

# **CHECKLIST**

# 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 supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) and Department of Defense (DoD) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. It should be used in any non-traditional vaccination clinic setting, including but not limited to: workplaces, community centers, schools, makeshift clinics in remote areas, operational environments, aid stations, and even medical facilities when vaccination occurs in the public areas or classrooms. Temporary clinics also include mass vaccination events, and vaccination clinics held during pandemic preparedness exercises. This checklist outlines CDC and DoD guidelines and best practices that are essential for patient safety and vaccine effectiveness. A clinic 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 your supervisor/HQ element.

## **INSTRUCTIONS**

- 1. An Officer-in-Charge (OIC) who will be at the vaccination clinic should be designated as the clinic 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 "NO" is checked in ONE OR MORE answer boxes that contain a , DO NOT move forward with the clinic. Follow your organization's protocols and/or contact the Defense Health Agency-Immunization Healthcare Division (DHA-IHD) 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 the DHA-IHD 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 DHA-IHD's Vaccine Storage and Handling Guide: <a href="https://health.mil/waccineshguide">https://health.mil/waccineshguide</a> and Toolkit: <a href="https://health.mil/Imm\_Toolkit">https://health.mil/Imm\_Toolkit</a>. For information about specific vaccines, consult the vaccine manufacturer's package insert.
- 6. This checklist applies ONLY to vaccines stored at REFRIGERATED temperatures (i.e., between 2–8° Celsius or 36–46°Fahrenheit).
- 7. Sign and date the checklist upon completion of the clinic or completion of your shift (whichever comes first). (If more than one clinic 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 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:		
1	Time (AM/PM)	Date (MM/DD/YYYY)
Signature of clinic supervisor:		
Signature of clinic supervisor:		· · ·

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

VACCINE SHIPMENT			
YES	<u>NO</u>	<u>N/A</u>	
			Vaccine was shipped directly to the facility/clinic site, where adequate storage is available. (Direct shipment is preferred for cold chain integrity.)
VACCIN	NE TRAN	SPORT (	(IF IT WAS NOT POSSIBLE TO SHIP VACCINES DIRECTLY TO THE FACILITY/CLINIC SITE)
YES	<u>NO</u>	<u>N/A</u>	
	•		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 DHA-IHD's Vaccine Storage and Handling Guide for information on qualified containers and pack-outs.
	□ ●		The person transporting the vaccines confirmed that manufacturer instructions for packing configuration and proper conditioning of coolants were followed. Each vaccine container should include a completed Vaccine Inventory Issue/Return Receipt form. (Your qualified container and pack-out should include packing instructions. If not, contact the company or DHA-IHD for guidance.)
			The person transporting the vaccines confirmed that all vaccines were transported in the passenger compartment of the vehicle (NOT in the vehicle trunk).
	•		Each vaccine storage unit had its own certified and calibrated temperature-monitoring device (TMD), placed directly with the vaccines and used to monitor temperatures during transport. The TMD was traceable to the standards maintained by the National Institute of Standards and Technology (NIST), and had a current and valid Certificate of Calibration Testing (or Report of Calibration).
			The amount of vaccine transported was limited to the amount needed for the workday.
VACCIN	NE STOR	AGE AN	D HANDLING (UPON ARRIVAL AT FACILITY/CLINIC)
YES	<u>NO</u>	<u>N/A</u>	
	□ <b>●</b>		If vaccines were shipped, the shipment arrived within the appropriate time frame (according to manufacturer or distributor guidelines) and in good condition.
	□ <b>●</b>		If the vaccine shipment contained a cold chain monitor (e.g.,TempTale), it was checked upon arrival at the facility/clinic, and there was no indication of a temperature excursion (i.e., out-of-range temperature) during transit. A cold chain monitor may not be included when vaccines are shipped directly from the Prime Vendor. <i>Note: Follow instruction sheet with vaccine shipment for reading and/or returning TempTale monitors</i> .
			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 DHA-IHD's Vaccine Storage and Handling Guide.
			Upon arrival at the facility/clinic, vaccines were still within the manufacturer-recommended temperature range (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines).
			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			
YES	<u>NO</u>	<u>N/A</u>	
			A contingency plan is in place in case vaccines need to be replaced. The plan addresses scenarios for vaccine compromised before arrival at the clinic and for vaccine compromised during clinic hours.

- » 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 DoD Public Health Department or DHA-IHD 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.



YES	NO	N/A	
		11/A	An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of
	•		the clinic. See paragraph 2-9 of the Joint Regulation (Army Regulation 40–562; BUMEDINST 6230.15B; AFI 48–110_IP; CG COMDTINST M6230.4G - <i>Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases</i> ).
	•		All on-site vaccination staff are certified in cardiopulmonary resuscitation (CPR), are familiar with the signs and symptoms of anaphylaxis, and know the location of epinephrine and are trained in its indications and use. DHA-IHD strongly suggests having a current Standing Order for anaphylaxis management available, which has been reviewed and discussed with all staff prior to the event.
			There is a designated area at the site for management of patients with urgent medical problems (e.g., fainting).
			Adequate infection control supplies are provided, including biohazard waste bags, disinfecting wipes, and supplies for hand hygiene. If administering injectable vaccines, gloves, adhesive bandages, individually packaged sterile alcohol wipes, and a sufficient number of sterile needles, syringes, disposable pads, andsharps containers 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 package insert for administration and have completed vaccine-specific competency training PRIOR to the event.
			If using a standing order protocol, the protocol is current and available at the clinic/facility site. (See DHA-IHD website for examples.)
	□		A sufficient number of vaccine information statements (VISs) for each vaccine being offered are available at the clinic/facility site (as required by Federal law).
			A sufficient number of screening forms are available at the clinic/facility site (see DHA-IHD website for examples). The screening forms are vaccine and patient-specific, as needed (e.g., routine or readiness, adult or pediatric, etc.).
			A designated clean area for vaccine preparation has been identified and set up prior to the clinic, separate from the immediate administration and away from potentially contaminated items. Location physical space dictates placement (e.g., a separate table versus a separate room).
			A qualified individual has been designated to oversee infection control at the clinic.
DURING	G THE	CLINIC	$\mathbb{C}$ (Please complete each item while the clinic is occurring, and review at the end of your shift)
VACCIN	E STOR	AGE AN	D HANDLING (AT FACILITY/CLINIC)
YES	<u>NO</u>	N/A	
			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 certified and calibrated digital data logger or temperature-monitoring device placed directly with vaccines. Follow the temperature monitoring guidance specified in DHA-IHD's <u>Vaccine</u> <u>Storage and Handling Guide</u> .
	□ ●		If vaccines are being stored in a medical-grade refrigerator 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 vaccines cannot be stored in a medical-grade refrigerator, they are being kept in the portable vaccine refrigerator or qualified pack-out with a digital data logger or temperature-monitoring device 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/sealed as much as possible.
			Vaccines are being protected from light during the vaccination clinic per the manufacturer's package insert.
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  - Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.



VACCIN	E PREP	ARATIO	N
YES	<u>NO</u>	<u>N/A</u>	
	□ ●		Expiration dates of vaccines (and diluents, if applicable) are being checked again during preparation, and only vaccines that have not expired are being administered. (Of note: If you are using multidose vials, be sure to review beyond use dates, along with manufacturer expiration dates.)
			Vaccines are being prepared in a designated clean area, away from immediate administration areas and potentially contaminated items.
	□		If using reconstituted vaccines, they are being prepared according to the manufacturer's package insert.
			Vaccines are being prepared at the time of administration.
			If vaccines are predrawn from a multidose vial, only the contents of 1 multidose vial are being drawn up at one time by each staff member administering vaccines (the maximum number of doses per vial is described in the package insert).
			If using single-dose or multidose vials, syringes are being labeled with the name of the vaccine and date/time of draw.
	□ <b>●</b>		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 your Immunization Healthcare Specialist (IHS) and/or DHA-IHD via the <u>PC-TSMP process</u> at <a href="https://health.mil/coldchain">https://health.mil/coldchain</a> .
VACCIN	E ADMI	NISTRA	TION
YES	<u>NO</u>	<u>N/A</u>	
	□ ●		Vaccine information statements (VISs) are being provided to every patient or parent/guardian before vaccination (as required by Federal law). Although laminated copies, posters, and digital versions of VISs may also be used, hard-copy handouts are available for those patients who would like to take one home.
	<ul><li>□</li><li>●</li></ul>		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. For additional guidance, see <a href="https://www.cdc.gov/clean-hands/hcp/clinical-safety/">https://www.cdc.gov/clean-hands/hcp/clinical-safety/</a> .
			If gloves are being worn by staff administering vaccines, they are being changed and hands are being cleaned using proper hygiene techniques before and 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 administering vaccine.
	<ul><li>□</li><li>●</li></ul>		Vaccines are normal in appearance (i.e., not discolored, without precipitate, and easily resuspended when shaken).
			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.
	□		Vaccines are being administered using aseptic technique.
	□ ●		Staff is administering vaccine to the correct patient (e.g., if a parent/guardian and child or siblings are at the vaccination station at the same time, each patient's name and date of birth are verified prior to their individual vaccination).
	□ ●		Staff is administering vaccines using the correct route per manufacturer instructions.
	□ ●		Staff is administering the correct dosage (volume) of vaccine.

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	□ ●		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 3-2 of the "General Best Practice Guidelines on Immunization."	
	□ ●		If vaccine administration errors are observed, corrective action is being taken and incident is immediately reported to the clinic supervisor.	
			Any persons with a needlestick injury, a vaccine administration error, or an urgent medical problem are being evaluated immediately by a licensed provider, and referred for additional medical care if needed.	
			Patients are being instructed/encouraged to stay at the clinic for 15 minutes after vaccination to be monitored for adverse events.	
ADMINISTRATION OF INJECTABLE VACCINES: In this section, N.A. is ONLY an option if the clinic is EXCLUSIVELY using non-injectable vaccines, such as live, attenuated influenza vaccine (LAIV)				
YES	<u>NO</u>	<u>N/A</u>		
			A new needle AND new syringe are being used for each injection. (Needles and syringes are NEVER used to administer vaccine to more than one person.)	
	□ ●		Single-dose vials or manufacturer-filled syringes are being used for only one patient.	
	□ ●		Vaccines are being administered 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 $\geq 3$ years; vastus lateralis muscle of anterolateral thigh [preferred] or deltoid muscle of arm for children aged $1-2$ years; vastus lateralis muscle of anterolateral thigh for infants aged $\leq 12$ months. For subcutaneous route: thigh for infants aged $\leq 12$ months; upper outer triceps of arm for children aged $\geq 1$ 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., most inactivated vaccines such as influenza, typhoid, etc.) or 45° for subcutaneous injections (e.g., live vaccines such as MMR, etc.).	
			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 are NOT being recapped.	
VACCIN	E DOCU	UMENTA	TION	
YES	<u>NO</u>	<u>N/A</u>		
			Each vaccination is being fully documented with name of person vaccinated; vaccination date; vaccine 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 unit/location address of person who administered the vaccine.	

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YES	<u>NO</u>	<u>N/A</u>		
			Documentation is being completed in the patient's electronic health record and/or service-specific Immunization Tracking System (ITS) (e.g. ASIMS, MEDPROS, MRRS, etc.).	
			Patients are given documentation of vaccines received for their personal records and to share with their medical providers.	
<b>AFTER</b>	THE C	CLINIC	(Please complete each item after the clinic is over)	
POST-C	LINIC A	CTIONS		
YES	<u>NO</u>	<u>N/A</u>		
	•		Temperature of remaining vaccine is 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 DHA-IHD for guidance. The Vaccine Inventory Issue/Return Receipt form is updated with the type/amount of remaining viable vaccine for turn-in.	
			Any remaining vaccine in provider-predrawn syringes, opened multidose vials, or activated manufacturer-filled syringes (MFSs) is properly discarded. 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, across state lines, or returned to the supplier for credit.	
	□ ●		Viable, unused vaccine is 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.)	
			Any needlestick injuries were reported to the clinic supervisor and appropriate entities (e.g., Public Health/Preventive Medicine), and the injured person was sent for appropriate care (e.g., Emergency Department).	
			Any vaccine administration errors were reported to all appropriate entities.	
			All biohazardous material is disposed of properly.	
POST-C	POST-CLINIC DOCUMENTATION			
YES	<u>NO</u>	<u>N/A</u>		
			All vaccinations were recorded in the service-specific ITS (and Electronic Medical Record, as applicable).	
			Any adverse events were reported to the <u>Vaccine Adverse Event Reporting System (VAERS)</u> .	
	□ ●		All patient medical information was placed in secured storage locations for privacy protection in accordance with Public Law 104-191, "Health Insurance Portability and Accountability Act of 1996" (HIPAA).	
			The staff sign-in sheet is attached to this document (with shift times, clinic location, and date).	

