



DoD Smallpox Vaccination Training

Cold Chain Management

17 Jul 09

UNCLASSIFIED





PURPOSE: To provide an overview of the proper distribution and cold chain management procedures for ACAM2000[®]

1. Key Principles of Cold Chain Management
2. Storage and Handling Procedures for ACAM2000[®] Vaccine and Diluent
3. Vaccine Ordering Procedures
4. Safeguarding of Temperature Sensitive Products
5. Vaccine Destruction / Disposal Procedures
6. Executive Summary (EXSUM) Development
7. Cold Chain Management Equipment





By the end of this presentation, you should be able to:

1. Discuss cold chain management (CCM) principles and why CCM is important
2. Identify the storage and handling procedures for ACAM2000[®]
3. Outline the ordering process for ACAM2000[®]
4. Describe safeguards that can be implemented to protect temperature sensitive medical products (TSMPs)
5. Describe the destruction/disposal process for ACAM2000[®]
6. Define Executive Summary (EXSUM) Procedures





Preparing TSMPs for shipment to ensure temperatures are maintained during the entire shipping process.

• Cold Chain Management

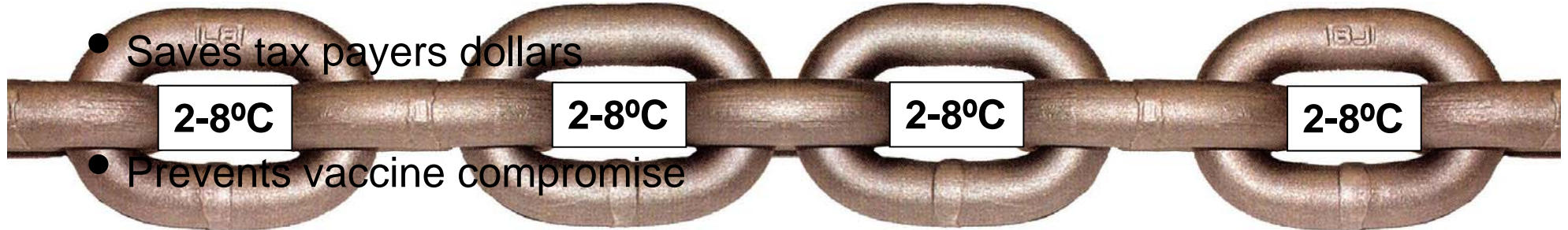
- Assures vaccine safety and efficacy

- Saves tax payers dollars

- Prevents vaccine compromise

- Assures maximum shelf life

- Minimizes rate of deterioration





Objective 1:

Discuss cold chain management principles and why CCM is important

- Partnership with Commercial Carrier Guarantees Express Delivery and as: **Cold Chain Management distribution is a combination of**
- Us Product
ter Packaging
ter Logistics
Mechanical hazards
- Inc Variable environmental conditions
- Inv **RISK MANAGEMENT**

proper





Un-reconstituted ACAM2000®

- All un-reconstituted ACAM2000® will have an 18 month expiration date
- Un-reconstituted ACAM2000® vaccine will be distributed and stored at 2-8 ° C (36-46 ° F)
- Un-reconstituted ACAM2000® vaccine should not be exposed to temperature conditions 23-27 ° C (73-81 ° F) for more than 48 hours



