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# **Extended Medical Countermeasure Distribution and Dispensing Considerations for Anthrax Incidents**

Version 1.0

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# Introduction

## Background

The U.S. Department of Health and Human Services (HHS) introduced the Cities Readiness Initiative (CRI) program in 2004 with the goal of distributing medical countermeasures (MCM) to affected populations following an aerosolized anthrax release. The Centers for Disease Control and Prevention (CDC) recommends a 60-day course of prophylactic antibiotic therapy following exposure to anthrax. The distribution of the required antibiotics takes place in two distinct phases: the first phase involves the rapid dispensing of a 10-day supply of antibiotics to those individuals who were potentially exposed to anthrax, and a second phase, which is a targeted distribution providing the remaining 50-day supply of antibiotics to those who were truly exposed. This second targeted phase of distribution is the focus of this paper.

In 2001, the CDC recommended incorporating anthrax vaccine adsorbed (AVA) vaccines into state and local 60-day anthrax response strategies. Administering AVA after exposure to anthrax requires a series of three vaccinations to provide long-term protection. With the incorporation of AVA and an enhanced understanding of the biological agent (*Bacillus anthracis*), there has been a renewed focus on distribution and dispensing operations during a sustained anthrax response to ensure all forms of protection are provided and there is no lapse in post-exposure prophylaxis (PEP) between the initial and secondary phases. MCM-related response efforts would include support of treatment, epidemiology, and completion and compliance of the recommended prophylactic course.

MCMs distributed and dispensed in response to the anthrax release are not limited to oral antibiotics and vaccines, and there are additional response efforts related to mass care and medical treatment for individuals displaying symptoms of anthrax exposure. The distribution mechanisms for different types of MCMs may vary by jurisdictional plans, event characteristics, and MCM characteristics. Some MCMs are distributed from CDC to the state then to the local level. Others are distributed by CDC directly to healthcare entities. Alternatively, CDC may distribute MCMs to the state level then directly to healthcare entities, or to the state level, which then go to the local level and, finally, to healthcare entities. These elements of the response require additional assets to support the delivery of treatment for those who require medical care, including intravenous antibiotics, anthrax antitoxins, ventilators, personal protective equipment (PPE), pediatric supplies, and ancillary medical supplies.

Per CDC guidance, MCM dispensing sites are defined as including open and closed points of dispensing (PODs), hospitals, and treatment centers. The state's warehouse distribution network, which includes a receipt, stage, and store (RSS) warehouse, and in many cases, local and regional distribution site (L/RDS) warehouses, must be capable of rapidly deploying MCMs to dispensing sites within the established timeframe (see [CDC document – Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness](#), Version 11, CDC, 2011.)

State and local jurisdictions must have plans for sustained (60-day) MCM operations to achieve “Established” or “Advanced” status in several areas of the Budget Period 4 (2015–2016) MCM Operational Readiness Review (ORR) tool. However, guidance is required to determine the capabilities that are necessary to distribute and dispense MCMs according to distribution requirements and deployment timelines. The availability of best practices, tools, and information will assist MCM planners

with developing plans for sustained MCM distribution and dispensing operations, in addition to coordinating treatment to support the alignment of MCM plans across jurisdictions and reduce duplication of effort.

## Purpose

This document outlines key topics, relevant resources, and current promising practices state and local MCM planners should consider when creating and implementing plans to transition emergency mass dispensing operations from the initial 10-day antibiotic distribution and dispensing effort to distributing and dispensing extended post-exposure prophylactic MCMs. This includes 50-day antibiotic supply, three shot vaccine series, and treatment supplies.

***Note: This document is not meant to supplement, supersede, or replace any official federal MCM guidance, nor is it intended to act as official MCM guidance. This document is a compilation of observations from state and local subject matter experts using the most up-to-date information available at the time of document release. This document does not reflect the opinion or recommendations of the CDC or any of its employees. Persons using this document should verify any assumptions and concept of operations included in their own jurisdictional plans with local, state, and federal MCM representatives as part of the planning process. ASTHO and NACCHO do not promote or endorse any product or service mentioned in this document.***

## Process

The Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO) MCM workgroups have recognized the importance of sustained dispensing campaigns as a key area for future development in MCM planning. Over the past year, both workgroups have collaborated to develop a guidance document to support this need.

In December 2015, ASTHO and NACCHO jointly distributed an online survey to their respective partners to identify topic areas for extended distribution and dispensing operations as part of a needs assessment process. Survey results showed that the majority of participants gave the highest priority to topics related to sustained anthrax response. The results of the survey were divided into three topical areas—distribution, dispensing, and cross-cutting sections. Generally, ASTHO members were assigned to develop guidance around distribution topics, NACCHO members were assigned to develop guidance around dispensing topics, and both groups worked together on cross-cutting topics. The complete list of topics included in the needs assessment survey can be found in Appendix 1.

The ASTHO and NACCHO workgroup developed a template to capture key information relative to each topic to ensure a consistent approach and output for each of the topical areas. The key data elements that were captured include the assumptions, topic description, promising practices, steps to implementation, opportunities for state and local health departments, critical points for plan improvement, and additional resources. Each of the topic headings and data fields are described in the table below.

| <b>Topic Headings</b>                                       | <b>Brief Explanation</b>   |
|---|--|
| <b>Assumptions</b>  | <i>Provides any topic-specific assumptions that are applicable to the post 48-hour response timeframe.</i>   |
| <b>Description</b>  | <i>Provides an overview of the topic specifically within the context of the post 48-hour timeframe of the MCM-related response to an anthrax attack incident.</i>  |
| <b>Promising Practices</b>                                  | <i>Identifies existing positive examples from state and local programs that have developed or implemented plans addressing this topic.</i>   |
| <b>Steps to Implementation</b>                              | <i>Addresses actions necessary to implement promising practice, including proposed partners, staff, and other recommended assets or equipment.</i>   |
| <b>Opportunities for State and Local Health Departments</b> | <i>Identifies assets that are uniquely valuable to state and local programs, partnerships that can be formed at the state or local level, as well as additional planning steps or assessments that could potentially be conducted to gather more information to assist in this topic area.</i> |
| <b>Critical Points for Plan Improvement</b>                 | <i>Addresses significant barriers (e.g., time and resources) or current information gaps (e.g., Strategic National Stockpile (SNS) asset's description).</i>   |
| <b>Additional Resources</b>                                 | <i>Provides recommended references to resources for the topic.</i>   |

The information provided in each topic area was collected from a variety of sources, including information contained in the Doxycycline Emergency Use Authorization (EUA), Emergency Dispensing Orders for Doxycycline and Ciprofloxacin, and Emergency Use Instructions (EUI), state and local MCM plans, and federal and state policy.<sup>1</sup> Additional resources used are listed at the end of each topic.

**Overarching Assumptions**

***Disclaimer: Assumptions listed in this document represent a sampling that may or may not be relevant for a particular jurisdiction, depending on each jurisdiction’s capacity and capabilities. Jurisdictions should assess whether the assumptions are valid for their jurisdiction as they work through long-term planning efforts.***

Below is a summary of the key overarching assumptions contained in this guidance document in a scenario-based format to provide a context for the topics covered in the subsequent sections. Each topical area may have additional assumptions and considerations, as indicated in its respective section. Additional relevant overarching assumptions that may be used to guide state and local planning can be found in Appendix 2.

- Federal and state disaster declarations, including the Public Readiness and Emergency Preparedness (PREP) Act, are enacted.

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<sup>1</sup> Doxycycline Emergency Dispensing Order, Food and Drug Administration, (2016). Available at: <http://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/UCM495925.pdf>. Accessed 4-12-2017.

- Appropriate regulatory mechanisms in combination with relevant FDA actions are in place (e.g., emergency dispensing orders, current good manufacturing practices waivers).
- After the detection of the bioterrorism agent, *Bacillus anthracis*, the decision has been made to dispense MCMs to communities that have been potentially exposed.
- Initial mass prophylaxis with 10-day course of antibiotics was successfully initiated and is still underway, but at a reduced level due to earlier successes.
- Distribution and dispensing operations have severely stressed personnel and response resources during the initial days of this prophylaxis campaign.
- MCM resources (i.e., 50-day antibiotic courses and vaccines) are available and CDC will deliver these MCM assets to project areas once requests are approved.
- In addition to these MCM assets, there continues to be a very large demand by hospitals for treatment-related MCM, which stresses MCM distribution. Treatment requirements also lower clinical staffing at PODs, since healthcare workers who have initially provided services at PODs are being called to work at hospitals and other healthcare facilities, as those sites are stressed with increased patient census.
- The following types of MCM—some of which require cold-chain storage and transport—will be deployed to impacted jurisdictions, as approved by local, state, and federal public health agencies:
  - Intravenous antimicrobials and antitoxins.
  - 50-day supply, unit of use (course), oral antibiotics (e.g., doxycycline, ciprofloxacin, amoxicillin including pediatric dosage forms).
  - Anthrax vaccine.
- State and local jurisdictions will have varying resources, which is an incident-specific condition and will either enable or hinder operations.
- Although only one metropolitan statistical area (MSA) is directly affected by an individual attack involving the aerosolized anthrax release, other local health jurisdictions outside an impacted MSA may activate PODs depending on details of the event and per local, regional, and state plans.
- The response will be further challenged by requirements to expand operations at PODs to include administration of anthrax vaccine.
- Vaccination sites for the public may or may not be the same as the PODs for oral dispensing; however, it is important to note that the head-of-household model for dispensing oral antibiotics cannot be applied to the administration of vaccinations.
- Administration of the vaccine to children will likely require parental consent, which would present an important planning consideration for unaccompanied minors.
- Collaboration and coordination through effective emergency management practices will be critical throughout the incident response.



# Distribution Topics

Maintaining routine essential functions.

**Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

**Description:**

Maintaining routine essential functions following an anthrax attack and throughout the activities associated with long-term MCM distribution and dispensing will be vital to success. Efforts, attention, and resources often wane during an extended response. It is precisely during this time that long-term distribution, dispensing, and vaccination efforts are needed. As the response continues, key mission essential functions must continue to occur to support the response. Maintaining adequate call center staffing and processing response documentation are examples of these mission essential functions. Pre-identified mission essential functions, strategies for augmenting staff, and pre-event training and exercising of the local continuity of operations (COOP) plan are important considerations for maintaining routine public health services.

**Promising Practices:**

1. Robust COOP plans at the local, state, and federal levels are a best practice to ensure staff are familiar with how to transition from day-to-day activities to response operations. In addition to preparations around COOP, regular review and exercising of plan elements, addressing improvement items and early consideration of activities to support sustained response operations will allow all levels of the response to ensure access to adequate resources (or the knowledge of shortcomings) to maintain essential functions.
2. To augment local staff during a protracted MCM response, it will be necessary to effectively engage mutual aid. Prior to requesting mutual aid support, the local jurisdiction must identify the capability that is needed (e.g., logistical support of MCM receipt and distribution operations). In addition, the request for mutual aid should be properly timed based on real or predicted needs and follow National Incident Management System (NIMS) protocols for placing the request.
3. Congestion of the transportation infrastructure is expected during an MCM response and a telework policy should be considered for non-responding personnel and for entities that are not part of the response effort.

**Steps to Implementation:**

- Continuity planning should be prioritized at all levels of government to support emergency response functions.
- COOP plans should identify the mission essential functions of the agency and what personnel support is needed. The Federal Emergency Management Agency (FEMA) [Continuity Guidance Circular 2 \(CGC 2\)](#) provides good instructions. It is important to note that mission essential functions are determined prior to an incident and approved by executive leadership.