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  - Follow your organization's protocols and/or contact your DoD Public Health Department or DHA-IHD 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.
- » If you check "NO" in ONE OR MORE answer boxes that contain a in the "After The Clinic" section, contact your DoD Public Health Department or DHA-IHD for guidance.

## ADDITIONAL INFORMATION AND RESOURCES

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

#### **REGULATIONS AND POLICIES:**

- The Joint Regulation (Army Regulation 40–562; BUMEDINST 6230.15B; AFI 48–110\_IP; CG COMDTINST M6230.4G Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases) http://www.health.mil/JointImmRegulation
- The 8 Standards for Military Immunization https://health.mil/immunizationstandards
- Vaccine Recommendations by AOR https://health.mil/CCMDvaccines
- Standing Orders <a href="https://health.mil/standingorders">https://health.mil/standingorders</a>
- The Defense Health Agency-Immunization Healthcare Division home page https://health.mil/vaccines

#### VACCINE INFORMATION/EDUCATION

- Vaccine Information Statements (VISs) <a href="https://health.mil/VIS">https://health.mil/VIS</a>
- Manufacturer's product information/package inserts <a href="https://health.mil/packageinserts">https://health.mil/packageinserts</a>
- Information Papers <a href="https://health.mil/vaccineinfopapers">https://health.mil/vaccineinfopapers</a>

#### VACCINE STORAGE, HANDLING, AND ADMINISTRATION:

- Vaccine storage and handling:
  - CDC Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
  - DHA-IHD Vaccine Storage and Handling Guide https://health.mil/vaccineshguide
  - o DHA-IHD Immunization Tool Kit https://health.mil/Imm Toolkit
- Cold Chain Management:
  - DHA-IHD https://health.mil/coldchain
  - USAMMA https://www.amlc.army.mil/USAMMA/Distribution-Operations-Center-Vaccine/
- Vaccine administration:
  - ACIP guidelines <a href="https://health.mil/ACIPguidelines">https://health.mil/ACIPguidelines</a>
  - https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
  - https://www.cdc.gov/vaccines/pubs/pinkbook/index.html
  - https://www.cdc.gov/vaccines/hcp/admin/resource-library.html

## SCREENING/RECORDKEEPING:

- Pediatric and Adult Influenza Screening and Immunization Documentation https://health.mil/fluscreening
- DD Form 3110 Routine Immunization Screening Form: Pediatric https://health.mil/pediatricscreening
- DD Form 3111: Routine Immunization Screening Form: Adult <a href="https://health.mil/adultscreening">https://health.mil/adultscreening</a>
- Immunization Tracking Systems Resources <a href="https://health.mil//ITS">https://health.mil//ITS</a>
- DHA Form 207 COVID Screening Form <a href="https://health.mil/covidscreening">https://health.mil/covidscreening</a>

#### TRAINING:

- Competency Assessment Checklists <a href="https://health.mil/vaccineCAF">https://health.mil/vaccineCAF</a>
- JKO Immunization training <a href="https://health.mil/IHDonlinetraining">https://health.mil/IHDonlinetraining</a>

## SAFETY/ADVERSE EVENTS:

- https://www.cdc.gov/injection-safety/hcp/clinical-safety/
- https://health.mil/vaccinesafety
- Medical management of vaccine reactions in adults <a href="http://www.immunize.org/catg.d/p3082.pdf">http://www.immunize.org/catg.d/p3082.pdf</a>
- Reporting an adverse event: VAERS http://vaers.hhs.gov

## **COVID-19 RESOURCES:**

• https://health.mil/COVID19vaccineresources HCP

This checklist is a valuable resource for use in temporary mass vaccination clinics and other vaccination exercises, such as those conducted in an operational environment or aid stations as part of force health protection or public health emergency preparedness (PHEP) program activities.

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

