Extended Distribution and Dispensing Campaign for Anthrax Scenario

An ASTHO and NACCHO Collaboration
Association of State and Territorial Health Officials, Emergency Medical Countermeasure Steering Committee

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Introduction

Background:
For many years, the Strategic National Stockpile Program has focused on the planning and execution of post-exposure prophylaxis during the first 48 hours of an aerosolized anthrax incident. Through these years of growth through preparedness activities and real incidents more focus has been placed on the ‘sustained dispensing’ time period, i.e. the next 50 days. This would begin presumably on the third day, after the initial dispensing period.

The 48 hour window is an important window to provide prophylaxis to the entire population in efforts to minimize negative health effects. The initial regimen dispensed lasts for 10 days. This creates the need to dispense again or ‘sustained dispensing’ or ‘extended dispensing’.

States and locals have been seeking guidance to assist in the development of extended dispensing best practices, tools, or any information to help direct jurisdictional plans. An extended dispensing campaign will impact distribution and dispensing, and will have cross-cutting themes too.

Purpose:
This document seeks to identify topics and link current promising practices for distribution and mass dispensing operations for an extended 50-Day treatment following exposure to Bacillus Anthracis.

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

A survey was sent out to both NACCHO and ASTHO partners to identify topic areas. Through the survey, high priority topics relating to the extended dispensing anthrax scenario were identified. These topic areas were divided into distribution, dispensing and cross-cutting sections. ASTHO members were assigned to distribution topics, NACCHO members to dispensing, and both groups to the cross-cutting topics. The complete list of topics can be found in Appendix 1. A template of each topic area was created to have a consistent format across each subject. The headings include the description, promising practices, steps to implementation, opportunities for states and locals, critical points for plan implementation, and additional resources. More information can be found below:

<table>
<thead>
<tr>
<th>Topic Headings</th>
<th>Brief Explanation</th>
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<tr>
<td>Description</td>
<td>The topic specifically applies to the post 48 hours timeframe of an anthrax incident.</td>
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<td>Promising Practices</td>
<td>Identifies existing examples of state/locals that have developed or implemented plans addressing this topic.</td>
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Steps to Implementation

Addresses actions necessary to implement promising practice, including proposed partners, staff, and other assets/equipment.

Opportunities for States and Locals

Assets that are unique to states and locals, partnerships that can be formed at state/local level, any additional planning or assessments that could potentially be conducted to gather more information to assist in this topic area.

Critical Points for Plan Improvement

Addresses significant barriers and/or current gaps of information.

The information provided in each topic area is based on current documents including Emergency Use Authorization (EUA) and Emergency Use Instructions (EUI) information, state and local plans, and federal and state legislation. Additional resources used are listed under each topic.

Overarching Assumptions:
Due to the unknowns of this timeframe of this type of incident, numerous assumptions are necessary to craft this document. While based on prior planning, training, and exercising, it is important to note these are assumptions of one particular development of an anthrax attack scenario. It is difficult to wrap one’s mind over all of the potential challenges that may occur, however this is a starting point to for those discussions.

Disclaimer: Note that assumptions listed in this document represent a sampling of assumptions 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 own long-term planning efforts.

Below are the overarching assumptions for the document, provided in a scenario-based description; setting the stage for all the sub-topic sections. Each sub-topic may have additional assumptions included in its section. Additional relevant overarching assumptions can be found in Appendix 1. Below are a summary of the most important overarching assumptions used for the creation of this document:

- After the detection of bioterrorism agents, the decision was made to provide MCM to entire populations of potentially exposed persons. Initial mass prophylaxis with 10-day regimens of antibiotics was successfully initiated and is still underway, but at a reduced level due to earlier successes. However, 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 regimens and vaccines) are available and CDC will deliver these MCM assets to project areas, within a few hours of approved requests.
- 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.
Within the first few days, or at least by the end of the first week of the response, the following types of MCM (some of which require cold chain storage) will begin to arrive in very large quantities:
  - Intravenous antimicrobials
  - 50-day supply, unit of use (regimen), antibiotics (e.g., doxycycline, ciprofloxacin, amoxicillin including pediatric dosage forms)
  - Anthrax Vaccine Absorbed (AVA)

Various combinations of the above MCM will need to be processed and redistributed, not only to existing PODs but also to clinics, hospitals, and other health care facilities.

Each state and local jurisdiction will have a varying amount of resources that will either enable or hinder the operation.

It can be assumed that only one MSA is directly affected by this bioterrorism attack.

Considering the above listed assumptions, it is clearly going to be a challenge to sustain operations at distribution sites (i.e., RSS/RDS warehouses). The challenges of this activation timeline, then will be to continue and expand operations at PODs, including not only dispensing oral dosage forms but also administering AVA. Vaccination sites for the public may or may not be the same as the PODs for oral dispensing; however, it is certain that the efficiencies of the head-of-household model for dispensing of oral antibiotics cannot be applied to the administration of vaccinations.
Distribution Topics

1. Maintaining Routine Essential Functions

Assumptions: *(note- these may already be elsewhere or could be shifted to the overall assumption area)*

Description:
Maintaining routine essential functions, following an anthrax attack and throughout the execution of activities associated with long-term medical countermeasure (MCM) distribution and dispensing, will be vital to the success of any response. Historically, it has been evident that efforts, attention, and resources often wain in the days and weeks following an event or incident, and those days and weeks following the event are exactly when both long-term distribution as well as multi-focused dispensing and vaccination efforts will be needed. Additionally, as a response continues, those routine and important, but not absolutely essential, functions that may have been discontinued in the short term will have to be resumed within the period of the long-term effort. Beyond the staff gains afforded through the suspension of non-essential services under COOP, the general use of 12-hour shifts and strict limitations on time off will both allow for an additional surge in available personnel resources from within local agencies. However, there will be a limit to the length of time during which staff will be able to operate effectively under these severe constraints on their scheduled down-time and this limit is sure to be reached well ahead of the end of the 60-Day period.

Pre-identified essential functions, mitigating staff burnout, and training and exercising the COOP plan are important in maintaining routine essential functions.

Promising Practices:

1. Robust and empowered Continuity of Operations Planning (COOP) at the federal, state, and local levels are a known promising practice. In addition to planning, annual review and exercising of plan elements, previous improvement items, and recovery activities allow all levels to ensure adequate resources (or the knowledge of shortcomings) to maintain essential functions.

2. COOP plans should identify the essential functions of the agency and what personnel support is needed. FEMA provides good instructions on this subtopic. The key item is that these essential functions are determined prior to an incident and approved by executive leadership.

3. In order to obtain the supplemental personnel resources required to continue, and even expand the level of response due to two forms of PODs (dispensing and vaccination) as well as increased medical demand, it will be necessary to effectively engage mutual aid. Two considerations that should be at the forefront of this strategy’s implementation are: (A) the rapid identification of the activities that are critical to the response but are most commonly performed by other types of professionals (e.g., MCM warehouse and delivery operations), and (B) timely submission of requests through the NIMS protocols for appropriate levels of outside assistance from mutual aid sources.
4. Given the potential traffic congestion of people traveling to PODs, implementing a telework system for staff could be productive. This system would allow staff to continue to work while mitigating direct risk to them and slowing down response operations. This could not be done for all programs.

**Steps to Implementation:**
Priority needs to be placed at all levels, including federal, state, and local, on continuity planning and the maintenance of essential function planning and COOP implementation. Leadership direction is important to identify essential functions and to understand when to implement COOP.

**Opportunities for States and Locals:**
Continuity planning and the maintenance of essential functions will have a profound overarching impact on all-hazards planning and response. States and locals should have a regular exercise schedule. Adding objectives to a MCM exercise such as the decision point to activate COOP plans or to assist with determining what essential functions are necessary in an anthrax attack, could bring to light the importance of determining COOP factors prior to an incident.

**Critical Points for Plan Improvement:**
During a mass dispensing campaign, a business or agency will most likely see a reduction of staff. This could be for a number of reasons including becoming ill. The result is a dramatic shift from normal operations to COOP. For large agencies that have not determined what operations must continue through disaster, another disaster is looming.

**Additional Resources:**

1. FEMA Continuity of Operations

2. FEMA Non Federal Continuity Plan Template and Instructions
   a. [https://www.fema.gov/planning-templates](https://www.fema.gov/planning-templates)
2. Supporting MCM requirements of Open and Closed PODs for antibiotics and vaccines

**Assumptions:** *No additional*

**Description:**
The primary area of focus for this document is MCM delivery responsibilities of States and Locals, which are required to complete all redistribution activities, including the “last mile”, as necessary to provide MCM to their dispensing sites, especially Open and Closed PODs.

The continuation of the MCM distribution response efforts (e.g., RSS/RDS warehouse and MCM delivery) to support the dispensing of the 11-50 day supply of antibiotics and the administration of multi-dose anthrax vaccine will require increased complexity of the MCM-related “customer” services performed by all participating jurisdictions in order to meet the urgent MCM needs of both Open and Closed PODs. As with any multi-jurisdictional, emergency response, in which time is a critical factor to success, the first two requirements are for the effective employment of coordination and information sharing systems, which support timely, complete, cross-jurisdictional, situation awareness and resource management processes.

Through the use of ICS structures and integrated communications systems, which were initiated most likely within the first day of the response, jurisdictions will have been supporting the requirements for situational awareness and resource management for several days. Of necessity, the extremely critical time constraints associated with the need to dispense the 10-day regimens of antibiotics to the jurisdiction’s entire population within 48 hours of the decision to activate the mass prophylaxis intervention will have required the adoption of some logistics shortcuts and system work-arounds. Often, these same moment-of-need shortcuts and/or system work-arounds, which allowed some early resource management successes (e.g., an initial push of fixed MCM amounts to all Open PODs), will not prove to be as appropriate for the long term (e.g., Post-Day-3 or 4). By Day-5, logistical response strategies should have transitioned from a bottom-line theme of “make it happen, on time, by any means available” to an improved theme of “make it happen, on time, and as effectively as possible”. Examples include the initial use of persons in positions that were not fully matched with skill sets (e.g., training and experience), and use of mismatched trucks or non-optimized delivery routes for MCM (e.g., Skipped use of TourSolver).

This transition toward logistical effectiveness is essential because, by Day-5, it is recommended that the required, next-phase, MCM assets (e.g., 50-day antibiotics; vaccines; needles/syringes) begin to arrive at the State’s RSS Warehouse in response to requests from LHJs. This time estimate for the commencement of next-phase, MCM deliveries at Day-5 is based on the projected need for LHJs to commence their second-round dispensing (11-50 day regimens) and administration of the first course of the multi-dose anthrax vaccine by approximately Day-7.

Therefore, as the level of the response intensifies through the addition of new intervention strategies (e.g., vaccination) and products (e.g., 50-day antibiotic regimens, vaccines and vaccination supplies), it will become increasingly critical that all involved government entities are able to effectively employ the policies and procedures of NIMS, while utilizing the most suitable organizational structure and principles of ICS. The effective application of these structures and systems will be crucial to resource management,
as well as the integration of the command and control functions, including support of a robust tactical communications system.

It is critical to preplan as much as possible, have employees with warehouse and logistics experience at the warehouse, access to ample and diverse transportation assets, and leverage the existing supply chain as available.

Best Practices:

1. Los Angeles County (LAC) DPH approached their FSE requirement with the assumption that the timeline for MCMDD of the 10-day regimens of antibiotics was too critically short to allow for moment-of-need development of an Incident Action Plan (IAP) and associated anthrax response strategies. Therefore, they pre-developed an IAP template for each of the two operational periods (OP) of the first 48 hours of their response. Later, at the onset of a response and through the use of immediately available incident specifics, the IAP for the first and second 24-hour OP can be modified, while changing as little as possible, and these preplanned MCMDD strategies can be rapidly implemented. Develop IAP templates for the first OP of the next-phase MCM response.

2. LAC DPH approached their MCM Distribution requirement with the assumption that the complexity of the logistical components of the RSS/RDS warehouse and the associated MCM delivery operations for the anthrax attack scenario were not within the traditional skill sets of a sufficient number of Public Health employees and therefore outside assistance was needed. Fortunately, the County’s Fire Department maintains three Type-3 Incident Management Teams (IMTs), which are each very skilled at coordinating all of the operational and logistical operations associated with fighting very large wildlands fires. Additionally, members of these IMTs have previously been deployed to Florida to manage commodity distribution warehouse and delivery operations for a state-wide hurricane response. In order to prepare these IMTs for an MCM distribution role, the IMT members were trained and exercised (TTX and FSE) in the activities required to support RSS/RDS warehouse and MCM delivery operations. Additionally, during these preparedness activities, Fire Camp Crews which consist of approximately 14 individuals, were identified as an excellent resource to supplement staff involved in the RSS/RDS warehouse floor operations. These crews are rapidly available, physically fit, practiced at performing within operations that require them to function as part of a team, and a couple of participants on each crew are certified fork lift drivers.

3. LAC DPH approached their MCM Distribution requirement for acquisition of delivery trucks and truck drivers, as well as for supplemental warehouse staff, with the assumption that privately contracted resources would be essential. LAC DPH pre-identified the companies, which would likely be included among those initially solicited for these moment-of-need contracts. Currently, LAC DPH has individual MOU’s with five vendors who are in the trucking business, generally. Additionally, LAC DPH has incorporated into their MCM distribution strategy procedures for acquiring these types of resources and/or services from any of the eleven vendors, which are pre-vetted as candidate companies for periodic County contracts related to moving and storage services under terms of an on-going Master Services Agreement (MSA). These MOU’s and the above MSA have been used to solicit and award MCMDD contracts.
4. LAC DPH approached their MCM Distribution requirement for support of deliveries to approximately 500 skilled nursing and assisted living facilities, which would be the greatest portion of their Closed PODs, with the assumption that support from privately contracted resources would be essential. LAC DPH pre-identified the pharmaceutical supply companies, which will be solicited for these moment-of-need contracts and initiated MOU’s. Currently, LAC DPH has individual MOU’s with three vendors who are in the pharmaceutical supply business and these three companies collectively deliver medications to most of the 500 sites on a day-to-day basis. The plan calls for one or more of these vendors to receive bulk deliveries of the antibiotics and to then use their existing pharmaceutical warehouse and delivery operations to redistribute MCM for the resident populations, as well as their respective staff and staff’s families. As part of their day-to-day activities related to facilities’ inspections for code compliance, LAC DPH maintains an up to date database that covers the majority of these facilities.

Promising Practices:
- None identified at the moment

Steps to Implementation:
- Through exercises, evaluate MCMDD response capabilities and identify resource gaps
- Analyze the above list of Promising Practices/Best Practices, to determine if any are appropriate solutions to address the identified gap(s)
- Identify the actions and partners, which would be required for each selected practice
- Engage partners and agency staff needed to collectively implement each selected practice
- Train and exercise the revised procedures, and then adjust the procedures, as necessary

Opportunities for States and Locals:
The PHEP grant requirements of full scale (FS) MCMDD exercises for each of the CRI jurisdictions, within the 5-year grant cycle, have greatly enhanced the ability of jurisdictions 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 FS exercises, as completed by multiple MSA’s, can be gleaned for best and promising practices that will serve as a foundation for preparedness to sustain (11-60 day timeframe) operations.

By planning for and exercising MCM distribution capabilities to support the resource requirements of their Open and Closed PODs during the initial 10-day dispensing requirement, LHDs will have gained a sound understanding of how to manage the flow of MCM between critical points of the MCM supply chain during their initial response to an anthrax event. The capacity for onsite training of response staff and the ability to process scalable numbers of people, with only short notice, are translatable skills that are crucial to the long-term response.

Critical Points for Plan Improvement:
Pre-identify and hold advance discussions with potential private vendors for contracted resources and services, as well as with public partners and local military commands regarding the potential for their
support through mutual aid. Information from this planning process should be included in the jurisdiction’s MCM Plan. The documentation of potential partnerships through development of MOUs can be very beneficial. Also, procurement personnel should be trained and skilled in use of moment-of-need contracts.

Handoff from CDC to states and from states to LHDs.

Additional Resources:
None
3. Operationalizing the Receiving Sites, with employment of effective staffing, equipment,
and cold-chain management (vaccine)

Assumptions: (List any assumptions that are specific to this topic)

- State and Federal emergency declarations would be declared immediately; thereby lessening
  funding, staffing, and logistics concerns.
- The CDC may authorize direct shipments of vaccine to pharmacies and primary care providers
during the second (day 32) and third (day 46) dosing phase of anthrax vaccine, similar to their
strategy during the H1N1 response. State and local jurisdictions may choose to implement
direct shipments to reduce staffing, and logistic concerns at the RSS.
- Every RSS/RDS/LDS is capable of having enough staffing, by the time of the receipt of 50-day
regimens of antibiotics and vaccine related MCM, to meet the MCM Distribution needs (population)
of their respective jurisdiction.
- Staff either will be pre-trained or can be sufficiently trained on cold chain management
standards.
- The CDC shipped enough 50-day regimens of antibiotics (i.e., ciprofloxacin and doxycycline) for
the entire population affected.
- The CDC shipped enough vaccine for the entire population affected, which may not be possible
but is assumed for planning purposes on this topic and various allocation strategies for vaccine
shortages will be addressed by other topics.
- Transitioning from the initial distribution plan to the extended plan is executed by day five of
the initial response.
- Medical staff are on hand to provide vaccine for newly arriving staff (e.g., first responders,
state/local staff, guard and reserve troops, etc.) prior to their participation as MCM distribution
responders to the event.
- Guard and reserve troops will be made available to augment distribution, security and logistics,
if needed; however, these resources must be requested well in advance.
- Demobilization would likely occur slowly throughout the entire event and would occur in stages.
- Requests will be made for additional Amoxicillin for patients with adverse reactions; however,
the available supply will not be adequate to meet the need.

Description:
The processes and resource requirements for extending MCM distribution from only the 10-day
regimens of antibiotics to include both the 50-day regimens and the vaccine related MCM assets should
remain relatively similar to the operational needs already in place in each jurisdiction with the addition
of cold chain management. CDC’s cold chain management guidelines are available and should be
followed (www.cdc.gov/mmwr/preview/mmwrhtml/mm5242a6.htm).

Three areas of additional MCM Distribution burden for these later activities are as follows:

1. The number of unique MCM items that are being processed and tracked by the RSS/ RDS/LDS
and MCM delivery operations will increase (e.g., receipt, store, pick, ship, and deliver), due to:
(A) the addition of multiple new antibiotic types and packaging (see #3, below); (B) new supply
requirements to support the vaccination campaign; and (C) an ongoing increase in MCM
requests associated with the simultaneous demands for treatment-related products associated
with anthrax, reactions to the antibiotics, and other
2. The RSS/RDS/LDS operation will become more complex as personnel and systems are required to support these: (A) additional numbers of unique items; (B) associated increases in storage options; as well as (C) fulfillment of more complex orders (e.g., item and quantity variations) to meet the specific MCM needs of an expanded variety of “customers”

3. The volume and packaging configuration of the ciprofloxacin will increase, because 100 tablet regimens require larger bottles than the 20 tablet regimens. Instead of 100 bottles per case and 96 cases per pallet (or 9,600 bottles), the 50-day regimens will likely arrive in 144 bottles per case and 36 cases per pallet (or 5,184 bottles). This 85% increase in the number of pallets for the 50-day regimen, as opposed to the same number of 10-day regimens of this single antibiotic, will result in an increase in the requirements for storage space. Transportation assets and warehouse staffing could create additional concerns during the extended operation. Personal safety is always a concern, the additional vehicle traffic coming in and going out could create some congestion. (Note: The doxycycline can still be packaged 110/case, 9,600/pallet.)

Promising Practices:

1. Determine the pediatric population needs for both initial and extended distribution/dispensing through the use of GIS mapping and weight criteria.
2. Information sharing/Inventory management (WEBEOC) Intermedix Corp. is developing a two phase inventory management database for Missouri. Phase 1 provides tracking for equipment and response trailers using WEBEOC boards and Phase 2 provides tracking for MCM from the Push Package/Managed Inventory using additional boards.
3. Mobile cold chain storage trailers
4. Develop third party logistics contracts to assist during the entire distribution process.
5. INTEGRATION

Steps to Implementation:

- Conduct jurisdictional work group sessions to brainstorm the unfilled needs of existing plans, as well as appropriate solution sets that should be further evaluated.
- Conduct table top exercises to evaluate the processes, including these new solution sets.
- Conduct a full-scale, extended MCM distribution and dispensing exercise, as is required in each five year grant period.

Opportunities for States and Locals:
Implement an all hazard approach to the MCM/SNS program, which is going to take everyone’s support for this type of event to be successful, given the size and time limits.
Leverage existing partners.

Critical Points for Plan Improvement:

- Enough staff for a long term distribution campaign.
- Requesting additional treatment medication from the CDC to treat the 33% plus with adverse reactions to the MCMs. Who is going to be responsible?
- Requesting additional treatment medication from the CDC to treat the significant portion of the population who require medical care associated with the incident, including those who have contracted anthrax as well as others who will report to treatment sites for care
- Monitoring health and safety; provide medical and behavioral health services.
• PPE fit testing
• Medical clearing staff

Additional Resources:
Mobile refrigeration trailer units, page 42 of attachment #1
4. Employing an effective Inventory Management System

Assumptions:

Ahead of a response:

1) The Division of the Strategic National Stockpile (DSNS) of the CDC and States/Directly-Funded Cities (“States”) will have reached an agreement regarding which items the DSNS will provide, as well as the total quantities and expected arrival time of these quantities. Quantities requested and approved by CDC will likely be contingent on the national response scenario - anthrax attack.

2) Prior to the submission of requests to CDC, each impacted State will have reached an agreement with Local Health Jurisdictions (LHJ) (if any) and/or local response jurisdictions regarding MCM items and quantities. Subsequent to the MCM request discussions between the State and CDC, any necessary adjustment(s) will be made based on results from 1) directly above.

3) The DSNS will have provided each receiving State with item information including: item #s, descriptions, units-of-measure (i.e. inner and case quantities), # of cases per pallet, and allowable temperature excursions.

4) States will advise the DSNS where deliveries are to be made, the contact for the RSS warehouse facility, and who is authorized to make/modify requests of the SNS.

5) States/Locals will have verified that they have contracted for enough warehousing and trucking capacity to account for the larger volume of materials represented by 50-day regimens of antibiotics (vs 10-day regimens), as well as the vaccines and associated vaccination supplies.

During a response:

1) Everything from the “Ahead of a response” section, which was previously resolved will require confirmation and open issues will require immediate resolution.

2) States will have on-demand access to an SNS system that includes records of the currently approved SNS requests for the State. This system’s records will also include information as to who made (or changed) the SNS request, and at what time. Additionally, the system will contain a phone # where State representatives can quickly receive and/or verify this information.

3) States will have on-demand access to a system that includes records of the Estimated Time of Arrival of trucks bound for the State’s RSS warehouse that already are, or will soon be, on-the-road. The system will provide access to details regarding the items and quantities on each truck. Preferably, there will also be a phone # where State representatives can quickly receive and/or verify this information.

4) Locals will have access from States to information as described in 2) and 3) directly above.

5) Drivers of DSNS contracted trucks will provide receiving staff at State warehouses with reports from temperature recording devices as they deliver antibiotics and vaccine.

6) The DSNS may ship antibiotics that are labeled as expired, but DSNS will not ship anything to States that cannot be dispensed during the current response. The DSNS will specify if any of the inventory with labeling that reflects a previous date can only be used under restricted conditions.
Description:
An Inventory Management System (IMS) must be used to track movements of medical countermeasures (MCM). At warehouses and dispensing sites, the activities of MCM movements during receipts, storage, and shipments/dispensing must be tracked in an IMS.

Promising Practices:
1) Make deliberate decisions about the redundancies of the network that the IMS will rely upon. Commit to the provision of redundant network capabilities and to protecting the IMS for ongoing use at the RSS/RDS/LDS warehouses. Set up backup networks (e.g., backup servers, backup connections to main and backup servers, spare hardware at warehouses, etc.) in advance of a response. Then, document procedures and test plans by switching back and forth between primary and backup networks. For dispensing sites, carefully develop very simple paper systems (or offline systems) for use in case networking systems are unavailable.

2) Assign responsibility for determining resupply requirements to a command center that directly oversees PODs (or other dispensing sites). Dispensing site staff generally will not have the time or skill set to make accurate and timely decisions about when to place resupply orders and how much MCM to order. Instead, focus on training staff, who will serve at dispensing sites, regarding the importance of providing command with timely reporting of dispensing throughput and supply receiving/inventory data.

3) Recycle unused 10-day regimens in the field to meet the dispensing needs for antibiotics for days 11-60. Where the dispensing site for days 1-10 will also be open for days 11-60 antibiotics, dispense five of the 10-day regimens using rubber bands or by overpack (e.g. put in a bag). Where a site is shutting down, perform reverse logistics to move excess antibiotics back to the warehouse so staff can overpack 10-day regimens as 50-day regimens. Adjust stock-on-hand records for the RSS Warehouse by decrementing the 10-day regimens and adding back the inventory to the IMS as 50-day regimens are created. These overpack regimens should be tracked in the IMS as a separate item # (from 50-day regimens received from the CDC). Once the additional antibiotics are repackaged, then process and track outbound shipments of these overpacked items in the IMS.

4) Tracking consumption of MCM at dispensing sites, it is not required that the IMS track specific item, quantity and lot # information to the level of individual clients. The tracking of individual antibiotic regimens and/or vaccine vials’ contents to the level of each individual recipient does not need to be tracked by the same IMS used for warehouse operations. This client tracking responsibility may be performed by an alternative means and/or system.

Steps to Implementation:
• Predetermine how Project Areas will report MCM inventory data to the CDC for both warehouses and dispensing sites (PODs, hospitals, etc.). Reporting inventory has been made easier for those health jurisdictions that have adopted IMATS; the CDC created Inventory Management And Tracking System (IMATS). However, all jurisdictions still face significant challenges associated with their capability to dynamically maintain inventory information for all their identified
dispensing sites. Additionally, those health jurisdictions, which have not adopted IMATS, should look carefully at how to automate the transfer of information from their respective IMS to meet the detailed technical requirements outlined by the CDC. Automation of this process (as much as is possible), will save much time/stress during days 11-60 given the large number of prophylaxis and treatment items involved.

- Create a process and corresponding report in the IMS to track actual inventory receipts against expected quantities requested from the DSNS/State.
- Pre-load item information in the IMS for items relevant to days 11-60.
- 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/confusion with the IMS.
- Pre-define outbound orders for the warehouse for orders to PODs, especially Open PODs, for days 11-60.
- Exercise material handling at the warehouse on a large scale. For days 11-60 items and orders, streamline both the physical and IMS processes as is necessary to allow completion of critical MCM distribution activities, while ensuring that physical and IMS processes remain in synch.
- Create detail and summary reports in the IMS for shipments that leave warehouses. To best support product recall efforts, detail reports should specify lot/expiry and all reports should indicate the dispensing site network to which a customer belongs (e.g. school ABC is a “Public POD”, which is also sometimes referred to as an “Open POD”).

Opportunities for States and Locals:

- None identified at the current time

Critical Points for Plan Improvement:

- Define a process for identifying temperature variation issues for inventory at receipt and during storage at the warehouse. A resolution process should include how to segregate this inventory in the IMS while the disposition of the inventory is being determined.
- Consult immunization staff about how best to pack vaccine bound for dispensing sites. Ask what packing supplies to use, what temperature indicators, and how to pack everything.
- Pre-identify suppliers and model #s for vaccine packing supplies (e.g., ice packs, vaccine containers, temperature indicators, etc.). Consider adding these items to the IMS and maybe even holding some inventory so LHJ’s are ready to start outbound vaccine packing operations.
- Locals should pre-train dispensing site staff regarding entries in the IMS for any inventory that is under quarantine/investigation, including when these restrictions/activities are in place due to temperature variation.

Additional Resources:

CDC Version 11
5. Supporting treatment-related MCM requirements of hospitals and other impacted sites

Assumptions:
- Competition of MCM needed at different sites
- Competition of transportation assets
- Hospitals do not participate in dispensing to the public

Description:
The distribution of MCM to hospitals may be underscored by the mass dispensing challenge. In an extended dispensing campaign, the hospital distribution may prove more challenging than distribution to PODs or other dispensing sites. Hospitals are most likely going to focus on treatment, not prophylaxis with the exception of their staff. This supply chain to keep the hospitals equipped with effective MCM for the treatment of anthrax is critical to save lives. If the normal supply chain is not able to support the hospitals treatments, requests would likely go through the RSS site. Since the hospitals are focused on treatment, timing of the delivery to meet the patients need will be challenging due to time constraints. Other clinical settings may have similar challenges such as long-term care, 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. Determination of an allocation strategy prior to the incident will assist in making difficult decision during an anthrax extended. Crisis Standards of Care would be a good resource to support allocation of treatment medication.

Promising Practices:
There are several promising practices used currently to keep the hospitals equipped with effective MCM. Below these practices are listed.
1. HPP Coalition partners utilize a warehouse (SETRAC)
2. Allocation strategy/model
3. Hospital Training & Exercising

Steps to Implementation:
- Create a list of all treatment facilities
- Determine the responsibility of hospitals and HPP
- Form an agreement (MOU or existing contract or existing legislature)
- Coordinate with hospitals for the allocation strategy and determine the mode of transportation
- Write a Concept of Operations
- Conduct training and exercise based on the CONOPS/Crisis Standard of Care

Opportunities for States and Locals:
States and locals can leverage the hospital coalitions to assist in planning activities and potentially operations too.

Critical Points for Plan Improvement:
At this time, it is unclear how the treatment products will be shipped to the states or if the products will be integrated with the normal daily supply chain and shipped directly to the affected hospitals. Additionally, it is unclear if the normal supply chain will be able to keep up with the demand of treatment centers. If this is the case, the RSS will most likely be in continuous operations post-48 hours until demobilization of the incident.

Additional Resources:
CDC MMWR: http://www.cdc.gov/mmwr/pdf/rr/rr6404.pdf
Dispensing Topics:

1. Operationalizing the POD Sites, with employment of adequate staffing

Assumptions:
- Local Health Departments will move from a non-medical model to a partial medical model for dispensing.
- EUA will be extended or valid for duration of long term dispensing operations.
- Exposed population will be defined, lessening vaccination burden.
- The health assessment/medication screening assessment will become lengthier and more in-depth than what was used for the 10-day dose of medication/antibiotics.
- Clinical staff will be taxed, decreasing clinical staff availability for PODs.
- There will be multiple PODs/Clinics needed for both dispensing of the 50-day antibiotics and/or administering vaccines for the 3 course series.
- A separate location may be set up away from the dispensing sites for vaccine administration.
- CDC will distribute 50-day medication dispensing and first Anthrax vaccination concurrently.
- CDC will distribute 50-day medication and Anthrax vaccines to the RSS site for local distribution.

Description:
The demand for adequate staffing, especially with clinical staff, will increase during long-term MCM dispensing. Maintaining adequate staffing for the 50-day medication dispensing, as well as multiple vaccination clinics will be challenging. Moving from a non-medical model to a partial medical model will require clinical staff (i.e. doctors, nurses, etc.) for dispensing operations, this will be difficult because those resources will be stretched thin.

Promising Practices:
1. Philadelphia Department of Public Health, see additional resources below.

Steps to Implementation:
- Develop long-term MCM distribution and dispensing plan
- Determine whether first dose of anthrax vaccine will be given at the same time as 50-day medication dispensing.
- Determine staffing needed to track vaccine given out and maintain schedule for all three series.
- Determine possible POD/clinic sizes, locations, and flows.
- Determine how many clinics/locations will be needed to administer vaccines based on vaccine prioritization tiers.
- Determine staffing requirements at the vaccine clinic and at the MCM dispensing sites (if they are not the same location).
- Determine staffing/volunteers available through established partnerships. (Both medical and non-medical)
- Review staffing contracts available locally or through mutual aid agreements
- Determine what health assessment/screening protocol will be used for the vaccine.
- Create training on use of the health assessment/screening protocol.
- Exercise long-term POD model(s).

**Opportunities for States and Locals:**
- Work with local/regional Medical Reserve Corps to pre-train clinical staff on dispensing/vaccination operations.
- Work with regional/local volunteer agencies to pre-train staff on long term dispensing operations
- Work with city/county/state local 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, schools of nursing, medicine, pharmacy, etc.
- Continue to develop state and local volunteer programs and train on dispensing operations.

**Critical Points for Plan Improvement:**
There is a lack of information regarding long-term MCM dispensing operations and much of the guidance that is available makes the assumption that adequate staffing will be available. Of course, this will change once a focus is placed on long-term MCM distribution and dispensing operations and states and locals begin planning and exercising these plans. Additional guidance on the operational aspects of administering the Anthrax vaccine is needed. The CDC guidance states that the first dose should be administered within 10 days of exposure, which would coincide with the 50-day medication dispensing, but additional guidance on how to incorporate the vaccination tier levels into dispensing operations is needed.

**Additional Resources:**
2. Identifying adequate medication, vaccination supplies, and other needed resources to continue and sustain operation of PODs

Assumptions:

- Local and State health departments will not have sufficient medication (antibiotic prophylaxis) caches 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 the vaccination prophylaxis.
- 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 have sufficient supplies or have the correct sized medical equipment.
- The next 50 day shipment of SNS materiel will consist of enough oral antibiotics (Ciprofloxacin, Doxycycline, Amoxicillin) for the full 60-day course, Anthrax Vaccine (enough vaccine for 1 dose per person), and Emergency Use Authorizations.
- Schools and other recommended POD sites may be unavailable for the entire 60 day prophylaxis campaign.

Description:
In long-term medical countermeasure distribution and dispensing operations, the identification and implementation of planning considerations for the following elements are paramount to a successful mission:

- Determination of medication requirements for affected population;
- Identification of necessary vaccine administration supplies (i.e. needles, syringes, alcohol swabs, etc.);
- Pre-established processes or procedures in place for Just-in-Time procurement of medical equipment;
- Extensive and adequate Federal guidance prior to any event;
- Adequate receive, store and stage (RSS) space allocation; and
- Adequate personnel to staff points of dispensing clinics and distribution sites through the duration of the extended dispensing campaign.

Promising Practices:
The following are several promising practices for local and state health departments which address a number of the planning considerations outlined above:

1. The National Association of County and City Health Officials (NACCHO). NACCHO has a published report from April 2013, entitled "Administrative Preparedness: Emergency Procurement Strategies for Health Departments". This report highlights several promising practices from

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various local health departments across the country regarding procumbent strategies including methods on implementing some of the strategies. This promising practice will assist local health departments in 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 many local health departments are faced with.

2. The Centers for Disease Control and Prevention, Division of Strategic National Stockpile, and is entitled: “Receiving, Distributing, and Dispensing: A Guide to Preparedness, Version 11”\(^2\). This document 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 where they tested multiple key components to a long-term dispensing campaign. The results of that exercise were recently published and have been presented on at multiple national public health preparedness conferences. “The 49th Hour: Analysis of a Follow-up Medication and Vaccine Dispensing Field Test”\(^3\) evaluated what a “dual model POD” (dispensing and vaccination clinic) would look like, as well as to identify staffing considerations for such a dispensing/vaccination campaign.

**Steps to Implementation:**
- Evaluate local and state health department receiving and distribution plans to determine if the current locations are suitable for a larger footprint of medical countermeasures and ancillary supplies.
- Identify planning considerations for staffing needs for a long-term dispensing/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 need to see each individual for vaccination.
- Convene key stakeholder meetings to evaluate current mass dispensing plans and begin to identify planning considerations for transitioning to 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 medical equipment in an expedited manner. If none exist, identify local medical supply companies where such purchasing processes can be established. It is advisable to also develop a Memorandum of Agreement/Understanding between the company and the health department outlining the procurement process and time considerations.

**Opportunities for States and Locals:**
By reviewing existing mass dispensing and distribution site plans with the focus on what the long-term dispensing and vaccination needs are, allows for critical evaluation of gaps as well as partnership opportunities with previously unknown 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), it is important to ensure that plans are consistently revised to reflect new federal or state guidance changes. Having flexible and scalable plans are also very important to consider. Continue to ensure that the planning cycle is followed after every critical change in the plans (train, exercise, evaluate, revise, etc).

Additional Resources:
1. NACCHO Medical Countermeasure Toolbox: http://toolbox.naccho.org/pages/index.html
   a. Has numerous resources from across the nation’s local health departments that are considered promising practices. Search for the medical countermeasure toolkit, then browse existing tools.
2. Association of State and Territorial Health Officials (ASTHO) Preparedness Resource Website: http://www.astho.org/Programs/Preparedness/Resources/
3. CDC Office of Public Health Preparedness and Response Website: http://www.cdc.gov/phpr/stockpile/stockpile.htm
3. Developing dispensing/vaccination strategies prioritization strategies for scarce resources (allocation of MCM that supports ethical access)

Assumptions:
- The risk for inhalation anthrax following exposure to *B. anthracis* spores is best estimated by the degree of exposure, not by health status or age. Therefore, frameworks to prioritize the use of prophylactic antibiotics following an anthrax attack should be based on a patient’s degree of exposure.
- Previous analysis has indicated that it is preferable to prophylax all asymptomatic individuals in the exposure region. The use of prioritization based on disease stage and/or age, while helpful, produces only second-order improvements in illness, resource consumption, and survival rates.
- In general, prioritization frameworks developed for an influenza pandemic – such as the framework developed by the Centers for Disease Control in partnership with the Advisory Committee on Immunization Practices (ACIP) for rationing influenza vaccine in the event of a shortage during a pandemic – are not appropriate to use for prioritization following an anthrax attack. The two events differ significantly based on factors such as communicability/mode of transmission, drug development timelines, potential adverse reactions, rates of hospitalization, and anticipated adherence to prophylaxis/treatment regimens.  
- 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, IV fluid, etc) may not keep pace with demand.
- 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.

Description:
Prioritization of medical supplies and equipment following an anthrax attack encompasses medications, supplies and equipment for prophylaxis and treatment.

For prophylaxis, if sufficient medications (vaccine or oral medications) are not available in the local jurisdiction to begin distributing the 50 day doses around day 7 or 8 of the response, state or local health departments may need to prioritize groups to receive the follow-on dose until such time as the supply expands and medications are available for all impacted individuals.

For treatment, 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. State or local health departments may need to collaborate with healthcare organizations, medical ethicists, community advocates and other partners to establish priorities for use of scarce medical resources, until such time as the supply expands and sufficient quantities are available to treat all impacted individuals.

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4 See “Additional Resources” below, Item 1
Promising Practices:

1. Department of Public Health, City of Philadelphia, Long-Term Mass Dispensing of Medical Countermeasures Plan, August 2015

   Available upon request to rhona.cooper@phila.gov

   Commits PDPH to identifying priority groups to receive the long-term MCMs first, if quantities of follow-up medications are limited. First responders and essential personnel are identified as two groups which may be prioritized to receive MCMs during both the initial and the follow up response.

2. Considerations for Anthrax Vaccine Absorbed (AVA) Post Exposure Prioritization Final, Centers for Disease Control and Prevention, 2013

   Available at http://emergency.cdc.gov/bioterrorism/pdf/AVA-Post-Event-Prioritization-Guidance.pdf

   Proposes a framework for Anthrax vaccine prioritization based on symptomology and age. May also be applicable to post exposure prophylaxis (PEP) using antibiotics.

3. Summary of post-event anthrax vaccine administration considerations, Centers for Disease Control and Prevention, 2013

   Available at http://www.astho.org/Preparedness/AVA-Post-event-Prioritization-Summary-and-Guidance-9-20-13/

   Proposes a tiering scheme for post-exposure prophylaxis using vaccine which could also be applied to PEP with antibiotics. 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.


   Available at http://www.health.state.mn.us/oep/healthcare/crisis/standards.pdf.

   A set of cards which facilitate regional decisions on resource shortfalls at healthcare facilities. Each facility then determines the most appropriate steps to implement the selected strategies. The guidance does not replace the judgement of clinical staff and consideration of other relevant variables and options during an event.

Steps to Implementation:
- None identified at the moment

Opportunities for States and Locals:
State and local health departments will have limited capacity to establish equitable and scientifically valid prioritization frameworks for anthrax post-exposure prophylaxis due to lack of expertise and lack of resources, since effective development requires a broad base of scientific and clinical knowledge.
Federal health organizations, academic institutions, national working groups, and other scientific researchers are best poised to develop scientifically valid frameworks for prioritization of medications for anthrax post-exposure prophylaxis.

In addition, standardization of priority groups for post-exposure prophylaxis at the federal level is preferred in case of multi-state responses.

The federal government has widely communicated that the supply of antibiotics following an anthrax event is expected to be sufficient to cover all who need, so states and local health departments have generally not focused on developing prioritization strategies.

State and local health departments should review the proposed anthrax PEP prioritization frameworks referenced below, and conceptualize and document how these prioritization frameworks would be implemented in their local or state medical countermeasure dispensing operations.

**Critical Points for Plan Improvement:**

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 doses must be dispensed. If medications are in short supply at the beginning of mass dispensing / mass vaccination operations and prioritization is in effect, those shortages are likely to extend into the period during which the 50 day doses are dispensed. Therefore prioritization frameworks implemented for the 10 day dose will most likely be continued for the 50 day dose.

However, it is possible that in a situation where supplies are restricted for the 10 day dose, sufficient medications will begin to flow into the impacted region that prioritization can be curtailed for distribution of the 50 day dose.

Conversely, there may be situations where a community has sufficient medications to distribute the 10 day dose to all impacted individuals, but the 50 day doses are in short supply.

Therefore, state and local health departments should remain prepared, flexible and nimble enough to implement and curtail prioritization as the supply dictates in the moment. Such efforts will require clear and widely communicated messaging to the public and dispensing / vaccination partners.

**Additional Resources:**

4. Centers for Disease Control and Prevention. Summary of post-event anthrax vaccine administration considerations, September 2013, letter from Christine Kosmos, CDC
5. Considerations for Anthrax Vaccine Absorbed (AVA) Post Exposure Prioritization Final, Centers for Disease control and prevention, 2013
4. Tracking adverse events for serious reactions to the antibiotics and/or the vaccine

Assumptions:

- The primary countermeasures for a mass prophylaxis campaign will be the antibiotics Doxycycline and Ciprofloxacin (with Amoxicillin as a possible alternative) and Anthrax vaccine absorbed (AVA).
- There will be individuals who experience mild and/or severe adverse events/effects after receiving medication and/or vaccine (either within the local health jurisdiction or another area).
- It is possible some individuals who receive prophylaxis will still become sick; this may cause concerns about efficacy and adverse effects.
- An adverse event is an undesirable health outcome that follows a given exposure, as to a vaccine and/or medication, but for which a causal relationship with the exposure may or may not have been established.
- If a causal relationship can be determined, adverse events can also be referred to as adverse effects or adverse reactions.
- The number and severity of adverse events will increase as the mass prophylaxis campaign continues past the 10, 30, and 60 day marks.
- There will be special interest groups who do not believe one or all countermeasures are safe.
- For the Anthrax vaccine, most adverse events will be identified within 10-15 minutes of administration; however, it is possible for individuals to experience adverse events after they have left the Point of Dispensing (POD) and could take days, weeks, even months or years to appear.
- For antibiotics, adverse reactions are not expected to be identified at the POD and may not manifest until a later time.
- Federal regulatory systems for reporting, investigating, and tracking adverse reactions (VAERS and MedWatch) will still be functioning; however, if there is a surge in the number of cases reported, reporting of results back to local health jurisdictions may be delayed.
- Local health jurisdictions will be asked for information on local adverse events data by media, elected officials, healthcare providers, the general public, etc.
- Some private physicians/healthcare entities may refuse to see patients with possible drug side effects and may refer them back to the local health department.
- Some individuals may report directly to the POD and/or local health department with possible drug side effects.
- Some individuals may report directly to healthcare provider or medical home.
- 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/work.
- Severe adverse events are defined as serious events resulting in hospitalization excluding ambulatory care and emergency department events (unless they resulted in hospitalization).
- Local health jurisdictions may be asked to provide guidance on treatment/care for individuals experiencing adverse events/reactions.
Description:

- The most common mild adverse effects associated with antibiotics are gastrointestinal (diarrhea, stomach pain, nausea, vomiting, etc.) or neurological (headache, dizziness, lightheadedness, fainting, etc.)
- The most common severe adverse events associated with antibiotics are anaphylaxis (hives, swelling of the lips, tongue, face, throat tightness, trouble breathing/swallowing, rash, etc.), photosensitivity (severe sunburn, blistering, swelling of the skin), hepatotoxicity (liver damage, severe nausea or vomiting, etc.), central nervous system effects (seizures, tremors, blurred vision, hallucinations, etc.), intestine infection, heart rhythm changes, and neuropathy
- The most common mild adverse effects associated with AVA are typically injection-site related (redness, soreness/sensitivity, bruising, mild rash, etc.) but can be systemic (fever, malaise, joint pain, etc.)
- 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/facilities at specified time intervals (active)
  3. relying on individual or provider self-reporting (passive)
   The nature/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/implication, and
  4. the adverse event, effect, and/or outcome experienced

Promising Practices:

1. The City of Philadelphia’s screening algorithm for the follow-up 50-day regimen includes the option to change drugs for the individual if they experienced mild negative side effects or an adverse event (available on the NACCHO MCM Toolkit)
2. In this same tool, there is also a database for patient tracking that would be useful for surveillance/follow-up of individuals with possible adverse events
3. Online training and sample report forms are available on both the MedWatch and VAERS websites
4. Several major pharmaceutical companies have begun to do studies on using social media data and other non-traditional approaches to monitor/identify possible adverse events, here are some examples:
   b. [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3675775/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3675775/)
   d. [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4013443/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4013443/)
5. There are several proprietary surveillance tools that can be utilized for adverse event reporting surveillance, including but not limited to MedWatcher (https://medwatcher.org/)

Steps to Implementation:

- Local health jurisdictions must work on plans for collaborating with hospitals, healthcare facilities, and private providers on a local reporting/tracking system for drug/vaccine adverse events
- Local health jurisdiction should develop plans and procedures for conducting both active and passive surveillance to determine the presence or absence of adverse events
- Follow-Up 50-day mass prophylaxis campaigns need to incorporate questions about adverse effects into screening tools and algorithms
- At a minimum, local health jurisdictions should plan to conduct adverse event surveillance at 10, 30, and 60 day marks of a mass prophylaxis campaign
- Local health jurisdictions should develop plans for follow-up with providers and individuals identified with possible adverse effects from the medication or vaccine
- During a mass prophylaxis campaign, plan to monitor/subscribe to VAERS and MedWatch alerts regarding dispensing countermeasures
- Consider adapting current syndromic surveillance efforts/mechanisms to identify possible adverse events
- Consider incorporating adverse event reporting into call center operations plans and/or agreements

Opportunities for States and Locals:

- LHJs 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
- LHJs can use available studies and research from the Department of Defense to assess and estimate the percentage and types of adverse events associated with the Anthrax vaccine
- LHJs can partner with local Immunizations programs and providers to utilize existing adverse event reporting tools and mechanisms
- CDC Surveillance data on adverse events for LRN personnel who receive AVA could be provided to local health jurisdictions to help identify possible adverse effects
- VAERS and MedWatch data is available on their websites for local health jurisdictions to conduct baseline data assessments of adverse events common with their geographic area
- Work with local poison control/call centers to increase capacity to identify self-reporting possible adverse events during a mass prophylaxis campaign
- For long-term surveillance/follow-up, local LHJs should consider including protocols for conducting post-event surveys, focus groups, sampling, CASPER studies, etc. in their mass prophylaxis plans

Critical Points for Plan Improvement:
• LHJs should not rely solely on VAERS and/or MedWatch for adverse event reporting and surveillance; LHJs should have plans and processes in place to conduct their own adverse event surveillance, investigation, tracking, and follow-up

• LHJs should train all staff and volunteers working in POD operations to be trained on adverse event reporting including how to report, who to notify, key elements of information, and what information to provide to the individual/provider reporting

• CERC/PIO plans must include messages on adverse events and how to address identified cases/reports with target audiences (media, elected officials, healthcare providers, general public, etc.)

Additional Resources:


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.
5. Providing effective public messaging to ensure that a full 60-day regimen and 3 shot series of vaccine are taken

Assumptions:
- A major public health event can potentially generate public 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 dose)
- Federal and/or national level public messaging will coordinate with local messaging efforts.
- The local health department(s) within the affected area(s) will serve in the joint information center (JIC).

Description:
In long-term medical countermeasure distribution and dispensing operations, public messaging will be key in success. Providing timely and informative messaging to the public is crucial to a successful long term dispensing operation. Public Information Officers (PIOs) have created messaging templates for 48-hour dispensing operations. Therefore, it is imperative that more work is done to create templates for the long term dispensing and vaccination operations as well as strategizing on how to coordinate those messages with all partners involved.

Promising Practices:
1) Yearly training incorporating neighboring jurisdictions as well as state and federal entities to simulate an event in which public information and messaging would take place. Regularly occurring meetings with Joint Information Center (JIC) partners to discuss planning efforts. Creation of POD Pre-dispensing and pre-vaccination messages.

Steps to Implementation:
- Update current Crisis Emergency Risk Communication (CERC) Plan to include information on long term dispensing messaging and vaccines
- Include the public messaging priorities and processes in the long term dispensing plan
  - Create message templates
  - Convene the Joint Information Center partners to discuss strategies
- Work with local, regional, and state partners to ensure the messages will be consistent.
- Train and exercise partners on the plan

Opportunities for States and Locals:
By pre-planning for public messaging for long term dispensing or vaccinations, LHDs will have at least a baseline understanding of how to appropriately provide the public accurate and timely messages during a long term dispensing. Vital partnerships include local media contacts, social media organizations, etc.
Critical Points for Plan Improvement:
The timing of when the vaccine will be available or when the 50-day dose will be available to the public is unknown and will be a significant factor on how or when the messages are released. The timing of the messages is very important.

Additional Resources:
1. Information about preventative medications for Anthrax with closed caption
2. Federal Communications Commission
   https://www.fcc.gov/consumers/guides/emergency-communications
3. Crisis and Emergency Risk Communication (CERC)
   http://emergency.cdc.gov/cerc/index.asp
4. CDC.gov
   http://www.cdc.gov/anthrax/
Cross-Cutting Topics

1. Topic: Activation Timeline following the 10-Day MCM Antibiotic Regimens (e.g., Dispensing of 11-60-Day Regimens and Administration of Multi-Dose Vaccinations)

Assumptions:
- To be reassessed

Description:
The challenges of this activation timeline will be to continue and expand operations at PODs, including not only dispensing oral dosage forms but also administering AVA. The good news is that there will have been at least three days (since this timeline begins at Day-3) to both develop a comprehensive response strategy and to lean forward with resource requests that will support timely implementation of that strategy by Day-5. Planning for the 50-day MCM distribution and dispensing (MCM DD), must start at the initial 10-day decision.

Promising Practices:
1. The PHEP grant requirement of full scale (FS) MCM DD exercises for each of the CRI jurisdictions, within the 5-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 FS exercises, as completed by multiple MSA’s, can be gleaned for best and promising practices that will serve as a foundation for preparedness to sustain (11-60 day timeframe) operations.

2. Los Angeles County (LAC) DPH approached their FSE requirement with the assumption that the timeline for MCM DD of the 10-day regimens of antibiotics was too critically short to allow for moment-of-need development of an Incident Action Plan (IAP) and associated response strategy. Therefore, they pre-developed an IAP template for each of the two operational periods (OP) of the first 48 hours of their response. Then, at the onset of a response and through the use of immediately available incident specifics, the IAP for the first 24-hour OP can be modified, by changing as little as possible, and implemented for MCM DD.

3. LAC DPH approached their MCM Distribution requirement with the assumption that the complexity of the logistical components of the RSS/RDS warehouse and the associated MCM delivery operations to Open PODs were not within the traditional skill sets of a sufficient number of Public Health employees and therefore outside assistance was needed. Fortunately, the County’s Fire Department maintains three Type-3 Incident Management Teams (IMTs), which are very skilled at coordinating all of the logistical operations associated with fighting very large wildlands fires. Additionally, these IMTs have previously been deployed to Florida to
manage commodity distribution warehouse and delivery operations for state-wide hurricane response. In order to prepare them for an MCM distribution role, these IMT resources were trained and exercised (TTX and FSE) to support RSS/RDS warehouse and MCM delivery operations. Additionally, during these preparedness activities, Fire Camp Crews which consist of approximately 14 individuals, were identified as an excellent resource to staff the RSS/RDS warehouse floor operations. These crews are rapidly available, physically fit, practiced at performing within operations as part of a team, and a couple of participants on each crew are certified fork lift drivers.

4. LAC DPH approached their MCM Distribution requirement for acquisition of delivery trucks and truck drivers, as well as for supplemental warehouse staff, with the assumption that privately contracted resources would be essential and the companies that will be solicited for these moment-of-need contracts should be pre-identified. Currently LAC DPH has individual MOU’s with five vendors who are in the trucking business, generally. Additionally, they have incorporated into their MCM distribution strategy the procedures for acquiring these services from any of the eleven vendors, which are pre-vetted as candidate companies for the County periodic contracts related to moving and storage services under an on-going Master Services Agreement (MSA). These MOU’s and the MSA have been used to solicit bids and award contracts.

5. LAC DPH approached their MCM Distribution requirement for support of deliveries to approximately 500 skilled nursing and assisted living facilities, as the greatest portion of their Closed PODs, with the assumption that privately contracted resources would be essential and the pharmaceutical supply companies that will be solicited for these moment-of-need contracts should be pre-identified. Currently LAC DPH has individual MOU’s with three vendors who are in the pharmaceutical supply business and collectively deliver medications to most of the 500 sites on a day-to-day basis. The plan calls for one or more of these vendors to receive bulk deliveries of the antibiotics and to use their current pharmaceutical warehouse and delivery operations to redistribute MCM for the resident populations, as well as the staff and staff’s families. As part of their activities related to facilities inspections for code compliance, LAC DPH maintains an up to date database for the majority of these facilities.

6. Use of National Guard and/or regular military

Steps to Implementation:
- Pre-event: Public Health does not perform massive redistribution activities of either stuff or staff during day-to-day operations, but there are agencies/vendors who are experts at these types of operations, so start identifying who you could call immediately after an attack for either contracting or mutual aid deployment
- Day-1: Start planning for the follow on MCM receiving, distribution, dispensing and vaccination activities once you are committed to a mass prophylaxis campaign
Day-1: Begin to evaluate which of the experts in the field of logistics you may need to procure/request in order to meet goals and objectives of the response

By Day-3, have a plan for your long-term MCM DD activities and list of all resource needs for that plan, including the development of at least a draft IAP

By Day-4, submit your resource requests (e.g., Facilities; Warehouse staff; Distribution resources and staff; Equipment; and MCM for 50-day regimens), and find an logistics partner to run your MCM distribution, including RSS/RDS and delivery operations (e.g., National Guard; a Commercial Transportation Services Provider; military; etc.)

By Day-5, turn over operations of your RSS/RDS warehouse and MCM delivery to the identified third party, logistics specialist to accommodate MCM surge

By Day-6, identify all of the locations that will be used for the dispensing of the 50-day regimens of antibiotics and the vaccinations, and make sure these sites will be available for deliveries the following day

By Day-7, deliver the 50-day regimens to the PODs

By Day-8, commence dispensing the 50-day regimens

**Opportunities for States and Locals:**
Identification of pharmaceutical cold chain storage facilities is a critical component for success in the 11-60 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-weight and cubes as well as quantities of product on each pallet) as it will be delivered to each of the distribution sites. Dispensing plans will need to be revised to determine the number, type, and location of sites to not only dispense oral antibiotics but to administer AVA.

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

Description:
Assuring access to and compliance with emergency medications by individuals, groups, and communities whose circumstances present barriers to obtaining information, and/or to accessing and using resources offered before, during, and after a disaster. Circumstances which 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; clients of the criminal justice system; chemically dependent; children; deaf, deaf-blind, and hard of hearing; developmentally disabled; homeless and shelter dependent; immigrant communities; impoverished; limited English or non-English proficient individuals; medically dependent or medically compromised individuals; individuals residing in rural locations; seniors; or undocumented persons.

Promising Practices:

1. **Closed PODs for people with disabilities.** Local health departments St Paul-Ramsey County, MN, and Oakland County, MI, utilize closed Points of Dispensing (PODs) to improve emergency planning for vulnerable populations including people with disabilities. These PODs allow for effective dispensation of medical countermeasures to populations who may not be able to easily access public PODs. (source: [http://nacchopreparedness.org/nacchos-2014-summer-preparedness-webinar-series/](http://nacchopreparedness.org/nacchos-2014-summer-preparedness-webinar-series/))

2. **Special Needs Area.** The State of Mississippi designates a “special needs area” at all open PODs in the state. Any individual presenting at the POD can receive additional support and attention, such as pictographs, an AT&T Language Line, videos that document the MCM/event, interpreters, Braille charts, and social workers and other professional staff to provide support. (Source: [http://wcphep.org/summary-of-existing-points-of-dispensing-pod-practices/practices-demonstrating-the-recommended-strategies/#sthash.yjYUmVri.dpuf](http://wcphep.org/summary-of-existing-points-of-dispensing-pod-practices/practices-demonstrating-the-recommended-strategies/#sthash.yjYUmVri.dpuf))

3. **Tools for Responders to Communicate with Specific Vulnerable Groups.** The Florida State Department of Health developed a communication resource guide for public health and emergency responders providing information or warnings during an emergency. The guide addresses communication with the elderly, people with physical and developmental disabilities, non-English speaking populations, dialysis clients, populations dependent on medical equipment like home ventilators, people receiving specialty care (methadone treatment, radiation/oncology care), migrant workers, and people who are economically disadvantaged. (Source: [http://wcphep.org/summary-of-existing-points-of-dispensing-pod-practices/practices-demonstrating-the-recommended-strategies/#sthash.yjYUmVri.dpuf](http://wcphep.org/summary-of-existing-points-of-dispensing-pod-practices/practices-demonstrating-the-recommended-strategies/#sthash.yjYUmVri.dpuf))

4. **Emergency Preparedness Dispensing Site Signage and Pocket Translator.** The Cambridge Advanced Practice Center in Massachusetts developed a series of pictograms designed to promote universal access to dispensing sites. A companion to the signage is the Pocket Translator, which was developed to assist clients with limited English language proficiency through the four main points in the dispensing site. (Source: [http://wcphep.org/summary-of-existing-points-of-dispensing-pod-practices/practices-demonstrating-the-recommended-strategies/#sthash.yjYUmVri.dpuf](http://wcphep.org/summary-of-existing-points-of-dispensing-pod-practices/practices-demonstrating-the-recommended-strategies/#sthash.yjYUmVri.dpuf))
5. **Deaf Smart Disaster Planning Workshop and POD Exercise.** St. Louis County, Minnesota, conducted a workshop/POD exercise tailored for Deaf and hearing-impaired participants to test access to a POD. (Source: [http://wcphep.org/summary-of-existing-points-of-dispensing-pod-practices/practices-demonstrating-the-recommended-strategies/#sthash.yjYUmVri.dpuf](http://wcphep.org/summary-of-existing-points-of-dispensing-pod-practices/practices-demonstrating-the-recommended-strategies/#sthash.yjYUmVri.dpuf))

6. **Remote Notification.** Oklahoma Weather Alert Remote Notification or OK-WARN is a program developed in partnership with the Oklahoma Departments of Emergency Management and Rehabilitative Services, the National Weather Service, and others to disseminate emergency messages via email and pagers to those who are deaf or hard-of-hearing. Individuals register themselves to participate in the program, and, in the event of a weather alert or an emergency, they are notified by the OK-WARN system. Message recipients must supply their own pager or other communication device, but the service is free. (Source: [http://www.ok.gov/OEM/Programs_&_Services/OK-WARN/index.html](http://www.ok.gov/OEM/Programs_&_Services/OK-WARN/index.html))

7. **Training first responders to communicate with individuals who have disabilities which may impair communication.** This program, developed by the Woodside Fire Protection District in Woodside, California, includes a manual with information on various disabilities and associated communication difficulties, a video showing communication techniques, a communications booklet for use during a response, and a poster for schools and organizations to use, which depicts first responders as “friends” and shows them in action. (Source: [http://www.woodsidefire.org/words.shtml](http://www.woodsidefire.org/words.shtml))

8. **The Special Needs Assistance Program (SNAP)** of the Fort Worth–Tarrant County Office of Emergency Management provides responders with information on residents who have permanent disabilities via an online registry. The registry encourages annual registration with the Office of Emergency Management and provides disability-specific personal preparedness information. The registry is linked to a GIS mapping tool that allows emergency planners to locate residents with special needs. To encourage people to use the registry, SNAP has formed strong partnerships with community organizations such as Meals on Wheels. (Source: [www.snapforyou.org](http://www.snapforyou.org))

9. **Vulnerable Populations Action Team (VPAT)** created by Public Health - Seattle & King County in partnership with community-based organizations (CBOs) is a community-based network focusing on the public health preparedness needs of populations with special needs. VPAT builds on the established relationships of CBOs with clients. In an emergency, VPAT contacts the CBOs and they share real time critical health alerts and instructions with vulnerable clients. The program also provides small grants to CBOs to develop emergency plans, technical assistance and trainings for CBOs, and works to identify the specific populations that are in need and the organizations best equipped to serve them. Source: [http://www.kingcounty.gov/healthservices/health/preparedness/VPAT.aspx](http://www.kingcounty.gov/healthservices/health/preparedness/VPAT.aspx)

10. **Emergency and Community Health Outreach (ECHO)** is a risk-communication program created by the Minnesota Department of Public Health targeted toward LEP populations. ECHO provides ongoing public health information on public television. They’ve produced a series of 20-minute programs in several different languages, covering a range of topics such as Lyme disease, severe weather warnings, and pandemic influenza. They also have the capacity to receive, translate, and distribute health and safety information during an emergency. through a network of community partners and via television, phone, and the Internet. Topics are customized for each language group and feature native-speaking on-air personalities and expert guests. Source: [http://www.echominnesota.org/](http://www.echominnesota.org/)

11. **Public Health Promotores.** El Paso, Texas, department of health engaged in a multistep program to address the growing needs of limited English proficiency populations. First, they used GIS technology to map areas with high concentrations of LEP persons regions likely to flood. Next,
they enlisted lay and professional promotores from local colleges to go into communities with larger numbers of LEP populations and communicate critical public health and security information about the dangers of and recovery from flooding. Promotores used bilingual, written and spoken information to communicate with residents about West Nile virus, fraudulent repair contractors, cleaning the mess left by the flood, and mold and mildew concerns. Promotores also provided a list of available resources from FEMA and other aid organizations.

12. **Tribal Outreach for Pandemic Planning.** In New Mexico, the Department of Health developed a tribal outreach project to assist tribes with pandemic planning via training sessions and a train-the-trainer manual offered on and off reservations across the state. The project aimed to empower tribes to improve their pandemic preparedness. Tribal members who participate in the training serve as trusted messengers and are best able to convey important public health messages to tribal population. Source: [http://pandemicpractices.org/practices/resource.do?resource-id=153&](http://pandemicpractices.org/practices/resource.do?resource-id=153&)

13. **The Kentucky Outreach and Information Network (KOIN)** is a network of community-based organizations formed to help distribute emergency information to hard-to-reach populations. Organizations in the network serve as liaisons between the emergency responders and special needs populations. Using trusted messengers increases the likelihood that emergency messages will be received, believed, and acted upon. The network has over 400 members. To maintain the network, KOIN distributes newsletters and holds yearly workshops to raise awareness among network members about disaster preparedness and to hear from members about how best to reach the populations with whom they work. Source: [http://chfs.ky.gov/dph/epi/preparedness/KOIN.htm](http://chfs.ky.gov/dph/epi/preparedness/KOIN.htm)

14. **Streaming videos on how to access and process medication vouchers during a bioterrorism event** in English and Spanish, produced by Public Health – Seattle & King County. The videos assist members of the public with printing a medication voucher for use during a medical countermeasure event; and assist POD staff with processing vouchers produced from the jurisdiction’s online medication screening tool (Dispense Assist). (Source: [http://www.kingcounty.gov/healthservices/health/preparedness/bioterrorism/videos.aspx](http://www.kingcounty.gov/healthservices/health/preparedness/bioterrorism/videos.aspx)

15. **Northeast Texas Public Health Department’s POD Site Video Series for At-Risk Populations.** This website contains videos and documents for local health departments to use at Point of Dispensing (POD) sites, which help disseminate emergency messaging to the whole community, including those with functional and access needs. (Source: [http://wcphep.org/existing-resources-and-practices/#sthash.BkOR3Opi.dpuf](http://wcphep.org/existing-resources-and-practices/#sthash.BkOR3Opi.dpuf))

**Steps to Implementation:**
State and local accountabilities in assuring access and compliance by at-risk populations are the same during extended dispensing as during initial dispensing
- Determine risks to the health of the jurisdiction
- Build community partnerships to support health preparedness planning
  - Involve representatives of special needs populations in emergency planning
  - Coordinate Preparedness and Response Efforts with Relevant Organizations
- Engage with community organizations to foster public health, medical, and mental/behavioral health social networks
- Issue public information alerts, warnings, and notifications in accessible formats
- Initiate and sustain medical countermeasure dispensing using a variety of methodologies targeted at the general population as well as the unique needs of diverse communities
• Identify and map vulnerable and at-risk populations for jurisdiction (see social vulnerability index maps at [http://www.kingcounty.gov/healthservices/health/preparedness/VPAT/integration.aspx](http://www.kingcounty.gov/healthservices/health/preparedness/VPAT/integration.aspx) for more detail)
• 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 (See more at [http://wcphep.org/findings-and-recommendations/#sthash.BNmKk6wO.dpuf](http://wcphep.org/findings-and-recommendations/#sthash.BNmKk6wO.dpuf))
• Establish standing workgroups for whole community inclusion in MCM dispensing (See more at [http://wcphep.org/findings-and-recommendations/#sthash.BNmKk6wO.dpuf](http://wcphep.org/findings-and-recommendations/#sthash.BNmKk6wO.dpuf))
• Incorporate ethical principles and community values into public health emergency preparedness strategies (See more at [http://wcphep.org/findings-and-recommendations/#sthash.BNmKk6wO.dpuf](http://wcphep.org/findings-and-recommendations/#sthash.BNmKk6wO.dpuf))

Opportunities for States and Locals:
• Greater time to create high quality translations and messaging in alternate formats
• Greater time to build relationships with impacted communities
• Greater time to develop targeting medical countermeasure dispensing strategies to meet the unique needs of diverse communities

Critical Points for Plan Improvement:
• To be effective, health departments must collaboratively design and implement targeted long term dispensing strategies which work for diverse populations. There is no one-size fits all solution.
• Local public health departments will have to 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 medical countermeasures unless significant investments are made to communicate in formats accessible to all. Creating high quality translations or messages in alternate formats (e.g. video, pictorial) can be time-intensive and expensive, especially during a fast-moving event.
• Despite implementation of the Affordable Care Act, certain populations still experience barriers to accessing health services. For example, local providers do not always participate in insurance plans sold through the ACA. It is expected that long-term medical countermeasure dispensing will highly leverage the healthcare system as a point of access, and poor access to healthcare services by certain populations could pose a barriers to access to long-term MCMs.
• Mistrust of government due to historical and current events such as the Tuskegee experiments and contamination of the water supply in Flint Michigan, may make certain populations hesitant to take medications provided by the government.
• Concurrent dispensing and mass vaccination efforts, combined with an orientation towards population-level health strategies focused on doing the greatest good for the greatest number of people, may combine to limit both the staffing and capacity to invest in serving diverse communities during an MCM response.

Additional Resources:
1. NACCHO Toolbox,
2. NACCHO/ASTHO Whole Community Inclusion Project,
4. DSNS and CDC OEPR websites
5. National Health Security Strategy
6. PHEP capability community preparedness
7. Operational Readiness Review
3. Roles of Health Departments and Partners

Assumptions:

- Point of Dispensing (POD) or other previously identified clinic space may not be available or capable of handling an increase in the total number of residents to be seen.
- Facilities designated for POD/distribution operations may not be available for the entire length of a long-term dispensing campaign.
- Law enforcement and other personnel may not be available in adequate numbers for the entire duration of a long-term dispensing campaign.
- The traditional non-medical model POD will need to be adapted to a hybrid medical/non-medical POD where residents will receive the next 50-day unit of use bottles of antibiotic prophylaxis, but also Anthrax Vaccine Adsorbed (AVA).
- Head of Household (HOH) forms will not be sufficient for use during the extended dispensing campaign, due to the vaccination that all affected residents will need. Thus every individual in the affected target area will need to receive both the remainder of the 50-day antibiotic prophylaxis and also the AVA (note- not all jurisdictions will utilize AVA; and not all exposed will be recommended to receive AVA).
  - New forms will need to be utilized for every individual including both oral antibiotics and vaccine.
- Local Health Departments (LHDs) will experience staffing shortages and burn-out of existing staff and volunteers due to working long hours over an extended period of time.
- Hours of operation for the PODs may need to be adjusted based on staffing availability and flow/throughput patterns
- The next 50-day shipment of managed inventory will arrive no later than day 8 of the initial dispensing campaign, and will include enough antibiotics for the full 60-day course, Anthrax Vaccine (enough vaccine for 1 dose per person).
- 50-day PEP will arrive in 50-day unit of use bottles. AVA will arrive in multidose vials. These may or may not contain adjuvant.
  - AVA will need to be administered in a 3-dose schedule at weeks 0, 2 and 4.
- Anticipated AVA first dose (week 0) will be provided to a larger percentage of the population until the target area is narrowed.

Description:

In long-term medical countermeasure (MCM) distribution and dispensing operations, the identification and implementation of planning considerations for the following elements are paramount to a successful mission:

- Epidemiological investigation and identification of target area affected by Anthrax;
  - Coordination between Lab, Epi, and Environmental Health to narrow exposed population;
- Determine space and allocation needs for receiving, storage, staging and distribution facilities for the full duration of the extended dispensing campaign;
- Determination and identification of total amount of staff and volunteers needed to run a dual dispensing/vaccination clinic for the entire sustained dispensing operation;
- Extensive and adequate Federal guidance prior to any event;
• Determination of POD clinic location availability for extended dispensing; including the possibility of standing up and demobilizing multiple times over the 60 days;
• Consideration of alternate vaccination clinic locations for AVA doses 2 and 3 (week 2 and week 4); could include private provider locations, pharmacy chains, or local health department clinics. Tracking of vaccination record critical;
• Determination of medication requirements for affected population;
• Identification of necessary vaccine administration supplies (i.e. needles, syringes, alcohol swabs, etc.);
• Procedures in place for cold chain storage and management for AVA;
• Public Information and messaging campaigns for dispensing and vaccination requirements, along with medication compliance and adverse event reporting;
• Waivers or other procedures in place for rapid vaccination for large percentage of population with AVA;
• Waivers and other procedures for dispensing operations that may extend beyond the disaster/PREP Act declaration;
• Consolidating POD/distribution sites based on traffic/flow/throughput patterns;
• Pick-up and/or redistribution of medication and vaccine from closed POD sites, hospitals, treatment centers, etc.;
• Activation of a public health call center to address questions/concerns regarding the medications and vaccine;
• Continuity plans/procedures for other health department critical/essential functions that may be impacted by a long-term dispensing campaign (including possible devolution of non-essential functions);
• Last two doses of AVA (week 2 and week 4) may be administered via traditional primary providers or local pharmacies, and may be directly shipped to these providers rather than the state or local distribution site.

Promising Practices:
There are few examples on conducting sustained dispensing operations for local health departments. However, there are several examples that we can draw from to assist in addressing the planning considerations outlined above.
• The Centers for Disease Control and Prevention, Division of Strategic National Stockpile guidance document: “Receiving, Distributing, and Dispensing: A Guide to Preparedness, Version 11” describes the space allocation needs for receiving and storing the 50-day medical countermeasure allotment, as well as some guidance on conducting a sustained dispensing operation.
• The Philadelphia Department of Public Health recently conducted a full scale exercise where they tested multiple key components to a long-term dispensing campaign. The results of that exercise were recently published and have been presented on at multiple national public health preparedness conferences. “The 49th Hour: Analysis of a Follow-up Medication and Vaccine

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Dispensing Field Test\textsuperscript{6} evaluated what a “dual model POD” (dispensing and vaccination clinic) would look like, as well as to identify staffing considerations for such a dispensing/vaccination campaign.

- Nurse Triage Line\textsuperscript{7} – could be used for screening/dispensing in a long-term campaign where staffing is limited. This is a joint initiative between CDC, NACCHO, ASTHO and several local jurisdictions.
- Dispense Assist\textsuperscript{8} – web-based screening tool that could be used where licensed medical staff are limited. Several local and state health departments have used this model successfully in a variety of exercises and events. It was developed by the Johnson County Health Department in Kansas.
- Local health jurisdictions who responded to the H1N1 mass prophylaxis campaign will have experience in 2nd dose vaccination campaigns and re-allocating antivirals and vaccine during a long-term event.

Steps to Implementation:

- Identify staffing and space requirements for an extended dispensing campaign using modeling software, like RealOpt\textsuperscript{9}.
- Evaluate both dispensing and vaccination requirements, including use non-medical and medical models.
- 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. These should include LHD staff, Department of Public Works, local Police Department, local Emergency Management Director, State health department staff, distribution and receiving site staff, etc.
- Convene meetings with epidemiology, environmental health staff and other subject matter experts to develop processes and procedures for conducting epidemiological investigation relative to Anthrax release.
- Consult with State Health Department staff on their sustained dispensing operational plans. Ensure alignment of plans between state and local health departments.
- Consider establishing relationships with other providers such as 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.
- Utilize CDC Receiving, Distributing, and Dispensing: A Guide to Preparedness, Version 11 to assist in revising plans, including public information and communication changes that are critical in ensuring medication compliance.

Opportunities for States and Locals:

\textsuperscript{7} Nurse Triage Line: http://archived.naccho.org/topics/emergency/pandemicinfluenzaprep/nursetriageline.cfm
\textsuperscript{8} Dispense Assist: https://www.dispenseassist.net/
\textsuperscript{9} RealOpt: http://www2.isye.gatech.edu/medicalor/realopt/research.php
By reviewing existing mass dispensing and distribution site plans with the focus on what the long-term dispensing and vaccination needs are, allows for critical evaluation of gaps as well as partnership opportunities with previously unknown stakeholders. Utilize existing tools, guidance documents, conversations and conferences to reconsider the planning needs for a sustained dispensing operation. The CDC Medical Countermeasure Operational Readiness Review (MCM ORR) tool may be of value during this plan review and revision process.

**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), it is important to ensure that plans are consistently revised to reflect new federal or state guidance changes. Having flexible and scalable plans are also very important to consider. Continue to ensure that the planning cycle is followed after every critical change in the plans (train, exercise, evaluate, revise, etc). Jurisdictions should make sure Memorandums of Understanding (MOUs), plans, etc. and stakeholders incorporate long-term dispensing campaigns that may last weeks and possibly months.

**Additional Resources:**
1. NACCHO Medical Countermeasure Toolbox: [http://archived.naccho.org/toolbox/](http://archived.naccho.org/toolbox/)
   a. Has numerous resources from across the nation’s local health departments that are considered promising practices. Search for the medical countermeasure toolkit, then browse existing tools.
2. Association of State and Territorial Health Officials (ASTHO) Preparedness Resource Website: [http://www.astho.org/Programs/Preparedness/Resources/](http://www.astho.org/Programs/Preparedness/Resources/)
3. CDC Office of Public Health Preparedness and Response Website: [http://www.cdc.gov/phpr/stockpile/stockpile.htm](http://www.cdc.gov/phpr/stockpile/stockpile.htm)
5. CDC Clinical Framework and Medical Countermeasure Use during an Anthrax Mass-Casualty Incident: [https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6404a1.htm](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6404a1.htm)
Conclusion

January 25th, 2016 in a webinar presentation titled ‘Overview of the Strategic National Stockpile’, Deputy Director of CDC’s Division of the Strategic National Stockpile, Steven Adams shared three observations on prior SNS activations. “Historic SNS responses rarely matched pre-event planning or expectation. Capable staff and flexible systems were able to adapt and “make it happen” anyway. Importance of coordination with supply chain partners to maximize utility of available supply.” (Slide 13)
Appendix 1

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 a prophylactic intervention 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 will be available in the quantities needed for the response (i.e., 10- and 50-day unit-of-use antibiotic regimens [e.g. doxycycline and ciprofloxacin], intravenous antibiotics, and anthrax immunoglobulin).
5. Some MCM resources, including 10- and 50-day unit-of-use antibiotic regimens of amoxicillin, pediatric formulations of antibiotic regimens, and Anthrax Adsorbed Vaccine (AVA) may be in limited supplies depending of the size of the response.
6. Vaccine administration supplies, including syringes and needles, may be in limited supplies depending on the size of the response.
7. Pediatric formulations and suspensions of antibiotics are available only in limited supply, pill crushing instructions 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 Receive, Stage, and Store (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 (LHD) (if any) and/or local response jurisdictions regarding MCM items and quantities needed in the request.
11. The Division of Strategic National Stockpile (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 Emergency Use Authorization (EUA) or Investigation New Drug (IND) 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 health care 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 National Incident Management System (NIMS) and impacted public jurisdictions have organized using the Incident Command System (ICS).
16. 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 warehouse and POD staff will receive training necessary to conduct response operations.

18. Mechanisms are established to provide responders and operational staff, as well as essential personnel, with MCMs 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/or vaccines from the worried well and residents of non-impacted jurisdictions even though they were NOT in an area of exposure.

21. 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 LHD (e.g., single RSS warehouse and/or multiple RDS/LDS warehouses model); however, if an incident is limited to one LHD, then upon the request of the State, the CDC may deploy the antibiotics and/or vaccines directly to the area of that LHD if local warehouse capacity exists (e.g., single warehouse).

22. 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 raxibacumab directly to healthcare facilities where seriously ill/symptomatic patients with inhalation anthrax will be treated

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 commence.

2. When provision of 50-day regimens begins, provision of 10-day regimens 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 regimen at that time.

3. States/Locals 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 regimens of antibiotics (vs 10-day regimens) and the expanding demands for MCM related to treatment.

4. MCMs for the sustained response will begin to be delivered from the RSS warehouse to local points of dispensing (PODs) within 1-7 days following the initial request (or approximately on or around Day 10) of the initial dispensing campaign.

5. By Day-3 post-event, 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.

6. By Day-3 post event, resource management system has been established between the EOC and/or DOC which is coordinating MCM allocations, the RSS/RDS warehouse and distribution centers, as well as the customer sites, which include points of dispensing (PODs) and treatment centers (e.g., hospitals; clinics).

7. Vaccination sites may or may not be the same as the PODs for oral dispensing.

8. 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 by Day-5, especially if these resources are officially requested by Day-3.

9. 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/or federal level.

10. The CDC has the capability and experience with direct shipment of vaccine to pharmacies and primary care providers during the second (Day-32) and third (Day-46) dosing phase of anthrax vaccine, similar to their strategy during the H1N1 response. State and local jurisdictions may choose to implement direct shipments to reduce staffing and logistic concerns at the RSS warehouse.

11. During the long-term MCM response to an anthrax incident, MCM will primarily come from Managed Inventory (MI), and not from the 12-Hour Push Package.