- State and local jurisdictions are responsible for maintaining a Multi-Year Training and Exercise Plan (MYTEP) with a calendar of scheduled activities. The plan should integrate MCM and COOP concepts to ensure staff understand decision points during a sustained response.
- Ensure that mutual aid agreements and memorandums of understanding are in place prior to an event to maintain routine essential functions.

**Opportunities for State and Local Health Departments:**

- State, regional, and local health departments can discuss mutual aid agreements, specifically agreements regarding crossing state lines.
- State, regional, and local health departments can form training and exercise workgroups to develop MYTEP.
- State, regional, and local health departments can develop joint COOP exercises in response to an extended MCM event.

**Critical Points for Plan Improvement:**

- There are limited templates that describe examples of public health COOP exercises.
- Suspending non-essential services under COOP, the use of 12-hour shifts, and limitations on time off may increase available personnel resources at first, but reductions in staff availability should be expected. This may be due to a number of factors, including staff illness, concern for family, position abandonment, and other competing needs. This may result in a need for immediate mutual aid support.
- Additional federal guidance regarding requesting out-of-state mutual aid for MCM operations and essential public health functions is needed.

**Additional Resources:**

1. [FEMA Continuity of Operations.](#)
2. [FEMA Non Federal Continuity Plan Template and Instructions.](#)
3. [ASPR TRACIE Continuity of Operations/Failure Plan.](#)
4. [County of Santa Barbara 2013 Statewide and Medical Health Exercise.](#)
5. [NACCHO Toolbox COOP.](#)

## Supporting MCM requirements of open and closed PODs for antibiotics and vaccines.

### **Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

- By the time MCMs are delivered to support an extended anthrax response, there will be agreement on items the Division of Strategic National Stockpile (DSNS) will provide, in terms of the quantity and projected delivery time(s), which are expected to reflect the national response scenario for an anthrax attack.
- The state will discuss local response needs prior to submitting MCM requests to CDC.
- Discussions regarding allocations of limited resources will include local and state jurisdictions, CDC, and HHS.
- States will update CDC on MCM delivery sites and RSS warehouse contact(s).

### **Description:**

This section focuses on delivering MCM to dispensing sites and to open and closed PODs in particular.

Sustaining MCM logistics operations (e.g., RSS and L/RDS warehouse receipt and distribution) to dispense the 60-day supply of antibiotics and administer the anthrax vaccine may be challenging during a large-scale response. To ensure success, jurisdictions must establish effective coordination and information sharing systems to support situational awareness and resource management processes across all stakeholders.

By implementing an Incident Command System (ICS) and integrated communications systems, jurisdictions can support situational awareness and resource management needs throughout a sustained MCM response. Time constraints associated with sustained anthrax response will require logistics ingenuity and flexibility. As examples, jurisdictions may initially distribute fixed amounts of MCMs to open PODs to ensure that all PODs have adequate supplies to open. Over time, an allocation and apportionment strategy could employ situational awareness. Staffing assignments may change over time to better match personnel knowledge, skills, and abilities with appropriate response roles.

Progressive improvements in logistic capabilities are essential to meet the timelines required to sustain a response (e.g., 50-day supply of antibiotics, anthrax vaccine). Given the amount of time needed to receive, distribute, and dispense the follow-on MCMs, states' RSS and L/RDS warehouses must be ready to receive next-phase assets by day five at the latest. Start times for next-phase MCM distribution and dispensing are prior to conclusion of the initial 10-day period (dispensing by day eight). Overlapping interventions support local health departments' (LHDs') need to commence second-round dispensing (the 50-day antibiotic courses) and administration of the first course of the multi-dose anthrax vaccine according to the recommended post-exposure prophylaxis schedule.

Planning is crucial to ensure sufficient logistical capability, staff, warehouse facilities, equipment, and transportation assets, while providing opportunities to develop partnerships and leverage existing resources within the supply chain.

### **Promising Practices:**

1. During the Los Angeles County Department of Public Health's (LACDPH's) full-scale exercise (FSE) of MCM distribution and dispensing operations in 2015, the department believed that the timeline for MCM distribution and dispensing of initial 10-day courses of antibiotics was too

short to allow for traditional development of an Incident Action Plan (IAP), including associated anthrax response strategies. Therefore, LACDPH developed an IAP template in advance to support the first 24 hours. The IAP template can be modified based on information received throughout the initial operational period(s). Information is structured in a standardized manner, which allows local planners to initiate advanced planning in preparation for a sustained MCM response.

2. LACDPH realized that the complexity of the logistical components of the RSS/RDS warehouse and delivery operations for the anthrax attack scenario were not within traditional skill sets of most public health employees. However, the Los Angeles County Fire Department (LACFD) maintains three Type-3 Incident Management Teams (IMTs) that have these skills. Also, LACFD IMTs were deployed to Florida to support statewide commodity distribution following successive hurricanes. LACFD IMT members were trained and, in 2015, supported RSS/RDS warehouse operations. Fire Camp Crews, with around 14 members, were identified as supplemental staff for RSS/RDS warehouse operations. They are rapidly available, physically fit, team-oriented, and some have forklift training.
3. LACDPH anticipated its need for supplemental warehouse and transportation resources, including MCM deliveries to approximately 500 skilled nursing/long-term care (LTC) facilities. Therefore, LACDPH did the following:
  - a. Established memoranda of understanding (MOUs) with five qualified trucking companies.
  - b. Developed contracting procedures with eleven pre-vetted moving and storage companies.
  - c. Established MOUs with three pharmaceutical supply companies to support LTC needs. One or more will receive bulk deliveries of antibiotics and distribute to facilities using internal resources, e.g., pharmaceutical warehouses and delivery assets.

#### **Steps to Implementation:**

- Through exercises, evaluate MCM distribution and dispensing response capabilities and identify resource gaps.
- Analyze above promising practices to determine if any provide solutions to these gaps.
- Identify actions and partners required for selected practice(s).
- Engage partners and agency staff to collectively implement selected practice(s).
- Train and exercise the revised procedures and adjust as necessary.

#### **Opportunities for State and Local Health Departments:**

- Public Health Emergency Preparedness (PHEP) grant requirements for MCM distribution and dispensing full-scale exercises by CRI jurisdictions have enhanced the ability of state and local health departments to respond to bioterrorism events. However, these exercises have primarily focused on the initial 10-day MCM distribution and dispensing activities.
- After action reports and improvement plans (AAR/IPs) on FSEs can be used to glean best practices as a foundation for sustained MCM distribution and dispensing planning.
- LHDs can leverage their sound understanding of the flow of MCM throughout the supply chain.

**Critical Points for Plan Improvement:**

- Identify and hold advanced meetings with private sector vendors to discuss contracted resources, and with public partners and local military installations to discuss mutual aid. Incorporate all pertinent information obtained into the jurisdiction's MCM plan.
- Partnerships should be formally established through MOUs to ensure a shared understanding of responsibilities.

**Additional Resources:**

1. [The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop Summary](#), Institute on Medicine (IOM), 2016.
2. [Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness](#), Version 11, CDC, 2011.
3. [LACDPH Incident Action Plan Template for Anthrax Attack Response](#).

Operationalizing the receiving sites, with employment of effective staffing, equipment, and cold-chain support (vaccine, antitoxins) during the extended phase of distribution.

**Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

- CDC may authorize direct shipments of AVA to pharmacies and primary care providers during the second (week 2) and third (week 4) administration of AVA, similar to the strategy employed during the H1N1 response.
- RSS/RDS/LDS will have sufficient staffing capacity to maintain long-term distribution tempo throughout the additional 50-days of antibiotics and vaccine operation.
- Staff are trained on cold-chain management standards.
- Enough 50-day courses of antibiotics (ciprofloxacin, doxycycline, and amoxicillin) are available to meet the needs of the exposed population(s).
- Sufficient anthrax vaccine for the entire population affected is unavailable, and distribution of vaccine should be prioritized per current CDC guidance, available at <http://www.cdc.gov/anthrax/medical-care>.
- Transitioning from the initial distribution plan to the extended plan is executed by day eight at the latest of the initial response.
- Demobilization occurs slowly and in stages throughout the event, though there may be a need to assign facilities to standby for reactivation.
- If the agent shows susceptibility to penicillin, requests will be processed for an alternate antibiotic from CDC.

**Description:**

The information provided in this section of the document addresses many of the concerns that planners need to include in their response plans to successfully complete the extended distribution campaign (day 11 through day 50).

**Promising Practices:**

1. WEBOEC (information sharing, inventory management) is a tool used effectively by a number of jurisdictions for information sharing related to distribution.
2. Companies with mobile cold-chain storage trailers may be available to assist with vaccine distribution. (Website listed in resources.)
3. Develop third-party logistics contracts to assist with distribution operations and supplement the resources that might be available at the state and local levels.
4. Explore partnerships with government agencies (federal, state, local) in the community.

**Steps to Implementation:**

- Conduct jurisdictional (state, local) workgroup sessions, brainstorm the unfilled needs of existing plans, and determine appropriate solution sets to be implemented.
- Utilizing Homeland Security Exercise and Evaluation Program (HSEEP) guidelines, conduct tabletop or FSEs to test documented processes.

- Seek the use of the CDC's Eagle Package cache during state and local FSEs.

**Opportunities for State and Local Health Departments:**

- Implement an all-hazards approach to MCM/SNS planning. Everyone's support is needed for the distribution operation to be successful.

**Critical Points for Plan Improvement:**

- Adequate staff for a long-term distribution campaign.
- Requesting additional treatment medication from the CDC.
- Identify agencies and partners who will be available to support the entire distribution operation. Partners may include the National Guard, military, Medical Reserve Corps, civil support teams, Vaccines for Children providers, pharmacies, etc.
- Monitoring the safety and health of all responders (CDC Capability 14).

**Additional Resources:**

1. [CDC Vaccine Storage and Handling Recommendations and Guidelines.](#)
2. [Chain Management Brief - Temperature Sensitive Medical Products \(TSMs\) Good Distribution Practices](#), US Army Medical Materiel Agency.
3. [Cold Management Trailers.](#)

## Employing an effective inventory management system.

### **Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

- States will utilize an Inventory Management System (IMS) that dynamically tracks MCM transactions and item status (e.g., including from request to delivery, and gross decrements as unit-of-measure quantities are dispensed and consumed).
- States will utilize the CDC [Countermeasure Tracking \(CIT\) Dashboard](#) that includes records of approved SNS requests. The CIT provides on-demand access to estimated time of arrival and access to details regarding items and quantities, per truck.
- At shipment, DSNS will provide each receiving state with information, including lot numbers, descriptions, units-of-measure (i.e., bottle-case packaging and total case quantities), number of cases per pallet, and temperature storage requirements.
- LHDs will have access to MCM information from state, as listed previously.
- DSNS may ship antibiotics from the Shelf Life Extension Program that are labeled as expired and require a special authorization, but DSNS will not ship anything that cannot be dispensed.
- States will use CDC’s Inventory Management and Tracking System (IMATS) or have an Inventory Data Exchange (IDE) capability in addition to their IMS, so that CDC can track inventory.

### **Description:**

An IMS must be used to track movements of MCM, including at warehouses and dispensing sites.

### **Promising Practices:**

1. Make deliberate decisions and commit to redundancies of the network(s) supporting IMS to protect access at the RSS/RDS/LDS warehouse(s), including pre-response solutions. Test documented plans for primary and backup networks. For dispensing sites, develop paper and/or Excel IMS in case networked systems are unavailable.
2. Assign responsibility for PODs (or other dispensing sites) resupply ordering to a command center. Dispensing staff generally will not have the time or skill set necessary for accurate and timely decisions about resupply orders. Instead, train staff at dispensing sites regarding the importance of providing command with timely reporting of dispensing throughput, supply receiving, and inventory-on-hand data. Command should pre-identify the potential inventory likely to be required for PODs for days 11–60.
3. Recycle unused 10-day courses in the field to meet dispensing needs for antibiotics for days 11–60. LHDs may consider dispensing five unused 10-day courses (i.e., overpack). When PODs close, perform reverse logistics to move excess antibiotics back to warehouse(s) so staff can overpack 10-day antibiotic courses as 50-day antibiotic courses. Adjust IMS records by decrementing 10-day antibiotic courses and adding back inventory as 50-day antibiotic courses. However, overpack courses should not show as 50-day antibiotic courses newly received from CDC.



4. Track consumption of MCM at dispensing sites. However, due to requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for any system that contains patient data, it is not recommended that the IMS for RSS/RDS/LDS warehouse and POD logistics operations also track specific item, quantity, and lot information to the level of individual clients. Use an alternate system separate from the IMS to track individual antibiotic courses and vaccine vials' contents to the level of each individual recipient.
5. Jurisdictions track MCM inventories throughout the distribution supply chain using an IMS and, typically, data entry corresponds dynamically with product movements. However, it has been demonstrated during exercises and during the H1N1 response that capabilities required for dynamic updates of the IMS may not always be available. Additionally, electronic systems and access to technology are not consistently available or adequately staffed. Therefore, agencies should establish offline IMS capabilities, including Excel and paper-only alternatives, as well as maintain supplies of pre-printed shipping documents for the most critical MCM deliveries. The corresponding IMS entries can then be made after the fact.

**Steps to Implementation:**

- Pre-determine how project areas will report MCM inventory data to the CDC for both warehouses and dispensing sites (e.g., PODs, hospitals). This requirement is supported for jurisdictions that employ CDC's IMATS application as their IMS. Health jurisdictions that have not adopted IMATS should meet the detailed technical requirements outlined by the CDC using an automated process. All jurisdictions still face significant challenges associated with their capability to dynamically maintain inventory information for all their identified dispensing sites.
- Create a process and corresponding report in the IMS to track actual inventory receipts against expected quantities requested from the DSNS and state.
- Pre-load item information in the IMS for items relevant to 50-day response.
- Choose simple workarounds to account for SNS inventory that is labeled as expired. Most IMS will not allow receipt or shipment of expired goods. Standardize the IMS workaround (add 20 years, use expiry of 12/31/2099, etc.) so that there is no slowdown or confusion with the IMS.
- Exercise material handling at the warehouse on a large scale. For 50-day response items and orders, streamline both the physical and IMS processes as necessary to allow timely completion of critical MCM distribution while keeping physical and IMS processes synchronized.
- Create detailed and summary IMS reports for shipments from warehouses. To best support product recall efforts, detailed reports should specify lot and expiration date and all reports should indicate the dispensing site network to which a customer belongs (e.g., school ABC is a "Public POD," sometimes referred to as "open POD").

**Opportunities for State and Local Health Departments:**

- CDC offers IMATS for free and version improvements have made this system more viable.

**Critical Points for Plan Improvement:**

- Define a process for identifying temperature variation issues for inventory, including how to segregate this inventory in the IMS while the disposition is being determined.

- Pre-identify suppliers and model numbers for vaccine packing supplies (e.g., ice packs, vaccine containers, temperature indicators), and then add these items to the IMS.
- LHDs should pre-train dispensing site staff regarding entries in the IMS for any inventory that is under quarantine or investigation, including when these restrictions/activities are in place due to temperature variation.

**Additional Resources:**

1. [Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness](#), Version 11, CDC, 2011.
2. [Countermeasure Tracking Systems \(CTS\) - Inventory Management and Tracking System \(IMATS\) – User’s Guide](#), Version 1.8, CDC, January 2016.
3. [Countermeasure Tracking Systems \(CTS\) - Inventory Data Exchange Specification: Release 1.0](#), Version 1.2, CDC, August 2016.

## Supporting treatment-related MCM requirements of hospitals and other impacted sites.

### **Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

- There will be competition for all MCMs needed at different sites as they are in limited supply.
- There will be competing requests for transportation assets to support operations.
- Hospitals will not participate in dispensing PEP MCMs to the general public.
- Following an anthrax event, federal medical stations (FMS) may be used to establish alternative care centers to reduce patient surge to hospitals and treatment centers. Coordination with the Office of the Assistant Secretary for Preparedness and Response on the strategic use of FMS during an anthrax response will be necessary.

### **Description:**

The preparedness and exercise activities associated with the distribution of MCM to hospitals may be overshadowed by the attention required for a mass dispensing effort. During an extended dispensing campaign, distributing resources to hospitals may prove more challenging than distributing to PODs or other dispensing sites. The main focus of hospitals will be treatment, not prophylaxis—the exception being the hospital staff and their families. A robust and reliable supply chain is essential to keep hospitals supplied with the necessary medications and equipment required to treat anthrax and save lives. If the normal supply chain is incapable of supporting the hospitals’ efforts, then requests for MCM will likely go through an approval process that leads to MCM order fulfillment by the RSS site. Since the hospitals are focused on treatment, timing of deliveries to meet the patient need will be challenging due to time constraints associated with patients’ conditions. Other clinical settings (facility types) may have similar challenges for MCM deliveries, such as long-term care facilities, urgent care centers, standalone emergency departments, and alternate treatment centers.

Additionally, with limited supplies of treatment medications and transportation assets, there could potentially be an allocation challenge for these resources. Determining an allocation strategy prior to the incident will assist in making difficult decisions during an anthrax incident requiring an extended dispensing operation. Crisis Standards of Care would be a good resource to support decision-making related to the allocation of limited treatment medication.

### **Promising Practices:**

There are several promising practices used currently to keep hospitals equipped with effective MCM, including the following:

1. Hospital Preparedness Program (HPP) coalition partners utilize an RDS site to distribute to hospitals. The practice comes from the Southeast Texas Regional Advisory Council. Not all hospital coalitions have the necessary resources to run warehouse operations, making this practice better for large coalitions.
2. An allocation strategy or model should be developed to assist in distribution to hospitals for prophylaxis and treatment purposes. Hospitals will be overwhelmed and MCM resources will be

a limiting factor. Identifying a process to determine the priority of delivery prior to the incident will help with difficult decisions about what treatment center orders are fulfilled.

3. Hospital training and exercising is important to build relationships between MCM and hospital partners. This includes hospitals and treatment centers as closed PODs for the employees and additional countermeasure support for patients.
4. The Chicago Department of Public Health (CDPH) developed standardized hospital kit lists for SNS materiel (including drugs, ancillary supplies, and airway management supplies and equipment) to treat 50 victims at a time for the initial phase of the response and for re-supply during the follow-up response. Hospital personal protective equipment (PPE) kit lists for staff were also developed. Hospitals were trained on kits and familiar with contents. Kits can be pre-assembled at RSS sites assuming needed supplies are available.

CDPH uses a three-pronged MCM distribution approach: (1) first responder/closed PODs; (2) public PODs; and (3) treatment centers/hospitals. Chicago builds and pushes standardized SNS-sourced medical materiel kits and CDPH-sourced PPE kits to hospitals based on threat and number of victims to treat. After this big initial push, the response enters the “pull phase,” where hospitals can request materiel from CDPH. These processes were tested during a full-scale exercise in June 2016. From the time SNS is dropped off at the RSS, the first hospital kit is ready to be delivered in less than one hour.

#### **Steps to Implementation:**

- Create a list of all treatment facilities.
- Determine who is responsible for decisions related to MCM requirements of hospitals and HPP.
- Form an agreement regarding MCM support (MOU, existing contract, or existing legislation).
- Coordinate with hospitals for the allocation strategy and determine the mode of transportation.
- Write a concept of operations (CONOPS) for distribution to hospitals.
- Conduct training and exercise based on the CONOPS and any approved crisis standards of care.

#### **Opportunities for State and Local Health Departments:**

- State and local health departments can leverage the hospital coalitions to assist in planning and operational activities.

#### **Critical Points for Plan Improvement:**

- The distribution mechanisms for different types of MCMs may vary by jurisdictional plans, event characteristics, and MCM characteristics. Some MCMs are distributed from CDC to the state and then to the local level. Others are distributed by CDC directly to healthcare entities. Alternatively, CDC may distribute MCMs to the state level and then directly to healthcare entities, or to the state level, which then go to the local level and, finally, to healthcare entities. Federal, state, and local planners should discuss expected distribution pathways for each type of MCM as part of MCM distribution planning.

**Additional Resources:**

1. [CDC MMWR on Clinical Framework and Medical Countermeasure Use During an Anthrax Mass-Casualty Incident.](#)
2. [Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness, Version 11, CDC, 2011.](#)
3. [Ethical Guidance for Public Health Emergency Preparedness and Response: Highlighting Ethics and Values in Vital Public Health Service.](#)

## Dispensing Topics:

Operationalizing the POD sites, with employment of adequate staffing.

### **Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

- Local health departments will move from a non-medical model (used for 10-day course) to a partial medical model for dispensing (50-day course) and vaccinations.
- Emergency Use Authorizations (EUAs) and Emergency Use Instructions (EUIs) will be authorized for duration of long-term dispensing operations.
- Exposed population may be defined, lessening vaccination burden.
- The health assessment or medication screening assessment will become lengthier and more in-depth than what was used for the 10-day course of antibiotics.
- Clinical staff will be taxed for treatment-related assignments, thereby decreasing clinical staff availability for PODs.
- There may be multiple PODs or clinics needed for both dispensing of the 50-day antibiotics and administering vaccines for the three-dose series.
- A separate location may be set up away from the dispensing sites for vaccine administration.
- CDC will distribute 50-day antibiotics and anthrax vaccine concurrently.
- CDC does not have sufficient ancillary supplies to administer anthrax vaccine. For this reason, state and local health departments should plan for providing the necessary ancillary supplies.
- CDC will distribute 50-day antibiotics to the RSS site for local distribution.

### **Description:**

Staffing demands will change as the MCM dispensing campaign transitions from a non-medical model to a partial medical model, which will require a larger clinical staff to meet demand (i.e., doctors, nurses, or others approved to provide vaccinations in a declared emergency). This will likely be a challenge for many jurisdictions due to limited resources.

### **Promising Practices:**

1. The Philadelphia Department of Public Health developed a dual dispensing POD model in which both 50-day antibiotics and the first dose of vaccine would be provided at a single POD. As part of this POD model, antibiotic screening and dispensing were combined into a single POD station function, while the vaccine station had separate staff conducting vaccine screening, vaccine drawing, and vaccine administration. The health department separated staff functions to optimize the use of clinical staff to administer vaccines, as those staff would likely be in the highest demand for this event. All other staff not administering vaccines would not need to be clinically licensed and could be filled by non-medical volunteers. (See additional resources to learn more about this model.)
2. The Fairfax County Health Department in Virginia is exploring how to use [www.whentowork.com](http://www.whentowork.com) to help manage staffing of volunteer shifts based on text messages from interested volunteers. The website allows the health department to account for anticipated and

scheduled time-off periods to avoid assigning volunteer staff when they are not available to work.

3. The use of paramedics and dentists to administer vaccines with the approval of the state licensing board and with the execution of just-in-time training might be a way to augment medical staff.

#### **Steps to Implementation:**

- Develop and exercise long-term MCM distribution and dispensing plan.
- Determine whether first vaccine dose will be given at the same time as 50-day medication dispensing.
- Determine staff needed to track vaccines administered and maintain schedule for all three doses.
- Determine which system will be used to track the administration of the vaccines.
- Determine possible POD or clinic sizes, number of clinics needed, locations, security plans, and flows. Must also have arrangements with POD sites for extended use and consideration as to how it may affect their normal operations.
- Determine staffing requirements at the vaccine clinic and at the oral antibiotic dispensing sites (if they are not the same location). Suggest using [RealOpt](#) or other modeling software.
- Determine staff and volunteers available through established partnerships (both medical and non-medical) and review staffing contracts available locally or through mutual aid agreements.
- Determine what health assessment or screening protocol will be used for the vaccine and develop training on its use.

#### **Opportunities for State and Local Health Departments:**

- Work with local or regional Medical Reserve Corps (MRC) to pre-train clinical staff on dispensing and vaccination operations.
- Work with regional or local volunteer agencies to pre-train staff on long-term dispensing operations.
- Work with city, county, state, or health department staff to train on long-term dispensing operations.
- Work with regional, state, and local health departments to develop mutual aid agreements, so that additional staff could be requested from health departments not involved in the response, as well as from schools of nursing, medical facilities or providers, pharmacy, etc.
- Work with the National Guard or other military personnel to determine their capacity to assist with distribution and dispensing operations.

#### **Critical Points for Plan Improvement:**

- There is limited guidance regarding long-term MCM dispensing operations and the guidance that is available makes the assumption that adequate staffing will be available.
- Currently, CDC guidance recommends administering the first dose of AVA within 10 days following anthrax exposure, which coincides with the transition to a partial medical model and the dispensing of the 50-day medication supply. However, operational guidance regarding how AVA vaccination tier levels will be merged into dispensing operations is still required.

**Additional Resources:**

1. [The 49th hour: analysis of a follow-up medication and vaccine dispensing field test](#), Philadelphia Department of Public Health.
2. [RAMPEx Full-Scale Exercise](#), New York Department of Health and Mental Hygiene.



Identifying adequate medication, vaccination supplies, and other needed resources to continue and sustain operation of PODs.

**Assumptions:** (“*Overarching Assumptions*” and “*Additional Overarching Assumptions*,” Appendix 2)

- Local and state health departments will not have sufficient medication (antibiotic prophylaxis) caches locally for the entire 60-day dispensing campaign.
- Local and state health departments will not have sufficient ancillary medical supplies, such as needles, syringes, or alcohol swabs, for vaccination administration.
- Local and state health departments will have adequate receiving space allocation to support the next 50-day shipment, including cold-chain storage for vaccines.
- Just-in-time inventory at medical supply distributors may not be able to provide sufficient supplies for vaccine administration.
- Schools and other recommended open POD sites may be unavailable for the entire 60-day dispensing campaign.

**Description:**

To be able to sustain long-term MCM distribution and dispensing operations, local and state health departments must determine medication requirements for the affected population, identify any necessary vaccine administration supplies (e.g., needles, syringes, alcohol swabs), and pre-establish processes and procedures for just-in-time procurement of ancillary medical supplies necessary for vaccine administration. State and local health departments also need adequate RSS warehouse space allocation and personnel to staff PODs, clinics, and distribution sites through the duration of the extended dispensing campaign as well as extensive and adequate federal guidance prior to any event.

**Promising Practices:**

The following are promising practices for local and state health departments that address several of the planning considerations outlined above:

1. [Administrative Preparedness: Emergency Procurement Strategies for Health Departments](#)  
This report, published by NACCHO in 2013, highlights several promising practices from various local health departments across the country regarding procurement strategies, including establishing processes and procedures for procuring medical equipment or other ancillary supplies. This could include just-in-time procurement strategies as a means to decrease the financial strain placed on many local health departments.
2. [Receiving, Distributing, and Dispensing: A Guide to Preparedness, Version 11](#): This document, produced by CDC’s Office of Public Health Preparedness and Response, addresses several long-term dispensing planning considerations, including space allocation requirements for the next 50-day shipment (which may also include anthrax vaccine storage requirements).
3. The Philadelphia Department of Public Health recently conducted a full-scale exercise to test multiple key components of a long-term dispensing campaign. The results of that exercise were recently published and have been presented at multiple national public health preparedness conferences. NACCHO and the Philadelphia Department of Public Health published a paper, [The](#)

[49th Hour: Analysis of a Follow-up Medication and Vaccine Dispensing Field Test](#), which describes what a dual model POD (dispensing and vaccination clinic) would look like and outlines staffing considerations for such a dispensing and vaccination campaign.

**Steps to Implementation:**

- Evaluate local and state health department receiving and distribution plans to determine if the current RSS or RDS warehouse locations are suitable for a larger footprint and cold-chain management of MCMs and ancillary supplies expected during the extended dispensing period.
- Identify planning considerations for staffing needs for a long-term dispensing and vaccination campaign. Convene key stakeholder meetings to discuss current staffing and volunteer levels for a normal 10-day dispensing campaign, and then add in the vaccination component and time required to see each individual for vaccination.
- Convene key stakeholder meetings to evaluate current mass dispensing plans and begin to identify planning considerations for transitioning from a non-medical POD to medical POD.
- Determine if any existing medical supply companies can support a just-in-time procurement process for ordering ancillary medical supplies in an expedited manner. If none exist, identify local medical supply companies with which such purchasing processes can be established. Health departments should consider developing memoranda of agreement/understanding with such companies that outline the procurement process and time considerations.

**Opportunities for State and Local Health Departments:**

- Review existing mass dispensing and distribution site plans to determine if the long-term dispensing and vaccination needs result in critical evaluation of gaps as well as partnership opportunities with new stakeholders.

**Critical Points for Plan Improvement:**

- As many of the critical elements to a long-term dispensing campaign remain uncertain (particularly regarding vaccination dosage requirements and target area identification), plans must be consistently revised to reflect new changes to federal or state guidance.
- Flexible and scalable plans are also very important to consider.
- Continue to ensure that the planning cycle continues after every critical change in the plans (train, exercise, evaluate, revise, etc.).

**Additional Resources:**

1. [NACCHO Medical Countermeasure Toolbox.](#)
2. [ASTHO Preparedness Resource Website.](#)
3. [CDC Office of Public Health Preparedness and Response Website.](#)

Developing dispensing and vaccination prioritization strategies for scarce resources (allocation of MCM that supports ethical access).

**Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

- The risk for inhalation of anthrax following exposure to *Bacillus anthracis* spores is best estimated by the degree of exposure, not by health status or age. Therefore, frameworks to prioritize MCMs should be based on a patient’s likelihood of exposure, if known.
- Previous analysis has indicated that it is preferable to administer prophylaxis to all asymptomatic individuals who live, work, or were known to have traveled through the exposure region or those who will serve in response roles that put them at greater risk of exposure.
- In general, prioritization frameworks developed for an influenza pandemic are not appropriate to use following an anthrax attack. The two events differ significantly based on factors such as communicability or mode of transmission, drug development timelines, potential adverse reactions, rates of hospitalization, and anticipated adherence to prophylaxis or treatment courses.
- An anthrax attack is likely to generate a surge in demand for medical care, and the availability of medical supplies and equipment such as ventilators and IV fluid—in the SNS or from any other sources—may not keep pace with demand.
- It is possible that, in a situation where supplies are restricted and prioritization is implemented, sufficient MCMs will begin to flow into the impacted region and prioritization can be curtailed.

**Description:**

A system for the prioritized distribution of medical supplies and equipment following an anthrax attack should encompass pharmaceuticals, medical supplies, and equipment required for prophylaxis and treatment of anthrax. For prophylaxis, if sufficient MCMs (vaccine or oral antibiotics) are not available in the local jurisdiction to begin dispensing the 50-day course of antibiotics around day eight or nine of the response, then state or local health departments may need to prioritize groups to receive the follow-on dose until the supply expands and MCMs are available for all impacted individuals. For treatment options such as antitoxins, IV antibiotics, IV fluids, and ventilation, medical resource shortages could occur at any time during the extended period in which hospitals and other healthcare facilities treat individuals impacted by the event. Depending on local governance structures, state or local health departments may need to collaborate with healthcare organizations, medical ethicists, community advocates, and other partners and exercise health officer authorities to establish priorities for using scarce medical resources, until the supply expands and sufficient quantities are available to treat all impacted individuals.

**Promising Practices:**

1. **The Philadelphia Department of Public Health’s Long-Term Mass Dispensing of Medical Countermeasures Plan, August 2015.** This document describes how the health department can identify priority groups to receive the long-term MCMs first if follow-up medication quantities are limited. First responders and essential personnel are identified as two groups that may be prioritized to receive MCMs during both the initial and the follow-up response. This report is available upon request by [emailing](#) the Philadelphia Department of Public Health Preparedness Program.

2. [Considerations for Anthrax Vaccine Adsorbed \(AVA\) Post-Exposure Prioritization Final, CDC, 2013](#). This document proposes a framework for anthrax vaccine prioritization. The prioritization scheme is based on presence in (or distance from) affected area during initial release, participation in high-risk activities in the affected area, and potential secondary exposure from entry into contaminated areas or other factors.
3. [Patient Care Strategies for Scarce Resource Situations V4.0, Minnesota Department of Health, Office of Emergency Preparedness, Minnesota Healthcare Preparedness Program, December 2014](#). This document is a set of cards that facilitate regional decisions on resource shortfalls at healthcare facilities. Each facility then determines the most appropriate steps to implement the selected strategies.
4. The Kentucky Department for Public Health developed guidance for local health departments within Kentucky embarking on long-term anthrax planning. This guidance includes additional information on MCM prioritization, MCM specifications, POD planning, public information, and other planning considerations. This document is not yet publicly available.

#### **Steps to Implementation:**

- For vaccine:
  - Review AVA Post-Exposure Prioritization Guidance for Vaccine.
  - Identify high-priority groups and critical infrastructure personnel.
  - Consult with regional public health partners, pharmacy partners, and other healthcare partners to draft strategy.
  - Develop decision-making framework to operationalize prioritization strategy.
- For oral antibiotics: none identified currently.

#### **Opportunities for State and Local Health Departments:**

- Standardization of priority groups for PEP may occur at the federal level in the case of multi-state responses.
- State and local health departments should review the proposed anthrax PEP prioritization frameworks and determine how these prioritization frameworks would be implemented in their local or state medical countermeasure dispensing operations.

#### **Critical Points for Plan Improvement:**

- In the event of medical resource shortages, it is beneficial for communities to develop coordinated regional strategies to address the shortages, rather than each facility acting alone.
- It is unlikely that epidemiologic, environmental, and criminal investigations initiated after the anthrax exposure will progress quickly enough to narrow the potentially exposed population before the 50-day course of antibiotics must be dispensed. If MCMs are in short supply at the beginning of mass dispensing or mass vaccination operations and prioritization is in effect, those shortages are likely to extend into the period during which the 50-day courses of antibiotics are

dispensed. Therefore, prioritization frameworks implemented for the 10-day course of antibiotics will most likely be continued for the 50-day course of antibiotics.

- Conversely, there may be situations where a community has sufficient antibiotics to distribute the 10-day course of antibiotics to all impacted individuals, but the 50-day courses of antibiotics are in short supply. Therefore, state and local health departments should remain prepared, flexible, and nimble enough to implement and curtail prioritization strategies as the supply dictates in the moment. Such efforts will require clear and widely communicated messaging to the public and dispensing and vaccination partners.

**Additional Resources:**

1. [Emergency response to an anthrax attack](#), *Proceedings of the National Academy of Sciences of the United States of America*, January 2003.
2. Centers for Disease Control and Prevention. [Summary of post-event anthrax vaccine administration considerations](#), September 2013, letter from Christine Kosmos, CDC.
3. [Ethical Guidance for Public Health Emergency Preparedness and Response: Highlighting Ethics and Values in a Vital Public Health Service](#).
4. [Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency](#).

## Tracking adverse events to the antibiotics, antitoxins, or the vaccine.

### **Assumptions:**

- An adverse event is any undesirable medical occurrence associated with the use of a drug or biologic in humans, whether or not considered drug or biologic related. If a direct causal relationship can be determined, adverse events can also be referred to as adverse reactions.
- There will be individuals who experience mild or severe adverse events or reactions after receiving MCMs. Mild adverse events are defined as mild or moderate symptoms that cause an individual discomfort and may require them to miss at least one day of school or work. Severe adverse events are defined as serious adverse events resulting in hospitalization excluding ambulatory care and emergency department events (unless they resulted in hospitalization).
- It is possible some individuals who receive MCMs will still become sick. This may cause concerns about efficacy and adverse events. There may be special interest groups who do not believe one or all MCMs are safe. Public messaging will need to address both issues.
- The number and severity of adverse events will increase as the mass prophylaxis campaign continues past the 10-, 30-, and 60-day marks.
- For the anthrax vaccine, as with most vaccines, severe adverse events such as anaphylaxis are expected to occur within 10–15 minutes of administration. For antibiotics, individuals will take the medication at home and therefore adverse events are not expected to occur at the POD. However, it is possible for individuals regardless of the type of countermeasure to experience adverse events days, weeks, or even months or years later.
- Federal regulatory systems for reporting, investigating, and tracking adverse reactions—Vaccine Adverse Event Reporting System (VAERS) for vaccine and MedWatch for medications—will still be functioning. However, if there is a surge in the number of cases reported, reporting of results back to local health departments may not occur. (Please note: there is no report-back procedure for MedWatch.)
- Local health departments will be asked for information on local adverse events data by media, elected officials, healthcare providers, the general public, and others. Local health departments may also be asked to provide guidance on treatment or care for individuals experiencing adverse events or reactions.
- Some individuals may report adverse events directly to their healthcare provider or treatment center. It is possible that those providers or facilities may report to the local health department or to VAERS or MedWatch directly.

### **Description:**

Given the number of people who will receive and consume MCMs, the severity of the event, and a likely high level of media interest or scrutiny, there is a high likelihood that all local health departments will receive reports of adverse events. While most of the adverse events will be mild, it is possible for local health departments to receive reports of severe adverse events as well. All local health departments must be prepared to receive, report, track, and follow-up with every adverse event report received.

There are three primary types of surveillance for adverse events:

1. Direct follow-up of all individuals receiving prophylaxis (active).
2. Systematic data collection from healthcare providers or facilities at specified time intervals (active).
3. Relying on individual or provider self-reporting (passive).

The nature or scope of the situation will determine what type of surveillance is most appropriate.

There are four essential elements of information for adverse event reporting:

1. The individual with the possible adverse event.
2. The reporter for the adverse event.
3. The product suspected or implicated.
4. The adverse event, effect, or outcome experienced.

#### **Promising Practices:**

1. Philadelphia's screening algorithm for the follow-up 50-day course includes the option to change antibiotics for the individual if they experienced mild negative side effects or adverse events, which is available in the [NACCHO MCM Toolkit](#). The toolkit also contains a database for patient tracking that would be useful for surveillance or follow-up of individuals with possible adverse events. The American College of Radiology also developed an [adverse event tracking log](#) that can be adapted for MCMs.
2. Online training and sample report forms are available on both the [MedWatch](#) and [VAERS](#) websites. The CDC will also deliver anthrax vaccination cards with the anthrax vaccine for each vaccine recipient to keep and track doses given or needed. This card provides VAERS website and phone number and informs the recipient what to do if they experience adverse events following vaccine administration.
3. A study published by the Agency for Healthcare Research and Quality developed a computer model for estimating the timing and number of adverse events that could occur following an anthrax mass prophylaxis campaign. The results can be found [here](#).
4. Several major pharmaceutical companies are studying how to use social media data and other non-traditional approaches to monitor or identify possible adverse events. Examples include the following:
  - a. [Social Media Listening for Routine Post-Marketing Safety Surveillance](#)
  - b. [Novel Data Mining Methodologies for Adverse Drug Event Discovery and Analysis](#)
  - c. [Digital Drug Safety Surveillance: Monitoring Pharmaceutical Products in Twitter](#)
  - d. There are also several proprietary surveillance tools that can be utilized for adverse event reporting surveillance, including [MedWatcher](#).

#### **Steps to Implementation:**

- Local health departments must work on plans for collaborating with hospitals, healthcare facilities, and private providers on a local reporting or tracking system for adverse events. These

plans must include both active and passive surveillance tools to determine the presence or absence of adverse events.

- Follow-up 50-day mass prophylaxis campaigns need to incorporate questions about adverse events into screening tools and algorithms.
- Consider how to conduct adverse event surveillance at regular intervals (i.e., 10-, 30-, and 60-day marks) of a mass prophylaxis campaign.
- Develop plans for follow-up with providers and individuals identified with possible adverse events.
- During a long-term dispensing campaign, local health departments should plan to monitor or subscribe to VAERS and MedWatch alerts regarding MCMs.
- Consider adapting current syndromic surveillance efforts or mechanisms to identify possible adverse events.
- Consider incorporating adverse event reporting into call center operations plans or agreements.

**Opportunities for State and Local Health Departments:**

- State and local health departments can use local electronic health information available from hospital and insurance claims databases to assess and estimate the percentage and types of adverse events associated with antibiotic use. Similarly, VAERS and MedWatch data are available on their websites for local health departments to conduct baseline data assessments of adverse events common within their geographic area.
- State and local health departments can use available studies and research from the Department of Defense and CDC to assess and estimate the percentage and types of adverse events associated with the anthrax vaccine based on military and Laboratory Response Network personnel who have received the anthrax vaccine.
- Local health departments can partner with local Immunizations programs and providers to utilize existing adverse event reporting tools and mechanisms and adapt them for MCMs. Most immunizations programs at local health departments have policies or procedures already in place for identifying, responding to, and reporting adverse events.
- State and local health departments can work with local and state poison control or call centers to increase capacity for provider and self-reporting of adverse events.
- For long-term surveillance and follow-up, state and local health departments should consider including protocols for conducting post-event surveys, focus groups, sampling, Community Assessment for Public Health Emergency Response studies, etc., in their long-term dispensing plans.

**Critical Points for Plan Improvement:**

- State and local health departments should not rely solely on VAERS or MedWatch for adverse event reporting and surveillance. Local health departments should have plans and processes in place to conduct their own adverse event surveillance, investigation, tracking, reporting, and follow-up.

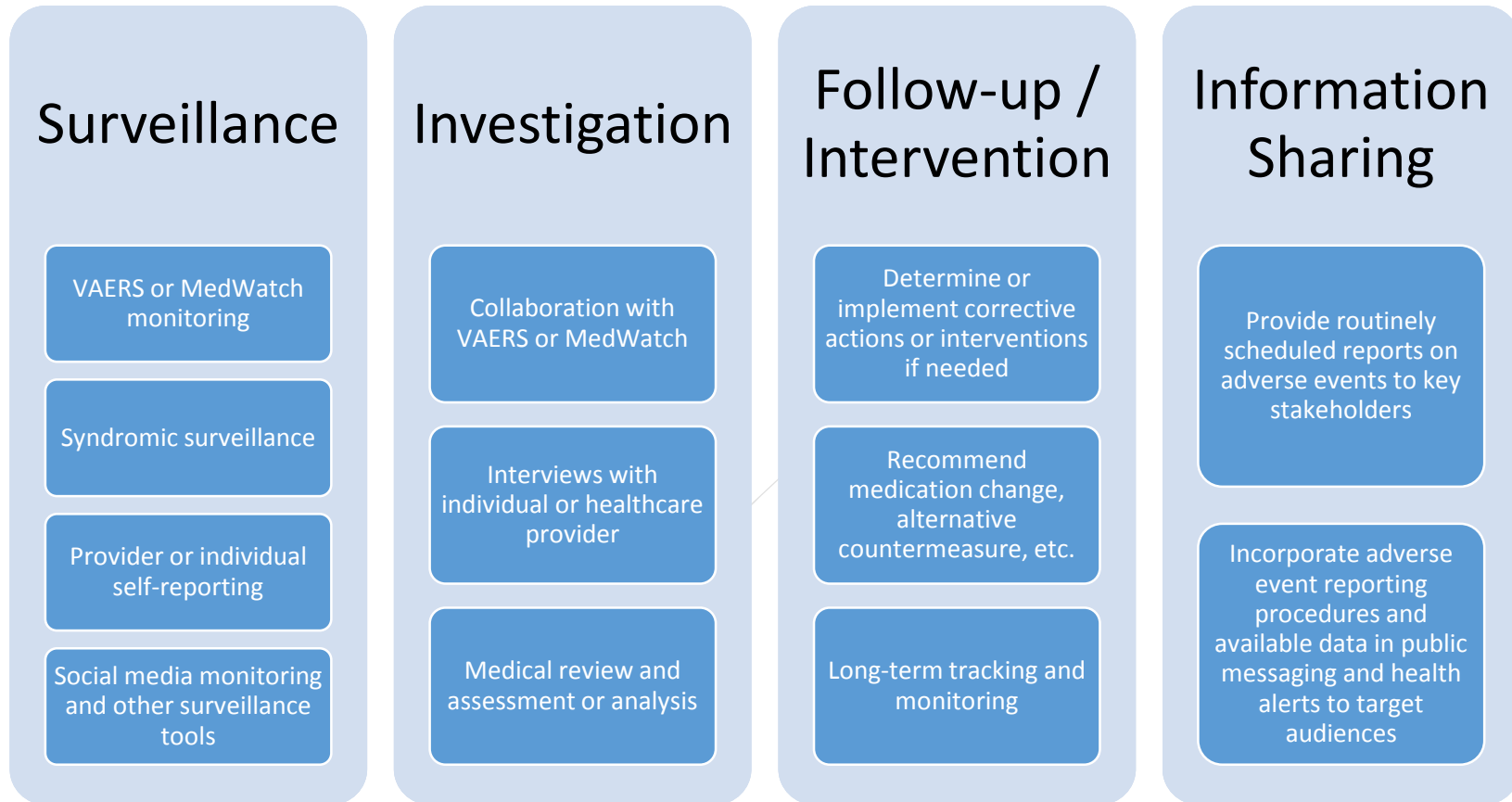


- State and local health departments should train and exercise with hospitals, healthcare facilities, and private providers on the local adverse event reporting system specifically for MCM dispensing campaigns.
- Local health departments should train all staff and volunteers working in POD operations on adverse event reporting including how to report, whom to notify, key elements of information, and what information to provide to the individual or provider reporting.
- Crisis and Emergency Risk Communications/Public Information Officer (CERC/PIO) plans must include pre-packaged, public messages on adverse events and should describe how to address identified cases or reports with target audiences (media, elected officials, healthcare providers, general public, etc.).

**Additional Resources:**

1. Information on adverse events associated with MCMs:
  - [Antibiotics](#) (FDA)
  - [Vaccine](#) (CDC)
  - [Antitoxin](#) (Medscape)
2. [Adverse Events Associated with Prolonged Antibiotic Use](#), 2008, *Pharmacoepidemiology and Drug Safety*.
3. [An overview of adverse events reported by participants in CDC's anthrax vaccine and antimicrobial availability program](#), 2005, *Pharmacoepidemiology and Drug Safety*.
4. [Antimicrobial Postexposure Prophylaxis for Anthrax: Adverse Events and Adherence](#), 2002, *Emerging Infectious Diseases*.
5. [The Anthrax Vaccine: Is It Safe? Does It Work?](#), 2002, Institute of Medicine (US) Committee to Assess the Safety and Efficacy of the Anthrax Vaccine.

## Adverse Event Surveillance and Reporting



The goal of adverse event reporting and surveillance during a mass prophylaxis campaign is to ensure client safety and assess effectiveness of the countermeasures being utilized.

Providing effective public messaging to ensure that a full 60-day regimen and three-shot series of vaccine are taken.

**Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

- A major public health event can potentially generate fear and anxiety, which can hinder dissemination of information, medication, or other public health services to the affected population.
- Public messaging has been underway for some time (prior to initial dispensing efforts of the 10-day course).
- Federal or national-level public messaging will coordinate with local messaging efforts.
- The local health department will coordinate messaging for this response.
- The local health department(s) within the affected area(s) will serve in the joint information center (JIC).

**Description:**

In long-term MCM distribution and dispensing operations, providing timely and informative messaging to the public is crucial to success. Public information officers (PIOs) have created plans and messaging templates for 48-hour dispensing operations, but these are not sufficient for long-term operations. Therefore, it is imperative that local, state, and federal public health agencies create templates for the long-term dispensing and vaccination operations and develop strategies to coordinate those messages with all partners involved, keeping in mind the different languages in each jurisdiction.

**Promising Practices:**

1. CDC is developing the StopAnthrax toolkit. This document will provide a substantial amount of messaging guidance related to emergency communications during the long-term dispensing response.
2. CDC is also developing additional Anthrax communication guidance, which will address both initial and long-term anthrax response needs.
3. FEMA’s PIO ([G290](#)) and JIC Training ([G291](#)) courses. These trainings provide an opportunity to practice and understand PIO roles during emergencies.

**Steps to Implementation:**

- Update CERC plan to include information on long-term dispensing messaging, medication, and vaccines.
- Include the public messaging priorities and processes in the long-term dispensing plan.
  - Create message templates.
  - Convene JIC partners to discuss strategies.
- Work with local, regional, and state partners to ensure all messaging will be consistent.
- Train and exercise with partners on the plan.
- Keep message at a low literacy level to allow for easier translation.
- Share translated materials with affected populations.

**Opportunities for State and Local Health Departments:**

- By pre-planning for public messaging for long-term dispensing or vaccinations, state and local health departments will have a baseline understanding of how to appropriately provide the public with accurate, timely messages during long-term dispensing operations.
- LHDs can create vital partnerships with media contacts, social media organizations, ethnic media outlets, etc.

**Critical Points for Plan Improvement:**

- The timing of when the 50-day course of antibiotics or the vaccine will be available to the public is unknown and will be a significant factor in determining how or when messages are released.
- The method of distribution or dispensing is unknown, which makes it hard to plan or create templates for messaging.

**Additional Resources:**

1. [Information about preventative medications for anthrax with closed captioning.](#)
2. [Federal Communications Commission.](#)
3. [Crisis and Emergency Risk Communication.](#)
4. [CDC Anthrax Webpage.](#)
5. [CDC's StopAnthrax mobile texting platform](#) is under development and was pilot tested at several local exercises.

## Cross-Cutting Topics

Activation timeline following the 10-day antibiotic courses (e.g., dispensing of 50-day antibiotic courses and administration of multi-dose vaccinations).

**Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

- Initial mass prophylaxis with 10-day antibiotic courses was successfully initiated in the first 48-hours of the response and is still underway after the first 48-hours, but at a reduced level due to earlier successes.
- The timeline for the follow-up response will begin in tandem with the initial response since the 50-day antibiotic courses will make their way from CDC to state RSS by day eight, prior to the completion of dispensing for the initial 10-day antibiotic supplies.
- This event will not impact most of the nation, so significant mutual aid may be available for the follow-up response, assuming appropriate resource requests are submitted early (by day four at the latest).
- Once the federal government has finalized its decision to deploy MCM assets, assuming MCM resources (i.e., 50-day antibiotic courses and vaccines) are available, CDC will deliver these MCM assets to project areas within 12–24 hours of the federal decision to deploy. The exception being anthrax vaccine, which will come in multiple shipments according the vaccination schedule.

### **Description:**

The challenges of this activation timeline will be to continue and expand operations at PODs, including dispensing oral antibiotics and administering vaccine. Depending on the response circumstances and timing, there may be time between the initial dispensing campaign and follow-up response to develop a comprehensive response strategy and to move forward with resource requests, which will support timely implementation. Planning for the 50-day MCM distribution and dispensing must start when the 10-day decision is implemented, which is referred to below as day one.

### **Promising Practices:**

1. The PHEP grant requirement of MCM distribution and dispensing FSEs for each of the CRI jurisdictions within the five-year grant cycle has greatly enhanced the ability of these entities to respond to bioterrorism events. However, these exercises have emphasized the initial detection, requesting, public information, receiving, distributing, and 1–10 day dispensing phases of an anthrax response. After-action reviews and improvement plans from these FSEs, as completed by multiple metropolitan areas, can be gleaned for best and promising practices that will serve as a foundation for preparedness to sustain (11- to 60-day timeframe) operations.

### **Steps to Implementation:**

*Disclaimer: The timeframes presented below are estimated and suggested based on the best available information at the time of publication. Timeframes may vary from general sequence listed below depending on the characteristics of the event and operational capacity at the state and local levels.*

- Pre-event: Public health does not perform massive redistribution activities of either resources or staff during day-to-day operations, but there are agencies or vendors that specialize in these types of operations; state and local health departments should start identifying and talking to those entities they could call immediately after an attack through either a contracting process or mutual aid deployment.
- Day 1: Begin discussions to determine estimated scope of response for the follow-up MCM receiving, distribution, and dispensing or vaccination activities once the health department is committed to a mass prophylaxis campaign.
- Day 1: Activate extended MCM distribution and dispensing plans and begin to confirm availability of necessary resources (staff, sites, supplies, MCMs, etc.) the health department may need to meet goals and objectives of the follow-up response.
- By Day 3, determine what resource shortfalls still exist and commence with the development of a draft incident action plan for the follow-up response.
- By Day 4, submit requests for additional resources for the follow-up response (e.g., facilities, warehouse staff, distribution resources and staff, POD staff, forms, equipment, and MCM for 50-day courses of antibiotics).
- By Day 5, finalize all locations that will be used to distribute the 50-day courses of antibiotics and the vaccinations.
- By Day 6, finalize all locations that will be used to dispense the 50-day courses of antibiotics and the vaccinations.
- By Day 8, ensure all response sites have in place the necessary resources to receive the 50-day courses of antibiotics or vaccines for the identified PODs. For the follow-up response, there may be multiple rounds of vaccination that occur after completion of the 50-day courses of antibiotic dispensing.
- When 50-day courses of antibiotics or vaccine arrive, begin distribution and dispensing operations as soon as possible.
- Continue epidemiological investigation to narrow down the target population.
- Maintain regular public message announcements to keep everyone informed.

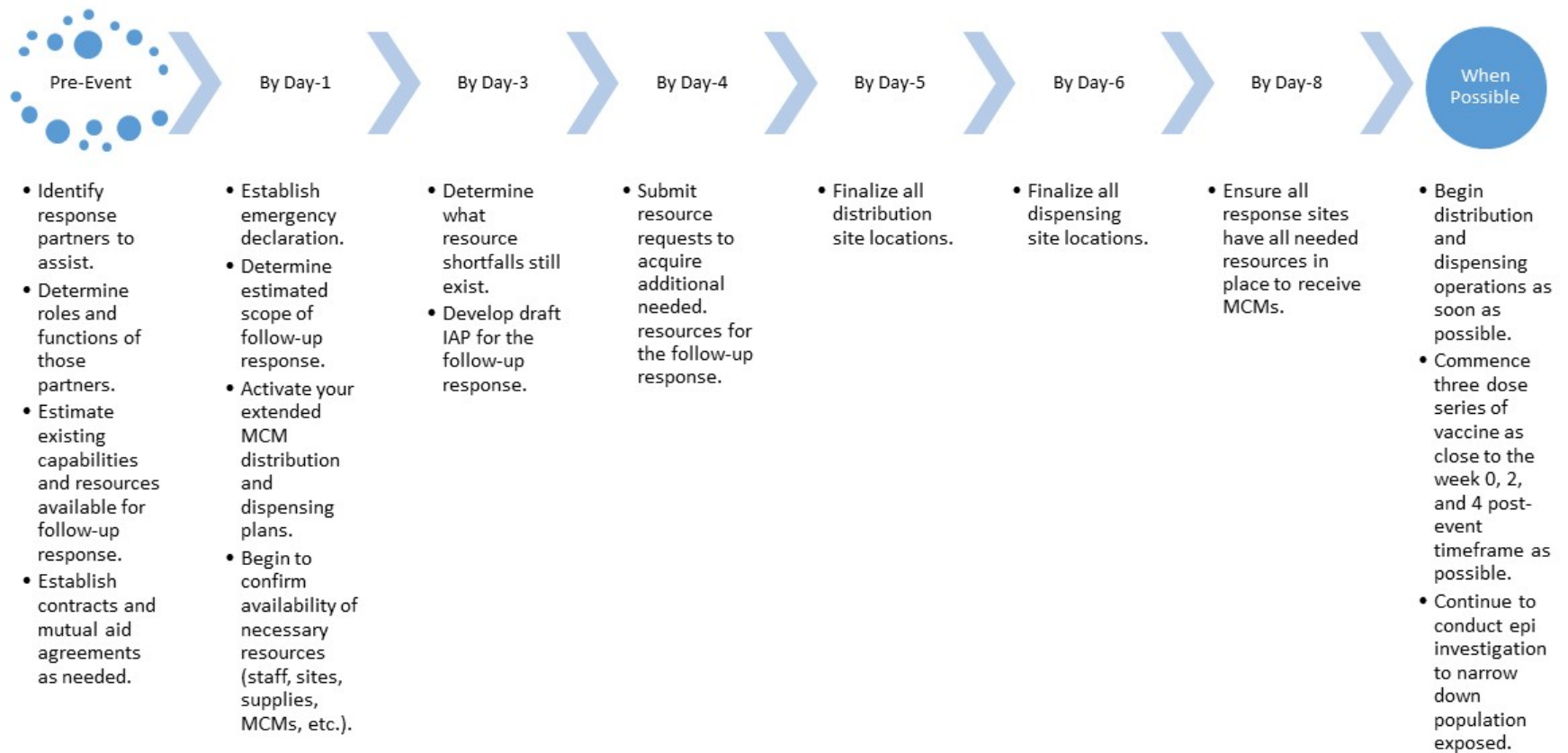
#### **Opportunities for State and Local Health Departments:**

- Identifying pharmaceutical cold-chain storage facilities is a critical component for success in the 11- to 60-day timeframe. State and local jurisdictions will need to look for partners in the public and private sectors to identify such sites. Additional trained staff will be required for ongoing, sustained operations.

#### **Critical Points for Plan Improvement:**

- CDC must provide detailed logistical information on the MCM that will be distributed from managed inventory (e.g., configuration in weight and cubes, as well as quantities of product on each pallet), as it will be delivered to each of the distribution sites.
- Local health departments will need to revise dispensing plans to determine the number, type, and location of sites needed to not only dispense oral antibiotics but to administer vaccine.

The following is a potential timeline of activities that will occur during the early days of a response that will impact activities in the 11- to 60-day timeframe:



\* This timeline may be compressed based on the incident, organizational capacity, and when CDC provides MCMs.

Vulnerable populations (pediatrics, pregnant, kidney or liver issues, those with contraindications, functional and access needs populations).

**Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

**Description:**

Assuring access to information and emergency medications before, during, and after a disaster is critical for individuals, groups, and communities whose circumstances may present barriers to obtaining and using these resources. Circumstances that may present barriers include physical, mental, emotional, or cognitive status; culture; ethnicity; religion; language; citizenship; location; or socioeconomic status. Populations disproportionately at risk during a disaster due to these circumstances include individuals who are blind, deaf, chemically dependent, medically dependent or medically compromised, developmentally disabled, children, homeless and shelter-dependent, clients of the criminal justice system, individuals residing in rural locations, seniors, immigrant communities, limited English or non-English proficient individuals, and undocumented persons. Visit [NACCHO’s Project Public Health Ready criteria](#) for information on defining vulnerable populations.

**Promising Practices:**

1. Local health departments of St. Paul-Ramsey County, MN, and Oakland County, MI, presented a webinar on [Improved Planning for Vulnerable Populations Through the Use of Closed PODs](#).
2. The Florida Department of Health developed a [Guide for Emergency Responders with Tools for Communication with Specific Vulnerable Groups](#).
3. The [Oklahoma Weather Alert Remote Notification](#) program disseminates emergency messages via e-mail, pager, and phone to those who are deaf or hearing impaired. Similar notification systems around the country could be used to push out information regarding locations and instructions for accessing emergency pharmaceuticals.
4. Public Health Seattle & King County’s [Community Resilience + Equity Program](#) and the Kentucky Department for Public Health’s [Kentucky Outreach and Information Network](#) are examples on how public health and community-based organizations can collaborate to provide emergency information to vulnerable populations.
5. The Fort Worth–Tarrant County Office of Emergency Management’s [Special Needs Assistance Program \(SNAP\)](#) is an online registry of residents with permanent disabilities who would require assistance during an emergency.
6. Cambridge Advanced Practice Center’s [Dispensing Site Signage and Pocket Translator](#) assists limited English proficiency clients through the four steps in the dispensing site.
7. The Minnesota Department of Health’s [Emergency and Community Health Outreach](#) provides health information on public television and rapid translation and dissemination of health and safety information during an emergency to low English proficiency populations.



10. The New Mexico Department of Health implemented a project on [Tribal Outreach for Pandemic Planning](#) to assist tribes with pandemic preparedness.
11. The Northeast Texas Public Health Department compiled a [video series](#) targeted to individuals with functional and access needs that local health departments may use at POD sites.
12. Alameda County Public Health offers translated [POD training videos](#) with closed captions for the hearing impaired.

#### **Steps to Implementation:**

- State and local accountabilities for assuring access and compliance associated with services to at-risk populations are the same during extended dispensing as during initial dispensing.
- State, territorial, and local health departments should review their current strategy for community engagement in emergency preparedness and planning and, if needed, incorporate whole community inclusion practices into their ongoing public health emergency preparedness and MCM dispensing programs.
- Incorporate ethical principles and community values into public health emergency preparedness strategies.
- Build community partnerships to support health preparedness planning and response efforts by involving representatives of special needs populations.
- Engage with community organizations to foster public health, medical, and mental or behavioral health social networks.
- Identify and map vulnerable and at-risk populations in the jurisdiction. This will also help determine the most appropriate MCM for an individual.
- Issue public information alerts, warnings, and notifications in accessible formats.

#### **Opportunities for State and Local Health Departments:**

- State and local health departments will be able to build relationships with impacted communities, develop MCM dispensing strategies to meet the unique needs of diverse communities, and create high-quality translations and messaging in alternate formats.

#### **Critical Points for Plan Improvement:**

- Health departments must collaboratively design and implement targeted, long-term dispensing strategies that work for diverse populations. There is no one-size-fits-all solution.
- Health departments must address multiple vulnerabilities simultaneously for any given event.
- Practices must be evaluated to determine if they are achieving the desired results.
- Circumstances such as low literacy, limited English proficiency, and poor health literacy will interfere with certain populations' access to and compliance with MCM dispensing or prophylaxis strategies. Health departments will need to make significant investments to communicate in accessible formats since they are time-intensive and expensive, especially during fast-moving events.

#### **Additional Resources:**

1. [NACCHO Toolbox](#).
2. [Enhancing Public Health Emergency Preparedness for Special Needs Populations: A Toolkit for State and Local Planning and Response](#) (RAND Corporation).

3. [CDC DSNS](#) and [CDC Office of Public Health Preparedness and Response \(OPHPR\)](#) websites.
4. [National Health Security Strategy](#).
5. [PHEP Community Preparedness Capability](#).
6. [CDC/DSL R On-TRAC System](#).
7. [CDC MCM Operational Readiness Review](#).

## Roles of health departments and partners.

### **Assumptions:** (*“Overarching Assumptions” and “Additional Overarching Assumptions,” Appendix 2*)

- Facilities designated for POD or distribution operations may not be available for the entire length of a sustained campaign.
- Hours of operation for the PODs may need to be adjusted based on staffing availability and flow throughput patterns.
- The traditional non-medical model POD will need to be adapted to a hybrid medical or non-medical POD where residents will receive the next 50-day PEP and the anthrax vaccine.
- New forms will need to be utilized in place of the head of household forms for every affected individual receiving the 50-day PEP and the anthrax vaccine. Children receiving the anthrax vaccine will need informed consent prior to receiving the first dose.
  - Not all jurisdictions will utilize the anthrax vaccine, and not all exposed will be recommended to receive the anthrax vaccine.
- Anthrax vaccine may be in limited supply and require development of a prioritization strategy.
- 50-day PEP may arrive in 50-day unit of use bottles or other configurations. Anthrax vaccine will arrive in multi-dose vials.
- Anthrax vaccine will need to be administered in a three-dose schedule at weeks zero, two, and four.
- Anticipated anthrax vaccine first dose (week zero) will be provided to a larger percentage of the population until the target area of the exposure is narrowed.

### **Description:**

In long-term MCM distribution and dispensing operations, identifying and implementing various planning considerations are paramount to a successful mission. Epidemiological investigation and identification of target areas affected by anthrax will be required to narrow the exposed population. Health departments will need to identify space and allocation needs for RSS or LDS facilities, including cold-chain storage accommodations. They will also need to determine POD clinic location availability, recognizing the possibility of standing up and demobilizing multiple times over the 60 days. Alternate vaccination clinic locations for anthrax vaccine doses two and three (week two and week four) should be taken into consideration. It is also important to identify all necessary vaccination administration supplies (e.g., needles, syringes, alcohol swabs) and establish the total number of staff and volunteers required to run dual dispensing or vaccination clinics. Tracking of vaccination records will be critical and can be facilitated by using DSNS vaccination cards sent along with the anthrax vaccine.

Other key elements to consider are public information and messaging campaigns (including use of call centers) for dispensing and vaccination requirements, MCM compliance, and adverse event reporting. Waivers or other procedures may be needed for the rapid vaccination of a large percentage of the population, as well as for dispensing operations that extend beyond the Public Readiness and Emergency Preparedness (PREP) Act declaration. Procedures should be implemented for the pick-up or redistribution of medication and vaccines from closed POD sites, hospitals, etc. It is also critical for health departments to have continuity plans and procedures to maintain essential functions.

### **Promising Practices:**

1. [Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness, Version 11](#). This CDC guidance document describes space allocation needs for receiving and storing the 50-day MCM allotment and contains guidance on conducting a sustained dispensing operation.
2. [The 49th Hour: Analysis of a Follow-up Medication and Vaccine Dispensing Field Test](#). This paper evaluates the dual model POD (dispensing and vaccination clinic) and identifies staffing considerations.
3. [Flu on Call](#), formerly known as the Nurse Triage Line, is a joint initiative between CDC, NACCHO, ASTHO, and several local jurisdictions to establish a national network of triage lines to use during a severe pandemic. It has the potential for use in medical screening and dispensing settings where staffing is limited.
4. Developed by the Johnson County Health Department in Kansas, [Dispense Assist](#) is a Web-based screening tool that could be used where licensed medical staff is limited. Several local and state health departments have used this model successfully in a variety of exercises and events.
5. LHDs that responded to the H1N1 mass prophylaxis campaign have experience in second-dose vaccination campaigns and re-allocating antivirals and vaccine during a long-term event.

### **Steps to Implementation:**

- Convene meetings with laboratories, epidemiologists, environmental health staff, state or federal EPA, and other subject matter experts to develop processes and procedures for conducting epidemiological investigations relative to an anthrax release.
- Ensure alignment of sustained dispensing operational plans between state and local health departments.
- Convene key stakeholder meetings to evaluate mass dispensing and vaccination plans to identify planning considerations for transitioning from non-medical PODs to medical PODs. Include state and local health department staff, department of public works, local police department, local emergency management director, distribution and receiving site staff, etc.
- Identify staffing and space requirements using modeling software like [RealOpt](#).
- Consider establishing relationships with primary care physicians, pharmacies, or other non-traditional medical providers who can assist in a long-term dispensing operation or provide MCM to the affected population.

### **Opportunities for State and Local Health Departments:**

- Reviewing existing mass dispensing and distribution site plans for long-term dispensing and vaccination needs will allow for a critical evaluation of gaps and new partnership opportunities.
- Utilize existing tools (e.g., CDC's MCM Operational Readiness Review), guidance documents, conversations, and conferences to reconsider the planning needs for a sustained dispensing operation.

**Critical Points for Plan Improvement:**

- Many elements of a long-term dispensing campaign remain uncertain, particularly regarding vaccination dosage requirements and target area identification. It is important to have flexible and scalable plans that are consistently revised to reflect new federal or state guidance changes.
- Ensure that the planning cycle continues after every critical change in the plans (train, exercise, evaluate, revise, etc.).

**Additional Resources:**

1. [NACCHO Toolbox](#).
2. [ASTHO Preparedness Resource Website](#).
3. [CDC Office of Public Health Preparedness and Response Website](#).
4. [CDC MCM Operational Readiness Review Guidance](#).
5. [CDC Clinical Framework and MCM Use During an Anthrax Mass-Casualty Incident](#).

## Conclusion and Next Steps

This document provides a snapshot of how health departments across the country are approaching an extended MCM dispensing campaign. However, many unanswered questions remain. State and local health departments must continue to develop plans and strategies addressing the challenges that are likely to arise during and after an extended MCM dispensing operation. By sharing and leveraging best practices, state and local health departments will be able to more rapidly and effectively develop and refine strategies tailored for their jurisdictions' unique characteristics and capabilities.

The workgroup's consensus is that conducting two mass dispensing campaigns—for the initial 10-day antibiotic course and then for a follow-on 50-day antibiotic course, as well as simultaneously managing a mass vaccination campaign—will overburden some health departments and limit their ability to deploy resources effectively.

The workgroup expressed concerns that epidemiological investigations, no matter how ambitious, will be slowed significantly by the resource challenges that will likely occur. The epidemiological investigations following an anthrax incident will most likely not have progressed adequately by day eight after exposure (the day long-term dispensing operations must be initiated), making it difficult to narrow down the affected population and resulting in a large number of residents who must receive the follow-on 50 prophylactic course.

Given these assumptions, the working group recommends that all MCM stakeholders in an anthrax response (federal, state, local, and tribal jurisdictions) expand the current SNS Courses of Action (COAs). The expanded COA would provide an additional option, one that supports the dispensing of a single 60-day course of prophylactic antibiotics rather than the current split course (i.e., both initial 10-day and follow-on of 50-day).

The development of this alternative COA for dispensing a single 60-day course of medication will not eliminate or replace the current COAs, but will instead provide an alternative when situational analysis reveals a single MCM dispensing to be the most judicious use of resources. In situations where the epidemiological investigation provides a reasonable expectation that the exposed population will be significantly narrowed by day eight following detection, the current COA remains a viable option for jurisdictions responding to an anthrax attack. As part of the development of this additional COA, the CDC would adjust its guidance documentation appropriately to reflect this change. Ultimately, selecting the appropriate COA for a given incident will be based on information available at the time of the event and the capabilities of the responding agencies.

### Next Steps

The workgroup will regularly provide updates as ASTHO and NACCHO develop and refine sections of this document not addressed in this first version. The workgroup will also make revisions to this document upon the release of official guidance and information relevant to the extended MCM dispensing concept. New plans, pertinent examples, and best practices will be added as they become available. If you would like to share information and resources on long-term MCM planning or would like to help develop future versions of this document, please contact either Raymond Puerini ([rpuerini@naccho.org](mailto:rpuerini@naccho.org)) or Neyling Fajardo ([nfajardo@astho.org](mailto:nfajardo@astho.org)).

## Appendix 1: Initial Topic Areas for Development

*The following topics were among those included in the needs assessment survey and available for development for the ASTHO/NACCHO distribution and dispensing workgroup to select for inclusion in this document. Topics highlighted in green were included in this version of the guide. Topics that were not highlighted may be addressed in future versions of this guide.*

| Distribution Topic Areas   |
|--|
| 1. Developing prioritization strategy for scarce resources (allocation of MCM that supports ethical access).*                |
| 2. Maintaining routine essential functions.  |
| 3. Supporting MCM requirements of open and closed PODs for antibiotics and vaccines.   |
| 4. Operationalizing the receiving sites, with employment of effective staffing, equipment, and cold-chain support (vaccine). |
| 5. Employing an effective inventory management system.   |
| 6. Supporting treatment-related MCM requirements of hospitals and other impacted sites.                                      |
| 7. Identifying adequate security resources for facilities and delivery vehicles.   |
| 8. Identifying adequate delivery vehicles and drivers.   |
| 9. Identifying adequate receiving sites.   |
| 10. Requesting MCMs for long-term response.  |
| 11. Communication with SNS about the status of supply deliveries to RSS warehouses (after the SNS request).                  |

\*This topic was combined with dispensing topic 4.

| Dispensing Topic Areas   |
|--|
| 1. Operationalizing the POD sites, with employment of adequate staffing.   |
| 2. Employing an effective client tracking system and maintaining a backup.*  |
| 3. Identifying adequate medication, vaccination supplies, and other needed resources to continue and sustain operation of PODs.                      |
| 4. Developing dispensing and vaccination strategies prioritization strategies for scarce resources (allocation of MCM that supports ethical access). |
| 5. Tracking adverse events for serious reactions to the antibiotics or the vaccine.  |
| 6. Providing effective public messaging to ensure that a full 60-day course and three shot series of vaccine are taken.                              |
| 7. Identifying effective security resources for facilities and staff escort (if needed).   |
| 8. Maintaining traffic flow and public transportation to facilitate access to PODs.  |
| 9. Providing effective pill-crushing procedures by parents and guardians.  |
| 10. Identifying adequate POD sites (e.g., open PODs, closed PODs, etc.).   |

\*Inadequate information was available to the workgroup for the development of a thorough report on this topic.

| Cross-Cutting Topic Areas  |
|--|
| 1. Activation timeline.  |
| 2. Epidemiological and environmental investigation for follow-up population refinement. *  |
| 3. Vulnerable populations (pediatrics, pregnant, kidney or liver issues, those with contraindications, functional and access needs populations). |
| 4. Roles of health departments and partners.   |
| 5. Laboratory services (antibiotic sensitivity and follow-up healthcare services).   |
| 6. Planning assumptions.   |
| 7. Continuity of operations and essential function planning.   |

\*Inadequate information was available to the workgroup for the development of a thorough report on this topic.



## Appendix 2: Additional Overarching Assumptions

***Disclaimer: Note that assumptions listed in this document represent a sampling that may be relevant for any particular jurisdiction. Some assumptions listed may not be relevant depending on each jurisdiction's capacity and capabilities. Jurisdictions should assess if the assumptions are valid for their particular jurisdiction on an individual basis as they work through their long-term planning efforts.***

### **Initial and Sustained Response Assumptions:**

1. State and federal emergency declarations would be declared immediately, thereby lessening concerns associated with funding, staffing, and logistics.
2. MCMs will be provided as prophylactic interventions to the entire population of potentially exposed persons who have not yet become ill with inhalation anthrax.
3. Distribution and dispensing operations have severely stressed personnel and response resources during the initial days of this prophylaxis campaign, which will continue as an issue throughout the response.
4. Some MCM resources may be available in the quantities needed for the response (i.e., 10- and 50-day, unit-of-use, antibiotic courses [e.g. doxycycline and ciprofloxacin], and intravenous antibiotics).
5. Some MCM resources, including 10- and 50-day unit-of-use antibiotic courses of amoxicillin, pediatric formulations of antibiotic courses, anthrax antitoxins, and anthrax vaccine may be in limited supply depending on the size of the response.
6. Vaccine administration supplies, including syringes and needles, may be in limited supply depending on the size of the response.
7. Pediatric formulations or suspensions of antibiotics are available in limited supply; however, pill crushing instructions for some antibiotics will also be distributed.
8. Requests will be made for additional amoxicillin for patients with adverse reactions to doxycycline and ciprofloxacin; however, the available supply may not be adequate to meet the need.
9. CDC will begin to distribute MCM assets to RSS warehouse locations within a few hours of approved requests.
10. Prior to the submission of requests to CDC, each impacted state will have reached an agreement with local health departments (if any) and local response jurisdictions regarding MCM items and quantities needed in the request.
11. The DSNS may ship antibiotics that are labeled as expired, but DSNS will coordinate with FDA to ensure that they do not ship anything to states that cannot be dispensed during the current response. The DSNS and/or FDA will specify if any of the inventory can only be used under restricted conditions, such as EUA or Investigation New Drug protocol.
12. Various combinations of MCM will need to be processed and redistributed, not only to existing PODs, but also to clinics, hospitals, and other healthcare facilities.
13. There is very large demand by hospitals for treatment-related MCMs, which stresses MCM distribution processes due to the increased complexity of these site-specific orders as compared to those of PODs.

14. Clinical staff available for POD site operation is limited due to surge needs at healthcare facilities.
15. All aspects of the response are operating under NIMS and impacted public jurisdictions have organized using the ICS.
16. The National Guard and each state's reserve troops will be made available to augment operations, security, and logistics, if needed; however, these resources must be requested well in advance and according to the established activation procedures of each state.
17. RSS/RDS/LDS (local distribution site) warehouse and POD staff will receive training necessary to conduct response operations.
18. Mechanisms are established to provide responders, operational staff, and essential personnel with MCM in conjunction with their participation in support of the response.
19. Demobilization activities will occur throughout the entire event and would occur in stages.
20. There will be additional demand for antibiotics and vaccines from the "worried-well" and residents of non-impacted jurisdictions even though they were NOT in an area of exposure.
21. There will be additional demand for treatment at healthcare facilities from the "worried-well" even though they have NOT contracted the illness.
22. In the event of an anthrax attack affecting multiple jurisdictions in the state, the state may deploy only a portion of the incoming MCM to each local health department (e.g., single RSS warehouse or multiple RDS/LDS warehouses model); however, if an incident is limited to one local health department, then upon the request of the state, the CDC may deploy the antibiotics and vaccines directly to the area if local warehouse capacity exists (e.g., single warehouse).
23. Anthrax MCM will, in almost every instance, be delivered to a pre-designated RSS/RDS warehouse facility. Rare exceptions include: CDC's plan for shipment of antitoxins directly to healthcare facilities where seriously ill/symptomatic patients with inhalation anthrax will be treated. This healthcare facility can also serve as the coordinating hub for other hospitals and redistribute MCMs as required.
24. The necessary command, control, and communication channels have been established between impacted local, state, and federal public health, emergency management, healthcare, law enforcement, government, and other supporting community agencies and partners.
25. A resource management system has been established between the EOC and DOC which is coordinating MCM allocations, the RSS/RDS warehouse and distribution centers, as well as the customer sites, which include PODs and treatment centers (e.g., hospitals, clinics).
26. When provision of 50-day courses of antibiotics begins, provision of 10-day courses of antibiotics is still underway but at a reduced level, and persons receiving antibiotics for the first time will receive both a 10-day and a 50-day course at that time.
27. For large states, this incident may not directly impact most of the geographic area of that state and other parts of the United States are not expected to be directly impacted; therefore, some significant mutual aid from other areas of the country can be available for actual commitments to local missions.

### **Sustained Response Only Assumptions:**

1. By day 10, epidemiologic investigation will not be completed. The target area or exposed individuals will not be fully identified by the time sustained operations commences.
2. States and local health departments will have verified that they have contracted for enough warehousing and trucking capacity to account for both the larger volume of materials represented by 50-day courses of antibiotics (versus 10-day courses of antibiotics) and the expanding demands for MCM related to treatment.
3. MCMs for the sustained response will begin to be delivered from the RSS warehouse to local PODs within 1–7 days following the initial request but at least by day eight of the initial dispensing campaign to prevent lapses in prophylactic courses.
4. Vaccination sites may or may not be the same as the PODs for oral dispensing.
5. Staffing shortages will be expected, especially after the initial campaign and resource support would be requested through mutual aid and escalated to the state and federal levels.
6. The CDC has the capability and experience, if requested by state or local health departments, to employ direct shipment of vaccine to pharmacies and primary care providers during the second (week 2) and third (week 4) dosing phase of anthrax vaccine, similar to their strategy during the H1N1 response.
7. State and local jurisdictions may choose to implement direct shipments to reduce staffing and logistic concerns at the RSS warehouse.
8. During the long-term MCM response to an anthrax incident, MCM for support of both the treatment and prophylaxis missions will primarily come from managed inventory, and not from the delivery of a 12-hour push package.

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