STRATEGIC NATIONAL STOCKPILE USE ONLY



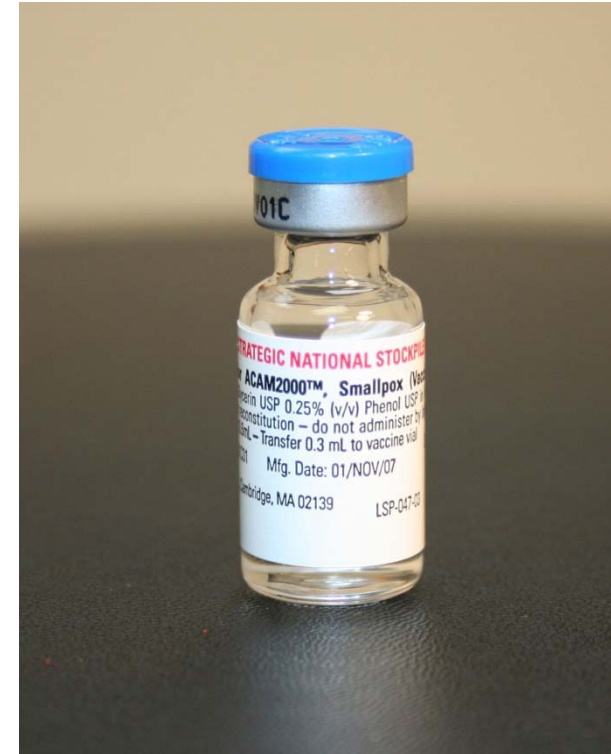


Objective 2:
Identify storage and handling
procedures for ACAM2000®

Diluent for ACAM2000®

REMEMBER: RECONSTITUTE WITH ONLY 0.3ml OF DILUENT

- During shipment diluent can be shipped between 2-30 ° C (36-86 ° F)
- The diluent for ACAM2000® vaccine must be stored at room temperatures 15-30 ° C (59-86 ° F)
- The expiration dating on the diluent is 5 years from the date of manufacture





Shipping and Handling Video

Objective 3:
Outline the ordering process for
ACAM2000®





Ordering Procedures

Objective 3:
Outline the ordering process for
ACAM2000®

- **Previously r**

- No need
- Go to <http://www.usamma.army.mil>
- Use the

- **New Custom**

- Must pre
- <http://www.usamma.army.mil>
- Select s
- USAMM
- DOC en
- Custom

The screenshot shows a Windows Internet Explorer browser window displaying the USAMMA website. The address bar shows <http://www.usamma.army.mil/vaccines/smallpox/index.cfm>. The page has a navigation menu on the left with links such as Home, Smallpox Vaccine Registration Form / Lost Password, Policies/Messages, Package Inserts© (ACAM2000, Dryvax (Wyeth)), ACAM2000 Medication Guide, Trifold Brochure (1 AUG 2007), About Your Shots, VHC Brochure, SmallPox Related MMQC Msgs, Handling Instructions, Redistribution of Smallpox Vaccine, Executive Summary (EXSUM), Disposition of Smallpox Vaccine, VaxiCool©, Cold Chain Management Processes & Procedures/Packing Protocols, and Home. The main content area features several informational boxes:

- USAMMA Distribution Operations Center (DOC)**: Hours of Operations: Monday - Friday 0700 - 1700 (EST), DSN 343, Commercial 301-619-4318, 1197, 4198. Fax: 301-619-4468. Email: USAMMADOC@amedd.army.mil. After hours call: 301-676-1184, 301-676-0857 or 301-728-4024 for urgent issues only.
- DoD Transitioning to New ACAM2000 Smallpox Vaccine Smallpox Vaccination Program (SVP)**
- FDA Approves Second-Generation Smallpox Vaccine-ACAM2000** (FDA News, 01 Sep 09) with link <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01693.html>
- Implementation Instructions For Transition To ACAM2000 In The DOD Smallpox Vaccination Program** (MMMQC-08-1036, 28 Jan 08) with link http://usamma.detrick.army.mil/ftp/mmqc_messages/Q081036.txt
- MILVAX Smallpox Website** and **MILVAX Smallpox Vaccination Program Website**

 The page also includes a search bar, 'Track Shipments', 'POCs', 'Links', and 'Search' buttons, and a 'Page Updated: Tuesday 20 May, 2008' timestamp.

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 stration
 age via email





- **Strategic National Stockpile**

- Packs and ships ACAM2000®
- Partnered with commercial carriers for shipping

- CONUS shipments on Mondays thru Wednesdays
- OCONUS shipments on Fridays
- **Emergency shipments are handled on a case by case basis**

- **NSN: 6505-01-559-0815, Smallpox (Vaccinia) Vaccine, Live with diluent, syringes, and needles**





Objective 4:

Describe safeguards that can be implemented to protect temperature sensitive medical products (TSMPs)

- Alarms and Backup Generators
- Assign Duties to Personnel who can:
 - Monitor operation of the vaccine storage equipment
 - Set up and maintain a monitoring/notification system
 - Assure appropriate handling during a disaster, power outage or mechanical failure
- Establish resource contact
 - Name, title, home phone number of the **primary** and **backup**
 - Equipment repair
 - Packing containers, gel packs
 - Backup storage
 - Plan to transport product to backup site



ing a disaster, power

LOSS

of the **primary** and





Vaccine Disposal

Objective 5:

Describe the destruction/disposal process for ACAM2000®

- DoD activities are responsible for disposal of compromised or expired vaccine
- ACAM2000® vaccine can be disposed:
 - In a hospital sharp container
 - Processed for destruction using a returns program
- Destruction memorandum should be routed up the chain of command prior to submitting to the US Army Medical Materiel Agency (USAMMA) Distribution Operations Center (DOC)
- Disposal instructions can be found at:
<http://www.usamma.army.mil/vaccines/smallpox/index.cfm>
- Destruction Codes and be found on the USACHPPM website: <http://chppm-www.apgea.army.mil>





Executive Summary (EXSUM)

Objective 6: Define Executive Summary Procedures

- Must report suspected loss of ACAM2000[®] that occurs for reasons other than expiration within 24 hours
- Executive Summary (EXSUM) submitted in Memorandum Format
 - No longer than one page in length
 - Explain circumstances surrounding suspected loss of vaccine potency
 - List Lot numbers
 - Number of unopened vials
 - Detailed explanation of course of action to preclude future losses
 - List names and telephone numbers of points of contact
 - Fax to USAMMA/DOC pharmacy consultant 301-619-4468
 - More information available at:
 - <http://www.usamma.army.mil/vaccines/smallpox/index.cfm>





Cold Chain Management (Equipment Requirements)

Objective 4:

Describe safeguards that can be implemented to protect temperature sensitive medical products (TSMPs)

- Choose the appropriate thermometer
 - Use a certified calibrated thermometer to assure validity
 - A certified, calibrated thermometer in a biosafe liquid is an inexpensive, adequate “quick read” monitor
 - Constant read/graph thermometers continuously record temperatures either on paper or electronic display
 - Digital thermometer/Alarm unit are the most accurate constant monitors and also offer continuous alarm capability
- Thermometer location
 - Place thermometer in a central location within the freezer such as the middle shelf
 - Place on the top shelf only if the refrigerator compartment is not in the path of the cold air vent from the freezer
 - Never place thermometer in the door of a refrigerator compartment

ACCURATE
CERTIFIED CALIBRATED THERMOMETER = VALID





COMMON MISTAKES



- The following actions help prevent vaccine compromise
 - **Failing to read the thermometer and record the temperature twice daily**
 - Reading thermometers and recording temperatures at least twice a day
 - **Reading the thermometer incorrectly**
 - Assign a log manager and a back-up log manager
 - Taking action when the thermometer is out of range
 - **Documenting out of range temperatures without taking action**
 - Not opening and closing refrigerator during loss of power
 - Filing the completed temperature log at the end of each period
 - Ensuring all completed temperature logs are kept for at least three years





VaxiCool Dual Mode Container

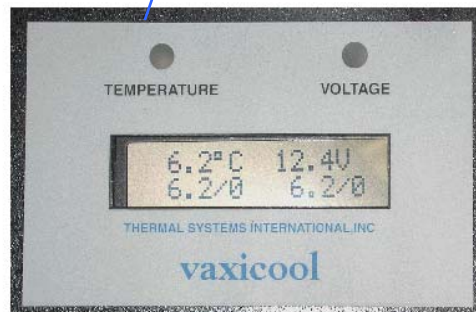
Objective 4:

Describe safeguards that can be implemented to protect temperature sensitive medical products (TSMPs)



BATTERY BOX CONTAINS
(2) 12 VOLT/20 AMPS
DRY GEL-CELL BATTERIES.

POWER PANEL CONTAINS SOLAR INPUT
PLUG, AC POWER FROM 90-270 VOLTS.



LCD SCREEN DISPLAYS THE TEMPERATURE AND
BATTERY VOLTAGE.

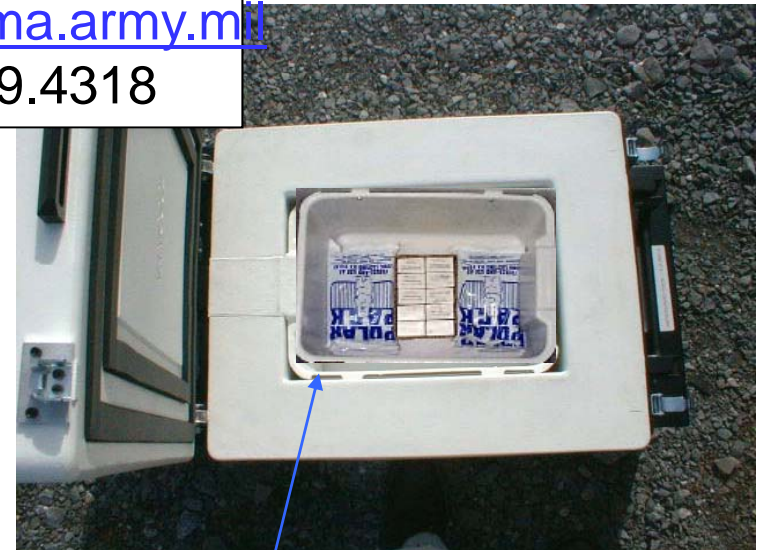
THE SYSTEM IS COMPRISED OF:

- a) A SUPER-EFFICIENT COMPRESSOR,
- b) A SUPER INSULATED CONTAINER USING VACUPANEL INSULATION DESIGNED TO MAINTAIN VACCINES AT APPROPRIATE TEMPERATURE BETWEEN 2-8 CELSIUS.

USAMMA

www.usamma.army.mil

301.619.4318



VAXICOOL HAS AN INSIDE DIMENSION OF 14 (LENGTH) BY
10-1/2 (WIDTH) BY 10 (DEPTH) ITS PAYLOAD



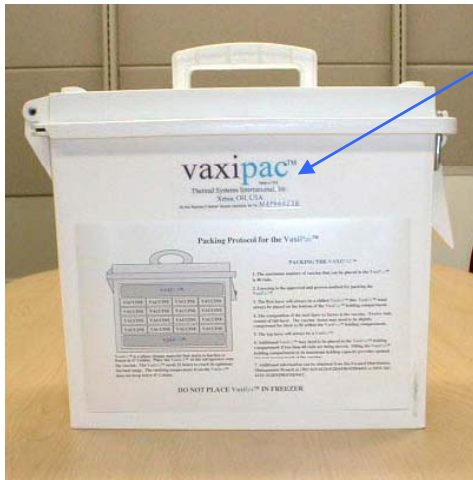


VaxiPac Shipping Container

VaxiPac is used for transport of small quantities of refrigerated products

Objective 4:
Describe safeguards that can be implemented to protect temperature sensitive medical products (TSMs)

EXTERIOR DIMENSION OF 15 (LENGTH) BY 7.75 (WIDTH) BY 11.38 (DEPTH)



VAXISAFE IS A PHASE CHANGE MATERIAL (PCM) THAT STARTS TO HARDEN OR FREEZE AT 6 CELSIUS.



WALLS LINED WITH VACUPANEL INSULATION





- **MILVAX Agency**
 - www.vaccines.mil
 - www.vaccines.mil/smallpox
 - www.smallpox.mil
 - vaccines@amedd.army.mil
 - 877.GET.VACC
- **DoD Vaccine Clinical Call Center**
 - 866.210.6469
- **Vaccine Healthcare Centers** *for help with adverse event management*
 - www.vhcinfo.org
 - 202.782.0411
- **Information for Civilian Healthcare Providers**

*Call the Military Treatment Facility (MTF) where the member is enrolled
OR contact the Military Medical Support Office (MMSO)*

 - www.tricare.mil/tma/MMSO
 - 888.647.6676 *if the member is not enrolled to an MTF*
- **USAMMA DOC**
 - www.usamma.army.mil
 - 301.619.4318
- **Smallpox Vaccine in Pregnancy Registry:**
 - NHRC-birthregistry@med.navy.mil
 - 619.553.9255





vaccines.mil/training





www.vaccines.mil



www.vaccines.mil

