



Antibiotic Cache Deployment Plan

Standard Operating Guide

Tennessee Department of Health | July 2019



Handling Instructions

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Signatory:

A handwritten signature in blue ink that reads "Paul Petersen, PharmD". The signature is stylized with large loops and a cursive script.

Dr. Paul Petersen, EP Director

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Executive Summary

The State Antibiotic Cache was created to provide prophylaxis to hospital personnel (including medical staff and ancillary staff), patients and hospital based emergency first responders, their families, and other key personnel, in the wake of terrorist-induced event or naturally occurring disease outbreak for which such medical countermeasures are appropriate. Having the ability to protect healthcare workers in an event of this type is a requirement under our Hospital Preparedness Program grant and this planning and preparation will speed subsequent distribution to the general public and reduce morbidity and mortality.

Key Findings

- The actual stock is 400 bottles of Doxycycline Hyclate 100 mg tabs 500ct.
- For an activation and deployment, the Regional Health Jurisdictions will be responsible for coordinating with hospitals or other critical infrastructure sites for the distribution of the antibiotic cache in coordination with the State SNS Coordinator or other EP staff.
- The antibiotic cache is located in the primary RSS in Nashville.
- The State Health Operations Center (SHOC) will make the decision to drop ship the antibiotic cache directly to the affected site(s) or to regional offices.
- Each healthcare coalition should have a plan to distribute medical countermeasures.
- Each hospital receiving cache assets shall be responsible for inventory storage, security, accounting and distribution.

State Antibiotic Cache Deployment Plan

Introduction

Hospitals and other funded healthcare organizations are required to meet the 2017-2022 Healthcare Preparedness and Response Capabilities, and the requirements in the HPP Cooperative Agreement. This cooperative agreement is administered by the Tennessee Department of Health and funds Healthcare Coalitions to support the medical/surgical acute care hospitals in the state. Although several of the capabilities address pharmaceuticals, Capability 3, Continuity of Health Care Service Delivery requires facilities to know how to obtain additional supplies including state stockpiles. The Tennessee Department of Health Emergency Preparedness Program meets a portion of this capability requirement by securing a cache of antibiotics, to respond to an anthrax attack.

This antibiotic cache, geographically located in the State's primary RSS, consists of Doxycycline to provide adult and pediatric prophylaxis to hospital personnel (including medical staff and ancillary staff), patients and hospital based emergency first responders and their families, in the wake of terrorist-induced event or naturally occurring disease outbreak for which such medical countermeasures are appropriate. Doxycycline is used for the treatment and prevention of the Category A Biological Agents:

- *Bacillus anthracis* (Anthrax) <https://www.cdc.gov/anthrax/index.html>
- *Yersinia pestis* (Plague) <http://emergency.cdc.gov/agent/plague/factsheet.asp>
- *Francisella tularensis* (Tularemia) <http://emergency.cdc.gov/agent/tularemia/facts.asp>.

This supply of medication is meant to initiate prophylaxis or treatment only until the Strategic National Stockpile (SNS) arrives. The SNS Formulary contains both tablets, intravenous and oral suspension antibiotics.

Inventory

The State Antibiotic Cache should be used to initiate prophylaxis or treatment only until the Strategic National Stockpile (SNS) arrives. Depending on the size of the event, the supply may or may not be sufficient to treat the needs of every hospital-affiliated individual or other responder affected by the event prior to the arrival of the Strategic National Stockpile.

However, it is assumed that antibiotics required to treat beyond the capacity of our state's cache will be obtained through delivery of the SNS. All responders, regardless of status as a first responder, critical infrastructure staff, hospital staff, volunteer responder or staff responder, will still have access to open and critical infrastructure points of dispensing if the emergency is beyond what the state cache can provide after the delivery of the SNS.

Hospital and other responders may also have additional locations to receive countermeasures if their locations are listed as closed or hospital PODs. Since the State Antibiotic Cache is for a regional or statewide emergency response, the State SNS Coordinator has the authority to pull the required pharmaceuticals from the cache to treat the affected population until the arrival of federal SNS assets.

*400 bottles of Doxycycline
Hyclate 100 mg tabs 500ct.*

Activation Process

In the event of a terrorist induced, naturally occurring disease outbreak, and/or disaster incident that requires distribution of the State Antibiotic Cache for prophylaxis or treatment, the Tennessee Department of Health (TDH) will be in charge of countermeasure distribution and the regions will be responsible for coordinating with hospitals for the distribution of the State Antibiotic Cache with the State SNS Coordinator or other

designated Emergency Preparedness (EP) staff. Once the TDH identifies the need for medical countermeasures, the State SNS Coordinator or other designated EP staff will direct the appropriate amount of antibiotics to be distributed to the affected hospital(s) or appropriate location based on the prevention and treatment recommendations of the Tennessee Department of Health. The contact information for the essential points of contact is contained herein. These individuals are also in the Tennessee Health Alert Network (TNHAN) for emergency notifications and the Healthcare Resource Tracking System (HRTS). The impacted/affected region will also notify other hospital officials as needed such as the ED Director and Safety Officer of the activation.

the regions will be responsible for coordinating with hospitals for the distribution of the antibiotic cache with the SNS Coordinator

The impacted/affected region will also serve as a resource guide for hospitals or critical infrastructure sites regarding medical countermeasure distribution and will provide the following information as it becomes available:

- Nature of the threat to health
- Description of the disease to be prevented and case definition for disease
- Who is at risk and will need to receive prophylaxis
- Anticipated time frame for completion of the prophylaxis
- Anticipated time of arrival of the medical countermeasures
- Storage and security requirements for the material
- Location of the nearest community-based Point of Dispensing (POD) and hours of operation
- How to obtain additional information about the progression of the event

Distribution Method

Transport of State Antibiotic Cache items will be determined by the State Health Operations Center (SHOC) depending upon the immediateness of the situation and transportation obstacles. It is intended that the initial supply of medical countermeasures reach the affected hospital(s) so that staff and their families are prophylaxed and can perform their duties to respond to the emergency.

The SHOC will make the decision to drop ship the antibiotic cache directly to the affected hospital(s) or to regional offices

Medical Countermeasure Distribution

Each hospital or other receiving entity should have a plan to distribute medical countermeasures to at least their primary and ancillary personnel. They can also distribute to employee family members and inpatients if there is a need. If choosing to prophylax family members, then use of the Tennessee Department of Health's medication registration form is recommended. Patients arriving at the emergency department needing only medical countermeasure and not requiring treatment of active disease should be referred to a community-based Point of Dispensing (POD) operated by the Regional Department of Health.

Each hospital or other receiving entity should have a plan to distribute medical countermeasures

Medical countermeasures will initially be provided in bottles of 500ct, so any plan should also include provisions for repackaging and labeling for individual consumption. At the very least, labels should include the drug name, quantity, lot number, expiration date, patient name, date dispensed, and directions for use.

Prophylaxis for Potential Exposure to BT Agents

	<u>Goal</u>	<u>Doxycycline Option #1</u>
<u>BT Agent</u>		Drug of choice for adults, without contraindications.
Anthrax	Prophylaxis 100% population within 48 hrs	<u>Adults:</u> doxycycline 100mg po bid X60 Days <u>Pediatrics:</u> doxycycline X60 Days Doxy in Peds <9yo - side effect - teeth staining, weigh risk benefit. ≥9yo & >45kg = (same as adult) ≥9yo & ≤45kg = 2.2mg mg/kg po bid x60d <9yo = 2.2mg mg/kg po bid x60d
Plague		<u>Adults:</u> doxycycline 100 po bid X7 Days (pediatric dose above X7 Days)
Tularemia		<u>Adults:</u> doxycycline 100 po bid X14 Days (pediatric dose above X14 Days)

Because the State Antibiotic Cache does not contain any oral antibiotic suspensions and none will be available until the SNS stockpile arrives, special instructions must be provided to children and adults not able to swallow pills. Instructions for pediatric administration and crushing of Doxycycline can be found at:

<http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm130996.htm>

Asset Management

Receiving: Each receiving entity shall be responsible for inventory storage, security, accounting, and distribution. The receiving entity will complete a Chain of Custody form to accompany every shipment from the antibiotic cache to include name of medication, strength, quantity, expiration and lot number. Upon delivery, cache assets must be physically received by personnel authorized to order and receive SNS assets. Medications should be secured in a locked room or cabinet and kept away from extreme heat or cold following proper cold chain management as required for the particular countermeasure.

Each hospital receiving cache assets shall be responsible for inventory storage, security, accounting, and distribution.

Handling: Each receiving entity is responsible for the dispensing and tracking of the assets to primary and ancillary medical personnel and their families. Since pharmaceuticals are supplied in quantities of 500ct per bottle, each location will be responsible for repackaging the medications for dispensing. If the receiving site is not an active pharmacy location, TDH will coordinate personnel to repackage the medications for dispensing. The TDH medication registration form may be used. The site will keep a running tally of the total number of persons and the number of employees or family members who have received prophylaxis and the percentage of the target population for which prophylaxis has been completed. This will be reported to the TDH every 24 hours or more often upon request.

Return: At the conclusion of the event, the receiving entity will consolidate any remaining assets for pick up by a Tennessee Department of Health designee. Materiel should be transported appropriately keeping in mind special circumstances such as cold chain. For returns, the state is under contract with FedEx (SWC 31006), which is the preferred shipping provider. The state also has access to additional transportation assets during an emergency through the Tennessee Emergency Management Agency's Logistical Operating Unit. Private entities should ship by any appropriate means. The entity shall provide an inventory list of the medications dispensed and those being returned.

Safety

All personnel, regardless of status as first responder, critical infrastructure staff, volunteer responder or staff responder, using received prophylaxis must have medical and behavioral health risks identified and communicated to them. Prophylaxis or other protective actions do not preclude safety or other briefings by subject matter experts. All responders must be cognizant of the potential dangers to health, safety, and other affects related to entering an area where specialized countermeasures are needed. Responders must have their health and safety monitored while on scene and actions appropriately modified based on the changing situation. During the incident and following, all responders must have their health and mental health tended to.

responders must be cognizant of the potential dangers to health, safety, and other affects

Drug Specifics

- Manufactured by PuraCap Caribe LLC.
Dorado, PR 00646, United States
- Doxycycline Hyclate Tabs USP 100mg
500ct/bottle
24 bottle/case
- 17 cases* (one partial case)
400 bottles
200,000 pills
- NDC: 24658-312-05
- Lot: 19D0050F1P8
- Weight with pallet: 200 lb
- Store at 20-25°C (68-77°F)



Contact Information

State of Tennessee: The following is a list of relevant State of Tennessee phone numbers to contact in an emergency:

- State Health Operations Center 866-327-9102
- TDH 24/7 Number 615-741-7247
- State Emergency Operations Center 615-741-0001
- Dr. John Benitez EP and EEP Medical Director 615-210-4773
- Dr. Paul Petersen EP Director 615-351-8776
- Matthew Hayes ESC 615-854-0483
- Sean Kice SNS Coordinator 615-840-1211
- Peter Koonz SNS Logistics 615-532-6267
- Dr. Calita Richards State Pharmacist 615-337-9532
- Joyce Gupton Inventory Control Manager 615-946-8077