate that the policies and procedures are in place and have documentation that they are assessed routinely.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www.izsummitpartners.org/content/uploads/2016/08/NAIIS-Vaccination-Clinic-Checklist_8-24-2016-FINAL.pdf

Reporting Vaccine Administration Errors

Real-Life Vaccine Administration Errors

- **During a worksite occupational flu vaccination clinic, 67 persons were vaccinated:**
  - With improperly stored vaccine
  - Using the same syringe, and
  - Using an incorrect dosage (amount)

Morbidity and Mortality Weekly Report (*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, PhD[1]; Rebecca Greeley, MPH[1]; Jill Cinitz-Sklar, MPH[1]; Nicole Mazur, MPH[1]; Jill Swanson, MPH[2]; JoEllen Wolicki, BSN[2]; Joseph Perz, DrPH[1]; 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.

Reuse of syringes for multiple patients, with or without reuse of needles, is recognized as a serious infection control breach that poses risks for bloodborne pathogen transmission [1–2]. Upon investigation additional concerns regarding vaccine administration and storage and handling were identified for this event. The nurse used only two multiple dose vials of vaccine [10 doses/vial] to administer vaccines to 67 adult participants; thus, participants did not receive the recommended dose of influenza vaccine. The health services company had shipped the vaccine to the nurse's home, where it was stored in her home refrigerator without temperature monitoring until the event. Vaccine doses were then transported from the nurse's home to the vaccination site using a styrofoam container and cold packs. After the event, unused vaccine doses were transported back to the nurse's home and stored in her refrigerator before being shipped back to the health services company in a container with cold packs.

In response to these injection safety and vaccine administration errors, the NJDOH, in consultation with CDC, recommended notification and testing of the New Jersey business employees who participated in the vaccination clinic for human immunodeficiency virus (HIV), hepatitis C virus, and hepatitis B virus. Postexposure prophylaxis with hepatitis B vaccine and readministration of influenza vaccination were also recommended. NJDOH sent an e-mail on October 2, informing the participants of the potential bloodborne pathogen exposures and recommendations for testing and vaccination. Certified follow-up letters also were sent. A dedicated NJDOH phone number and e-mail address were created to assist the affected patients. The West Windsor Health Department collaborated with an urgent care center to perform blood draws and administer the vaccines on October 5 and 6; HIV and mental health counselors were available on-site. NJDOH also provided letters for participants to bring to their private physicians outlining the situation, risk assessment, and public health recommendations. Forty-seven of 67 participants received services through the urgent care center and the West Windsor Health Department; an unknown number of participants received treatment from their private health care providers. Follow-up clinics were arranged at 1 month and at 4 months for hepatitis B vaccination and testing.

Recommendations for appropriate injection safety and vaccine storage, handling, and administration were not followed at the influenza vaccination clinic [3–6]. Response to this event required rapid and extensive communication and coordination among public health partners, including CDC, NJDOH, the New Jersey State Board of Nursing, and the West Windsor Health Department, as well as private entities. The contracted nurse voluntarily surrendered her license within 1 week of the initial report.

MMWR 2015;64(49):1363-4. www.cdc.gov/mmwr/preview/mmwrhtml/mm6449a3.htm

Reporting Vaccine Administration Errors

First step:

- **Establish an environment that values reporting and investigating errors as part of risk management and quality improvement**

What if a Vaccination Error Occurs?

Next steps:

- **Inform the patient/parent of the error**
- **Determine the status of the patient**
- **Know how to "correct" the error**
  - Contact your local health department, the vaccine manufacturer, or nipinfo@cdc.gov for guidance
  - Not all errors require revaccination!
- **Explain any needed next steps to the patient/parent**
- **Record the vaccination as it was given on the medical record**
- **Contact the immunization information system (IIS) for additional information as needed**
- **Follow the policies and procedures of your facility for medication errors**

Reporting Vaccination Errors to VAERS

- Report all significant adverse events that occur after vaccination of adults and children
- VAERS accepts all reports, including reports of vaccination errors
- Providers are encouraged to report vaccination errors without health events if they believe the error may pose a safety risk

There are 3 ways to report to VAERS – online, fax, or mail

Vaccine Adverse Event Reporting System www.vaers.hhs.gov/esub/index

Immunization Resources

CDC Resources for Staff Education

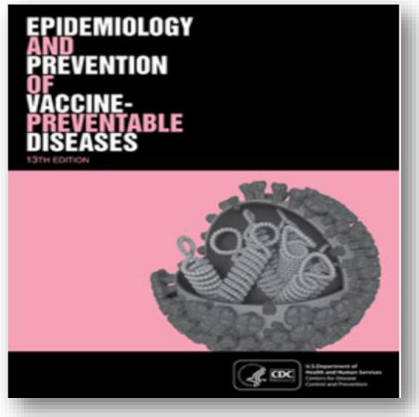
- **Competency-based education for staff is critical**
- **Multiple educational products available free through the CDC website:**
  - Immunization courses
  - "You Call the Shots" self-study modules
  - Netconferences
- **Continuing education is available**

CDC Immunization Education and Training web page

CDC Immunization education and training web page www.cdc.gov/vaccines/ed/index.html

Epidemiology and Prevention of Vaccine-Preventable Diseases Webinar Series

- **Provides:**
  - Information about vaccine-preventable diseases and the vaccines that prevent them
- **2017 series begins in June**
  - 2016 archived presentations available online now
- **Free continuing education**
- **For more information:** www.cdc.gov/vaccines/ed/webinar-epv/index.html



Course text available online – view, print, or download
Bound copies may be purchased

CDC Immunization Apps for Health Care Personnel

Childhood and adult immunization schedules
www.cdc.gov/vaccines/schedules/hcp/schedule- app.html

Influenza information
www.cdc.gov/flu/apps/cdc-influenza-hcp.html

Morbidity and Mortality Weekly Report **(MMWR)**
www.cdc.gov/mobile/applications/mobileframework/mmwrpromo.html

Travel well
www.nc.cdc.gov/travel/page/apps-about

CDC Vaccine and Immunization Resources

- **Question? Email CDC**
  - Providers — nipinfo@cdc.gov
  - Parents and patients — www.cdc.gov/cdcinfo
- **Twitter** — @DrNancyM_cdc
- **Vaccines and Immunizations** — www.cdc.gov/vaccines
- **Vaccine Safety** — www.cdc.gov/vaccinesafety
- **Vaccine Administration** — www.cdc.gov/vaccines/hcp/admin/recs-guidelines.html
- **Vaccine Storage and Handling** — **www.cdc.gov/vaccines/hcp/admin/storage-handling.html**

Other Vaccine and Immunization Resources

- Immunization programs at state and local health departments
- One and Only Campaign www.oneandonlycampaign.org
- Immunization Action Coalition www.immunize.org
- EZIZ www.eziz.org
- AIM Provider Toolkit www.aimtoolkit.org

Take Home Messages

- Comprehensive skills-based training is needed for all staff that store, handle and administer vaccines
- Integrate best practice strategies into clinical procedures
- Use immunization job aids and resource materials to keep staff on the same page
- Report administration errors to VAERS

Questions?

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For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov