Temperature Sensitive Medical Products (TSMPs) Good Distribution Practices (GDP)

DHA Immunization Healthcare Branch
Immunization Program Leaders Course

Distribution Operations Center
United States Army Medical Materiel Agency

Overview

- Historical Events
- USAMMA DOC Functions
- Core Products Overview
- Why Are We Here
- Cold Chain Management (CCM) Process and Procedures
- Safe Guarding Temperature Sensitive Medical Products (TSMPs)
- CCM Equipment
- Cold Chain References/Guides

Historical Events

1997 – Secretary of Defense approved Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP)
**Army designated Executive Agent (EA)

1998 – Loss of 200,000 doses of Anthrax Vaccine (AVA).

1998 – USAMMA tasked to perform DoD distribution of AVA
**Created Distribution Operations Center (DOC) to manage DoD AVA Distribution
**Cold Chain Management Principles/Procedures (CCM) were developed

1999 – DHA Immunization Healthcare Branch (formerly known as Military Vaccine Agency – Vaccine Healthcare Centers Network (MILVAX-VHCN) replaced MEDCOM as AVIP policy developer/clinical guidance

USAMMA DOC FUNCTIONS

The Distribution Operations Center (DOC) manages critical vaccines and pharmaceutical products which may or may not require Cold Chain Distribution, to include; the packaging, storage and special handling requirements of the medical material requiring refrigeration; the management of the shipment; and the oversight of the product from initial requesting agency to end user, in support of DOD personnel and operations.

DOC is also responsible for DOD Medical Materiel Quality Control (MMQC) messages and Army Medical Materiel Information (MMI) messages.

Core Products Overview

- Anthrax Vaccine
- Smallpox Vaccine (ACAM2000)
- Influenza Vaccine
- Adenovirus Vaccine (Type 4 & Type 7)
- Vaccinia Immune Globulin Intravenous (VIGIV)
- Investigational New Drug (IND) products
- Foreign Military Sales (FMS)
- Other Temperature Sensitive Medical Products (He-Bat, Rabies etc.)
- Other Non-Temperature Sensitive Critical products

Why Are We Here?

- The Great Loss of 1998 – Over 200,000 doses of Anthrax Vaccine were compromised due to freezing
- Sites contribute to thousands of dollars each year in vaccine losses due to the following major factors:

  - Mechanical Failures - such as alarm system and power outages/supply malfunctions
  - Human Process Failures - such as poor cold chain management techniques
  - Failure to follow policies - procedures and local regulations
  - Training

Cold Chain Management (CCM) Process and Procedures

Vaccines are sensitive biological substances that can lose their potency and effectiveness if exposed to heat, extreme cold and/or light

- **Minimize waste/save thousands of taxpayer dollars**
  - Prevent vaccine from being compromised
  - Assures vaccine maximum shelf life and suitability for use by minimizing the rate of deterioration
  - Some vaccines are in critically short supply
- The loss of vaccine potency **CANNOT** be reversed
- Assures leadership, service members and DoD beneficiaries that vaccine/products are safe to use and at full potency when administered

US Pharmacopeia (USP) Temperature Standards

- Refrigerated Storage - Thermostatically controlled from 2°C to 8°C; approximately 35°F to 46°F

- Frozen Storage - Thermostatically controlled from -20°C to -10°C; approximately -4°F to 14°F

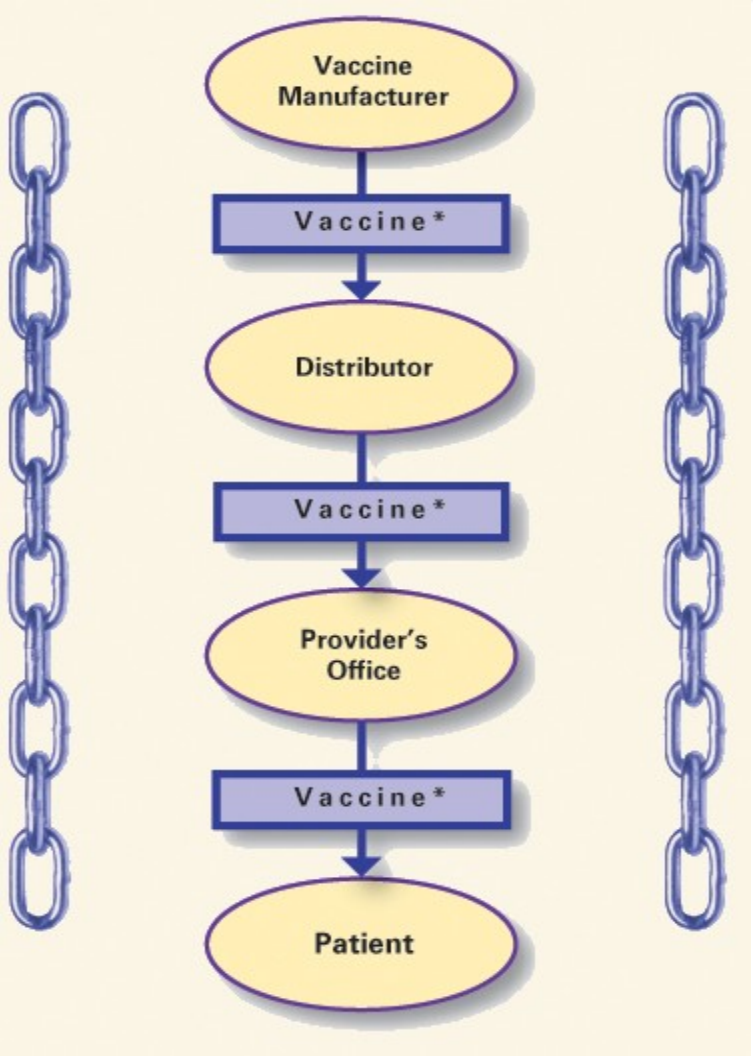
- Room Temperature - Thermostatically controlled from 20°C to 25°C; approximately 68°F to 77°F

What is Cold Chain Management

Cold chain begins with the cold storage unit at the vaccine manufacturing plant

Extends through the transfer of vaccine to the distributor

The Chain is most Compromised at the point of Provider to Patient



TSMP Coordinator

Responsible for:

Developing a Routine Vaccine Storage and Handling Plan, kept in a visible location near all vaccine storage units.

- Current contact information for the primary and back-up vaccine coordinators
- Pharmacy, logistics, local Immunization Healthcare Specialist (formerly known as Regional Analysts), USAMMA
- Vaccine manufacturers, the medical equipment repair office
- Storage unit alarm company
- Written emergency plan – natural disasters, power outages etc.
- Temporary placement of vaccine in a working refrigerator

TSMP Storage & Handling Equipment

Storage Unit Selection and Characteristics

- Medical grade stand-alone refrigerators and freezers (over-the-counter type) are the most highly recommended
- Combination refrigerator and frost-free freezer for home use is acceptable but only the Refrigerated section is recommended due to the freezer going through defrosting cycle
- **NOT AUTHORIZED** (SB 8 75 11) – Dormitory style refrigerators, due to National Institute of Standards and Technology (NIST) vaccine study, showed that units displayed **severe temperature control and stability issues**

Medical Grade Refrigerators/Freezers

- Medical grade refrigerators/freezers ensure temperature consistency
- Provide ease of serviceability, integrate with wireless temperature monitoring systems
- Able to bring temperatures down much more quickly than non-medical grade units
- Greater efficiency of compressors in medical grade refrigerators

Features / Checklist

- Consider serviceability
- Storage volume
- Ability to maintain consistent temperature
- Front-mounted compressor will allow for easier service

Construction Material:

- Stainless steel refrigerators are highly durable
  - Non-medical grade refrigerators - plastic and other less sophisticated components
  - Cheap or flimsy hinges and seals will result in temperature leaks and an overburdened compressor
  - Glass front doors, which allow you to visually inspect product without opening the door; fewer openings will positively impact the life of the unit.

When determining the cubic volume you require

- Consider your current, as well as future, storage needs

Thermometers

Accurate thermometer readings are essential to determine whether vaccines are maintained at the required temperature

- Storage units should have a National Institute of Standards and Technology (NIST) certified and calibrated thermometer – in each compartment (refrigerator/freezer)
- Continuous graphic recorder thermometer that monitors ranges and durations is recommended
- Uncertified liquid (mercury or alcohol) thermometers and dial-type are not authorized
- Thermometers should be placed in the center of the compartment away from coils, walls, floor, and fan

Thermometers

Based on studies of thermometers conducted by NIST in 2012, the CDC recommends using a digital thermometer with a detachable probe that is kept in a glycol-filled bottle. NIST studies found that these probes in glycol-filled bottles can determine the actual temperature of the vaccine vial temperature when it is placed in the same area where the vaccine is stored.

- At least one reading/15 min
- Memory storage : *39 days recording
- Battery life: 6 months minimum

Monitoring & Recording Temperatures

- Manually confirm the temperature of ALL vaccine storage units a minimum of TWO times a day – once at the beginning of the workday, and once at the end of the workday.

- Applies regardless of whether or not there is a 24-hour/7-day temperature alarm system, chart recorder thermometer, or a digital data logger.

THERE IS NO SUBSTITUTE FOR MANUALLY CHECKING/ DOCUMENTING THE TEMPERATURE TWICE A DAY

- Document the date, time, and temperature on a vaccine log.

- Pay special attention to any trend in deviation of temperature as this could indicate a possible future mechanical malfunction or power outage of the storage unit

Temperature Monitoring

Immunization Healthcare Branch

Temperature Log for Refrigerator and Freezer — Celsius

Month/Year:_____ Days 1–15

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month's completed form for 3 years, unless state or local jurisdictions require a longer time period.

If recorded temperature is in the shaded zone take immediate corrective action:

This represents an unacceptable temperature range. Follow these steps:

1. **Move vaccine(s) to a working storage unit.**
2. Label the vaccine(s) as **"do not use", do NOT destroy/discard the vaccine(s).**
3. Activate your facilities vaccine Emergency Retrieval and Storage Plan.
4. **Contact *USAMMA/DOC as well as your Immunization Healthcare Specialist (IHS)** and standby for further instructions on the disposition of the vaccine.
5. **Document the action taken** on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Room Temp.															
Exact Time															
°C Temp	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Too warm — ≥11°															
Refrigerator temperature — 10°			Take immediate corrective action if temperature is in shaded section*												
9°															
8°															
7°															
6°															
Aim for 5° — 5°															
4°															
3°															
2°															
Too cold* — 1°															
0°			Take immediate corrective action if temperature is in shaded section*												
≤-1°															

Too warm — ≥-12°															
Freezer temp — -13°			Take immediate corrective action if temperature is in shaded section*												
-14°															
-15°															
-16°															
≤-17°															

*USAMMA/DOC Emergency Contact: Phone: (301) 619-3017/4318, DSN (343), After hours: (301) 676-0808/1184, email: usarmy.detrick.medcom-usamma.mbx.doc@mail.mil

MILVAX-VHCN (15 Sep 14) (877) GET-VACC www.vaccines.mil

Protecting the Power Supply

- Avoid using power outlets with built-in circuit switches, power switches, or outlets that can be activated by a wall switch.
- Use a safety-lock plug or an outlet cover to reduce the chance of a storage unit becoming inadvertently unplugged.
- Post a warning sign at the plug and on the refrigerator and freezer unit, and label fuses and circuit breakers to alert people not to turn off the power to the storage unit.
  - ❖Labels/SOPs should include who to call and the steps to take if the power is interrupted, and checked periodically by the TSMP Coordinator.

Safeguarding Alarming Devices

- Alarms should be monitored electronically and physically 24 hours a day, seven days a week – **NO EXCEPTIONS**

- At the time of a power failure the system should:

  - **IMMEDIATELY** notify an accountable person

  - be able to provide continuous temperature monitoring in order to verify that the integrity of the vaccine stayed within the proper temperature during storage.

- **Monthly** testing of the entire system ensures that POCs and phone numbers are accurate.
  - Records should be kept for three years.

- Backup generators should be capable of running for 72 hours

TSMP Inventory Management

Immunization Healthcare Branch

- Identify and be accurate when ordering a supply of vaccines.
- Disposal of expired vaccine leads to costly waste of taxpayer money.
- Vaccines are expensive, and the cost is continuously rising.
- **DO NOT OVERSTOCK** vaccine. If a compromise occurs, there is a risk of losing a large amount of vaccine.
- Monitor vaccine usage and rotate stock.

Receiving TSMP Shipments

- Upon delivery, open the package as soon as possible.
  - Verify that the amount received matches the packing slip.
  - Check the expiration dates on the vaccines (using the shortest-dated vaccine first)
  - Refrigerate vaccines in their original box – removing exposes the vaccine to room temperature and light
  - Immediately place vaccine in the proper storage container within the refrigerator/freezer

Anthrax Vaccine / Smallpox Vaccine / Adenovirus Vaccine

Once the box is delivered, call USAMMA DOC immediately. A case manager will instruct you to read the TempTale. Place it in the appropriate return envelope, pending the digital reading from the TempTale. The case manager will determine if the vaccine is 'verbally released' or suspended.

Safe Guarding TSMPs

- Store vaccines on the middle shelves. **NEVER** store vaccines on the doors or vegetable bins.
- Proper air circulation is imperative – leave adequate space between packages to maintain proper airflow.
- Proper storage of vials within the storage unit
  - eliminates the wrong type of vaccine being administered
  - makes monthly inventory more accurate
  - makes expiration and tracking of the vaccine easier
- Store each vaccine in its own labeled section.
- Bins and/or baskets with slotted sides should also be labeled.
- Verify the type of vaccine and expiration date before administering.

TSMP Transport Procedures

Protecting Vaccines at Off-Site Immunizations Sessions

- Pack only the expected amount that will be used during the immunization session.

- Minimize the number of times the container is opened.

- Transport vaccine in an approved/validated insulated container **ONLY**.
  - No brown paper bags
  - No uncertified Styrofoam coolers

- Vaccines taken to an off-site clinic:
  - Fill out an issue receipt/number/type of vials taken.
  - Vaccine must be maintained at proper temperature.

- Returning vaccine:
  - Document the number/type of vials returned.
  - Verify the vaccine was maintained at proper temperature.

Equipment Used to Support Cold Chain Distribution

Immunization Healthcare Branch

"Medically Ready Force…Ready Medical Force"

CCM Equipment - Temperature Monitors

The TempTale multiple use temperature monitor system provides complete time and temperature history on all of our temperature sensitive product shipments. Data collected is used to validate that the products have preserved their integrity during distribution from the manufacturer to the end user. The TempTale temperature monitor is manufactured by Sensitech, Inc. This device can be set to read every ten (10) minutes for approximately two (2) weeks and record 2,000 data points.

CCM Equipment
Insulated Shipping Container

- The insulated shipping container (EnduroTherm box) is used to ensure the cold chain distribution process is not broken during transporting TSMPs.

- There are four different sizes: small, medium, large, and extra large. The boxes have gone through various testing protocols and can maintain the required temperature (guaranteed for 3 days and, depending upon environment, up to 7 days.

VaxiPac (PX1L) Shipping Container

PERFORMANCE OF ACUTEMP PXC (+7°C)

- **AcuTemp PXC (+7°C) is a safe replacement for ice** used to keep vaccines and other temperature sensitive goods cold in the **AcuTemp PX1L without accidental freezing.**
- Used according to the instructions, the **AcuTemp PX1L system will maintain** vaccines/products between 2-8°C (35 – 46°F) for more than 20 hours at an ambient temperature of 24°C (75°F).
- As the ambient temperature increases, the hold time will decrease:

a. 15 hours @ 30°C (86°F)
b. 12 hours @ 37°C (99°F)
c. 9 hours @ 48°C (118°F)

PXC (+7°C) must be chilled at 3°C (±1°C) for 24 hours.

A maximum of 24 vials can be placed in the VaxiPac (a full layer consists of 12 vials).

When placing PXCs in the PX1L, be sure to keep the pull-tab "UP" so that the pack can be removed easily.

AcuTemp PX6L Courier

- Handheld container for small-scale transportation of TSMPs
- Holds approximately 88 vials
- Used according to the instructions, the AcuTemp PX6L will maintain vaccines/products between 2-8°C (35 – 46°F) for up to 48 hours at an ambient temperature of 24°C (75°F).

**Comes with a carrying strap and handle for ease of transportation

AcuTemp AX27L Mobile Refrigerator/Freezer

Defense Health Agency
Immunization Healthcare Branch

The **AcuTemp AX27L** mobile refrigerator/freezer addresses the need for a small, non-chlorofluorocarbon refrigeration unit that offers energy efficiency, precision temperature control and easy portability. With a 27-liter payload capacity and two temperature set-points (+4°C or -22°C) to accommodate payloads requiring refrigeration or freezing, this mobile thermal management unit is designed to safely transport and store temperature-sensitive vaccines, drugs, specimens and other bio-medical materials.

Power Sources

Grid power (standard): 115 VAC or 230VAC, 50-60 Hz
Battery (standard): Two 21 amp. hr. gel cell batteries
Car lighter outlet (available): 12VDC

This versatile cold chain solution is capable of operating for up to five days on battery power only, making it perfect for global distribution of small, temperature-sensitive loads.

Payload Volume:
27 liters (1 ft 3 in)

Payload Dimensions (H x W x L): 26.7 cm x 27.3 cm x 37.5 cm (10.5 in x 10.75 in x 14.75 in)

Tare Weight: 52 kg (114.4 lb)

Responding to TSMP Storage and Handling Problems

Potentially Compromised Vaccine Procedures

- Ensure that the vaccines are placed in a working refrigerator and/or freezer.
- Label the vaccines with the words **"DO NOT USE".**
- **DO NOT** destroy the vaccines.
- Complete a Potentially Compromised Vaccine Response Worksheet.
- Contact USAMMA-DOC, as well as your Immunization Healthcare Specialist (formerly known as MILVAX Regional Analyst (RA), and stand by for further instructions.
- Prepare an Executive Summary (EXSUM) if Command requires.
- A refrigerator and/or freezer should have a stabilized temperature and power supply for at least 24hrs before vaccines are placed back in the unit.

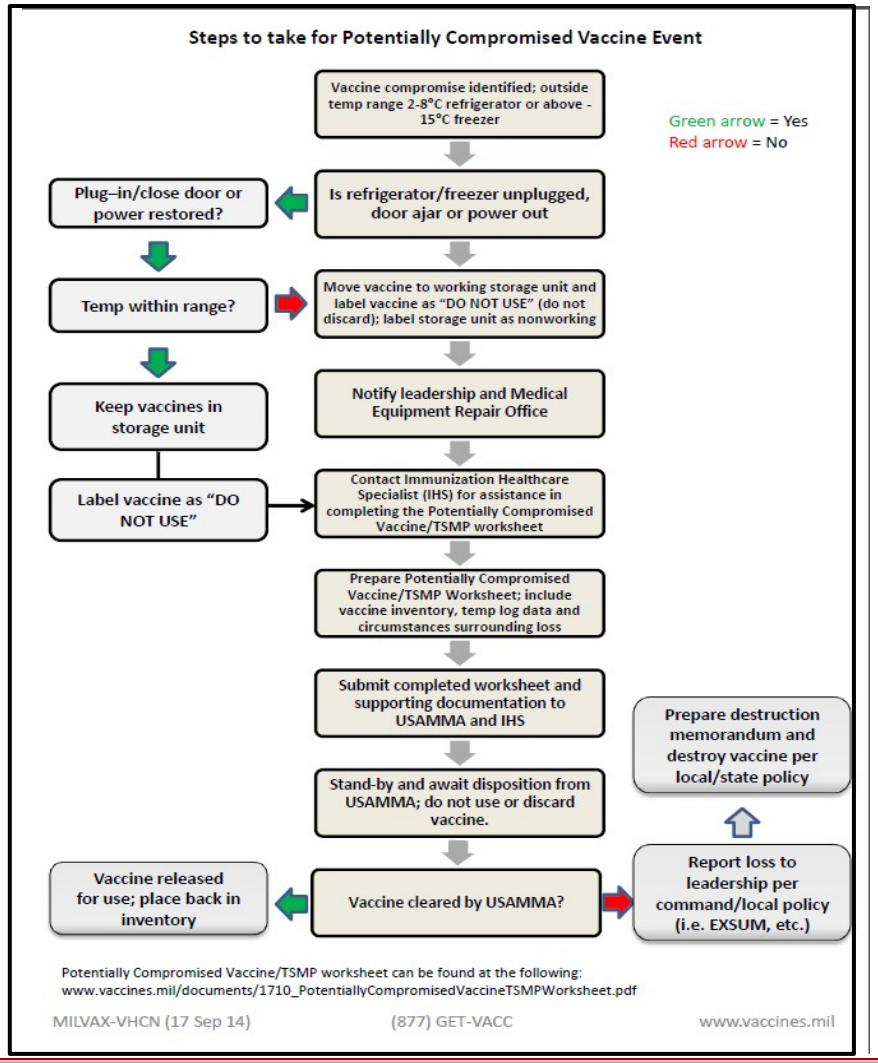
Emergency TSMP Retrieval and Storage Plan Worksheet

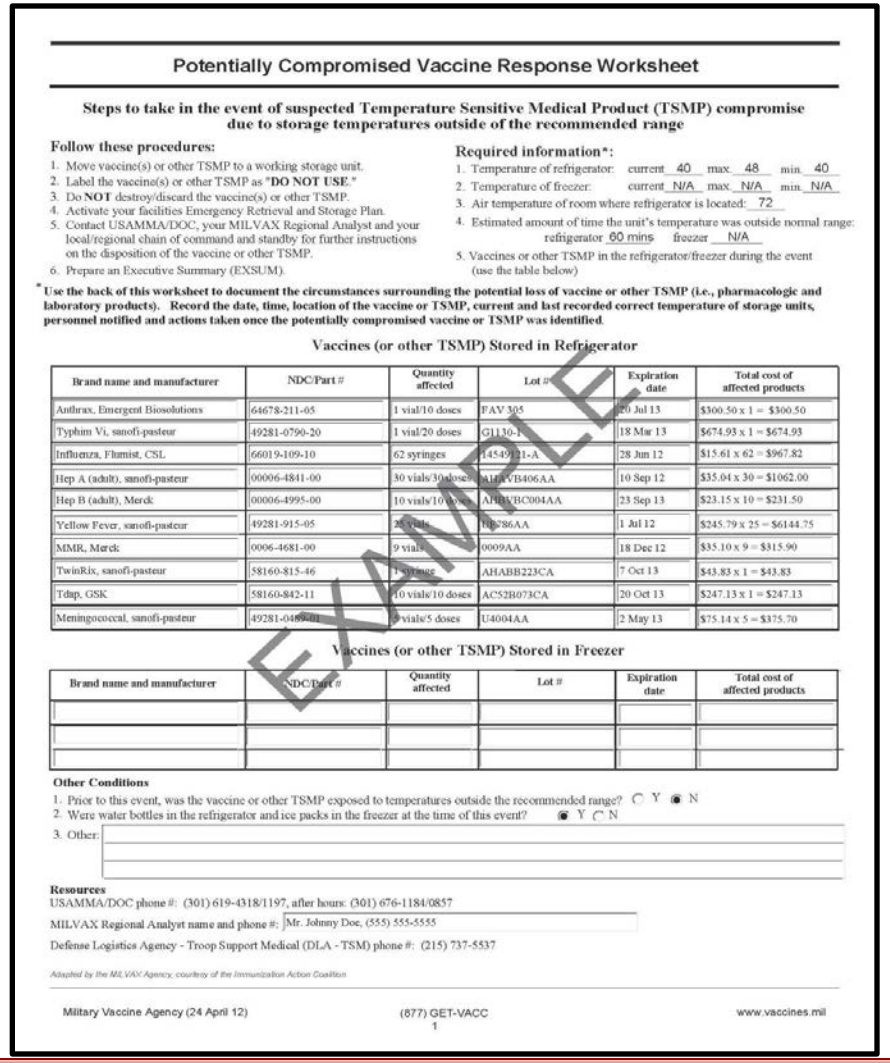
Defense Health Agency
Immunization Healthcare Branch

- Vaccine Coordinators – Telephone (Home and Cell)
- Emergency Staff Contact List – Telephone (Home and Cell)
- Refrigerator Repair Technician, Dry Ice Vendor, Electric Power Company, Temperature Alarm/Generator Repair Company(s)
- Alternate Vaccine Storage Facility(s)
  - Location, Contact Person, Address, Telephone Number
- Emergency Resources Contact List
  - USAMMA/DOC – 24 hour Emergency Line (301)676-0808/1184
  - Defense Logistics Agency – (215)737-6658 or (215)284-6586
  - Immunization Healthcare Specialist (formerly known as MILVAX Regional Analyst (RA))

Compromised Workflow & Worksheet

Immunization Healthcare Branch





Potentially Compromised Vaccine Response Worksheet

Steps to take in the event of suspected Temperature Sensitive Medical Product (TSMP) compromise due to storage temperatures outside of the recommended range

Follow these procedures:

1. Move vaccine(s) or other TSMP to a working storage unit.
2. Label the vaccine(s) or other TSMP as **"DO NOT USE."**
3. Do **NOT** destroy/discard the vaccine(s) or other TSMP.
4. Activate your facilities Emergency Retrieval and Storage Plan.
5. Contact USAMMA/DOC, your MILVAX Regional Analyst and your local/regional chain of command and standby for further instructions on the disposition of the vaccine or other TSMP.
6. Prepare an Executive Summary (EXSUM).

Required information*:

1. Temperature of refrigerator: current 40 max. 48 min. 40
2. Temperature of freezer: current N/A max. N/A min. N/A
3. Air temperature of room where refrigerator is located: 72
4. Estimated amount of time the unit's temperature was outside normal range: refrigerator 60 mins freezer N/A
5. Vaccines or other TSMP in the refrigerator/freezer during the event (use the table below)

* **Use the back of this worksheet to document the circumstances surrounding the potential loss of vaccine or other TSMP (i.e., pharmacologic and laboratory products). Record the date, time, location of the vaccine or TSMP, current and last recorded correct temperature of storage units, personnel notified and actions taken once the potentially compromised vaccine or TSMP was identified.**

Vaccines (or other TSMP) Stored in Refrigerator

Brand name and manufacturer	NDC/Part #	Quantity affected	Lot #	Expiration date	Total cost of affected products
Anthrax, Emergent Biosolutions	64678-211-05	1 vial/10 doses	FAV305	20 Jul 13	$300.50 x 1 = $300.50
Typhim Vi, sanofi-pasteur	49281-0790-20	1 vial/20 doses	G1130-1	18 Mar 13	$674.93 x 1 = $674.93
Influenza, Flumist, CSL	66019-109-10	62 syringes	14549121-A	28 Jun 12	$15.61 x 62 = $967.82
Hep A (adult), sanofi-pasteur	00006-4841-00	30 vials/30 doses	AHAVB406AA	10 Sep 12	$35.04 x 30 = $1062.00
Hep B (adult), Merck	00006-4995-00	10 vials/10 doses	AHBVBC004AA	23 Sep 13	$23.15 x 10 = $231.50
Yellow Fever, sanofi-pasteur	49281-915-05	25 vials	B3686AA	1 Jul 12	$245.79 x 25 = $6144.75
MMR, Merck	0006-4681-00	9 vials	0009AA	18 Dec 12	$35.10 x 9 = $315.90
TwinRix, sanofi-pasteur	58160-815-46	1 syringe	AHABB223CA	7 Oct 13	$43.83 x 1 = $43.83
Tdap, GSK	58160-842-11	10 vials/10 doses	AC52B073CA	20 Oct 13	$247.13 x 1 = $247.13
Meningococcal, sanofi-pasteur	49281-0489-01	5 vials/5 doses	U4004AA	2 May 13	$75.14 x 5 = $375.70

EXAMPLE

Vaccines (or other TSMP) Stored in Freezer

Brand name and manufacturer	NDC/Part #	Quantity affected	Lot #	Expiration date	Total cost of affected products

Other Conditions

1. Prior to this event, was the vaccine or other TSMP exposed to temperatures outside the recommended range? ○ Y ● N
2. Were water bottles in the refrigerator and ice packs in the freezer at the time of this event? ● Y ○ N
3. Other:

Resources

USAMMA/DOC phone #: (301) 619-4318/1197, after hours: (301) 676-1184/0857

MILVAX Regional Analyst name and phone #: Mr. Johnny Doe, (555) 555-5555

Defense Logistics Agency - Troop Support Medical (DLA - TSM) phone #: (215) 737-5537

Adapted by the MILVAX Agency, courtesy of the Immunization Action Coalition

Military Vaccine Agency (24 April 12) (877) GET-VACC www.vaccines.mil

"Medically Ready Force…Ready Medical Force"

TSMPs Disposal

- DoD activities are responsible for disposal of compromised or expired vaccines.

- Destruction memorandums pertaining to Anthrax, Smallpox, Adenovirus, VIGIV, and Army Influenza vaccines should be routed up the chain of command for review and endorsement before scanning and emailing to usarmy.detrick.medcom-usamma.mbx.doc@mail.mil or faxing to (301) 619-4468.

Methods of Destruction:

- Vaccine vials can be destroyed using the local hospital/clinics disposal procedures for all biohazard/hazard materials.
- Can be disposed of using return programs when applicable.
- Disposition instructions available: http://www.usamma.army.mil/assets/docs/Vaccine_Disposition.pdf

TSMP Issues, Responses, and Prevention Strategies

TSMP Issues

Three categories of issues may lead to compromised vaccines:

- **Non-Preventable Loss**
  - Equipment/Alarm system failure
  - Power outage during a natural disaster/storm
- **Negligence**
  - Refrigerated vaccines placed in freezer; frozen vaccines placed in refrigerator
  - Storage unit unplugged
  - Vaccines not returned to a storage unit
  - Alarm batteries not charged
- **Non-Compliance**
  - No validated packing/transport equipment available
  - No temperature log posted on storage unit
  - Staff did not record temperatures on temperature log
  - Emergency plan was not current or not properly followed

Example A

Facts presented from an actual reported TSMP compromise with no identifying information of the facility or location.

Total dollar value of vaccines

Issue	Response
	✓ Prevention strategy

Example # 1

Site A was redistributing refrigerated vaccine (2-8°C) set to expire within the next two months to a site that could utilize the vaccine within the timeframe. Vaccine was packed with a TempTale monitor in an EnduroTherm box with gel packs. Upon receipt of vaccine, monitor was alarmed, and the reading showed the temperatures were out of range for the duration of the shipment.

Total value: $3,650

Non-Compliance	**Temperature was above range from time it was packed until the time it was opened.** ✓ Ensure gel packs are preconditioned for at least 24 hours (preferable 48 hours) before shipment. ✓ Pack box in compliance with protocol instructions according to temperature requirements or TSMP and ambient temperature at receiving site.
Remember!	USAMMA DOC can provide assistance and guidance for sites seeking to redistribute TSMPs: **0700 – 1630 (EST):** 301-619-3017/3954/4318 **After Hours:** 301-676-0808/1184

Example # 2

Site received notification at 0636 via text message that refrigerator alarm was going off. At 0910, POC checked unit and noticed that the temperature had been out of range for about 3 hours. Upon further inquiry, site POC learned that the loss of power to the unit was the result of a scheduled outage and the storage unit location housing the vaccines was not connected to emergency back-up power. Refrigerator was resorted at 1245 and reached appropriate temperature range by 1310. Vaccines remained in the unit for the entire time that the power was off and temperature out of range, no attempt to relocate vaccines was made.

Total value: $25,699.58

Negligence	**Delayed response time after alarm.** ✓ Please attend to your vaccines as quickly as possible after notification that it may have gone out of range.
Negligence	**No backup power during a scheduled power outage.** ✓ Ensure the unit has a back-up power source and test monthly. ✓ Plan for a scheduled outage and move vaccines to a designated temporary storage facility.
Negligence	**Delayed response time after alarm.** ✓ Please attend to your vaccines as quickly as possible after notification that it may have gone out of range.

Example # 3

Off sites coordinator entered Pharmacy to pick up vaccine for Logistics and found frozen vaccines stored in the refrigerator. Upon inspecting further, coordinator found refrigerated vaccine stored in the freezer. Vaccines had been delivered that morning and had been out of range for approximately 3 hours. POC immediately moved vaccines to proper storage and contacted TSMP coordinator and local IHS.

Total value: $3,769.15

Negligence	**Vaccines placed in incorrect storage unit.** ✓ Ensure personnel pay close attention to details concerning temperature storage requirements for vaccines. ✓ POC who discovered the compromised responded appropriately by immediately moving vaccine to the proper storage unit and following Potentially Compromised Vaccine steps. ✓ Emergency Storage & Handling plan had clear instructions on who to contact and steps to take.
Remember!	Communication between all personnel handling vaccines is key (i.e. warehouse, clinic, off-sites clinic personnel)

Example # 4

Warehouse received vaccine shipment and filled out inventory sheet. Refrigerated vaccine was placed inside of appropriate unit, but frozen vaccines were left on the counter.

Total value: $6,311.09

Negligence	**Vaccines not stored in any storage unit.**
	✓ Ensure that all vaccine is placed into appropriate storage unit immediately upon receipt. ✓ Inspect package for damage, verify quantity and lot numbers, then store all TSMPs in corresponding unit.

Example # 5

Refrigerator alarmed at 1700 and alarm facility paged two on-duty personnel. One pager was on mute and the other was not acknowledged. After an hour of no acknowledgment, alarm facility monitor called the clinic to notify about the temperature being out of range. Technicians found the thermometer's fluid bath had leaked, resulting in the compressor to malfunction and freeze.

Total value: $157,170.98

Non-Preventable Loss	**Compressor malfunction.**
	✓ Establish routine maintenance procedures for storage units.
Non-Compliance	**Appropriate POCs could not be reached by alarm facility.**
	✓ Alarm alerts should be set up to notify POCs through multiple devices (i.e., work phone, after duty phone, email, mobile phone).

USAMMA Website/Cold Chain Web Links

USAMMA:
www.usamma.amedd.army.mil

DOC Homepage:
http://www.usamma.amedd.army.mil/net/Pages/docHome.aspx

DOC Cold Chain Management:
http://www.usamma.amedd.army.mil/net/Pages/doc/coldChainManagement.aspx

DOC Potentially Compromised Vaccine:
http://www.usamma.amedd.army.mil/net/Pages/doc/potentiallyCompromisedVaccine.aspx

Cold Chain References/Guides

U.S. Army Medical Materiel Agency (USAMMA)/Distribution Operations Center(DOC). Available at http://www.usamma.amedd.army.mil/net/Pages/doc/coldChainManagement.aspx

Centers for Disease Control and Prevention. General Recommendations of Immunizations. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011; Vol. 60 (No. 2).

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book). Atkinson W, Wolfe S, Hamborsky J, eds. 12th ed. Washington DC: Public Health Foundation, 2011; 61-74.

Centers for Disease Control and Prevention (CDC). Notice to Readers: Guidelines for Maintaining and Managing the Vaccine Cold Chain. Recommendations of the Advisory Committee on Immunization Practices. MMWR 2003; 52(42); 1023-1025.

Centers for Disease Control and Prevention, Vaccine Storage and Handling Toolkit. Available at http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm

Department of the Army, MEDCOM Memorandum, “Safeguarding Temperature Sensitive Medical Products (TSMP),” dated 05 March 2010. Available at http://www.usamma.amedd.army.mil/assets/docs/SAFEGUARDING%20TSMP.PDF

SB-8-75-11, Department of the Army Medical Department Supply Bulletin. Section 3-65: Temperature Sensitive Medical Products (TSMP) Storage and Handling (pg 62) Available at http://www.usamma.amedd.army.mil/net/assets/doc/pdf/CCM/Policy_Safeguarding_TSMPs.pdf

Questions and Comments

Immunization Healthcare Branch

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Training Dates:
Regularly scheduled trainings occur on the first Thursday of each month at 0900 and 1400 hrs *(exception: Federal Holidays)*